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AN OVERVIEW OF CALOTROPIS PROCERA'S PHYTOCHEMICAL COMPONENTS AND PHARMACOLOGICAL POTENTIAL

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ABSTRACT

Calotropis procera is a member of the Apocynaceae family and subfamily Asclepiadoideae. It is commonly known as Aak or Madar in Hindi and milk weed in English. Despite being a wasteland plant, its blossoms are dedicated to Lord Shiva, a Hindu god, making it a sacred plant. The herb is used by tribes worldwide to treat a wide range of illnesses, including skin conditions, sexual dysfunction, cancer, asthma, epilepsy, bodily discomfort, and snake bites. Numerous phytoconstituents, including cardenolides, oxypregnanes, terpenoids, flavonoids, and steroids, are present in this plant. Despite the abundance of articles regarding the chemical makeup, pharmacological activity, and ethnomedicinal uses of Calotropis procera that come up in literature searches, there aren't any recent papers that give a summary of the toxicity and therapeutic potential of the plant. In light of this, the review's goal is to present a comprehensive overview of the phytochemistry, pharmacology, toxicity, and therapeutic potential of Calotropis procera while also highlighting information gaps to serve as a source of inspiration for further investigation. Other names for Calotropis procera include Aak and Madar. The phytochemistry, toxicity, pharmacology, and therapeutic potential of Calotropis procera are all systematically summarized in this paper.

KEYWORD : *Calotropis procera calotropin , Aak , Milkweed , Calotropis gigantea*

INTRODUCTION

Calotropis is a member of the Apocynaceae family, also referred to as Aak or milkweed.
This genus of plants is called milkweed because various plant sections exude a white, sticky latex.
Calotropis procera (Rakta arka) and Calotropis gigantea (Sweata arka), two common species in the genus Calotropis, are said to have important pharmacological qualities for Ayurvedic toxicology and treatments. C. acia and C. sussuela are other species. Calotropis procera (Aiton) W. T. Aiton is an erect, deciduous evergreen perennial shrub commonly known as 'Sodomaomena' or 'Madar bush'. It is known as "Akanda" in Bengali and "Aak" in Hindi. It is widely used in the traditional medical systems of India, Arabia and Sudan to treat global ailments.Dangas tribe in Gujarat, 1 Singhum tribe in Bihar, 2 Ghatigaon forest tribe in Gwalior, 3 Andhra Pradesh tribe4 used this plant to treat various diseases like earache, cough, fever, stomachache. Dysentery and elephantiasis.Calotropis procera is more poisonous than Calotropis gigantea and is thought to be even more poisonous than cobra venom. Interestingly, the cobra and other poisonous snakes cannot even stand its smell; Therefore, snake charmers of Bengal use this plant to control or tame cobras.5Previous reviews 6-16 have discussed the phytochemistry, ethnobotany and pharmacological potential of Calotropis procera. A review of Calotropis species 17-20 comparing procera and gigantea discusses their therapeutic importance. This review summarizes the phytochemistry, pharmacology, commercial aspects, traditional medicinal uses, toxicology and recent research on Calotropis procera. The future scope of Calotropis procera was also confirmed, explaining its multiple biological functions and mode of action.

Scientific Classification

Kingdom	Plantae
Clade	Tracheophytes
Clade	Angiosperms
Clade	Eudicots
Clade	Asterids
Order	Gentianales
Family	Apocynaceae
Subfamily	Asclepiadoideae
Tribe	Asclepiadeae
Genus	Calotropis R.Br.[1]

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Toxicity

C. procera is distributed in many regions of the world. What makes its phytochemistry interesting is the secretion of a milky and poisonous latex from all parts of the plant. Latex is called plant mercury because it has mercury effects on the human body.21Every part of this plant is poisonous, but the stem (latex) and roots are more poisonous than the leaves. The leaves of this plant contain three toxic glycosides, calotropin, calotoxin and uscarin, while its latex contains calotropin, calotoxin, and calactin, which are corrosive and poisonous in nature. In addition, the concentration of calactin, a poisonous glycoside, increases as a defense mechanism against locust or insect attack and is the reason why cattle or other livestock do not eat the plant.In addition, osmotin, a laticin protein purified from latex, protects plants against phytopathogens.23 Its milk is irritating, neurotoxic and anticholinergic, causing toxicity and fatal complications. The sap and latex of madar have a bitter taste and a burning pain that causes salivation, stomatitis, vomiting, diarrhea, dilated pupils, titanic strangulation, collapse and death. The time to death varies from half an hour to eight hours.24 When latex enters the eye, it causes keratitis, corneal swelling and blurred vision without pain.25–27 In some cases, permanent damage of endothelial cells was observed, which was obvious. . . after three weeks.5.28C. Procera was found to be toxic to chicken embryos at a dose of 100 mg kg-1. Its toxicity has caused hepatocellular degeneration in the liver, brain congestion, dilation of central veins, sinuses, underdeveloped lungs and kidneys.29 Therefore, considering the toxic effects of certain extracts and glycosides, further research should focus on clarifying toxicity and safe use. C. longa.

2.The ability to survive in extreme climatic conditions.

Another interesting feature of this plant is its ability to withstand adverse environmental conditions such as lack of water, dry environment or any harsh climate. To understand this, Akhkha30 studied the effects of water deficit stress and found that although the photosynthetic machinery remained unchanged, the rate of photosynthesis actually increased under mild water conditions (50%), which could be considered a compensatory mechanism. In addition, Ramadana et al.31 investigated the effect of light and irrigation on β-sitosterol accumulation in C. proceras. They hypothesized that the β-sitosterol biosynthetic pathway supported the plant's tolerance to drought and light intensity.

1. **Commercial prospective**

Use As Biofuel :- C. procera is rich in hydrocarbons and contains biologically degradable materials similar to that found in other agricultural crops. Traore32 conducted fermentation experiments and found that it is a good substrate for biogas synthesis. Barbosa et al.33 found that oil composition of its seeds varies from 19.7 to 24.0% which proves its future potential as biodiesel, specially in those areas where people rely mainly on wood as source of energy production.

Use as Biopesticide :- To evaluate the biological role of latex, the insecticidal activity of Calotropis procera latticifer proteins (LP) against various crop pests was determined. Diets containing 4% latex reduced weight gain (ED50 = 3.07%) and affected survival (LD50 = 4.61%) in third stage Ceratitis capitata.34 Crude fraction of flavonoids (Cf), latex protein fraction (LP) and methanol extract of leaves showed. Significant insecticidal activity .35 These studies suggest that it can be developed as a natural biopesticide.

In Future of Industry :- For Cheese Production

In West Africa, the crude aqueous extract of C. procera is used as a milk coagulation enzyme in the traditional cheese making method.36 It showed optimal activity at 75 °C, which is required for cheese. 37 The plant enzyme calotropin is more effective than papain, physin and bromelain, and can also cause curdling of milk, disintegration of meat, casein and gelatin.38,39 These studies supported its traditional use as a cheese-making agent.

As Surfactant

C. procera milk latex was used as a surfactant for the facile synthesis of Eu3+-activated La(OH)3 and La2O3 nanophosphors via a green-mediated hydrothermal route. The latex reflected a good splitting ability in controlling the morphology and phase of the nanophosphorus.40 Thus, its latex can be a good source of natural surfactant..

As Corrosion Inhibitor

It shows anti-corrosion effect of C. procera extract was investigated by weight loss, electrochemical, SEM and UV methods, a significant anti-corrosion effect was shown on mild steel in sulfuric acid environment.41 So it can be used as a green corrosion. An inhibitor.

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As Dehairing Agent Of Leather

C. procera latex peptidases showed a complete senescence process when analyzed against typical skin substrates, although no changes in skin structure were observed. Thus, it can be a suitable environmentally friendly depilatory agent compared to the toxic sodium sulfite used in tanneries.42.

Ethnomedicinal Use

Misra et al. compiled an overview of the Ayurvedic, Unani and folk use of various parts of C. procera and C. gigantea for the treatment of various diseases.43 The ethnomedicinal use of C. procera plant parts in the treatment of various diseases was summarized..

Fig.(1) **Calotropis procera plant**

An Important Milestone in Calotropis Phytochemistry.

The phytochemistry of Calotropis procera has always attracted the attention of researchers because, despite its toxicity, it still has wide applications in the traditional system of medicine. Starting in 1936, calotropin 55 was identified as the first compound from this plant by Hesse et al. In addition, Hesse and his collaborators56,57 isolated cardiotoxins or cardiac glycosides, namely calotropin, calotoxin, calactin, uscarin, voruscarin and uscaridine.58 The root powder of this plant was used tribally to induce abortion in women and as a remedy. . uterotonic medicine since ancient times. It was later discovered that this was caused by the compound calotropin. Gupta et al59 administered calotropin to gerbils and rabbits and found a 65% and 94% decrease in sperm count.In 1955, Rajagopalan et al.60 identified the chemical constituents of the seeds viz. coroglautsigenin, corotoxigenin and frugoside (cardenolides). Later, Bruschweiler et al.61 identified three more cardenolides, viz. uzarigenin, siriogenin and proseroside. Quaquebeke et al.62 isolated a new cardenolide, 2'-oxovoruscarin, from the root bark and converted it into a semi-synthetic derivative, i.e., UNBS1450. Akhtar and Malik63 isolated a new cardenolide named proceragenin from the hexane-insoluble fraction of C. procera.An interesting property of the plant is its ability to slow Alzheimer's disease and #039 (AD), the main cause of neurodegenerative dementia. Its dried latex showed the weakening of β-amyloid accumulation in the mouse brain and the protective function of the brain.64 Therefore, it is necessary to evaluate the mechanism of the metabolites, so that it can lead to a promising direction to search for new ones. Scaffolds for AD. Therapy In 2015, Mohamed et al. isolated three non-glycosidic cardenolides from the latex, namely calactoprosin, prokegenin A and prokegenin B. 65The patent claimed that a polar extract of C. procera exhibited dose-dependent antiulcerative colitis activity in mammals and was found to be more. Effective than the standard drug Prednisolone.66.

Pharmacology

Over the last many years, researchers have carried out numerable pharmacological activities, which are summarized in Table 2

Brief summary of the pharmacological properties

S. no.	Pharmacological activities	Parts/extracts/possible chemical constituents	References
1	Wound healing potential	Latex: aqueous extract	67
		Latex	68
		Bark: ethanolic extract	69
		Leaves: aqueous extract	70
		Bark: aqueous extract	71
2	Anticoccidial activity	Dried leaves powder	72
3	Toxicity activity	Leaves: aqueous extract	73 and 74
		Leaves and stem bark extracts	75

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		Leaves and stem: ethanolic extract	29
		Leaves: ethanolic extract	79
4	Biopesticidal/insecticidal activity	Leaves: extract	80 and 81
		Leaves: methanolic extract, latex protein fraction, flavonoids (quercetin-3-*O*-rutinoside)	35
5	Antimycoplasmal activity	Leaves: acetone extract	82
6	Hepatoprotective activity	Root bark: methanolic extract	83
		Flowers: hydroethanolic extract	84
		Roots: chloroform extract	85
7	Antimicrobial/antibacterial activity	Leaves: methanolic extract, flavonoids (quercetin-3-*O*-rutinoside)	86
		Leaves and latex: ethanol, aqueous, and chloroform extract	87
		Leaves and stem: aqueous, ethanolic, methanolic extract	88 and 89
		Endophytic fungi of *C. procera*	90
		Seeds: chloroform extract	91
		Root: pet. ether, methanolic extract	92
		Flowers: ethanolic extract	93
		Latex	94
		Leaves: methanolic extract	95
		Leaves, flower, root bark: ethanolic extract	96
		Leaves and latex: aqueous, ethanolic extract	97 and 98
		Leaves: aqueous, methanolic extract	99
		Latex: aqueous extract	78
8	Central nervous system activity	Latex proteins	100
9	Antioxidant activity	Leaves, flower, fruit, latex	101
		Leaves: aqueous, methanolic extract, quercetin and its derivatives	76
		Leaves: aqueous and methanolic extract	102
		Leaves, flowers and fruits: methanolic extract	103
		Bark: ethanolic extract	69
10	Antinociceptive activity	Latex protein	104
11	Antihelmintic activity	Flowers: crude powder, aqueous and methanolic extract	105
		Latex: fresh, dried aqueous extract	106 and 107
12	Antiinflammatory activity	Dry latex	108 and 109
		Stem bark: chloroform and hydro-alcoholic extract	110
		Latex: hexane, dichloromethane, ethyl acetate, *n*-butanol and aqueous extract	77
		Latex: pet. ether, acetone, methanol extract	111
		Leaves: aqueous extract	112
		Flowers: ethanolic extract	93
13	Antidiarroheal activity	Bark: Arkamula Tvarka (Ayurvedic preparation)	45
		Latex	113
14	Antifungal activity	Aqueous bark extract	114
		Leaves: aqueous, methanol, acetone and ethanol extract	115
		Root bark	116
	Antimycotic activity against dermatophytes	Latex	117
	Antimycofloral activity (fungi in wheat)	Fresh latex	118
15	Larvicidal activity	Crude latex and ethanolic extract of leaf	119
		Leaves: ethanolic extract	120
		Leaves: aqueous extract	121
		Flower, young bud, mature leaves and stems: ethanolic extract	122

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		Flowers: aqueous extract	123
16	Tobacco mosaic virus (TMV) inhibitor activity	Latex	124
17	Antifertility activity	Ethanolic extract of roots	125
		Leaves: ethanolic extract	79
		Roots (calotropin)	59
	Abortifacient activity	Latex	126
	Antisperm activity	Root: chloroform extract	127
	Oestrogenic/antiovulatory activity	Roots: ethanolic and aqueous extract	128
18	Plasma clotting activity	Protein fraction isolated from fresh latex	129
19	Antiplasmodial activity	Different plant parts: ethyl acetate, ethanolic and acetone extract	130
		Leaves extract	131
20	Antipyretic activity	Dry latex: aqueous extract	132
		Flowers: ethanolic extract	93
21	Antiasthmatic activity	Flowers	133
22	Anticonvulsant activity	Root extracts	134
23	Cytotoxic activity	Root (2″-oxovoruscharin)	62
		Laticifer proteins (LP) recovered from latex	135
		Root: methanolic, aqueous, ethyl acetate, hexane extracts	136
		Plant: methanolic extract	137
		Stems: uzarigenin	138
		Root bark: calotroprocerol A	139
		Root: alcoholic, hydro-aqueous and aqueous	140
		Leaf: ethanolic extract	149
24	Analgesic activity	Flowers: Ethanolic extract	93
25.	Antihyperglycemic activity	Leaves: pet ether, methanol and aqueous extracts	141
26	Antiarthritis activity	Latex	142
		Protein sub fraction of latex	143
27	Antimolluscicidal activity	Latex: 95% aqueous ethanol (uscharin)	144
28	Antitermites activity	Latex	145
29	Antimigraine activity	Dried terminal leaves	146
30	Anti-ulcer activity	Root: chloroform extract	147
		Plant: 50% ethanolic extract	148
		Leaf: ethanolic extract	149
		Stem bark: chloroform and hydroalcoholic extract	110
31	Spasmolytic activity	Plant: aqueous extract	150
32	Allelopathic activity	Leaves: aqueous extract	151
33	Anti-keloidal activity	Latex	68
34	Anti-hyperbilirubinemic activity	Leaves: aqueous extract	70
35	Antiapoptotic activity	Latex	152

Phytochemistry:- C. procera contains cardenolides, flavonoids, sterols, oxypregnanes, triterpenoids, glycosides and other compounds described in Table 11.7. Flavonoid and its glycosides are the most important compounds isolated from C. procera leaves. Steroids and cardenolides (are the main secondary metabolites found in latex. Cardenolides have also been reported from other plant families of Apocynaceae or Asclepiadaceae, such as Strophanthus, Cerbera, Apocynum, Nerium and Thevetia.159 They are traditionally used to treat congestive heart failure.160 Cardenolides are C23 steroids with an asteroid glycoside. Part at C-3 and the lactone part at C-17.6 Cardiac glycosides may be new antitumor agents because cancer cells are more sensitive to these compounds.159 Terpenoids (ursane, oleanane-type and pentacyclic triterpenes, etc.) isolated from flowers, rhizomes and latex. Oxypregnane glycosides 5) were recently reported from the root bark of this plant.153,154 They have a steroid backbone containing a 2deoxysugar moiety. These oxypregnanes have a benzoyl group at C-12 and a straight sugar chain of 5-7 units linked to the aglycone at C-3.6 Some glycosides , wood glycosides terpene glycosides and caffeic acid derivatives 9) was also isolated from this plant..

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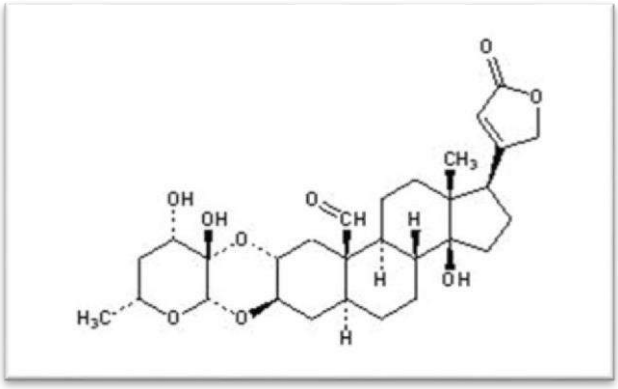

Structure of Calotropin

CONCLUSION, DISCUSSION

This review summarizes the research progress on the phytochemistry and pharmacology of C. procera. There were acquisitions in the study; However, we found some shortcomings in our research, which are as follows 1) C. procera has been used by people and tribes since ancient times; further research can be done on when the traditional use of C. procera begins.(2) The secondary metabolites of a plant vary according to several factors such as region, environment, soil quality, age of the plant, etc. In addition, latex and rhizome seem to be the most studied plant constituents, flowers, pods and pods have not been studied much. Fyoconstituentsis seeds were implemented. Further investigation of these components may lead to the discovery of new phytoconstituents of interest.(3) The device can be used commercially because scientific studies have shown its use as a cheese-making agent, skin depilatory agent, natural surfactant, biopesticide and corrosion inhibitor.(4) Many efforts have been made to confirm its cytotoxic and anti-inflammatory potential. Some were made for its migraine, plasmodial and anticonvulsant effects. Further research in these areas can provide medicine with effective and promising new drugs.(5) Most of the cytotoxic actions performed are in vitro, except that performed with UNBS1450; semi-synthesized cardenolide. Further studies should be conducted to investigate its in-vivo potential.(6) The right method of administration and the right dose can turn a terrible poisonous substance into an excellent medicine, while a medicine can become a deadly poison if the doses and method of administration are not done. Human practitioners used C. procera as an antifertility and uterine tonic. Further studies using positive controls, toxicity and side effect studies may lead to the discovery of effective and natural contraceptives.(7) The active ingredients underlying many activities are unknown, apart from the known cytotoxic, antibacterial, antifertility, mollusc and insecticidal activities. More research can be done to know the active ingredients to make effective medicines.(8) Renewable and environmentally friendly energy sources are the need of the hour, Calotropis procera is a rich source of various hydrocarbons, so it can be a promising biofuel.In general, this document covers pharmacology, toxicology, traditional uses, use of secondary metabolites, clinical trials and quality control. However, there seems to be a good correspondence between pharmacological functions and traditional uses. Further research in this area is needed to determine the active principles and underlying mechanisms..

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SMART HYDROGELS FOR DRUG DELIVERY: A REVIEW OF RECENT ADVANCES AND FUTURE DIRECTIONS

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ABSTRACT
Smart hydrogels are intelligent materials that can respond to environmental stimuli to control drug release1. This review article discusses recent advances in smart hydrogels for drug delivery, including thermoresponsive1, pH-responsive, light-responsive, and enzyme-responsive systems. We highlight their applications in cancer treatment, diabetes management, wound healing, and neurological disorders. The advantages of smart hydrogels, including improved efficacy and reduced side effects, are also discussed. Finally, we address the challenges and future directions in this field.1,2

INTRODUCTION

"Smart hydrogels are a class of advanced biomaterials that can respond to various stimuli, such as temperature, pH, light, and enzymes, to control drug release. 1These intelligent materials have revolutionized the field of drug delivery, offering unprecedented precision, targeting, and efficacy. With their unique properties and versatility, smart hydrogels have shown great promise in treating a wide range of diseases, from cancer and diabetes to neurological disorders and infectious diseases3. This review aims to provide a comprehensive overview of the recent advances in smart hydrogels for drug delivery, highlighting their design, mechanisms, applications, and future directions."4,5

RECENT ADVANCES

- Thermoresponsive hydrogels for controlled drug release1
- pH-responsive hydrogels for targeted delivery2
- Light-responsive hydrogels for on-demand release
- Enzyme-responsive hydrogels for targeted therapy

Thermoresponsive hydrogels for controlled drug release

Thermoresponsive hydrogels are a type of smart hydrogel that can respond to temperature changes to control drug release.1 Here's a more detailed overview:

Principle_

Thermoresponsive hydrogels are made from polymers that change their swelling behavior in response to temperature changes. Below a certain temperature (Lower Critical Solution Temperature, LCST), the hydrogel is swollen and hydrophilic, while above the LCST, it becomes dehydrated and hydrophobic.1,3,4

Mechanism

1. At low temperatures, the hydrogel is swollen, allowing drugs to be loaded.1,6
2. As the temperature increases, the hydrogel dehydrates, releasing the loaded drugs.8
3. The rate of drug release can be controlled by adjusting the temperature and hydrogel properties.7

Advantages

1. _Controlled release_: Thermoresponsive hydrogels can release drugs in response to specific temperature changes.6
2. _Targeted delivery_: Hydrogels can be designed to release drugs at specific sites or tissues with unique temperature profiles.9
3. _Biocompatibility_: Thermoresponsive hydrogels are made from biocompatible materials.7

Applications

1. _Cancer treatment_: Targeted delivery of chemotherapy drugs 6
2. _Diabetes management_: Controlled release of insulin6
3. _Wound healing_: Sustained release of growth factors and antibiotics7

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Examples of Thermoresponsive Polymers:_
1. Poly(N-isopropylacrylamide) (PNIPAAm)

2. Poly(N-vinylcaprolactam) (PNVCL)
3. Poly(ethylene glycol) (PEG)3[3,4,5]

Challenges
1. _Temperature control_: Maintaining precise temperature control in vivo
2. _Hydrogel stability_: Ensuring hydrogel stability during storage and use
3. _Scalability_: Scaling up hydrogel production while maintaining properties[3,4,5]

Thermoresponsive hydrogels offer a promising approach for controlled drug release, with potential applications in various fields. Ongoing research addresses challenges and explores new[4,5]

pH responsive hydrogels for targeted delivery
pH-responsive hydrogels are a type of smart hydrogel that can respond to changes in pH to control drug release. Here's a more detailed overview:[2]

Principle_
pH-responsive hydrogels are made from polymers that change their swelling behavior in response to pH changes. These hydrogels can be designed to release drugs in response to specific pH conditions, such as those found in cancerous tissues or the stomach.[2]

Mechanism
1. At a specific pH, the hydrogel changes its swelling behavior, releasing the loaded drugs.
2. The rate of drug release can be controlled by adjusting the pH and hydrogel properties.[10,11,12]

Advantages_
1. _Targeted delivery_: pH-responsive hydrogels can release drugs at specific sites or tissues with unique pH profiles.
2. _Controlled release_: Hydrogels can release drugs in response to specific pH changes.
3. _Biocompatibility_: pH-responsive hydrogels are made from biocompatible materials.[12,13]

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Applications_
1. _Cancer treatment_: Targeted delivery of chemotherapy drugs to acidic tumor environments.
2. _Gastrointestinal diseases_: Targeted delivery of drugs to the stomach or intestines.
3. _Infectious diseases_: Targeted delivery of antibiotics to infected tissues.14,15

Examples of pH-Responsive Polymers
1. Poly(acrylic acid) (PAA)
2. Poly(methacrylic acid) (PMAA)
3. Poly(ethylene glycol) (PEG) with pH-sensitive linkers13,14

Challenges
1. _pH control_: Maintaining precise pH control in vivo
2. _Hydrogel stability_: Ensuring hydrogel stability during storage and use
3. _Scalability_: Scaling up hydrogel production while maintaining properties

pH-responsive hydrogels offer a promising approach for targeted drug delivery, with potential applications in various fields. Ongoing research addresses challenges and explores new applications, driving innovation in this area! applications, drivingC:\Users\ARNAV14\Downloads\10,11,12,13 innovation in this area!10,11,12,13,14,15

Light -Responcive Hydrogels for on-Demand Release
Light-responsive hydrogels are a type of smart hydrogel that can respond to light exposure to control drug release. Here's a more detailed overview:16,17

Principle_
Light-responsive hydrogels are made from polymers that change their swelling behavior in response to light exposure. These hydrogels can be designed to release drugs in response to specific wavelengths or intensities of light.16,18

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Mechanism
1. Light exposure triggers a chemical reaction, changing the hydrogel's swelling behavior.
2. The hydrogel releases the loaded drugs in response to the light-induced change.19,20

Advantages
1. _On-demand delivery_: Light-responsive hydrogels can release drugs in response to external light cues.
2. _Spatial control_: Light can be directed to specific areas, allowing for targeted delivery.
3. _Temporal control_: Light exposure can be controlled to release drugs at specific times.19,20

Applications_
1. _Cancer treatment_: Targeted delivery of chemotherapy drugs
2. _Diabetes management_: Controlled release of insulin
3. _Neurological disorders_: Targeted delivery of neuroactive compounds17,18

Examples of Light-Responsive Polymers
1. Photo-crosslinked hydrogels
2. Spiropyran-based hydrogels
3. Azobenzene-based hydrogels20,21

Challenges
1. _Light penetration_: Ensuring sufficient light penetration in tissues
2. _Hydrogel stability_: Maintaining hydrogel stability during storage and use
3. _Scalability_: Scaling up hydrogel production while maintaining properties

Light-responsive hydrogels offer a promising approach for on-demand drug delivery, with potential applications in various fields. Ongoing research addresses challenges and explores new applications, driving innovation in this area!19,20,21

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Enzyme Responsive Hydrogels For Targeted Therapy

Enzyme-responsive hydrogels are a type of smart hydrogel that can respond to specific enzymes to control drug release. Here's a more detailed overview:22,23

Principle

Enzyme-responsive hydrogels are made from polymers that change their swelling behavior in response to specific enzyme activity. These hydrogels can be designed to release drugs in response to enzymes overexpressed in diseased tissues.22,23,24

Mechanism

1. Enzyme activity triggers a chemical reaction, changing the hydrogel's swelling behavior.
2. The hydrogel releases the loaded drugs in response to the enzyme-induced change.25,26

Advantages

1. _Targeted therapy_: Enzyme-responsive hydrogels can release drugs in response to specific enzymes overexpressed in diseased tissues.
2. _Biocompatibility_: Enzyme-responsive hydrogels are made from biocompatible materials.
3. _Controlled release_: Hydrogels can release drugs in response to specific enzyme activity.23,25

Applications_

1. _Cancer treatment_: Targeted delivery of chemotherapy drugs
2. _Infectious diseases_: Targeted delivery of antibiotics
3. _Inflammatory diseases_: Targeted delivery of anti-inflammatory drugs24,22

Examples of Enzyme-Responsive Polymers

1. Peptide-crosslinked hydrogels
2. Glycosylated hydrogels
3. Phosphorylated hydrogels22,23,24

Challenges

1. _Enzyme specificity_: Ensuring specificity of enzyme response
2. _Hydrogel stability_: Maintaining hydrogel stability during storage and use
3. _Scalability_: Scaling up hydrogel production

Enzyme-responsive hydrogels offer a promising approach for targeted therapy, with potential applications in various fields. Ongoing research addresses challenges and explores new applications, driving innovation in this area!24,25,26

FUTURE DIRECTIONS

1. _Combination therapies_: Loading multiple drugs or therapeutics
2. _Injectable hydrogels_: Minimally invasive delivery

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3. _Smart hydrogel nanoparticles_: Enhanced targeting and penetration

Injectable Hydrogels
Injectable and implantable hydrogels are designed to be delivered directly to the site of disease or injury, enabling targeted therapy with reduced side effects. These hydrogels can be:
- Injected into tissues or organs using minimally invasive procedures
- Implanted surgically or using minimally invasive procedures

Once in place, these hydrogels can:
- Release drugs or therapeutics in a controlled manner
- Provide mechanical support or scaffolding for tissue regeneration
- Act as a barrier or sealant to prevent further injury or damage

Some potential applications of injectable and implantable hydrogels include:
- Cancer treatment: targeted delivery of chemotherapy drugs directly to tumors
- Tissue engineering: scaffolding for tissue regeneration and repair
- Wound healing: sustained release of growth factors and antibiotics
- Spinal cord injuries: implantable hydrogels for tissue support and regeneration

Researchers are exploring various materials and designs to create injectable and implantable hydrogels, including:
- Biodegradable and biocompatible polymers
- Hydrogel nanoparticles and microparticles
- Biohybrid hydrogels combining synthetic and biological materials
- Shape-memory hydrogels that can change shape in response to stimuli

The development of injectable and implantable hydrogels is an exciting area of research, with potential to transform the treatment of various diseases and injuries11,15,26.

Combination Therapies_
Combination therapies involve loading hydrogels with multiple drugs or therapeutics, enabling enhanced treatment efficacy. This approach can:
- Improve treatment outcomes by targeting multiple disease pathways
- Reduce side effects by using lower doses of individual drugs
- Enhance patient compliance by reducing the number of administrations

Some potential applications of combination therapies using hydrogels include:
- Cancer treatment: co-delivery of chemotherapy drugs and immunotherapies
- Diabetes management: co-delivery of insulin and glucose-lowering agents
- Wound healing: co-delivery of growth factors and antibiotics
- Neurological disorders: co-delivery of neuroactive compounds and anti-inflammatory agents

Researchers are exploring various strategies to develop combination therapies using hydrogels, including:
- Co-encapsulation of multiple drugs or therapeutics within hydrogel particles
- Layered or multi-compartment hydrogels for sequential drug release
- Hydrogel-based drug delivery systems with integrated sensing and feedback mechanisms

The development of combination therapies using hydrogels is an exciting area of research, with potential to transform the treatment of various diseases and improve patient outcomes.1,15,11,26

Nanoparticle-Hydrogel Hybrids_.
Nanoparticle-hydrogel hybrids combine the benefits of nanoparticles and hydrogels, enabling enhanced drug delivery and treatment outcomes. These hybrids can:
- Improve drug loading and release kinetics
- Enhance targeting and penetration of tissues and cells
- Provide sustained release and reduced toxicity

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Some potential applications of nanoparticle-hydrogel hybrids include:
- Cancer treatment: targeted delivery of chemotherapy drugs using nanoparticle-hydrogel hybrids
- Gene therapy: delivery of genetic material using nanoparticle-hydrogel hybrids
- Tissue engineering: scaffolding and growth factor delivery using nanoparticle-hydrogel hybrids
- Vaccine development: delivery of antigens and adjuvants using nanoparticle-hydrogel hybrids

Researchers are exploring various materials and designs to create nanoparticle-hydrogel hybrids, including:
- Nanoparticle-decorated hydrogels
- Hydrogel-encapsulated nanoparticles
- Nanoparticle-hydrogel composite materials
- Biohybrid nanoparticle-hydrogel systems combining synthetic and biological materials

The development of nanoparticle-hydrogel hybrids is an exciting area of research, with potential to revolutionize drug delivery and treatment outcomes.15,26

CONCLUSION

"In conclusion, smart hydrogels have emerged as a powerful tool for controlled drug delivery, offering unprecedented precision, targeting, and efficacy. The versatility of these materials has enabled their application in various disease models, and their potential to revolutionize drug delivery is vast.

While significant progress has been made, challenges and limitations remain, including scalability, biocompatibility, and regulatory hurdles. However, ongoing research and innovation are addressing these challenges, and the future of smart hydrogels for drug delivery looks bright.

As we move forward, it is essential to continue exploring new designs, mechanisms, and applications for smart hydrogels. Collaboration between researchers, clinicians, and industry experts will be crucial in translating these advances into clinical practice. Ultimately, smart hydrogels have the potential to transform the field of drug delivery, enabling more effective, personalized, and targeted therapies. As we continue to push the boundaries of what is possible with these materials, we may unlock new possibilities for improving human health and quality of life."9,11,19,26

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TURKEY'S INVOLVEMENT IN RESOLVING REGIONAL CONFLICTS

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ABSTRACT

Today, global political and economic crises, conflicts, and disputes are leading to the erosion of the foundation and decisive principles of the international relations system. Confrontation and protectionism are causing the fragmentation of the world economy and the disruption of supply chains. New barriers are emerging that hinder effective cooperation between states in the areas of trade, finance, investment, technology, and innovation transfer. In particular, the events unfolding around Ukraine and in the Middle East demonstrate that the international geopolitical balance has entered a state of crisis. As a result, traditional trade and transport chains are being disrupted, logistics costs are significantly increasing, and new obstacles are appearing. In such an unstable situation, the Republic of Turkey is also striving to protect its national interests in its foreign policy, as well as to create conditions for establishing sustainable peace and development not only in the Eurasian region but also in the world. This article provides a scientific analysis of Turkey's participation in resolving regional conflicts.

KEYWORDS AND EXPRESSIONS: *Türkiye, global security, opportunities, challenges, foreign policy, alliances, diplomacy, leadership, conflicts.*

INTRODUCTION

Today, Turkey remains one of the countries actively involved in resolving regional conflicts. It is worth noting that in recent years, the geopolitical situation, international security threats, and strategic interests in the South Caucasus, Eastern Europe, and the Middle East regions have been significantly influencing Turkey's foreign policy decisions. In this process, Turkey is engaged in managing and resolving regional conflicts through several strategic approaches.

Currently, Turkey places great emphasis on diplomatic mediation and negotiations in conflict resolution. For instance, during the war between Russia and Ukraine in 2022, Turkey organized negotiations between the parties and mediated the "Black Sea Grain Initiative". As is known, the Grain Deal, or the Black Sea Grain Initiative, is an international agreement signed between Russia and Ukraine on July 22, 2022, in Istanbul, under the mediation of Turkey and the United Nations. It aims to ensure the safe export of Ukraine's grain and other agricultural products through the Black Sea[1]. This agreement was of crucial importance at a time when the war posed a threat to global food security.

The main objective of the agreement is to establish a corridor for the safe and uninterrupted export of grain and other food products from the Ukrainian ports of Odessa, Chernomorsk, and Yuzhny, as well as to remove obstacles to the export of Russian food and fertilizers. Indeed, Ukraine is one of the world's major grain suppliers, and grain exports ceased after the outbreak of war, leading to a sharp rise in global food prices and food shortages. Initially, the agreements were concluded for 120 days, and in November 2022, they were extended for the same period. On May 18, 2023, Russia announced that it would extend the agreement by 60 days, until July 17, 2023, stating that this time would be sufficient to assess the implementation of the memorandum signed with the UN. Subsequently, Russia declared that the Grain Corridor Agreement would be suspended from July 18, 2023[2]. The reason given was that the West had not fulfilled any of its promises related to Russia's interests within the framework of the agreement. Russia announced that it would suspend its participation in the initiative until all conditions of the grain agreement were met. However, Turkey is still actively working to preserve the grain agreement.

MAIN PART

Overall, Turkey's initiative contributed to ensuring global food security and, as a result of the resumption of grain exports from Ukraine, led to a decrease in global agricultural product prices and reduced food shortages. According to UN data, millions of tons of grain products were exported as a result of the agreement, which was particularly important for countries in Africa, the Middle East, and Asia. This demonstrated Turkey's significant influence on the world order. Moreover, this agreement showed that it is

[1] *https://en.wikipedia.org/wiki/Black_Sea_Grain_Initiative*
[2] *https://mid.ru/ru/foreign_policy/news/1897157/*

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possible to reach a consensus even in the conflicting situation between Russia and Ukraine. In a sense, this became a success for Turkey's foreign policy.

It is known that by 2013-2014, a new organization threatening the security of the Republic of Turkey - the Islamic State of Iraq and the Levant (ISIL) - began to emerge. Initially, Turkey attempted to support the opposition and address security issues with the assistance of the West and NATO, and even joined the anti-terrorist coalition. However, their interests regarding the Syrian crisis did not always align. In this context, Turkey began to address its security concerns through military operations in 2016, against the backdrop of its policy of independence from other countries. It is worth noting that almost all of these operations were actually directed at Kurdish structures, rather than ISIL, which is recognized as a terrorist group.

The first of Turkey's military campaigns began in August of that year following a deadly terrorist attack organized by militants in the border city of Gaziantep[3]. Operation "Euphrates Shield" which was not agreed upon with the official Syrian government, commenced in the spring of 2017. Through this operation, Turkey succeeded in capturing the Al-Bab region and pushing the Kurds away from its borders.

Furthermore, Turkey's subsequent military operation was named "Olive Branch" and commenced in January 2018. The main objective of this military campaign was to liberate Afrin, which had been occupied by Kurdish structures of the "Democratic Union" party and the national self-defense units.

In addition, on October 9, 2019, Turkish President R.T. Erdogan announced the launch of a military operation called "Peace Spring" against the Kurdistan Workers' Party (PKK), which is banned in Turkey, and ISIS. This operation concluded on October 22, 2019, as a result of negotiations between the leaders of Russia and Turkey. It is particularly important to note that Turkey's "Peace Spring" operation was not supported in either the West or the Middle East.

In recent years, Turkey has been actively involved in the peaceful resolution of the Syrian conflict. In particular, Turkey is striving to strengthen its regional influence through the "Astana Process" and has achieved several important successes as a result. This process, which has been ongoing since 2017, was established with the aim of ending the war in Syria and resolving the conflict through political means. Turkey has actively participated in this process as one of the main "guarantor" states (*along with Russia and Iran*). Turkey's main achievements through the "Astana Process" can be summarized as follows:

1. Creation of de-escalation zones
During the "Astana Processes," Turkey achieved a reduction in military conflicts in Syria and ensured the safety of civilians. Based on the agreement signed in 2017, four de-escalation zones were created, in which measures were taken to cease fire and provide assistance to civilians. The establishment of de-escalation zones helped to reduce the level of violence in Syria.

2. Active mediation role in political negotiations
As part of the Astana Process, Turkey, together with Russia and Iran, held negotiations between the main military and political forces in Syria. Through this process, Turkey gained the opportunity to directly influence the conflict and strengthen its mediating role in the region. Turkey also actively participated in the Geneva process and played an important role in seeking political solutions in cooperation with the international community.

3. Creating conditions for humanitarian aid
Through the "Astan Processes," Turkey has managed to create conditions for the continuous provision of humanitarian aid in Syria. During this process, agreements were signed aimed at creating safe zones for refugees and improving the socio-economic situation in Syria. This contributed to the recognition of Turkey as a leading country in providing humanitarian aid.

4. Regional security
Through the Astana Process, Turkey gained the opportunity to protect its national security interests and reduce the influence of Kurdish militants and terrorist groups in Syria. The establishment of de-escalation zones in the northern regions of Syria held strategic importance for Turkey, as it allowed Turkey to successfully ensure its border security in these areas.

5. Strengthening geopolitical influence
Through the "Astana Process" Turkey has increased its geopolitical influence in the region. By cooperating with Russia and Iran, Turkey has strengthened its position in Syria and become an important player in international diplomacy. This process has enhanced Turkey's influence in the Middle East, transforming it into one of the key mediators in resolving regional issues.

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In conclusion, Turkey has achieved significant progress in resolving the Syrian conflict, providing humanitarian aid, and mediating political negotiations through the "Astana Process". This process has given Turkey the opportunity to protect its national security interests, strengthen its regional influence, and play a role as a key mediator in international diplomacy. The "Astana Process" has served to reduce the level of violence in Syria, enhance dialogue, and improve the situation of the civilian population.

RESULTS AND DISCUSSIONS

The most sensitive point in Turkish-Israeli relations is the ongoing struggle for territory between Israel and Palestine. Considering that the majority of Turkey's population consists of Muslim citizens, Turkey, as a Muslim state, considers it its duty to support the Palestinians. Israel, however, expresses dissatisfaction with this stance.

By March 2018, a new wave of tensions had resurfaced in the region. This was attributed to the relocation of the US Embassy to Jerusalem. The President of Turkey declared Israel a terrorist state and proposed convening an extraordinary meeting of the Organization of Islamic Cooperation.

Moreover, relations between the two sides further deteriorated due to the conflict that erupted in the Gaza Strip on October 7, 2023. Simultaneously, Turkey's independent policy is causing negative dynamics in the relations among regional countries. Relations with Iraq have also worsened due to Turkey's arbitrary military operations on Syrian territory. Turkey's direct or indirect involvement in all political processes in the region and its pursuit of hegemony are causing discontent among leading countries such as Saudi Arabia, Israel, and Iran.

It should be noted that Turkey is attempting to restore its position by providing humanitarian aid to countries in the region. To date, it has extended a helping hand of unconditional assistance to countries such as Yemen and Palestine. Only time will tell how effective this strategy proves to be.

The measures taken by Turkey against Israel's policies towards Muslims have led to an increase in its standing among Arab and Islamic countries. In response to Turkey's harsh measures against it, Israel has announced its full support for PKK militants located in Turkey's most troubled southeastern region and the entire Kurdish nation in pursuing an anti-Turkey policy.

Taking advantage of the political instability in contemporary Arab countries, we can observe that Turkey is trying to reduce Israel's military potential in the region while increasing its own power and sphere of influence. The policy aimed at displacing Israel from its leadership position in the Middle East region has demonstrated that Turkey is enhancing its prestige among Islamic countries, thereby signaling significant changes in its foreign policy.

The improvement of relations between Iran and Turkey does not fully align with Israel's interests. In particular, the inclusion of Egypt and Saudi Arabia in the improvement of these relations may lead to Israel's isolation in the region. In turn, it can be observed that Israel is also striving to maintain its sphere of influence in the region with all its might.

In addition, Turkey supported Azerbaijan in the Nagorno-Karabakh conflict between Azerbaijan and Armenia, achieving several successes during this war. During the conflict in the fall of 2020, Turkey established close military cooperation with Azerbaijan, thereby successfully strengthening its regional influence. We can list the following as Turkey's main achievements in the Azerbaijan-Armenia war:

1. Strengthening geopolitical influence

Turkey bolstered its geopolitical influence in the South Caucasus by supporting Azerbaijan. Through this assistance, Turkey developed a close strategic partnership with Azerbaijan and emerged as a powerful player in the region. Following the war, Turkey's political and military influence in the South Caucasus region increased significantly, which enhanced Turkey's competitive position in the area.

2. Strengthening the leadership role in the Turkish world

Turkey strengthened its leadership role in the Turkish world by strengthening strategic cooperation with Azerbaijan. During the war, President Erdogan's open support for Azerbaijan and his strong anti-Armenian stance increased Turkey's leadership position among the Turkic states. Through this, Turkey strengthened the principle of "one nation, two states" with Azerbaijan and achieved further rapprochement between the Turkic peoples.

3. Testing and exporting military technology

During the war, Azerbaijan achieved significant success using Turkish-developed "*Bayraktar TB2*" unmanned combat aerial vehicles. These drones proved highly effective on the battlefield, destroying numerous military equipment units of the Armenian

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army. This success further elevated the reputation of Turkey's defense industry on the international stage and provided a strong impetus for expanding its military technology exports.

4. Opportunities for implementation of joint infrastructure projects
After the war, when Azerbaijan regained its sovereignty in territories bordering Karabakh and Armenia, opportunities arose to implement new infrastructure projects with Turkey. In this regard, the project to restore land communication between Turkey and Azerbaijan through the Zangazur corridor is of great importance. This corridor not only strengthens trade and economic ties, but also serves to develop the transport network connecting the Turkish world.

5. Regional cooperation and expansion of economic opportunities
Azerbaijan's victory has created new economic opportunities for Turkey in the region. Turkish companies have participated in rebuilding infrastructure in the Karabakh area and gained investment prospects. Additionally, Turkey is taking steps to strengthen cooperation in energy and trade within the region, which is expanding the scope of economic benefits.

6. Promoting the peace process with Armenia
After the war, Turkey is endeavoring to establish diplomatic dialogue with Armenia to strengthen peace and stability in the region. Within the framework of the peace agreement between Armenia and Azerbaijan, Turkey is also striving to restore relations with Armenia and reinforce peace. This is considered an important step in safeguarding Turkey's strategic interests in the Caucasus.

In summary, Turkey has achieved significant gains in the Azerbaijan-Armenia war by supporting Azerbaijan, thereby enhancing its regional influence, consolidating its leadership role in the Turkic world, increasing exports of military technologies, implementing infrastructure projects, and expanding economic opportunities. Concurrently, Turkey continues its efforts to ensure stability in the region and improve diplomatic relations with Armenia. These achievements have further strengthened Turkey's strategic role in the South Caucasus and transformed it into a key player in the region.

CONCLUSION

In conclusion, it should be noted that Turkey is one of the countries actively involved in resolving regional conflicts, and its political, economic, and military strategies are manifested in various ways. Turkey operates in several areas in order to expand its influence in the international arena, protect its national interests, and ensure regional stability. The following key areas describing Turkey's participation in dispute resolution are presented:

1. Diplomatic Mediation and Negotiations
Turkey is assuming the role of diplomatic mediator to facilitate peaceful resolution of conflicts in the region. For instance, during the 2022 Russia-Ukraine war, Turkey acted as an intermediary to establish dialogue between the parties. This involvement resulted in the signing of the "Grain Deal" which contributed to ensuring global food security. Additionally, to resolve the Syrian conflict through political means, Turkey, Russia, and Iran jointly initiated the "Astana Process." This process served to reduce violence and establish peace in Syria.

2. Military Operations and Security Measures
Turkey is conducting military operations to ensure regional security and stability. Several military operations have been carried out against Kurdish militants and terrorist groups in Syria and Iraq. Specifically, the "Olive Branch" and "Peace Spring" operations were aimed at protecting Turkey's national security and ensuring safety in border areas. During the Libyan Civil War, Turkey supported the Government of National Accord (GNA) and provided it with military assistance.

3. Humanitarian aid Programs
Turkey is implementing humanitarian programs to provide assistance to populations affected by regional conflicts. During the war in Syria, Turkey has actively participated in receiving, accommodating, and assisting millions of refugees. Additionally, Turkey has provided support to the local population in Afghanistan by implementing assistance programs in the fields of medicine, education, and other social sectors.

4. Establish Regional Alliances and Strategic Alliances
Turkey is playing a crucial role in conflict resolution by strengthening regional alliances and strategic partnerships. For instance, during the Nagorno-Karabakh conflict in 2020, Turkey provided political and military support to Azerbaijan, contributing to Azerbaijan's victory in the dispute with Armenia. Additionally, during the political crisis in the Persian Gulf, Turkey supported Qatar by establishing a military base there and developing strategic cooperation with the country.
In conclusion, Turkey has been employing various methods and means to resolve regional conflicts, increasing its influence through diplomatic mediation, military operations, humanitarian aid, and strategic alliances. These approaches reflect Turkey's aspirations to maintain regional stability, protect its national interests, and play a significant role in international politics. This involvement serves to enhance Turkey's prestige both in the region and on the international stage.

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STEM CELL APPROACHES IN ORGAN REGENERATION AND REPAIR

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ABSTRACT

Recent advances in stem cell research have provided new hope for treating a variety of diseases and conditions that currently have no effective cure. Stem cells have the unique ability to differentiate into various cell types, enabling them to support tissue growth and replace damaged or specialized cells throughout the lifespan. Among the most promising types of stem cells are mesenchymal stem cells (MSCs), which are easily harvested from adipose tissue and can be cultured and expanded in the lab. Due to their versatility, MSCs have become a focal point in tissue regeneration and have been widely used in animal studies and clinical trials involving humans. This review aims to summarize the current understanding of MSCs, focusing on the various types of stem cells isolated from different animal models such as horses, pigs, goats, dogs, rabbits, cats, rats, and mice. Given the growing interest in MSCs, we will also discuss their applications in veterinary and regenerative medicine. Current research highlights the potential of MSCs in treating conditions like heart failure, wound healing, and tooth regeneration, demonstrating their broad therapeutic potential.

KEYWORDS: *Mesenchymal stem cells (MSCs), animal models, cell-based therapy, regenerative medicine*

Classification of Stem Cells

Stem cells are categorized based on their ability to differentiate into different cell types, with four primary classifications: totipotent, pluripotent, multipotent, and unipotent. These classifications reflect how many types of cells the stem cells can turn into. In addition to this, stem cells are also classified by their stage of development, which includes embryonic, fetal, infant (including umbilical cord blood), and adult stem cells.

Toti-Potent Stem Cells

Totipotent cells have the unique ability to develop into any type of cell found in the organism. In fact, they can give rise to all the cells of the body, including the three primary germ layers of the embryo (ectoderm, mesoderm, and endoderm), as well as extra-embryonic tissues like the placenta. This remarkable versatility makes totipotent cells capable of forming an entire organism from a single cell.

Pluri-Potent Stem Cells

Pluripotent stem cells are a type of stem cell that can develop into nearly all cell types in the body. This includes cells derived from the three primary germ layers: mesoderm, endoderm, and ectoderm, which form early during the differentiation of embryonic stem cells (ESCs). Essentially, pluripotent cells have the ability to give rise to most, if not all, tissues in the body, though they cannot form an entire organism like totipotent cells can.

Multi-Potent Stem Cells

Multipotent stem cells have a more limited ability to differentiate compared to totipotent and pluripotent cells, but they can still give rise to a variety of related cell types. These cells are typically restricted to producing cells from one specific germ layer, such as mesenchymal stem cells (MSCs), which can differentiate into various cell types within the mesoderm, or hematopoietic stem cells (HSCs), which primarily produce blood cells. Adult stem cells also fall into this category. In general, multipotent stem cells are capable of differentiating into a closely related family of cell types, but their potential is more restricted compared to the earlier stages of stem cell differentiation.

Tissue Specific Stem Cell or Adult Stem Cells

Adult stem cells are undifferentiated cells that remain in various tissues throughout the body after embryonic development. They have the ability to multiply and regenerate damaged tissues through cell division. Recent research has shown that adult stem cells might be more versatile than previously thought, with the potential to differentiate into different types of cells from various germ layers. For example, bone marrow stem cells, which come from the mesoderm, can not only produce cells from the mesoderm (like muscle and bone) but also cells from other layers, such as lung, liver, and digestive tract cells (endoderm). Another example is neural

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stem cells (NSCs), which originate from the ectoderm. These cells have been shown to differentiate into other types of cells, including those from the mesoderm and endoderm. This expanding potential has demonstrated the therapeutic value of adult stem cells, making them increasingly important in cell therapy and regenerative medicine.

Cancer Stem Cells (CSCs)

In the late 1990s, John Dick and his team first identified cancer stem cells (CSCs) in cases of acute myeloid leukemia and other blood cancers. CSCs are a specific type of cancer cell found within tumors or hematologic cancers. What makes them unique is that they share characteristics with normal stem cells, meaning they have the ability to generate all the different types of cells found in a particular cancer. Over time, more and more evidence has supported the cancer stem cell hypothesis, which suggests that, just like normal stem cells help repair and regenerate damaged tissues in the body, CSCs play a similar role in fueling the growth and spread of tumors. Many studies have shown that a tumor's ability to grow and spread depends on a small group of cells with stem-like properties—these are the CSCs.

MSCs

Embryonic connective tissue contains a type of tissue called mesenchyme, from which many different types of connective and blood-forming tissues (hematopoietic tissues) are derived through interactions between the endoderm and ectoderm. However, mesenchymal stem cells (MSCs), despite their broad differentiation potential, do not give rise to blood cells. In 1924, Alexander A. Maximow used detailed histological techniques to identify a specific precursor cell within mesenchyme that could develop into various types of blood cells. MSCs are a unique type of stem cell known for their ability to differentiate into multiple cell types and their capacity for self-renewal. These cells are found in many tissues and organs, including adipose tissue, bone marrow, skin, peripheral blood, the fallopian tubes, cord blood, liver, and lungs, among others.

Today, stem cells are used in a variety of applications, particularly in human therapies like cell transplantation and cell engraftment. In addition to human medicine, stem cell use in veterinary medicine is also gaining attention. The goal of this review is to provide an overview of the different types of stem cells isolated from various animal models, such as horses, pigs, goats, dogs, rabbits, cats, rats, and mice. Given the widespread use and growing interest in MSCs, we will focus particularly on how these cells are being utilized in veterinary medicine.

Application of MSCs in Regenerative Medicine in Animal Models

The wide variety of stem cell sources and their broad potential applications make it challenging to choose the right type of cell for therapy. Animal studies have shown that cell-based therapies, including those using stem cells, can treat a range of diseases. However, there are still concerns about the immune response when using stem cells in therapy. To address these challenges, improving animal models and refining methods for cell transplantation and engraftment are crucial steps toward ensuring the safe and effective use of stem cells in clinical settings.

In this section, we review both current and past studies on the development of animal models that can help advance the use of stem cells in regenerative medicine. Significant progress has been made in stem cell-based therapies, offering new ways to treat diseases that can't be cured with traditional medicine. Stem cells stand at the forefront of regenerative medicine because of their ability to self-renew and differentiate into various cell types, giving them immense therapeutic potential.

A lot of current research focuses on human stem cells, including both embryonic stem cells and adult stem cells, as well as induced pluripotent stem cells (iPSCs), which are reprogrammed from adult cells to behave like embryonic cells. While stem cell therapy has advanced significantly in the last decade, challenges still remain, such as the migration of transplanted cells and poor cell survival after transplantation. To overcome these hurdles, researchers have begun using biocompatible and biodegradable biomaterials in cell therapy. These materials help reduce cell loss and improve the long-term retention of stem cells in the body, which is a critical step in making stem cell treatments more effective and sustainable.

Heart Failure

Heart failure is becoming an increasingly common and serious problem in human populations, with a poor prognosis for many patients. For decades, mesenchymal stem cells (MSCs) have been explored as a potential treatment for heart disease, particularly in regenerative therapies aimed at improving cardiovascular health.

In a study by Dhein et al, bone marrow-derived MSCs (BMSCs) were shown to improve cardiac function in a rabbit model of non-ischemic cardiomyopathy, a type of heart failure. Similarly, in a study by Davies et al, cord blood stem cells were transplanted into a sheep model of heart failure, leading to significant improvements in heart function. The right ventricle showed increased mass, and both systolic and diastolic functions of the heart were enhanced.

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Another important study by Nagaya et al. found that MSCs could help treat dilated cardiomyopathy (DCM), a condition where the heart becomes enlarged and weakened. The MSCs appeared to promote the growth of new blood vessels (angiogenesis) and reduce fibrosis (scar tissue formation) in the heart, which is critical in preserving heart function.

MSCs are also beneficial in cell transplantation therapies, as they can differentiate into cardiomyocytes (heart muscle cells), vascular endothelial cells (which form blood vessels), and produce factors that reduce cell death (anti-apoptotic) and promote blood vessel growth (angiogenesis).

In 2015, Roura et al. highlighted that umbilical cord blood MSCs (UCBMSCs) could be a promising therapeutic option for conditions involving vascular damage, as these cells have the potential to regenerate blood vessels and support tissue repair.

A study by Ammar et al. compared bone marrow-derived MSCs (BMSCs) and adipose tissue-derived MSCs (ADSCs) in treating heart damage caused by the chemotherapy drug doxorubicin. The results showed that both BMSCs and ADSCs were equally effective in improving heart function. They did so by reducing collagen buildup (which leads to scarring) and promoting the growth of new blood vessels, which helped protect the heart from further damage.

Overall, MSCs show great potential in improving heart health, offering hope for regenerative therapies that could significantly improve the treatment of heart failure and related cardiovascular conditions.

Wound Healing

Chronic wounds are a common and frustrating issue for many patients, causing significant physical and emotional distress. One promising source of stem cells for wound healing is dental tissue-derived MSCs, which are rich in cytokines and growth factors that can promote tissue repair. Previous studies have suggested that stem cells from deciduous teeth (baby teeth) in horses could offer a novel approach for treating chronic wounds and might eventually be used in clinical settings for non-healing wounds.

However, more research is needed to fully understand how these stem cells work, particularly the specific growth factors that play a role in the healing process. Early studies indicate that deciduous teeth-derived stem cells have the potential to support wound healing, as demonstrated in rabbit models of excisional wounds.

In another study, Lin et al. (2013) explored the use of adipose-derived stem cells (ADSCs) in a mouse model. Their findings showed that ADSCs could serve as an effective treatment for full-thickness skin wounds, suggesting they might be a viable option for promoting healing in deep or complex wounds.

These studies highlight the growing interest in using stem cells from various sources to accelerate wound healing, though further research is needed to fully harness their therapeutic potential.

Application of MSCs in Neurodegenerative Disease in Animal Model

As mentioned earlier, stem cells have a wide range of therapeutic applications due to their ability to self-renew and differentiate into various cell types. This gives rise to great hope that stem cell-based therapies can one day treat serious diseases like Alzheimer's, Parkinson's, and other neurodegenerative disorders. In particular, embryonic stem cells (ESCs) are being studied for their ability to differentiate into functional neural cells, which could be used to treat neurological diseases.

A newer category of stem cells, called induced pluripotent stem cells (iPSCs), is also being explored to generate dopamine-producing neurons for Parkinson's disease. In animal studies, such as those using rats, iPSCs have shown potential for developing functional neurons that could help restore lost function in Parkinson's patients. Additionally, neural stem cells (NSCs) and mesenchymal stem cells (MSCs), including those derived from bone marrow, are being tested for their therapeutic potential in treating conditions like Alzheimer's, Parkinson's, and stroke.

For example, bone marrow-derived MSCs (BMSCs) have been shown to reduce brain amyloid deposits and stimulate the activation of microglial cells (which are involved in brain immune responses) in mouse models of Alzheimer's disease. A study by Lee et al. found that BMSCs could increase the number of activated microglia, which helped reduce amyloid-beta (Aβ) deposits—one of the hallmarks of Alzheimer's. Supporting this, Liu et al. showed that transplanting BMSCs into the brains of mice with Alzheimer's led to reduced amyloid-beta buildup, increased levels of brain-derived neurotrophic factor (BDNF, a protein that promotes brain health), and improved social recognition.

Beyond BMSCs, NSCs have also been identified as promising tools for treating neurodegenerative diseases because of their ability to generate appropriate cell types for brain repair. For example, a study by Åkerud et al. demonstrated that NSCs could efficiently

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produce glial cell line-derived neurotrophic factor (GDNF), a protein that helps protect and repair neurons, suggesting that NSCs could be used in treating diseases like Parkinson's.

In one of the most promising studies, Venkataramana et al. transplanted BMSCs into the brains of seven patients with Parkinson's disease. The results were encouraging, showing potential benefits for patients with this debilitating condition.

These studies underscore the growing potential of stem cells, particularly BMSCs and NSCs, in treating neurological diseases. While more research is needed, these therapies offer hope for future treatments for conditions that currently have few effective options.

CONCLUSIONS

The human body is equipped with a unique group of cells known as mesenchymal stem cells (MSCs), which have the remarkable ability to both self-renew (make copies of themselves) and differentiate into a wide variety of specialized cell types. These include fat cells (adipocytes), bone cells (osteocytes), cartilage cells (chondrocytes), and even nerve cells (neurons). What makes MSCs especially valuable is that, in addition to their ability to regenerate different tissues, they are relatively easy to isolate, can be safely transplanted into injured areas, and have immune-modulating properties, meaning they can help reduce inflammation and promote healing.

Over the years, many studies, both in laboratory settings (in vitro) and in live animal models (in vivo), have shown promising results regarding the potential of MSCs to treat a variety of diseases and injuries. They have been successfully tested in models for conditions like heart failure, wound healing, and even tooth regeneration. These successes suggest that MSCs could one day become a key part of treatments for such conditions in humans.

However, despite these positive findings in animal models, clinical outcomes in humans have not always been as encouraging. While many initial results look promising, translating these successes from animals to humans is a complex process. Challenges like immune rejection, difficulty in controlling the differentiation of stem cells, and ensuring the long-term survival and integration of transplanted cells remain significant obstacles.

One area where MSCs have generated a great deal of interest is in the treatment of neurodegenerative diseases, particularly conditions like Alzheimer's diseas and Parkinson's disease. These are diseases that involve the progressive loss of nerve cells in the brain, leading to symptoms like memory loss, motor dysfunction, and cognitive decline. MSCs hold potential for these conditions because they can support nerve cell regeneration, reduce inflammation, and protect remaining healthy neurons. In both preclinical studies (animal models) and early clinical trials, MSCs have shown promise in promoting neural repair and improving function in conditions like Parkinson's, though more research is needed to refine these treatments.

In summary, MSCs are an exciting and versatile tool in regenerative medicine, with the ability to treat a broad range of diseases. Despite the challenges that remain in translating animal model success into clinical practice, their potential for treating conditions like heart failure, chronic wounds, tooth damage, and neurodegenerative diseases continues to drive research forward. As the science behind MSC therapies improves, these cells could play a key role in revolutionizing the treatment of many debilitating diseases.

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CONCEPT OF LAW IN ANCIENT INDIA

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ABSTRACT

Introduction*: The definition of law and its proposition can be found in Indian literature dating back to the Rigveda, the oldest scripture. Ancient Indian literature also provides information on the chronological development of law. In ancient India not only there was tremendous development of mathematics, astronomy, medicine, grammer, philosophy, literature, etc. but there was also tremendous development of law. This is evident from the large number of legal treaties written in ancient India (all in Sanskrit). Only a very fraction of this total legal literature survived the ravages of time.*

Material and methods*: Ayurvedic texts, modern science textbooks, published articles, research journals, and the internet.* ***Result:*** *It is said that Hindu Law originated from the Vedas (called Shruti). In fact, the Hindu law really emanated from books like Manusmriti, Kautilya Arthashashtra etc. These were books written by certain Sanskrit Scholars in ancient times who had specialized knowledge in law.*

Discussion and conclusion*: In comparison with modern law, the classical Hindu law was a peculiar legal system as it followed a unique arrangement of law. The main aim of the law in the Vedic period was to preserve "Dharma" which means righteousness and duty.*

KEY WORDS: *Law, Emergence, Ancient*

AIM AND OBJECTIVES

- To study in brief about ancient and modern legal system
- To evaluate the contents of *Kautilya Arthashastra, Manusmriti* and other books w.s.r. to medical jurisprudence.

MATERIALS AND METHODS

- The materials were compiled from traditional Ayurvedic texts, modern science textbooks, published articles, research journals, and the internet.

INTRODUCTION

In the *Rigveda*, the term *Rit*[1] (Rit means right, honest, true, fixed or settled order, law, rule, divine law, faith, divine truth) denoted law. It was concerned with the truth. It originated from the *tap*[2]. In the *Rigveda*, *Mitravarun* was regarded as the administrator of law and justice[3]. *Dirghtama* elevated law above divine power[4]. He believes that divine powers exist to benefit humanity[5]. The Vedic *Rishies* did their best to create successful social inclinations against antisocial powers.

Rit is 'truth', 'welfare', and *Dharma*, but it did not originate with the supreme power. It is the ultimate power. The description of Rit represents both truth and continuity. The law is unchangeable and firm.[6] The Vedic literature makes it clear that law, morality, and religion are eternally interconnected. In Vedic literature, the term *Rit* was used to denote law, which includes truth (सत्य), Dharma or duty (कर्तव्य), welfare (कल्याण), and firmness (दृढ).

Law and Religion:

Dharma is the Sanskrit word for law, and it has a very broad meaning. *Dharma* refers to a moral code that unites people. The term "*Dharma*," meant something that was set in stone, unwavering, and unchanging, like a law, statute, ordinance, usage, custom, observance of customs, duty, right, justice, virtue, morality, religion, and so on. Generally speaking, the term "*Dharma*" refers to the natural, social, and moral laws and duties that citizens must uphold. There were two interpretations of the term "*Dharma*":
(1) It came to be associated with a virtue ethic or moral perspective. Buddhism elaborated on this concept further.

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(2) It came to be associated with the specific social responsibilities of the four orders (*Varnas*).
Even though the word "*Dharma*" is translated as "religion" in English, this translation is not accurate or complete. The word "*Dharma*" is used frequently in the epic to refer to the application of justice. It is taught by thinkers that *Dharma* is dependent on time and place, but in reality, it is not a set principle of life; rather, in its spirit, it is ever-changing and is adjusted in accordance with the emerging circumstances. The King is the protector of *Dharma*, and it is his duty to ensure that the people follows it. If one of the four Orders (*Varnas*) violates righteousness, the King must punish accordingly. Thus, *Dharma* represents ethical values, duties, good work, religious virtues, universal truth, divine justice, social and individual responsibilities, and international law. The various laws available in the *Manusmriti* have been presented as *Dharma*. It contains various laws that can be classified as *Varn-Dharma*, *Ashram-Dharma*, *Varnshram-Dharma*, *Raj-Dharma*, *Purush-Dharma*, *Nitya-Dharma*, *Nemmitik-Dharma*, *Kul-Dharma*, *Desh-Dharma*, and so on. It includes separate rules and duties for each *Varna*[7]. Each man will follow the rules and duties established for his own order (*Varna*). As a result, *Manu* most likely declared it the King's special responsibility to protect the *Varnshram-Dharma* system[8]. The rules for these four orders (*Varnas)* can be divided into four categories: *Brahmin-Dharma*, *Chatriya-Dharma*, *Vaishya-Dharma*, and *Shudra-Dharma*[9]. The *Manusmriti*, like *Varna-Dharma*, contains certain rules and duties that people from various Ashrams must follow. Each person was required to follow the duties assigned to his Class or Ashram. *Manu* classified the Ashrams as *Brhamcharya-Dharma, Grahastha-Dharma, Vanprasth-Dharma,* and *Sanyas-Dharma*[10]. He considered it the King's responsibility to maintain the *Ashram Dharma-system*[11]. He established *Danda* (punitive measures) as the initiator of the Ashram system. He made it the King's liability to punish anyone who violates this system[12].

Raj-Dharma
Manu had made it clear that the King had to carry out his duties in a certain way. He believed that the King's duty was to protect his subjects in a judicial capacity[13]. *Raj-Dharma*, as mentioned in the *Manusmriti*, refers to those regulations and obligations that a King must fulfill[14]. In fact, *Raj-Dharma*, which contains provisions to prevent the King from becoming a cruel, upholds the legitimacy of autocracy (governed by one person with absolute power) because the corrupted King, who violated the *Raj-Dharma*, has been eliminated by *Danda* (punishment)[15].

Nitya-Dharma
Manu had laid out some rules and duties for the *Dwizs*, which included *Brahmins*, *Chatriyas*, and *Vaisyas*. It had been known as *Nitya-Dharma*. For example, it is the responsibility of each individual to perform a daily bath, *tarpan*, and *pujan* in the morning and evening[16]. As a result, each individual had to work hard to keep his senses under control[17]. Manu had given the *Shudras* permission not to perform these duties[18].

As a result, the legal system of ancient India is built upon strong, well-defined foundations. While the term "law" in modern refers to commands of the State that are enforceable by the Authority, but in ancient India a command issued by the King had legal force because the King could enforce it with his punitive powers. In fact, the King's command, controlled by a variety of rules, would be governed by the orders (*Varna*) and *Ashram-Dharma*. Though Manu did not regard the State or the King as sources of law, he made it the King's special responsibility to enforce the *Shastrokt* (in accordance with *Dharmashastras*) laws on the subjects. The King must perform his duties in accordance with the *Dharma*. In fact, there appeared to be no distinction in the *Manusmriti* between Dharma and law. Dharma was accepted as equal to the law. The *Manusmriti's* legal system is a successive system based on the principles of supremacy and equality before the law. The goal of introducing the principles of *Dharma* or duty is to encourage people to follow the law voluntarily[19]. Thus, *Manu* believes that voluntary compliance with the law can effectively reduce crime. Aside from that, the only way to control it is through severe punishment.

Given the preceding discussion, it is clear that both the King and the subjects held a high regard for the rule of law. The fact that law was synonymous with *Dharma* is great. *Dharma* encompasses all aspects of society, including social, religious, moral, spiritual, and judicial issues.

Law and Society
No civilized society can exist without law based on broad principles. The face of law in ancient Indian society reflects the state of civilization. Human beings are social creatures. For social harmony, they also need laws. In the social structure of humanity, there are various kinds of social behaviors. In ancient times, social behaviors could only be limited to some extent. However, with the passage of time, expansion in social behaviors is inevitable. As social behaviors increase, the need for laws also increases. Manu enacted legislation through both jurists and sociologists. As such, he can be referred to as both a sociologist and a jurist. Manu had attempted to establish a direct connection between law and the *Vedas*. *Manu's* goal was to put human behaviour on a social foundation. Because of the

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sociological and legal aspects, he could not ignore the impact of social circumstances on the creation of law. The reason for preserving the origin, despite keeping contact with changes, is the traditionalism of Indian law; however, after accepting the *Shruti* to the *Smriti* period, significant changes in law were required. The majority of the laws were included in *Shrutis* but not in *Smritis*. In this way, changes in the law were made based on factors such as region and time, while the original was also preserved. The Vedic law was connected to other laws. As a result, in addition to general guidelines for individuals, special laws for a specific branch of the population were created. In the ancient judicial system, equality of law was disputed and criticized. The concept of absolute equality of law could not be implemented or sustained in any society. The reason is that differentiation and individuality promote feelings of superiority and dominance. They have the willpower to influence the behaviour of others. Different types of disparities in society are equally responsible. It is undeniable that strong people have dominated weak people. Laws cannot be equal because not all people are equal.

Man and Law

A man was held responsible to society in more than one way: he was expected to fulfill all of his obligations to his fellow beings, and he was also held accountable to society for his actions. Hindu legislators prescribed the expulsion of individual sinners from society. They even stated that offenders of the moral code should not be associated in any way. Individuals' membership in society is conditional on their adherence to the *Dharma*. The entire system effectively affirmed the individual's accountability to society. *Manu* argued that society should not have any contact with the unrepentant sinner, but added that a man who had duly apologized for his sin by performing the prescribed punishment should never be humiliated by reminding him of his past crime[20].

Equality in Ancient Law

The idea that "all human beings are born unequal" was another fundamental tenet of ancient Indian society. However, one established democratic principle held that all human beings must be made equal if a democratic social structure is to be achieved. Therefore, *Manu*, advocating for the democratic set-up of the Hindu social structure, proclaimed this idea as follows: "Even though all human beings are born unequal in their capacity of execution, they all are equal in their capacity of enjoyment," meaning that all people should be made to work according to their abilities but that everyone must be given an equal share in the enjoyment of the social production. All people, male or female, highly intelligent or extremely stupid, shared the same sense of hunger, thirst, sleep, fear, and other emotions, even though their productivity levels may vary greatly.

Family and Law

In building the Hindu social structure, men and women together, as husband and wife, formed the smallest social unit[21]. Every family was granted complete authority to create its own laws that addressed both meeting their fundamental needs and establishing standards of behavior for the family[22].People were granted the financial freedom to select a career path based on their aptitude and experience[23].Castes were formed by families with similar occupations, and each caste acted as a sovereign authority in its own field of expertise.

Many religious rituals are eligible for the couple only. Some household duties can neither be performed by a woman alone nor by a man alone[24]. In this assumption, the clear influence of divine law is evident. Where the secular aspect of marriage provides social discipline to the relationships between women and men, it also assists in the spiritual upliftment of individuals, making its spiritual aspect stronger[25]. The sanctity of this bond provides humans with the strength that is also rare for God[26,27]. The law that separates or breaks marital relationships, lacking a divine basis, also does not help in strengthening social discipline. This law affects both family unity and discipline. It is not appropriate to label the law that breaks relationships as secular law. Even though such a law may fulfill political objectives by breaking the unity of society and family, it renders the real principle of law meaningless.

As a result, each member of Hindu society was able to benefit from the people's sovereignty, whether it be in his or her own right or as a group. The goal was to attain the ideal of "from each according to his ability, to each according to his needs" in this way.

NEW FORM TO SOCIAL LAW

Manu specifically attributed the evolving social law, especially evident in the *Dharmaasutras*, to divine origin. The genesis of the four components of society from the limbs of *Virat* was acknowledged from the *Rigveda* or *Yajurveda*. However, to strengthen the structure of social organizations, *Manu* gave it a new form. He considered a society structured around the four *Varnas* as divine. Their rights and duties were defined, and they too were considered divine. Abandoning one's prescribed *Dharmaa* and *Karma* for another religion or action was considered sinful (*Paap*) and punishable, as it violated the unity and will of *Virat*.

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Manu attempted to bring his social system in line with the Vedic arrangement of divine origin on a legal basis. In this context, two preceding ideologies influenced his approach: the legal authority derived from the state and the doctrine of *Karma*. *Manu* accepted state law as a means to an end. It presented an framework for each *Varna* to fulfill its rights and duties and regulated them within their respective paths[28].

In this scenario, the state was considered the guardian of *Dharma*. To institutionalize the social system, *Manu* expanded the sources of law. He harmonized the *Vedas* with *Smriti* (remembered texts), *Sadachaara* (right conduct), and *Atmapriya* (what is dear to oneself), integrating them with the preceding tradition and accepting two other sources to uphold individual dignity. While reconciling the sources of law and social regulations, *Manu* encountered some challenges. He was not inclined to accept the legitimacy of non-Vedic social systems. Therefore, immediately after outlining such a system, he stated that the "*Dwijati*" should not deviate from the sources of law, the *Vedas* and *Smriti.*

Supremacy of Social Law

By the time of the (*Nitigrantha*) treatises, both economics and ethics had evolved into traditions. They integrate the tradition of *Arthashastra* by *Kautilya* with the *Smritis*. According to them, "Society (*Varna*) can only be saved from destruction by adhering to its laws (*Dharmaa*)." The state's necessity lies in establishing the adherence to social laws. Thus, *Kamandaka* (author of *Nitisara*) acknowledges the necessity of the state by prioritizing social laws. Regarding the law based on ethical scriptures, they assert, "The conduct of *Aryas* (noble ones) is based on law (*Dharmaa*), and their prohibition is considered irreligious (*Adharmaa*)."

In this way, *Kamandaka* presented the supremacy of social law by reconciling the teachings of *Apastamba*, *Manu*, and *Arthashastra*.

- The enactment of a law proposed for moral upliftment and social structure is considered to be a practiced or practical law, and the expected impact of such a law is bound to affect society significantly. Before advocating a legal principle, the outline of social progress should be determined. It is often expressed that the formation of ancient societies was based on religious foundations. Because human life is fundamentally dependent on economic resources and it is also understood that a civilization that does not develop the means of economic production, that civilization remains undeveloped. From this perspective, the formulation of a law should be such that it can assist in economic production and other material developments.
- In summary, everyone was subject to the ancient India teachings- high or low, wealthy or impoverished, king or common man. No unfair distinctions were made. These were clearly wise guidelines for both thought and behavior. That is our understanding of the principles and guidelines contained in the ancient scriptures. To be honest, though, there are no records indicating whether or not these principles applied to everyone. But there is one thing that is known for sure. For the most part, the Hindu social structure was harmonious, cohesive, and close-knit. The principles set forth in the ancient books were fully respected by both the King and the commons. The ancient book's purity and sublimity of thought still arouse our respect and compel us to walk the path of righteousness. The type and seriousness of the offense determine the severity of the punishment.

Law and Morality or Good Conduct (*Sadachaar*)

- In ancient India, administrations were responsible for developing good conduct (*Sadachaar*) and promoting moral values among citizens. It was the notion that anyone who acts against morality and has a tendency for misdeed should be punished in order to bring him back on track. The punishment imposed on him would serve as an incentive. It would serve as a warning to others against deviating from morality and righteous behavior. It would encourage people to follow moral principles and conduct themselves appropriately.
- The reason for establishing state power is that those who act against *Dharma* may be forced to follow the right path[29]. Punishment must be awarded for offenses committed so that one may have fear of being punished[30]. Punishing the offender is a process of purification for society and the state. Punishment may be light or harsh, depending on the nature of the offense. Its flexibility in any form would encourage the stronger to harass the weaker. The punitive system is a form of societal therapy. In this process, the judge has the feeling of purity and welfare, similar to a physician[31].
- The ancient treatises demonstrate that in the past, people believed that good behavior, or *Sadachaar*, was the highest form of Dharma. The King's primary duty was to suppress anti-*Sadachaar* activities. The principle of crime and punishment must be upheld because it benefits both the public and the King. Moreover, if the King did not act in this way, he would be a sharer in sin[32].
- The ancient treatises, allows for a detailed discussion of the necessity and utility of punishment[33]. It states that maintaining *Sadachaar* and morality among the subjects was the primary goal of both the administration and the judicial system. In ancient India, educated scholars and sages supported harsher punishments to eliminate anti-social elements.

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- In the *Vedas*, sin is compared to death. It can be argued that harsh punishment for sin and crime may not work. Punitive measures by themselves are insufficient. Criminals and sinners may be given the opportunity to change and adopt virtuous behavior. If they do not correct, however, they may receive even harsher punishment.
- The reformatory theory of punishment changes the culprit. However, the ancient sages supported harsh punishment as a deterrent to misdeed. In reality, strict punishment is ineffective. However, it cannot be denied that the only two reasons that man abstains from committing crimes are fear of punishment and fear of violating *Dharma*.
- Manu believes that when a person is consumed by misconduct, they are more likely to engage in criminal behavior[34]. Thus, man must obey his *Dharma* in order to avoid being overpowered by immorality; however, if one fails to avoid immorality and commits a crime, he must be punished severely so that crime is not encouraged.
- It was up to the King to punish those who violated *Sadachaar*. Religious scriptures emphasize that such Kings deserve more reverence than God. *Manu* established that the King whose kingdom contains no thief, wicked, dacoits, or murderers would be eligible for entry into *Indralok* (divine enjoyment)[35]. In other words, the King who frees society from culprits receives celestial glory. He deserves a place in heaven.
- It demonstrates that in the ancient Indian judicial system, the King was expected to be vigilant in order to maintain *Sadachaar*. In the absence of moral values, the crucial distinction between right and wrong will vanish, and moral values must be superimposed. Without morality, society will be governed by the law of the jungle.
- Maintaining *Dharma* was an important function of the State, to the point where it was stated that sovereignty exists for the sake of *Dharma*. *Manu* believes that people become righteous solely because they are afraid of *Danda*. Its absence, extinction, or anomaly will cause panic in society[36]. Hence, *Danda* is an essential component of *Dharma*[37].
- The term "*Rit*" or "*Dharma*" refers to the moral order of the universe that controls and directs events in order to guarantee that truth, or *Dharma*, always succeeds and that untruth, or *Adharma* (moral wrong or unjust act), is ultimately defeated. In ancient India, the *Dharmashastras* were considered a major source of morality. The *Dharmashastras* are the highest authority and virtually the only source of the ritualism that Hindus practice today.
- The word "*Dharma*" comes from the root "*Dhr*," which means "to sustain" or "to support." This definition of *Dharma* has given a slight bias to all of Hindu thought in favor of social stability. Hindu law-givers have placed a major emphasis on individual duties that directly contribute to the stability and harmonious preservation of the social order. They have recognized two types of duties that individuals must fulfill: class duties that are required of them due to their class and stage of life, and universal duties that apply to all people. The primary concern of Hindu law-givers has been social stability.
- To summarize, actions such as devotion, sacrifice, gift, and merit can lead to bondage, whereas non-attachment or detachment promotes moral ethics. Controlling undesirable elements is critical for creating a moral atmosphere. Inner feelings such as *Kama* (sex), *Krodha* (anger), and *Lobha* (avarice/greed) must be controlled and cleansed. Only good conduct (*Sadachaar*) and morality would lead to the achievement of the cultural goal[38].
- As we dicussed earlier, *Kamandaka* presented the supremacy of social law by reconciling the teachings of *Manu*, and *Arthashastra*. Their influence also extended to social morality. There was a need to protect "inherited morality." *Kamandaka* made the state a medium for this purpose. In defining the relationship between social morality and the state, *Kamandaka* follows the path of *Kautilya*. According to him, to eradicate antisocial morality, the state can employ all kinds of policies. Thus, the state could eliminate the power opposing the welfare of the state and society even through "immoral" means, which was considered the duty of the state. *Kamandaka* thus acknowledges the tradition of state behavior in economics and adheres to the tradition of *Smritis* based on social law, morality, and the foundation of the state. However, the situation of that time influences the relationship between social law and the state, where the state remains the only medium for the protection of social law.

Relationship Between Morality and Legality

Some rules of law are eternal, unaffected by time or adverse circumstances. These rules are found in every era. While the form of these laws may change with the evolution or alteration of civilization, but their purpose remains consistent. It cannot be said that such laws undergo transformation. For example, the punishment for murder has remained unchanged since ancient times. Despite opposition, this penalty has not been removed from legal statutes. While there may have been changes in agricultural and commercial laws, fundamental actions remain unchanged. The impact of mindset on such laws is minimal. Historical studies also reveal that regardless of the country or civilization, murder and theft were never considered legitimate actions or integral to morality. Although it can be argued that if there is an unbreakable relationship between morality and legality, any action that cannot be considered moral cannot be legal either, yet changes in civilization have not altered the human perspective on these actions. These historical facts indicate that certain rules in law are indispensable, found within society, and are also related to political systems. Nevertheless, societal changes cannot affect these rules. The stability of legal mindset indicates the existence of a trait inherent in human society, one that continually prompts adherence to the law. Indeed, the presence of this trait within human society is the subject matter of historical legal principles.

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State and Law

The primary function of the state was to protect its subjects from both external and internal attacks and threats. In carrying out this function, it was the State's primary responsibility to control people's actions (*Vyavahar*), the law, the courts, *Sadachar* (good behavior), and so on.

***Saptang-Rajya* (A Seven-Element State)**

- The Manusmriti[39] also discusses the principle of *Saptang-Rajya* (a seven-element state). Yagyavalkya and Narad also discussed the idea of Saptang Rajya. All three Smrities mentioned above, namely the Manusmriti, the Yagyavalkyasmriti, and the Naradsmriti, provide a description of seven State elements.
- Manu defines the seven elements of the state as:

Swami (King), *Amatya* (Minister), *Pur* (Territory) *Rashtra* (State), *Kosh* (Public Exchequer), *Dand* (Justice), and *Mitr* (other states trusted as Friends).

- *Yagyavalkya's Saptang* Theory of State Advances was similar to Manu's. But, instead of *Pur* and *Rashtra*, he used *Jan* and *Durg*[40].
- *Man*u and *Yagyavalkya's Saptang* (seven limbs) theory of the State differs slightly from one another. Manu denotes the capital, whereas *Rashtra* refers to the entire nation. However, instead of describing these two separately, *Yagyavalkya* combined them under the heading *Jan* and added a constituent of the state known as *Durg*. But *Manu,* despite not including *Durg* in the *Saptang* (seven limbs) list separately, considered it all inclusive. As a result, it is possible to say that they both arrived at the same conclusion.
- The seven limbs mentioned in the above *Smritis* were discussed in order of importance.

According to *Manu*, every limb of the State that performs a specific function is considered to be specialized in doing so. Because that particular limb has a special capacity to performing its function, no other limb can do so as efficiently. As a result, regardless of their specialty, all limbs are given equal importance.

- However, they were ranked in order of importance when they were all considered together. This allows these limbs to be evaluated in two different ways.
  First, because of their expertise in performing specific functions, they were granted the authority to do so; second, their significance as a component of the *Saptang* (seven limbs) of the State was demonstrated. However, neither part is inferior to the other in their respective spheres. All of these interdependencies are equally important[41].
- In the *Arthshastra*, *Kautilya* referred to *Swami, Amatya, Pur, Rashtra, Janpad, Durg, Kosh, Dand,* and *Mitra* as the seven *Prakrities* (parts) of the State.
- *Sukranitisar*, a later treatise, also identified *Swami, Amatya, Mitra, Kosh, Rashtra, Durg,* and *Bal* as the seven *Prakrities* of the State[42].

Formation of State

The formation of the State, as discussed in the *Smritis,* is quite ancient. That formation was thoroughly discussed in an ancient Indian treatise (predating the Smrities). The seven limbs of the state, *Swami, Amatya, Mantri, Janpad, Durg or Pur, Kosh, Dand* or *Bal*, and *Mitra*, are known as *Prakrities* and have been discussed in *Mahabharat*[43], *Manusmriti*[44], *Arthashastra*[45], *Yagyavalkya Smriti*,, *Shukrnitisar*[46], and other texts.

- ***Swami***, which means head or master, is mentioned as such in all sources. *Swami*, according to *Kautilya*, should possess qualities derived from noble birth, such as wisdom, enthusiasm, and personal ability. The characteristics of noble birth deserve special attention because they exclude the possibility of men of humble origins ascending to the status of king.
- The modern constituents of the State, such as sovereignty, government, territory, and population, are governed by the elements of *Swami*, *Amatya*, and *Janpad*, as outlined in the *Saptang* theory of the State. Perhaps it is difficult to associate sovereignty with the head who is required by the law-givers to govern in accordance with *Dharma's* principles.
- In modern times, unless a State receives recognition from other States, its *de jure* status is not recognized. This element in the modern State can be compared to *Mitra* (ally), though the goal in ancient times was to secure allies rather than recognition from other states. Although population is not mentioned in the *Saptang* theory, the term *Janpad* clearly refers to the inhabited territory. In contrast, the modern definition of the State excludes the army, taxation, capital, and ally. Clearly, the ancient definition of the State is both concrete and extremely practical.

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IMPORTANCE OF KING

- Among the *Saptang* (seven limbs) of the State, the King was regarded as the most important. The *Rigvedic* King was known as the protector of the public at large (गोपा जनस्य). He was charged with two tasks: maintaining state peace and protecting the state from *Anarya* (foreign) invasions. Thus, despite being a military chief, the King was also entrusted with the functions of chief of judicial administration, though the King was never regarded as the source of justice.
- *Varun* was the *Rigveda's* governing God of *Dharma*. He also regulated the Rit[47]. Until the time of the *Brahmins*, the reign-related (राजत्य) theory was fully developed. According to *Shatpath Brahman*, the King is responsible for the state's proper functioning (सुसंचालन), firmness (दृढता), agriculture, happiness (सौख्य), and development, among other things.
- When the King became God *Varun's* representative, he became the official in charge of punishing the culprits. However, the power he misused made him liable for punishment.
- As a result, mutual relations between the King and *Dharma* were established, with *Dharma* taking precedence over the King. The *Dharmsutras* considered doing justice to be the King's most important duty. The *Dharmsutras* clearly state that the King received a sixth part (षडभोग) as compensation for maintaining peace among subjects and protecting the State from external attacks[48].
- After the rituals of *Indramahabhishek*, *Brahmin Purohit* touched the enthroned King three times with *Dand*a. It demonstrated that if the King failed to perform his duties properly, he would be punished under the same law (*Danda*). He isn't more important than *Dharma*. The King, as the *Saptang* State's first limb, was given the authority to enforce state law (*Rajyavidhi*).

Rajyavidhi (State Law)

- *Rajyavidhi* (State law) refers to 'the law established and administered by the state'. In ancient India, the judicial system was centered on the concept of 'supremacy of law'. This tradition persisted until the *Dharmasutras* were written. According to *Gautam*, the King's judicial administration must be inspired by the *Vedas*, *Dharmshastras*, and *Purans*[49]
- The State recognizes the authenticity of *Desha*, caste, *Kul*, and other traditions and behaviours (*Vyavahar*), but nothing that contradicts the *Vedas*. Artists, farmers, herders, and others followed authentic rules and regulations in their respective fields. As a result, the *Vedas* and treatises based on them, such as the *Dharmshastras*, emerged first as sources of state law. The customs and traditions of various local, social, and economic organizations were ranked second.
- In the administration of state law, the commentators of argument (तर्क), purpose (हेतु), approach (*Aagam*), and precedents (दृष्टांत). Along with the King, the commentators were within legal bounds. The King was not permitted to interfere with the expositions given by the commentators. The relationship between State law and Social law established the rights and responsibilities of individuals in society. In this way, they represented both the law and society.
- In such a case, the King acted as the guardian and protector of the law, ensuring that it was not infringed upon by state law. As a result, the King was responsible to both society and the law. In fact, the State law included the law governing crime and punishment. However, the State remained merely a means to an end, with no authority to make laws. The King was allowed to carry out his duties only. Violation or transgression of the law, local and social traditions, or state law could result in the king being dismissed or his life being taken away.
- *Kautilya's Arthashastra* is primarily a political treatise. The implementation of law saw the state's power becoming significantly important. In this context, the coordination between law, social tradition, and state law became a crucial issue. As stated, *Arthashastra* aligns with the Vedic tradition's success. It considers the foundation of society as the "*Trayi*" (three)- *Dharmaa* (religious law), *Artha* (economics), and *Vyavahara* (forensic science), along with *Nyaya* (reasoning). In administration, the king had to accept the means inherited from tradition. However, here *Arthashastra* was also considered another basis for state law.
- *Kautilya* had attempted to give the State a welfare component. He refused to accept traditions, customs, and conduct in their original form as integral parts of the welfare state. *Kautilya*, while establishing State law, proposed some modernity alongside its traditional practices.
- He recognized the region (*Desh*), caste (*Jati*), and clan (*Kul*). He delegated the task of compiling lists to state employees. This action was deemed necessary for the newly conquered territories. In this respect, *Kautilya* made a significant change. He only approved new and ancient virtuous conduct (*Aachar*) that was not detrimental to the State or society[50].
- In this way, *Kautilya's Arthashastra* granted the State the right to conduct itself in a manner that is not improper. It may be not only rejected, but also repealed. In the event of a conflict between the State law and virtuous conduct (*Aachar*), the State law would take precedence over virtuous conduct. Among *Dharma*, conduct, character, and State rule, *Kautilya* ranked State law

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first. However, this cannot be considered a source of law, and yet, in the administration of judicial sovereignty, the State administration is given precedence. In terms of the sources of State law, the *Manusmriti* itself supports the previous ideology.

- According to *Manu*, the King would decide verdicts based on eighteen categories, regional practices (देश-दृष्ट), and sacred canons. Manu believes that the King should not violate the traditional conduct of his class (*Shreni*), clan (*Kul*), or any other economic group. *Manu* had achieved coordination between law and state by depriving the King of legislative powers.
- According to *Shukra*, the foundation of state law is *Dharmashastra*, and the use of *Arthashashtra* is accepted only in a manner consistent with *Dharmashastra*[51]. The judiciary is where *Arthashashtra* is applied according to *Dharmashastra*. *Smriti* is a means of justice. Along with this, they also consider governance, customs, and tradition as the basis of state law. According to them, the king should make decisions in justice by harmonizing scriptural perspective, regional perspective, caste, region, category, family, and regional customs. *Shukra* says that different regions have different practices, and uniformity cannot be imposed in all cases. In this, *Shukra* acknowledges the tradition of previous *Smriti* writers and economists. On one hand, they consider *Dharmashastra* and on the other hand, they consider public opinion, customs, and tradition as the source of state law; however, they do not want to ignore regional and caste customs in any situation. Thus, even with the development of state power until this time, the basis of state law could never be solely the king's order. Its control was maintained by social forces. Changes in social values and the environment also led to partial changes in the legal system.

DISCUSSION

In the past, the legal systems were regarded as important branches of society that carried out the administration of justice. The King upheld the *Rajadharma*, which forbids discrimination, in order to administer justice. The king could not protect the people because of the insufficient power of kingship. As a result, the great *Dharma*, or "the law," was created, superseding the king. "Law is the King of Kings, nothing is superior to law; the law aided by the power of the King enables the weak to prevail over the strongs" is the definition of the law (or Dharma= Justice).

CONCLUSION

To summarize, *Manu* and other *Rishies* of ancient India provided a more refined definition of state than Western thinkers. It demonstrates that ancient India had a well-developed society. The concepts of law and politics were extensively developed. Even though it was in its infancy, the administration of justice in ancient India was well-organized. This system offers a great basis on which the contemporary justice administration system has been assembled and organized.

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GROWTH OF AI IN AUTOMOTIVE INDUSTRY AND MANUFACTURING TRENDS

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ABSTRACT

In the automobile industry and the functions of artificial intelligence. During the process of manufacturing, a functional system and sensor-related work can be done with the help of artificial intelligence, which helps monitor the function of the vehicles. And the growth of EV vehicles through the support of AI. Nowadays, it plays an important role in the automobile industry and helps the R&D department to research new products and new developments in the automobile industry. It largely encourages automatic vehicles and expands its sales in the domestic market.

KEYWORDS— *artificial intelligence, sensor-related work, automatic vehicles, automobile industry, domestic market*

INTRODUCTION

In many organisations, the R&D department is crucial. It seeks to innovate and improve products, services and new product development processes. In this sector, we first take market research or product development research. This research report helps manufacture products with the help of advanced technology. This type of research is aimed at gaining a deeper understanding of the market of products and theories. It is often exploratory and not immediately focused on practical applications of the new product development process. Now, artificial intelligence has become an online research tool with the help of artificial intelligence, knowing the market strategies and demand for the new product. Artificial intelligence now reduces the workload of the R&D department because all the reviews and feedback are available with the help of artificial intelligence. It helps the R&D department develop products using scientific technologies and updated automatic versions of the products. AI improves the growth of automatic-based products and services, which are increasingly available 24*7. It offers the service anytime and anywhere, so it will be easily accessible to everyone. Nowadays, AI generates a systematic approach to providing machine-based services to customers. This type of technology accelerates the R&D and new product development department to complete the work more easily and stands for achieving more and more. AI supports the R&D department in developing products or services that satisfy customers' needs today. It can reduce the work pressure on employees in the R&D and new process development sectors. In automatic and system-oriented products or services, any complaints found can be easily sorted out by using artificial intelligence. Many organisations can use artificial intelligence to develop their products and services, manufacture quality products to satisfy customer needs, and supply products worldwide.

Growth of AI in Automotive Industry

- AI plays a crucial role in the automobile and manufacturing industries. It improves the systematically advanced technologies in the automobile sector.
- It can reduce the workforce of the production department, and all the working functions are performed using AI and automatic force.
- Once functions are programmed with AI help, all of their tasks will be monitored and managed by AI. It does not need any personal intervention in the production process.

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source: Roots Cast Customers

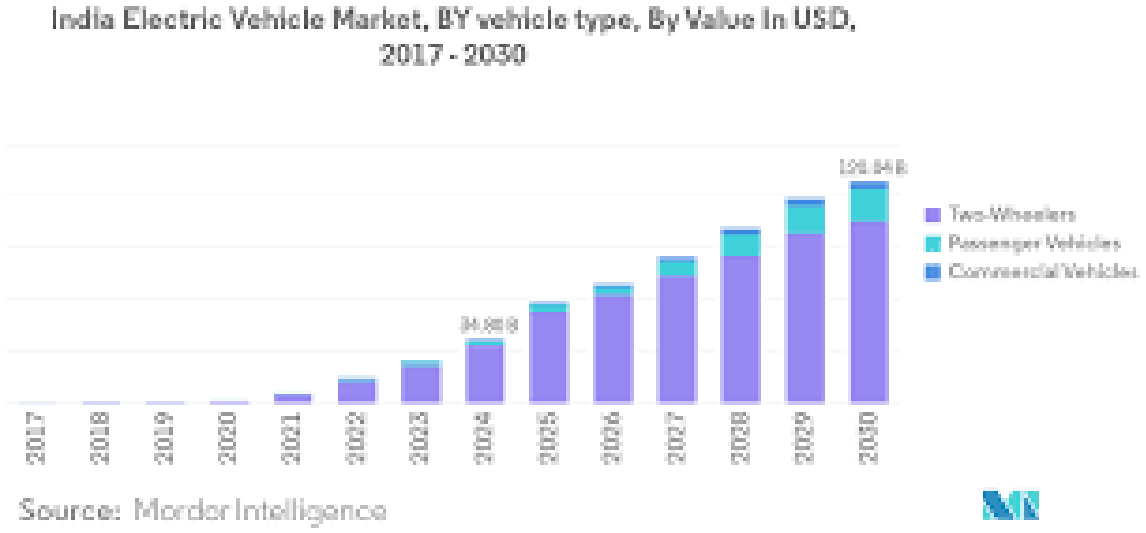
- AI is one of the tools. It approaches a function through systematic monitoring of the production process. If a malfunction occurs, the production process will be stopped.
- Many functions of an organization's R&D department will be carried out with AI support.

Manufacturing Trends in Automotive Sector

India is one of the world's main hubs for the automotive industry. It has a large workforce and good facilities for its sector in India. All types of vehicle parts and spares are manufactured and exported from India to other countries. Industry can be divided into,

- Automotive industry
- auto-component industry

India manufactures many types of commercial and passenger vehicles, as well as their parts, spares, and components. It is the fourth-largest automobile market in the world. Nowadays, electronic-based cars are being introduced, and their demand is expanding domestically and globally. In FY 2023, the Indian EV market is expected to grow at a CAGR of 36% until 2026. EV vehicles are focused on the battery market, which is forecast to expand at a CAGR of 30% during the period.



This chart represents the growth of electricity vehicles in the Indian market by category and also forecasts the future growth of EV vehicles. This type of vehicle is used in cargo, hospitality and passenger vehicles. EV vehicles are an alternative to the traditional culture and are welcomed by customers nowadays.

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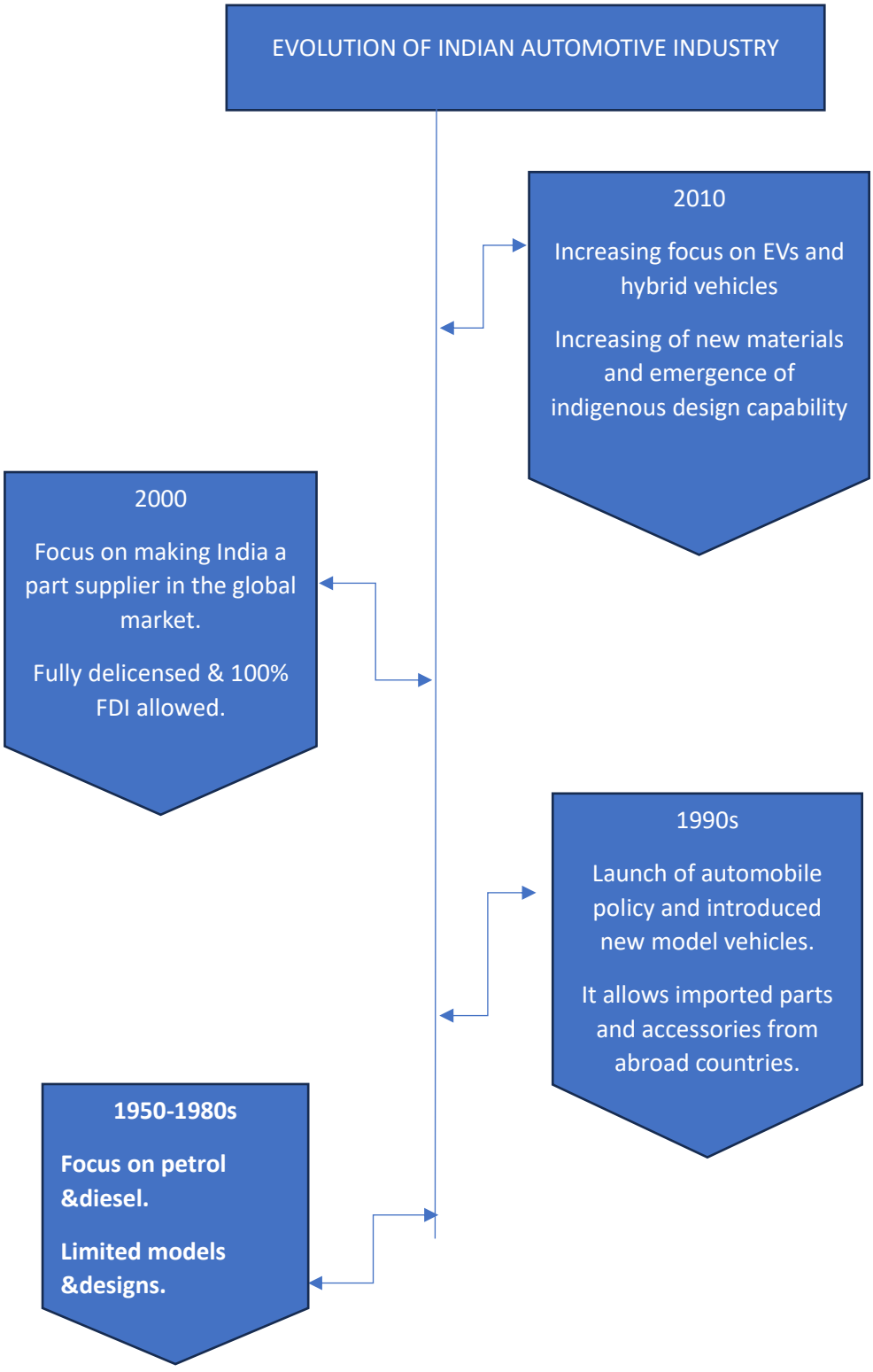
History of Automobile Industry in India



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CONCLUSION

AI has become an important ingredient in the making of cars and is rapidly changing how many things are done in the automotive world. AI has been adopted at every step of production, from design and prototyping to assembly and testing. In automobile applications, one of the core trends in utilizing AI is automation. In manufacturing plants, we see the use of AI-powered robots that require less human involvement yet have made things faster and more efficient. They are able to repeat tasks with more precision and speed than human beings, causing fewer errors and greater-quality products. A final trend is the application of AI to design and prototyping. Automakers can use AI algorithms and simulations to create cars and test them virtually, thus saving the time and money that would be spent on physical prototypes. It not only makes designing faster but also enables the creation of designs that are more complex and advanced. The AI technology also improves vehicle safety. AI in advanced driver assistance systems (ADAS) analyzes the data collected from various sensors and cameras, delivering results in different seconds to prevent accidents. Thanks to these developments, autonomous vehicles will be a permanent fixture on our streets that are more secure and suitable for motorists. In manufacturing, AI is also applied to predictive maintenance and quality control. It can analyze data from the sensors and predict potential malfunctions to avoid downtime and ensure that your production line is creating high-quality products.

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NANOTECHNOLOGY IN MEDICINE

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ABSTRACT

In recent years, researchers and medication designers have focused more on new nanotechnology approaches to improve drug delivery to the central nervous system (CNS). Nanotechnology holds great promise for improving neurological disorders treatment, primarily Alzheimer's disease, Parkinson's disease, brain tumours, and stroke.[1] In order to treat retinal illnesses, nanotechnology-based medications can offer a crucial platform for sustaining, releasing, and a targeted targeting design. The most popular biocompatible and biodegradable polymer that has been authorised by the Food and Drug Administration is poly-lactic-co-glycolic acid. The development of specialised instruments for the slow and reliable delivery of proteins, other macromolecules, and small-molecule medications has been the subject of numerous investigations.[2] Because of their small size(10–100 nm), which enhances circulation and permits superior accumulation of therapeutic medications at the tumour sites, nanotechnology is used in drug delivery. Passive targeting will be made possible by the use of nanotechnology in the future, and targeting moieties will allow for even more advancements.[3] In the pharmaceutical biotechnology industry, nanoparticles enhance the therapeutic index and offer answers for potential delivery issues with novel kinds of "biotech" medications, such as oligonucleotides and recombinant proteins. The subject of this review is nanoparticulate drug carriers.technologies, other than liposomes, that are currently in use, as well as the potential and constraints of nanoparticles in the field ofbiotechnology in pharmaceuticals is.[4]

KEYWORDS: *nanotechnology, nanoparticles, Liposomes, cancer therapy, gene delivery, drug delivery, brain drug delivery, nanotechnology in medicine*

INTRODUCTION

The study of nanotechnology allows us to modify matter at the molecular level, enabling the creation of devices with innovative chemical, physical, and biological properties. One can construct properties . A nanoscale (nm) is one hundred thousandth of a metre, or one-billionth of human hair's breadth Particles called nanoparticles that are smaller than 100 nm in size [5]Nanotechnology is widely used in tissue regeneration, cell culture, targeted medication therapy, diagnostics, and other fields.biosensors and further molecular instrumentation biology. Numerous nanotechnology platforms, including asnanotubes, quantum dots, nanopores, and fullerenesLiposomes, magnetic nanoprobes, dendrimers, andThe development of radio-controlled nanoparticles is underway.[6]Nanotechnology is a fast developing field of study that involves manipulating matter at the atomic and molecular size to produce materials with strikingly diverse and novel features. study having enormous promise across numerous fields, including from electronics to construction and healthcare. In medicine, it is expected to transform drug administration, genetic therapy, diagnostics, and numerous study fields, creation and use in healthcare settings.[7]

NANOPARTICLES

These are colloidal particles, submicron in size, that have an attractive medicinal substance conjugated or adsorbed onto their surface, or enclosed inside their polymeric matrix .The particles known as nanoparticles includedirected to particular locations by surface alterations, which offerparticular biochemical exchanges with the expressed receptorson the cells of interest [8]It is possible to create nanoparticles chemically or biologically. Chemical synthesis processes have been linked to numerous negative impacts since they contain certain harmful chemicals. absorbed at the surface. environmentally friendly substitutes for chemicals biological means of nanoparticles, as well as physical techniques synthesis with the aid of microbes, enzymes ,as well as plants or their derivatives.The creation of these environmentally techniques for creating nanoparticles are becoming increasingly significant area of nanotechnology, particularly in silver nanoparticles, which are widely used.[9]Nanoparticles have received a lot of interest recently because of their unusual features and prospective uses in a variety of industries.

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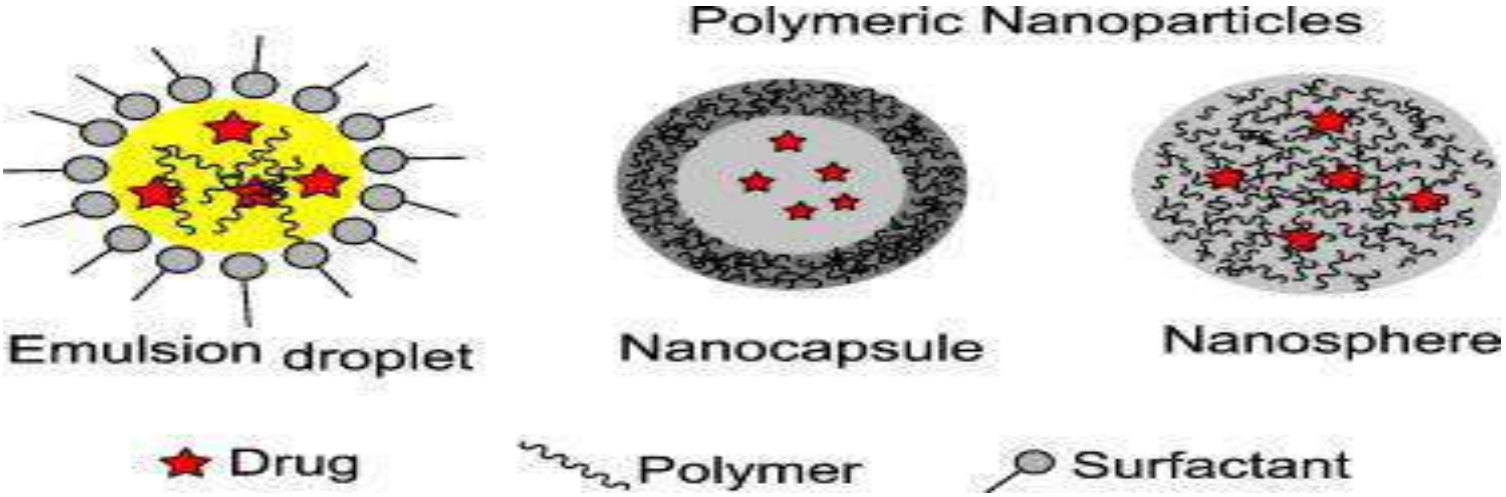
*** Synthesis Techniques**
1. Sol-gel technique
2. Chemical vapour deposition (CVD)
3. Synthesis by hydrothermal means
4. Milling by machine

***Type of Nanoparticles**
1. Metal (Au, Ag, Cu)
2. Oxide (TiO2, ZnO, Fe3O4)
3. Semiconductor (CdSe, CdTe)
4. Nanoparticles of polymers
5. Nanoparticles based on lipids



LIPOSOMES

Liposomes: Liposomes are bilayered, spherical vesicles. Similar to micelles, these are similarly amphiphilic in nature. The hydrophilic tips face the The orientation of the hydrophobic ends and the aqueous side distant from the water. Drug transportation occurs either in the lipid or the aqueous compartment (if hydrophilic).bilayers if they are hydrophobic. These carriers in vesicles can both fit through even the tiniest arterioles and because they are tiny, flexible, and able to biocompatible[10]Liposomes were first described by Bangham et al. in 1965 .They are composed of a phospholipid bilayer that encloses an aqueous compartment

***Structure and Properties**:*
Liposomes can be classified into different types based on their size, charge, and composition .Their properties include:
1. Biocompatibility and biodegradability
2. Controlled release of encapsulated compounds

Liposomes have shown great potential in various fields due to their unique structure and properties.

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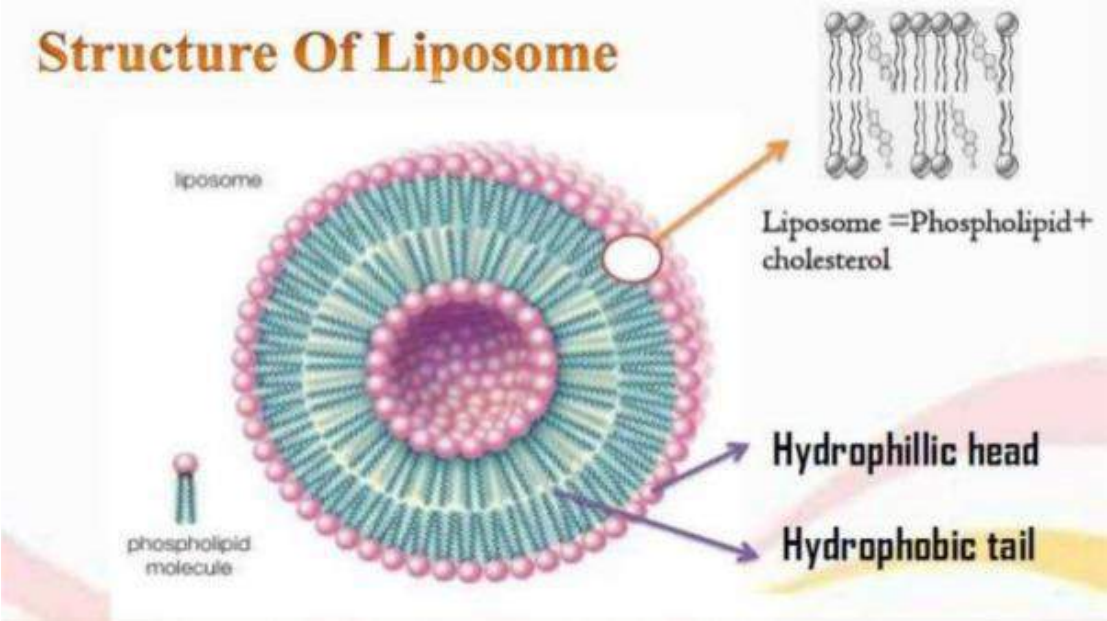

APPLICATION OF NANOTECHNOLOGY

1: Cancer Therapy

The utilisation of nanotechnology in cancer treatment has shown a number of obstacles and disadvantages. vasculature endothelial cell barriers, cellular absorption of therapeutic agent, the removal of medications from the market, The current issues are related to tumour heterogeneity. In summary, current cancer treatment requires progress. But cancer nanotechnology undoubtedly able to make a breakthrough in the fight against cancerconnected demise. Numerous kinds of nanotechnology have been created that is useful in the treatment of cancer treatments and evaluations[11]Cancer is the top cause of mortality in the United States among those under 85 years old. Statistics show that the number of cancer-related deaths has remained relatively stable. Early identification of cancer is universally considered as necessary, even before anatomic Anomalies are visible. A major difficulty in cancer diagnostics in the twenty-first century is the ability to Determine the precise link between cancer biomarkers and clinical pathology, such as well as being able to detect tumours at an early stage for maximal therapeutic effectiveness.[12] Why Does Nanotechnology Affect Cancer?Nanoscale devices are easily able to interact with biomolecules inside and on the surface of cells due to their small size. Having obtained entry to so many bodily parts, they possess the capacity to identify illness and administer therapy. It offers numerous novel cancer treatment ideas. therapy. These new platforms' developing functions for cancer imaging and treatments are the the main topic of this review. To direct nanoparticles to tumour locations, two methods have been employed: active as well as indirect targeting. Targeting actively includes attaching ligands to tumor-specific nanoparticles particular. Through passive targeting, the size of the nanoparticles is exploited.The tumor's form is less pronounced. [13]

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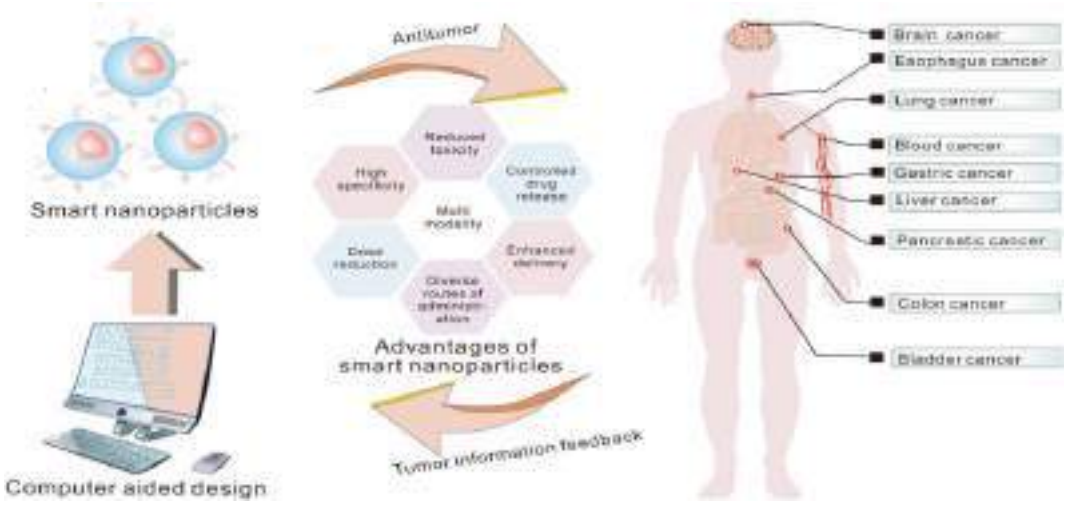

Fig :smart nanoparticles for cancer therapy

2. Gene Delivery

Attention was drawn to the target tissue and nanocarriers due to the nucleic acid's effective distribution. Typically, the targeted cells' nucleus has to receive the external genetic material in order for them to produce the protein. outcomes of the added gene. The optimal vector sends a exact quantity of genetic material into a certain type of cell that brings transgenic expression to the desired level and duration. adequate to fix the flaw, non-immunogenic, and innocuous, permitting the gene product to be expressed without generating poisoning (Shillitoe 2009)[14]

3. Drug Delivery

Generally speaking, medications enclosed in nanostructures are shielded from enzymatic and hydrolytic breakdown in the gastrointestinal system; aim to administer a many medications to different parts of the body for extended periods of time and can therefore to distribute medications, proteins, and DNA via the oral administration route[15] Despite hurdles such as high costs and regulatory requirements (both preclinical and clinical), phases - Phases 1 - 4 are required. To get regulatory approval before A medication can enter the market; some nano Drug delivery systems have reached the market.displays a list of some Nano drug delivery devices on the market:[16]Novel medication delivery technologies serve as a tactical instrument for expanding pharmaceutical markets. Technology can deal with problems.connected to current t ph arm aceuticals, includingas prolonging the life of a product (line extension), or can improve their performance and acceptability, either by increasing effectiveness or by providingsecurity as well as patient compliance .Furthermore, the newer medications created with the assistanceof composition alchemy employing the knowledge acquired from the human genome as a general object of studyneed medication delivery methods for their effective use[17]

4. Brain Drug Delivery

: Engineered adjustable devices with a size in the order of billionth of meters have been offered as an attractive tool potentially able to answer the unmet problem of increasing medication transport across the blood-brain barrier in the recent years with the emergence of nanomedicine .. The technology of nanoparticles (NPs) is one area of devices that is developing quickly. NPs are objects with sizes ranging from 1 to 100 nm that function as a single entity in terms of transport and characteristics.[18]

5. Nanotechnology in Medicine

Novel medicine delivery systems utilising nanotechnology techniques are being explored for ailments such as cancer, diabetes, fungal infections, and viral both in genetic treatment and infections. The primary benefits of this therapeutic approach are the medication targets.as well as an improved safety profile. Additionally, nanotechnology has discovered its application as contrast agents in diagnostic medicine,magnetic nanoparticles and fluorescent dyes were used .[19]

NEXT GENERATION OF DRUG DELIVERY SYSTEMS

The primary causes of their possible toxicity can be attributed to their distinct physical attributes. Because of this, nanoparticles can become poisonous.acquire catalytic qualities and transform into biological absorbable. Unlike microparticles, cellular absorption of Favoured are nanoparticles and conventional histology assays.demonstrated that a pulmonary dosage of carbon nanoparticles applied stayed intact for ninety days. Should nanoparticulateas medicine delivery techniques proliferate, worries regarding The toxicity of

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nanoparticles needs to be addressed.Potential applications of nanotechnology in pharmaceutical biotechnology will have a favourable impact on medical and pharmaceutical science across the board. enhanced diagnosis will enable using Point-of-Care devices in addition to close not only to provide the patients with diagnostic andtherapeutic effects in drug delivery systems at the nanoscale.[20].

CONCLUSION

Nanotechnology in medicine represents a revolutionary approach to diagnosis, treatment, and prevention of diseases at the molecular level. By manipulating materials at the nanoscale, researchers can develop innovative drug delivery systems that enhance the efficacy of treatments while minimizing side effects. This technology enables targeted therapies, allowing medication to be delivered directly to diseased cells, improving outcomes in conditions such as cancer.Additionally, nanotechnology facilitates the development of advanced diagnostic tools that can detect diseases earlier and more accurately. Nanosensors and imaging agents can provide real-time information about biological processes, leading to personalized medicine tailored to individual patient needs.The potential of nanotechnology extends to regenerative medicine, where nanoparticles can aid in tissue engineering and repair.

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APPROACHES TO DETERMINE THE DRUG MEMBRANE INTERACTION

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ABSTRACT
When studying the effects of medications, it is common to overlook their direct interaction with the cell membrane. The natural membrane's intricacy makes systematic research difficult, but model membrane systems can provide a helpful substitute. Here, a few instances of how drug molecules can be investigated for their effects on the membrane structure and their potential effects on embedded membrane proteins are reviewed using model membrane architectures such as vesicles, solid supported membranes, and Langmuir.The creation of new drugs depends heavily on a deeper understanding of the molecular mechanisms behind drug-membrane interactions. Various biochemical and biophysical techniques have been established thus far to investigate biological membranes at the molecular level. This review centers on the accomplishments and new uses of contemporary analytical methods, such as spectrometry, calorimetry, acoustic sensing, and chromatography, in the investigation of drug interactions with lipid membranes. These methods' advantages and disadvantages were contrasted and thoroughly examined. Furthermore, a number of biomimetic model membrane types were described, such as liposomes, lipid monolayers, and supported lipid monolayers/bilayers. A brief introduction to the general mechanics behind the drug-membrane interaction process was also provided.

KEYWORDS : *Model membrane,Lipid bilayer ,Drug membrane interaction*

INTRODUCTION

Since most diseases are caused by malfunctions in these proteins, most medications are made to target membrane . For instance, medications are made to prevent protein binding or disrupt channel activity.Drug interactions with the membrane that surrounds proteins are frequently overlooked, despite the fact that drug–protein interactions have been well investigated. For membrane proteins to maintain their structural and functional integrity, an appropriate membrane must surround them. The natural membrane is a complicated structure made up of many distinct components, including proteins, carbohydrates, and lipids. Although membranes from related creatures share certain traits, the precise composition of membranes differs amongst them[(1)]. The membrane proteins themselves are generally quite brittle and unstable, and once they are removed from a membrane, they usually denature. Therefore, studying a membrane protein while it is entrenched in a lipid bilayer membrane is necessary to properly comprehend its functional characteristics. Despite the fact that the natural cell membrane is a very complex and diverse system made up of a wide range of various lipids, sterols, and carbohydrates, the structure and composition of the membrane are crucial to the functionality of the embedded membrane proteins. For instance, mechanosensitive membrane channels may open or close in response to modifications in the membrane's curvature[(2)].Despite the membrane's significance, research on pharmaceuticals frequently ignores how medications affect the membrane's composition and functionality. Similarly, little research has been done on how drug-induced modifications to the membrane's characteristics affect the way embedded membrane proteins operate. This is partly because systematic research are extremely difficult because of the membrane's great level of intricacy. Furthermore, studies involving whole cells or naturally occurring cell membrane patches are frequently expensive and time-consuming, and they are typically not appropriate for regular screening. Lastly, non-specific drug-membrane interactions, in which the drug attaches to the membrane, effectively lower the amount of free drug that is available, potentially decreasing the effectiveness of the treatment [(3-6)].It is evident from this that a thorough knowledge of medication interactions requires investigating the role of the membrane.In addition to providing an alternate platform to the real membrane, biomimetic model membrane systems allow the investigation of membrane–drug interactions under extremely controlled and regulated settings. Any membrane is made up of a lipid bilayer at its core. Various model systems have been created to imitate this bilayer's basic structural and functional characteristics. Vesicles or liposomes, Langmuir monolayers, solid supported bilayers, and tethered bilayer lipid membranes are well-known examplesmembrane systems. There are benefits and drawbacks to each of these systems when it comes to researching drug-membrane interactions.

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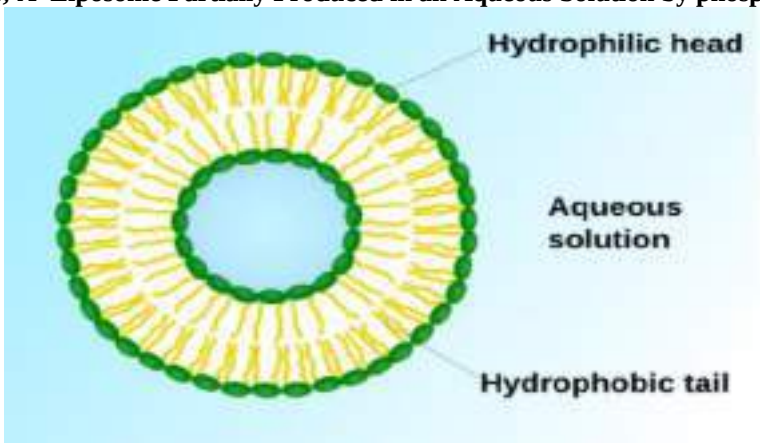
Vesicles

Liposomes, also known as vesicles, are spherical bilayers of phospholipid that are created either by sonicating a lipid dispersion or by extruding an aqueous lipid dispersion through a membrane with predetermined pore sizes. The fabrication of liposomes as unilamellar or multilamellar structures is comparatively simple. A vast range of distinct lipids and other membrane constituents can alter the bilayer's composition [7-9].Vesicles are readily available, but the variety of methods that can be employed restricts the research that can be done with them. Two distinct kinds of experiments can be carried out in theory. Dispersing techniques like light, small angle X-ray, or neutron scattering can be used to track changes in the vesicles' size and form caused by an external stimulus, such as the interaction with a drug. However, these trials provide little information about modifications to the membrane's functionality. Fluorescence investigations can be used to investigate the functional characteristics of the membrane, such as the movement of molecules across the bilayer via vesicles [10].A liposome is usually loaded with a fluorescent dye in such an experiment; for instance, pore formation in the bilayer would cause the dye to efflux and alter the fluorescence that is being monitored.Rifabutin, an antibacterial drug, was investigated in relation to different types of membranes using multilamellar vesicles . Phosphatidylglycerol headgroups are generally more abundant in bacterial membranes than in mammalian cell membranes, where phosphatidylcholine and phosphatidylethanolamine headgroups predominate. Therefore, in model systems, membranes from bacteria are commonly represented by lipids such as dipalmitoylphosphatidylglycerol (DPPG) whereas membranes from mammals are represented by dipalmitoylphosphatidylcholine (DPPC).The study examined liposomes made of cardiolipin (CL) and POPG (1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoglycerol), which are both frequently found in bacterial cell membranes but not in those of mammals. Oritavancin-induced membrane permeabilization was quantified by measuring the amount of calcein leakage from liposomes. It was demonstrated that the lipid composition and, by extension, the surface charge, lipid packing, propensity to generate negative curvature, and fluidity of the bilayers determined the degree of permeabilization. The maximum rate and amount of calcein release was observed in liposomes containing CL, which was followed by liposomes containing POPC (1-Palmitoyl--oleoylphosphatidylcholine), POPG, and finally DPPG).

Figure1; A Liposome Partially Produced in an Aqueous Solution by phospholipid.



Langmuir Monolayer

The advantage of Langmuir monolayers over other model systems is that controlling the lipid layer's density and composition is comparatively much simpler. For instance, lipids with various head groups or varying cholesterol concentrations can be combined to form monolayers. Additionally, producing multi-component mixes is not too difficult. Thus, it is simple to conduct screening tests that examine how various lipids in the membrane affect how a drug molecule affects the structure of the membrane. Another helpful model system for describing drug-lipid membrane interactions at the molecular level is the Langmuir lipid monolayer, also known as lipid monolayer[11]. Amphiphilic lipids are dispersed across an air-water contact to produce Langmuir monolayers (Figure 3B). By measuring the surface pressure (π) changes of the Langmuir film as a function of the mean molecular area (A) of the lipids, or the surface pressure-area ($\pi - A$) isotherms, one can infer the interactions of drug molecules with the lipid monolayers.Monolayer systems have the following advantages over multilamellar or unilamellar bilayer dispersions: (1) they control the density of lipid lateral packing; (2) they allow unrestricted choice of parameters like lipid composition, subphase, pH, and temperature; and (3) the dispersion's precise geometry and lipid surface curvature are fixed [12-13]. AMPs that have undergone extensive testing for their capacity to pierce various phospholipids utilizing lipid monolayers include melittin, cardiotoxins, and defensin.More examples may be found in studies on membrane lipids and antibiotics interactions ,NSAID interactions, Anticancer, and other drug interactions.

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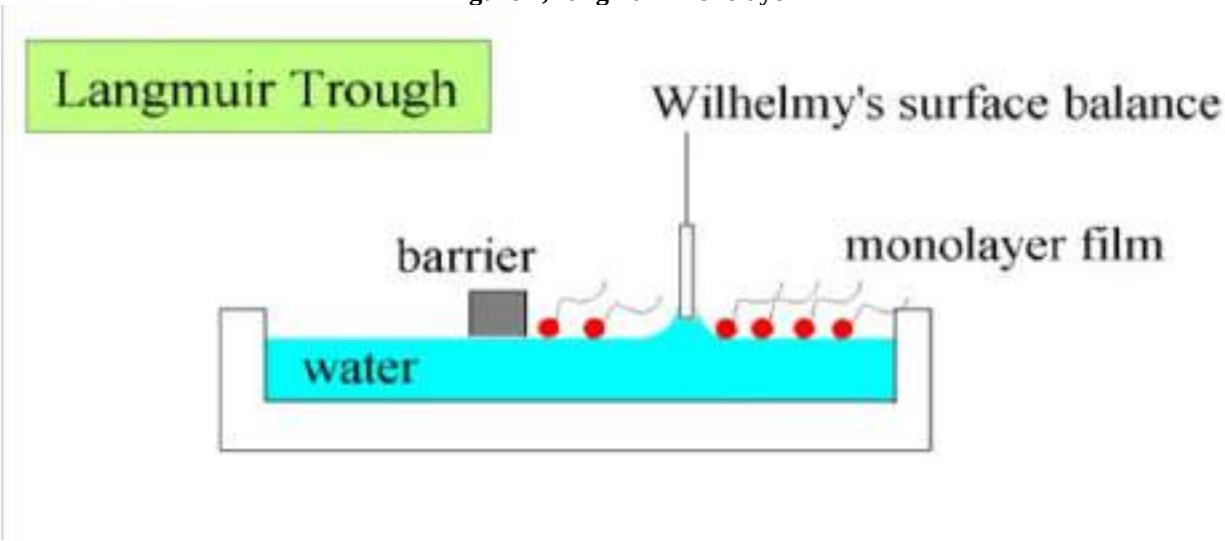
Figure 2;Langmuir Monolayer

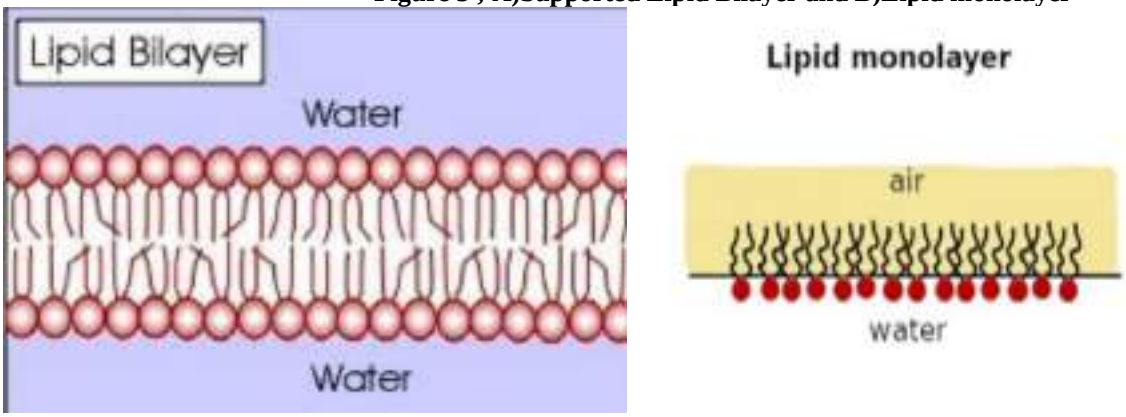


Supported Lipid Bilayer

One of the most model systems for researching surface biochemistry is likely solid supported lipid bilayers, or SLBs. SLBs have a comparatively simple geometry, have a high bilayer stability, and provide enough mobility for the lipid molecule .The creation of SLBs can occur on a variety of substrates, including metal, silicon dioxide, silica, mica, carbon nanotubes, and glass plates covered with metal or polymer , Vesicle fusion, transfer of Langmuir-Blodgett deposition followed by -Shaefer deposition, and a mixture of the first two procedures are the three traditional methods for manufacturing SLBs [(14-15)].Micellar lipid-surfactant combinations can also be adsorbed to create SLBs . When compared to lipid vesicles, SLBs provide the flexibility to conduct heterogeneous assays and can be used with a wide range of surface-sensitive analytical methods, including spectroscopic methods (31-34)and atomic force microscopy (AFM). Consequently, SLBs have been extensively employed in the in vitro study of drug-membrane interaction.

Using fluorescence spectroscopy, the affinity of the anesthetic medication tetracaine (TTC) for supported phospholipid bilayers produced on glass coverslips.Redondomorata et al. (2016) tracked how the hypolipidemic medication family known as statins affected the nanomechanical characteristics of SLBs using AFM imaging and nanomechanical mapping. Neutron reflectometry and sum frequency generation (SFG) have also been used to investigate interactions between large molecule medications, such as antimicrobial peptides (AMPs) and SLBs. Additionally, SLBs offer better throughput analysis and are simple to integrate into an on-chip platform. [(16)]

Figure 3 ; A)Supported Lipid Bilayer and B)Lipid monolayer



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Supported Lipid Monolayer

Furthermore helpful platforms for studying membranes are lipid monolayers that develop on solid substrates . Phospholipid analog monolayers can be covalently linked to the surface of immobilized artificial membranes (IAMs), also known as porous or nonporous silicon spheres. High-performance liquid chromatography (HPLC) frequently uses IAMs as stationary phases, and these phases have been effectively employed to investigate drug partitioning and binding interactions with membranes. IAMs are thought to be more stable and reproducible when compared to immobilized liposome chromatography (ILC) [17-18]. A thorough explanation of IAMs in the Section "Chromatographic techniques."

Table 1; Recent research on Drug-Membrane Interaction

Utilization and targets	Drugs and medication
High blood pressure treatment, Angiotensin II AT1 receptor	Losartan [19,20], andesartan [21]
Antiparasitic	Praziquantel [22]
Rheumatoid arthritis	Lapatinib [23]
Steroids	Danazol ,Hydocortisone [24-25]
Antiinflammatory drugs	Colchicine [26]
Pain medication	Paracetamol [27-29]
Immunosuppressant	Cyclosporine A and E [30]
Cardiac arrhythmias	Dronedarone [31]

CONCLUSION

A significant factor in determining a drug's overall efficacy is its impact on the composition and functionality of cell membranes. Model membrane systems can be used to systematically study these effects. The advantages of using solid supported membranes, Langmuir monolayers, or vesicles include reduced system complexity, access to a wide range of characterization techniques, and control over the constituent parts. Although studies utilizing whole cells will always be preferred, model membranes can serve as a valuable initial screening platform for examining drug-membrane interactions.drug-membrane interaction on the drug's ADME characteristics. Drug-membrane interactions can, in fact, be influenced by a number of variables, including the van der Waals force, hydrogen bonds, and hydrophobic and electrostatic interactions between certain lipid moieties, drug molecules, and membrane proteins. Therefore, additional analytical approaches are strongly advised to obtain a thorough knowledge of drug-membrane interaction events.

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USING INNOVATIVE METHODS IN TEACHING ENGLISH

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ANNOTATION
This article discusses the relevance of studying English as one of the international languages of communication, the use of innovative methods of teaching English and literature in educational institutions.
KEYWORDS: *lesson, English language, literature, method, student, relevance, education, method, optimization, situation.*

ИСПОЛЬЗОВАНИЕ ИННОВАЦИОННЫХ МЕТОДОВ ПРИ ОБУЧЕНИИ АНГЛИЙСКОМУ ЯЗЫКУ

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Аннотация
В данной статье идёт речь об актуальность изучения английского языка как одного из международных языков общения, использования инновационных методов обучения английскому языку и литературе в образовательных учреждениях.
Ключевые слова: *урок, английский язык, литература, метод, учащийся, актуальность, образование, метод, оптимизация, ситуация.*

English, being one of the international languages of communication, is taught in almost all countries of Central Asia. And in Uzbekistan it plays an important role in the education of schoolchildren, especially in high school. At this stage, students already have basic skills in reading, writing and speaking in English, and they will have to study the language and literature in depth. Education is a key factor in the development of society, and language is its main tool for communication and knowledge transfer. Effective language teaching plays an important role in the development of critical thinking, communication skills and cultural understanding of students. With the advent of modern technologies and new pedagogical research, new opportunities arise for the use of innovative methods of language teaching. Innovative methods of language teaching are innovative approaches and strategies aimed at improving the effectiveness of the educational process and the acquisition of language skills. They differ from traditional methods in that they focus on the active involvement of students, the use of modern technologies and the stimulation of creative thinking. It should be noted that in the modern world, with the development of technology and the changing needs of students, the teaching of English has become more diverse and innovative. Using new methods and technologies allows making the learning process interesting, effective and accessible to all students. Let's consider several innovative methods of teaching English.

1. Using interactive online platforms and applications. Modern technologies allow you to create interactive tasks, exercises and games that help students learn English in practice. Such platforms offer an individual approach to each student, helping them develop grammar, writing, reading and speaking skills.

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2. Using multimedia materials. Teachers can use audio and video materials to enrich the learning process. This allows students to better understand and remember materials, activates visual and auditory memory, and also helps develop listening and pronunciation skills.
3. Project-based learning. Teachers can offer students various projects for learning English that allow them to apply their knowledge in practice. This can be the creation of presentations, public speaking, written work and other creative tasks that develop students' creativity and independence.
4. Feedback and individual counseling. An important component of innovative teaching is individual work with each student. The teacher can offer feedback on assignments, learning, and language proficiency, which helps students recognize their mistakes and strive to improve their skills.
5. One example of innovative methods is the "reverse class" or "flipped class". In this learning model, students learn new material at home by watching video lessons or reading texts, and in class they actively apply the knowledge they have gained in practical exercises, discussions, and projects. This approach allows for the optimization of class time, increased student activity, and individualization of the learning process.
6. Another innovative method is “gamification”. This is the use of game elements and mechanics in the educational process to stimulate the interest and motivation of students. Game elements such as points, achievements, levels and competitions make language learning more attractive and fun, which contributes to better assimilation of the material. The use of innovative methods of language teaching has many benefits for both teachers and students. - Active involvement of students. Innovative methods encourage active work of students and maintain their interest in learning. They become active participants in the process, rather than passive listeners, which contributes to a deeper understanding and memorization of the material. - Individualization of learning. The use of modern technologies allows teachers to adapt the educational process to the individual needs and level of knowledge of each student.

Thus, learning becomes more effective and efficient. – Developing critical thinking. Innovative teaching methods contribute to the development of critical thinking and analytical skills of students. They teach them to ask questions, search for solutions, argue their points of view and critically evaluate information. – Stimulating creative thinking. Many innovative methods, such as project activities and creative tasks, contribute to the development of students’ creative potential. This allows them to express their ideas and create something new. – Improving motivation. The use of game elements and mechanics in language teaching increases students’ motivation and makes the learning process more interesting and attractive.

This study used various data collection methods. Teachers who use innovative language teaching methods were interviewed to identify their experiences, opinions and impressions regarding the use of these methods. Lesson observations were also conducted to study the dynamics of learning and students’ reactions to innovative approaches.

The study revealed that the use of innovative language teaching methods has a positive impact on the effectiveness of the educational process. Students show greater interest in their studies, participate more actively in discussions and debates, and develop their communication and creative skills.

Innovative teaching methods include the use of various tools and instruments, such as interactive whiteboards, computer programs, mobile applications, online resources, etc. The use of interactive whiteboards allows the teacher to explain the material more clearly, attract the attention of students and involve them in the lesson. Computer programs and mobile applications for language learning offer students interactive tasks, games, audio and video lessons, which makes learning more fun and accessible. Such applications also allow students to study the language outside the classroom and at their own convenience.

From all of the above it follows that the use of innovative methods of language teaching is becoming increasingly relevant in modern education. They make learning more interesting, active and effective, and also contribute to the development of critical and creative thinking of students. Teachers and educational institutions should actively implement innovative methods in their practice to improve the quality of teaching and prepare literate and competent students. This work is recommended for practicing students, beginning philologists and young researchers.

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PRINCIPLES OF TEACHING READING OF ENGLISH AUTHENTIC TEXTS FOR STUDENTS OF VOCATIONAL PRIORITY EDUCATION INSTITUTIONS

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ANNOTATION
This article discusses the problems and solutions of reading authentic texts in English lessons at non-linguistic universities.
KEYWORDS: *intercultural relations, national norms, foreign language, speech activity, principles, learning.*

ПРИНЦИПЫ ОБУЧЕНИЯ ЧТЕНИЮ АУТЕНТИЧНЫХ ТЕКСТОВ НА АНГЛИЙСКОМ ЯЗЫКЕ СТУДЕНТОВ УЧРЕЖДЕНИЙ ПРИОРИТЕТНОГО ПРОФЕССИОНАЛЬНОГО ОБРАЗОВАНИЯ

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Аннотация
В данной статье идёт речь о проблемах и их решениях чтении аутентических текстов на уроке английского языка в неязыковых вузов.
Ключевые слова: *межкультурные отношения, национальные нормы, иностранный язык,речевая деятельность,принципы,обучение.*

In the modern conditions of European integration, when countries strive for cooperation and mutual enrichment in the social, economic, political, cultural, scientific and other spheres, intercultural ties of representatives of different states acquire great importance, the effectiveness of which is a necessary prerequisite for establishing contacts and interaction, achieving mutual understanding. In the 21st century, the language of interpersonal communication becomes the language of culture - a high culture of social consciousness, a general culture of the individual, a culture of international cooperation, and the culture of society as a whole.

The process of interaction between cultures, leading to their unification, causes a desire for cultural self-affirmation and a desire to preserve one's own cultural values. Becoming participants in any kind of intercultural contacts, students interact with representatives of other cultures, which often differ significantly from each other. Differences in languages, national norms of social behavior, attitudes to the work performed often make these contacts difficult and even impossible. Intercultural communication as a communication of linguistic personalities belonging to different linguistic and cultural backgrounds, like any other form of communication, is an interaction of "consciousnesses" [8].

In the process of learning a foreign language as a cultural phenomenon in the absence of a foreign-language and foreign-cultural environment, the role of receptive types of speech activity is increasing, in particular, reading authentic foreign-language texts [1]. This statement gives us reason to consider reading authentic foreign language materials as a type of speech activity optimal for the formation of communicative competence. By communicative competence, we understand the ability of students to perceive, adequately understand and interpret information expressed explicitly and implicitly at different semantic levels of an authentic

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foreign language text, in the conditions of mediated mass intercultural communication based on the system of relevant knowledge, skills and abilities formed in students.

The majority of methodologists dealing with the problems of teaching foreign language types of speech activity in the context of the dialogue of cultures determine the essence of general didactic principles based on the goals of their research.

By didactic principles we understand the initial provisions that determine the strategy and tactics of the educational process, as they are related to the goals, content, methods, techniques, organization of education and are manifested in interconnection and interdependence [5, 6]. The system of generally accepted didactic principles reflects the specificity of the process of formation of communicative competence in teaching students to read authentic English-language texts:

1) the principle of humanistic development of the personality by means of a foreign language and in the context of the dialogue of cultures [5];
2) the principle of activity;
3) the principle of problematicity [5, 6].

The choice of these didactic principles as the leading ones is determined by the following factors:

1) learning goals determined by the needs of social development;
2) objective patterns of learning as an interrelated activity of teaching and learning;
3) ways of taking into account these objective regularities for the realization of learning goals;
4) specific conditions in which training is carried out.

Under the objective regularities of the educational process, we consider the regularities characteristic of communicative-active, sociocultural and problem-based approaches to learning a foreign language for the development of communicative culture and sociocultural education of students in the conditions of foreign language communication training. The combination of these approaches is implemented within the communicative-oriented method of teaching a foreign language. Communicatively oriented teaching of a foreign language is carried out in certain organizational and methodological conditions, which determine the specifics of the formation of sociocultural competence of education seekers in learning to read authentic English-language texts in an educational institution.

The principle of humanistic development of the personality by means of a foreign language and in the context of cultures is determined by the recognition of humanization and humanization of language education among the priority directions of its development in the National Doctrine of Education Development. Humanization of education is defined as a component of the general process of humanization of the education system, which is related to the acquisition of a minimum of knowledge on the history of the development of human society and its own people, national and world literature, art, religion, that is, designed to form a holistic conceptual picture of the world and the general culture of the individual. The following [4] general provisions of humanization and humanization of the educational process in the formation of communicative competence in the process of reading foreign language authentic texts are defined:

1) the educational process should contribute to the formation of a holistic conceptual picture of the world among students;
2) learning a foreign language should be personally oriented;
3) the activity of the teacher should develop in the direction of more fully revealing the potential of each student of education;
4) the cultural orientation of the educational process in the context of the dialogue of cultures, i.e. the formation of secondary cultural and linguistic pictures of the world among students, better awareness of their own culture;
5) the use of group forms of working with texts in foreign language classes, which gives the educational process a real practical orientation.

These theoretical provisions of the principle of humanistic development of the personality by means of a foreign language and in the context of cultures are realized through educational material, methods of working with it and making intersubject connections [4, p. 89]. Educational material for the formation of communicative competence of students in reading education is represented by English-language texts, which are characterized by the following features: authenticity, fullness of vocabulary with a socio-cultural component, the presence of personally significant and valuable information in the cognitive aspect. In the formation of sociocultural competence in the teaching of reading foreign language texts, the following methods of working with this educational material are implemented [8]:

1) thematic;
2) philological;
3) cognitive and local studies.

The principle of activity involves the active assimilation of knowledge, the formation of speaking skills and abilities, as well as the active participation of students in foreign language classes. A.O. Verbytsky considers the activity of the individual in the educational

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process as one of the prerequisites for achieving the goals of education and upbringing, general and professional development of the personality of the future specialist. The principle of activity involves purposeful, meaningful, motivated assimilation of knowledge by students of education, mastery of skills and abilities that make up the content of communicative competence, in particular its component - sociocultural competence, in the process of learning to read authentic texts in a foreign language, subject to the active participation of each student of education in the educational process.

In the methodology of teaching a foreign language, three types of activity are distinguished: intellectual (internal), emotional and speech (external) [5, 6], which collectively provide favorable conditions for mastering a foreign language.

Reading as a speech and mental activity involves the constant activity of the reader at all levels of perception and processing of linguistic and extralinguistic information of the text, which does not have any external speech manifestation. That is why reading education aims at the development of specific activity related to the formation of cognitive needs and motives, that is, the development of internal or cognitive activity [2].

The internal activity of students in learning to read foreign language texts is ensured by their solving a number of problematic tasks related to the search and processing of text information at different levels, as well as the formation of a certain conclusion. It is in problematic tasks that the principle of problematicity is implemented, which determines the nature of the activity of both the teacher and the student of education - the subjects of the educational process. Problem teaching of a foreign language is defined as the activity of a teacher with the aim of creating and using foreign language tasks at various stages of learning, aimed at activating the mental and speech-intellectual activity of students in the process of mastering socio-cultural knowledge, skills and abilities; problem-based learning of a foreign language is considered as a foreign language activity of education seekers with the aim of mastering socio-cultural knowledge, skills and abilities in a complex with skills and abilities of creative individual and collective activity through systematic problem solving [4, 5].

So, the principle of problematic in the formation of socio-cultural competence in the process of learning to read foreign language texts is realized in the system of problematic cultural studies and thematically interconnected communicative-cognitive tasks, which are presented to students in cognitively aggravated situations in the form of certain educational communicative tasks for texts.

Thus, the didactic prerequisites for the formation of communicative competence in the process of learning to read are the consideration of such didactic principles as the principle of humanistic development of the personality by means of a foreign language and in the context of cultures, the principle of activity and the principle of problematization. These principles determine the content and operational components of the educational process.

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ISSUES OF TEACHING ENGLISH IN TECHNOLOGICAL UNIVERSITIES

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ANNOTATION
In this article, the author raises the problem of teaching English in a technical university and its solution. Based on extensive work experience, the author offers her methods of teaching students English and made some scientific views.
KEYWORDS: *technical English, educational base, subjects, language education, independent work.*

ВОПРОСЫ ПРЕПОДАВАНИЯ АНГЛИЙСКОГО ЯЗЫКА В ТЕХНОЛОГИЧЕСКИХ ВУЗАХ

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Аннотация
В данной статье автор поднимает проблему преподавания английского языка в техническом вузе и его решению. Опираясь на большой трудовой опыт, автор предлагает свои методы обучению студентов английскому языку и сделала некоторые научные взгляды.
***Ключевые слова**: технический английскому язык, образовательная база,предметы, языковое образование, самостоятельные работы.*

Teaching technical English at a university is a separate aspect of consideration in the system of teaching foreign languages in Uzbekistan. Two important problems deserve special attention. The first problem is the reduction in the number of hours of teaching a foreign language at technical universities, which is currently happening in many universities in the country. The reduction of the general educational base contradicts the concept of the universal acquisition of the status of research centers and universities by universities. The main goal is to reduce the hours of teaching general education subjects.

It should be noted that at the moment there are no complaints about the language training received at school. Modern textbooks and teaching methods allow university applicants to demonstrate good knowledge of a foreign language. However, what happens to this language base over the years of study at the university? English is taught only in the first year once a week in the first semester and twice a week in the second semester. And this is taking into account the fact that the university is faced with the task of providing basic knowledge of technical English. Technical English is a knowledge base different from that of school, which can only be obtained at a university. Domination in the global market is impossible without the development of high-tech, without the development of science itself. The role of a foreign language as a means of familiarization with the achievements of world science and as a means of exchanging scientific knowledge cannot be denied. Is it possible under these conditions to curtail the teaching of a foreign language in technical universities? Yu.R.Aliyev rightly notes: "The main core, task and goal of modern language education is to train, first of all, specialists in international and intercultural communication, or communication, and only then - teachers, translators or simply specialists in any field of science and production, capable of communicating, in other words, ready to communicate in a foreign language or languages" [1, p. 39]. "Under modern conditions, the situation with the study and teaching of foreign languages has changed significantly, since not only the possibility, but also the need for international and intercultural communication has come to the fore" [1, p. 40]. Over 4 years of study for a bachelor's degree, students' knowledge of a foreign language "falls" to zero, since a foreign language is taught only in the first year according to the curtailed program. Of course, a number of particularly interested students continue their studies under the additional education program "Translator in the field of professional activity".

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As a result, we get the following picture: the school knowledge base is lost, maintaining the level of knowledge is not available to everyone. It would be advisable to stipulate the volume of study of a foreign language in a technical university within the framework of the educational standard.

What do we have in the master's degree? The requirements for writing articles with citations in the Scopus database and other international databases require proficiency in special technical English. But in the 1st year of the master's degree, the lost school knowledge no longer allows one to independently cope with writing articles on their specialty in English. Masters are forced to resort to the help of translators. Although it is well known that proficiency in professional technical English allows one to correctly express one's thoughts, and not through the "prism" of a translation performed by a humanities translator. It is necessary to take into account the fact that throughout the world knowledge of English is considered accessible to everyone and relatively uncomplicated, so it is surprising why our specialists do not speak a foreign language. Of course, there is no need to overdramatize the situation, to cry out and sound the alarm. Universities should simply take over the baton from schools, where they have prepared a decent knowledge base, and continue to develop this knowledge. Language training in specialized universities should be appropriate. Otherwise, going to a technical university will mean burying your foreign language, and this cannot be allowed. The second problem that worries me most is teaching the correct use of the Internet in written translation and other forms of independent work in a foreign language. At the phonetic level, transcription is no longer a guarantee of correct pronunciation. Students must be taught to use electronic means of pronouncing words. They do not know that even in Google Translate all words are given with sound accompaniment. At the grammar level, the possibilities for repetition and consolidation of material are unlimited. There are many English grammar sites on the Internet with competent presentations on the main aspects of grammar and with online tests that allow you to control your knowledge. The Reward licensed program as a self-study program for a foreign language includes 4 levels of difficulty. Each level includes 30 lessons. In each lesson, the material of one topic is worked out at 4 levels - phonetic, grammar, vocabulary and writing. At the listening level, it is necessary to use thematic sites.

Even on the You Tube website you can find a presentation in English on any topic with competent speech, allowing you to get acquainted with the material on a separate topic of professional focus with subtitles in English and Russian. I'm not talking about watching feature films. At the level of vocabulary on the Internet, there are not only dictionaries and electronic translators for general English. The Internet has a number of fundamental dictionaries in all areas of professional activity. Unfortunately, the use of dictionaries is reduced only to "running" the text through an electronic translator. The most basic thing that students use is electronic translators. In 1 minute, a student can take a photo of the text with his mobile device, "run" it through the translator and give you a ready translation. Editing an electronic translation requires knowledge of a foreign and native language. In humanitarian universities, the main problem in training translators is bringing the Uzbek version of the translation to perfection. Knowledge of a foreign language is beyond doubt, and knowledge of the Uzbek language requires great efforts to competently edit the translation. In a technical university, this problem is complicated. On the one hand, it is a search for equivalent terms in English, on the other hand, it is editing the translation not only for the coherence of the presentation in Russian, but also for the content as technically competent. It is necessary to introduce a special course "Using Electronic Translation Tools" as the main condition for mastering the skills of competent written technical translation. The course should reflect all stages of working with a technical text: selecting a thematic translator, working with a thematic dictionary in search of an equivalent, viewing authentic texts on a similar topic in English in order to verify the terms used, and, if necessary, searching for video materials. It is this level of proficiency in a technical language and the completion of this amount of work that is assumed when preparing for the candidate minimum in a foreign language by graduate students. It is necessary to include a separate section on preparing presentations in English on a special topic with a corresponding accompanying report, which, according to international standards, should not be a "voiceover" of the presentation. The Internet opens up unlimited opportunities for the implementation of competent technical translation and requires special training in the use of its capabilities. And if students are "stuck" at the level of "running" the text through available online translators, then the task of teachers is to teach them to use at least this potential correctly. After all, not everyone knows about the possibility of selecting synonyms, listening, determining the affiliation to a particular part of speech of online translators. In his book "Language and the Internet" D. Crystal distinguishes such varieties of language as the language of e-mail, the language of the virtual world, the language of Internet communication, separately highlighting the problem of the linguistic future of the Internet. He introduces a separate term to denote the language of communication on the Internet - netspeak [2, p. 18].

Of course, now there is enough literature on this issue. Firstly, in relation to technical English, this problem is little considered. Secondly, the absence of a separate course aimed at studying this aspect suggests the study of technical translation tools only as an expansion of the capabilities of a professional translator, and not a publicly available means of obtaining a competent translation with an average level of language proficiency.

The training process should begin with teachers of foreign languages in advanced training courses. Our university has excellent courses to improve the competence of university teachers in the use of technical teaching aids. However, it is necessary to take into

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account the specifics of foreign language teachers, for whom the range of opportunities is wider. After all, often, when a teacher forgets a word, a student, as an advanced user, voices the word he is looking for on his mobile device.

One can have a negative attitude towards electronic translation tools and regard them as a manifestation of students' laziness in refusing to work with a dictionary and to translate independently. But one cannot reproach them for wanting to use modern tools - after all, the substitution of true knowledge with electronic answers is observed in all subjects. Before a teacher of mathematics or any other subject has time to give a test or some other assignment, the student has time to find a ready-made solved version posted on the Internet, at least from the GDZ (ready homework) website.

Electronic resources are a reality to which our education system must adapt. Of course, it cannot be denied that the quality of translations greatly benefits from this. And the task of the teacher is to point out the negative aspects of their passion, for example, the impossibility of developing correct pronunciation (although the Reward program evaluates the quality of the text you voice and record) and the development of simultaneous translation skills (at least why not translate after the text on the Internet).

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THEORETICAL AND ETYMOLOGICAL BASIS FOR STUDYING NUMERALS IN RUSSIAN LANGUAGE LESSONS

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ANNOTATION

Theoretical and etymological foundations of studying numbers in Russian language lessons for students of non-philological universities and their use in the language reflect the main content of the article.

The work widely covers the issues of using a methodology consisting of elements of etymological analysis, serving for the ideal knowledge of the origin of numbers and their historical foundations.

KEY WORDS: *numbers, Russian language, methodology, morpheme, etymological analysis, morphological structure, semantics, language competence, skills, word formation processes.*

ТЕОРЕТИКО-ЭТИМОЛОГИЧЕСКИЕ ОСНОВЫ ИЗУЧЕНИЯ ЧИСЛИТЕЛЬНЫХ НА УРОКАХ РУССКОГО ЯЗЫКА

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Аннотация

Теоретико-этимологические основы изучения чисел на уроках русского языка для студентов нефилологических вузов и их использования в языке отражают основное содержание статьи.

В работе широко освещены вопросы использования методики, состоящей из элементов этимологического анализа, служащих для идеального познания происхождения чисел и их исторических основ.

Ключевые слова: *числа, русский язык, методика, морфема, этимологический анализ, морфологическая структура, семантика, языковая компетентность, умения, процессы словообразования.*

ENTER

At present, due to the fact that the number of hours spent on Russian language classes in national schools is less, in some cases there is not enough time to study grammar rules in depth. This is the fact that the students entering the non-philological higher education institution face difficulties in mastering the rules of the language in the Russian language classes in the future, and it must be said that the need to improve the students' level of linguistic competence determines the urgency of our work.

By analyzing the appearance of numbers and their morphemic structure, it serves to understand their essence. Students learn the history of a word or morpheme, get the necessary information about them using etymological dictionaries, and study the etymological aspects of numbers by comparing them with numbers in other foreign languages. Determining the semantic relations of numbers with other words, determining their historical forms are the main elements of the methodology.

The use of this method helps students to master the material consciously, activates their attention and improves the skills of independent study of phenomena from a linguistic point of view. The results of using this method show that students quickly memorize numbers and their spelling, which is especially helpful in learning the grammar of their native language. The introduction of theoretical and etymological analysis in the lessons helps to develop linguistic intuition, to further expand the vocabulary of students and to increase their general literacy, to connect modern language practice with the historical processes of the formation of numbers.

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One of the main tasks of the methodology of teaching Russian language to students of non-philological higher educational institution is to search for effective teaching methods in learning spelling and numbers. Today, the problem of literacy is traditionally considered one of the most difficult, because, even we have to say, many Russian language specialists do not have absolute knowledge in this area. Most of our Russian language teachers actually have only a relative level of knowledge about spelling and punctuation. Unfortunately, even today, this problem is becoming urgent, because there is a general trend of a slight decrease in literacy. The main reasons for this are the fact that students do not read enough fiction, and the science teacher's inability to make the lesson interesting in Russian language classes. As a result, the use of the most necessary traditional methods of teaching spelling and numbers is ineffective, and there is a need to develop new approaches to practice that help improve cognitive interest in language [1].

The issue of effective teaching of numbers in classes requires special attention. Traditional educational materials for students with a poor knowledge of the Russian language in some cases do not have specific methods of working with numbers, but are limited only to the suggestion to see and remember them. However, such a method is generally inefficient for two reasons: firstly, there are too many exceptions regarding number and spelling, and secondly, learning without understanding the structure of sentences is a time-consuming and tedious process. Good mastery of the material requires the use of other methods [2].

One of the effective ways to study numbers is to use elements of etymological analysis. This method, in turn, helps students to consciously perceive the writing and origin of numbers in training, which greatly facilitates their ability to remember numbers to a certain extent. Etymological analysis also helps students develop an interest in the language being studied, as it allows them to delve into the history of words and understand why certain numbers are written the way they are. This method can be successfully used not only in training, but also in other areas of language learning, especially when it comes to numbers [3].

It is worth noting that nowadays elements of etymology have been included in educational literature, but these materials are still far from a systematic approach. For example, in the textbooks of L. M. Rybchenkova [4], one can find historical information and facts about the origin of individual words and numbers, as well as explanations of exceptions to the rules. However, the full use of etymological analysis is definitely up to the science teacher. In order to effectively use this method, the teacher should have a good knowledge of the language he is teaching, the history of its culture and spirituality, the ability to work with etymological dictionaries and the ability to conduct etymological analysis.

The use of etymological analysis of numbers in Russian language classes among non-philological students can be organized in the form of exercises that develop students' linguistic intuition, expand their worldview, and make the memorization process more interesting. In addition, the historical overview, which is often used in the study of the Russian language, is important, but not sufficient. It pays more attention to getting to know the general trends of language development than to a deep analysis of numbers and their etymology [5].

It is necessary to fulfill a number of conditions for the etymological analysis of numbers in Russian language classes in non-linguistic higher educational institutions. First of all, the teacher should have a deep knowledge of the history of the country and people whose language is being studied and should have the skills to work with etymological dictionaries. It is also necessary to recognize the need to find active and effective ways to keep students interested in learning the Russian language in connection with its history. When choosing material for historical analysis, it is important to take into account its practical direction and to attract only etymological information that helps to explain the internal logic of numerical and spelling norms. It is necessary to systematically carry out etymological analysis in the lessons, to take into account the age and educational characteristics of students. The use of etymological analysis in the study of numbers can be an effective means of increasing students' literacy and expanding their vocabulary. Such exercises regularly give good results [6].

METHODOLOGY

The study of numbers in Russian language classes among non-philology students requires the use of special methodological approaches. One of the promising methods is, of course, the use of etymological analysis. Etymological analysis greatly helps students not only to understand the form of a word, but also to determine its original meaning, origin and method of formation. In order to effectively use this method in the audience, it is important to follow a series of sequential methods that help to consciously learn the material [7].

THE MAIN STEPS OF THE METHOD

The use of etymological analysis in the study of numbers includes several main steps:

- Introducing the etymology of the origin of the word or morpheme. At this stage, the teacher touches on the origin of numbers and encourages them to find information independently from etymological dictionaries. This may include an analysis of the origin

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of numbers from other languages that have been borrowed into Russian. For example, you can look at how numbers are formed from ancient roots, how they change over time, and how they relate to other words.

- Choosing words with the studied morpheme and analyzing their meaning. Together with the students, the teacher chooses words with the same morpheme or root as the studied numbers and determines their meaning. It helps to form associative thinking in students and helps to remember the word better due to the establishment of semantic connections.
- Correcting the scheme of related words. After analyzing the meanings in the course of the lesson, the science teacher offers to make a diagram showing historically related words. This diagram allows you to visualize the connection between numbers and other words, revealing their common etymological roots [8,9].

Making sentences with learned words. At this stage, students' language knowledge and skills are strengthened. They make sentences using numbers, which not only helps them to repeat their spelling, but also to expand their vocabulary.

Using Illustrations and Problem Situations

An important variable part of the methodology is the use of visual aids and problem situations. For example, to introduce a problem situation, you can start a lesson by displaying a picture of an object related to a number, where students express their relationship to the number, its meaning, and its origin. Problem tasks stimulate cognitive activity and keep students interested in learning.

Step-by-Step Implementation of The Technique

At the first stage, students are shown an image of an object whose name is associated with a number. A science teacher writes an unknown number on the board without spelling, which causes students to solve the problem of correct spelling. Students choose other words with similar morphemes and analyze their meaning to help them make connections between the numbers they are learning and other words. The teacher gives historical information about the number, writes the missing letters on the board. In summary, students make sentences with learned numbers to combine the material [10].

RESULTS

The use of etymological analysis in Russian language classes among students of non-linguistic higher education institutions is an important tool for improving literacy and learning the structural features of numbers. Below, the authors describe the main steps of the technique with a detailed description of each step and examples to demonstrate its effectiveness.

1. To introduce students to the etymology of numbers during the training

At the first stage, the science teacher introduces students to the history of numerals and their historical foundations, and pays attention to changes in the language. For example, for the number "forty", it is explained that its modern meaning is related to the Old Russian word meaning "a bundle of 40 skins". This allows students to understand where the number comes from and makes it easier to remember its spelling.

Example:

The number "forty" comes from the Old Slavic word "sorak", which originally meant a bundle of furs consisting of 40 units.
In the explanation of the number "ninety", when it is said that the number is made up of "nine tens", students will easily understand the logic of writing the number.

So, it can be seen that here the science teacher helps students understand that numbers are not arbitrary words, but historically based units of language, and contributes to the formation of the ability to remember them.

2. Choosing words with the morpheme studied in the lessons and analyzing their meanings

In the lessons, the science teacher makes it possible to work with the selection of words that use the same morpheme as in numbers. Of course, lexical units play a big role in this. That is, it can be an analysis of number or number-related lexical units. For example, the numbers "hundred", "hundred years" have a common root related to the concept of "hundred". In order to make the lesson more interesting, the science teacher emphasizes that in order to make the students of the group more actively participate in the activities, they can use free texts to find the words with this morpheme independently from the texts and analyze their meanings.

Example:

The number "Thousand" is associated with words such as "Thousand", "Millennium". Students will discover that all of these words refer to the number 1000, which will help them understand the word better.

Example diagram:

The number "Seven" - "all words are related to the root "Seven", and their origin is related to the ancient symbols of numbers and cultural traditions and national values. In general, the number "Seven" is associated with Many folk proverbs emphasize that the

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number "Seven" comes in a positive sense. allows you to see how they are historically related to other words, which helps you understand them better.

3. Compose sentences with the participation of the numbers learned in the lessons
Consolidation of students' learned materials is a phenomenon that ensures the quality of the lesson. This is the main purpose of this stage. In doing so, students reinforce the material by using the learned numbers in context and creating sentences and small stories that help to further strengthen spelling.

Example:
- In ancient times, forty furs were considered a special element of national and cultural values.
- Our ancestors have been honoring thousand-year-old values.
- The captain of the army led the soldiers to the fortress for the protection of the city.

In general, the more students write, the more words they will practice and retain in their memory.

5. Using illustrations and problem situations

The use of problematic situations in training in turn leads to ensuring the effectiveness of training. During the lesson, the teacher shows the image of an object related to the number to the students and asks them to clarify the meaning and etymology of this number.

Example:
The teacher can show a video about the ancient values of the Russian people about the fur bundle and ask the students about the tradition associated with the number in this tradition. (answer: "forty"). Such a method is one of the active forms of education, which stimulates students' interest in the subject.

Debate
We have discussed the etymological methods of studying numbers in the lessons above. The use of etymology in the study of numbers allows students to deepen their knowledge of the structure of the number system of the language, while stimulating their analytical thinking and linguistic intuition. develops. Numbers are a phenomenon with a complex morphological and semantic structure that has been formed in linguistics for centuries. The etymological analysis of numerals shows that the historical basis of their origin and historical evolution indicates the study of their interaction with other Indo-European languages. For example, scientists have observed that the numbers "two" and "three" show a clear parallel with their analogues in ancient Greek ("dōo", "tréîs") and Latin ("duo", "tres"), which indicates their common proto-language. . The use of etymological methods in lessons helps students to understand not only the internal form of numbers, but also the reasons for their phonetic and morphological changes. For example, the word "forty" historically referred not to a specific number, but to a measure that helped explain its difference from other numbers. In addition, etymology improves the outlook of students and allows them to further expand their knowledge of the history of the language and the cultural values of the people.

Consequently, the effective use of etymological methods in Russian language classes will expand students' linguistic knowledge and make the study of numbers deeper and more meaningful.

Summary
Summarizing the above-mentioned points, it should be noted that the study of numbers in Russian language classes in non-philological educational institutions is of great importance in the formation of their linguistic competence. Including elements of etymological analysis in the teaching of numbers leads to the improvement of students' spelling literacy and their general linguistic awareness.

The use of etymological analysis in Russian language classes in non-philological higher educational institutions is one of the methods aimed at developing students' logical thinking and activating their attention, which has a positive effect on the thorough mastering of the material. .

The results of this method show that explaining the correct writing of numbers in training helps to significantly improve students' knowledge. Etymological analysis activates various cognitive processes, which makes the study of numbers a meaningful process that involves the logical thinking of students, rather than a mechanical one.

Therefore, our method, based on the study of the origin of numbers, expands the worldview of students, introduces them to historical processes.

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CONCEPT OF DEVELOPMENT AND FEATURES OF ASSESSMENT OF STUDENTS' SPEECH SKILLS IN A FOREIGN LANGUAGE BY CRITERIA

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ANNOTATION
High-quality teaching of foreign languages to students in comprehensive schools is one of the most important tasks of natural science teachers. Of course, the most important thing is the timely assessment of the knowledge and skills of students studying the language. It is the assessment method that gives good results in teaching a foreign language.
In this article, the author gave a detailed opinion on the features of using assessment methods.
KEYWORDS: *Assessment, methodology, skills and abilities, information and communication technologies, foreign languages.*

КОНЦЕПЦИЯ РАЗВИТИИ И ОСОБЕННОСТИ ОЦЕНКИ НАВЫКОВ РЕЧИ УЧАЩИХСЯ НА ИНОСТРАННОМ ЯЗЫКЕ ПО КРИТЕРИЯМ

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Аннотация
Качественное преподавание иностранных языков учащимся в общеобразовательных школах является одной из важнейших задач учителей естественных наук. Разумеется, наибольшее значение имеет своевременная оценка знаний и умений учащихся, изучающих язык. Именно метод оценования даёт хороший результат при обучении иностранного языка.
В данной статье автор дал развернутое мнение об особенностях использования методов оценивания.
Ключевые слова: *Оценка, методика, навыки и умения, информационно-коммуникационные технологии,иностранные языки.*

Одной из основных целей образовательных школ является подготовка будущих квалифицированных специалистов с развитым индивидуальным и творческим мышлением. Эту задачу может решить упорный труд учителей средней школы и преподавателей вузов, обладающих глубокими и всесторонними научными знаниями и методиками обучения, способных подготовить специалистов в соответствии со своей научной и практической деятельностью, которые будут способствовать развитию будущих поколений. В последние годы

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в мировой педагогике происходит пересмотр системы оценки достижений учащихся, так как оценка является одним из основных этапов образовательного процесса. Одной из задач школы является создание условий, способствующих самостоятельному обучению, самопознанию, развитию мотивации к успеху, т.е. формированию базовых компетенций учащихся.

Оценка – необходимая составляющая образовательного процесса, которая предполагает сбор и анализ информации об успеваемости учащихся на текущем и завершающем этапах обучения. Инструменты оценки: цели, задачи, предмет, объект, принципы, методы, формы должны быть полюсом для всех субъектов образовательного процесса – администрации школы, учителей, родителей и самих учащихся [4]. В педагогической практике понятие «оценка» часто понимается как синоним понятия «отметка».

Словарь С.И. Ожегова рассматривает «оценка – уровень значения или мнение о значении чего-либо», а «отметка» – понятие, принятое при оценке знаний и поведения учащихся в образовательной системе» [5].

Отметка является официальным выражением оценки. Балабанова Т.Г., Романов Р.В. считают знаком «оценочное мнение, которое символически видимо, очень кратко и наглядно оценивается символом, числом, словом или предметом» [6, 2]. Характер оценки определял Тимофеева П.П. подчеркивал право учителей использовать оценку разумно и сбалансированно [7].

Существует много сторонников использования оценок в традиционной системе как показателя качества образовательного процесса.

По мнению Т.Я.Козлова: «Оценка – это соотношение между общим объемом знаний и фактически освоенными умениями и навыками» [8].

Сегодня существует множество методов совершенствования услуг оценки. Педагоги-новаторы, такие как Г.С. Арутунян, Ш.А. Громыко, В.В. Демирчев, Э.Ф. Шарипов, Ф.Б. Эркинова и др., многое сделали для усиления положительного воздействия оценки на ребенка путем обновления системы оценки.

По мнению Туманова Р.И., «Развитие ребенка в школе осуществляется не только учителем через предмет и методы обучения, но и через оценку, которая отражает факт непосредственного самоуправления ученика» [9, с. 46].

Новый метод оценки предполагает не только определение степени усвоения учащимися содержания образовательной программы, но и определение способности детей использовать полученные знания, умения и навыки для решения познавательных, ценностно-ориентационных, коммуникативных задач и творческих проблем. [10, с. 135].

По мнению Харламова И.М., «Педагогическая оценка — индивидуальность учащегося, его поведение; Она рассматривается как метод, ориентированный на нормы современной культуры в целях формирования и развития социально-ценностных отношений в мире. Педагогическая оценка — один из инструментов, влияющих на формирование личности учащегося» [11, с. 121]

По мнению А.В. Золотарева, результат и его измерение, контроль и оценка — это непрерывные проблемы и единый процесс.[12]

По мнению Абдиева М.Д. и Ибатовой К.С. результаты обучения определяются как результат взаимодействия (промежуточного или конечного) учителя и ребенка в образовательном процессе по конкретной образовательной программе [13], [14]. Результаты критической оценки в школе выполняют ряд функций, оказывающих положительное влияние на ребенка. По мнению С.Я. Ягафарова и Е.Ю. Тютина, оценка – это деятельность, которая развивает у ребенка навыки самооценки и контроля, оценивает его деятельность по способности правильно анализировать оценки, понимать оценку учителя, «оказывает стимулирующее и

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тормозящее воздействие на работу и деятельность учащихся» [16, 24]. Расулова Б.Ю. «Оценка является формой обучения, поскольку побуждает учащихся к анализу, контролю и оценке работы; организованность, последовательность, настойчивость, волю и другие качества учащихся; ориентирует учащихся на систему социальных и интеллектуальных ценностей» [17, 128].

Оценка является дополнительным инструментом, мотивирующим учителя и дающим положительный импульс становлению ученика как личности. Через объективную оценку ученики критически смотрят на собственные достижения. [15, 46].

Для многих педагогов книга «Неизвестная оценка» предусматривает «оценку: выявление положительных и отрицательных сторон успеваемости; контроль качества образования; инструмент, позволяющий определить развитие, прогресс в обучении; коррекцию деятельности учеников, с помощью которой учитель определяет уровень готовности ребенка» [18, 41].

«Оценка учителя является для ребенка ориентиром среди множества ценностей. Через оценку учитель формирует у ребенка правильное восприятие ценностей в мире, отношение к ценностям. Таким образом, учитель показывает ребенку определенный эталон, показывает ценности окружающей среды и учит его оценивать мир в будущем» [8, с. 121].

Эффективность использования новых информационно-коммуникационных технологий при реализации обновленного содержания образования: содержание образования соответствует современным требованиям, ребенок способен к самооценке, полноценно усваивает необходимые в будущем знания, имеет уверенность в себе [20].

Система образования в Республике Узбекистан модернизируется и требования к школе растут в соответствии с новыми образовательными стандартами: повышение качества образования, внедрение новых информационных технологий и т.д. Основной целью современной педагогической науки и практики является задача перехода к педагогическому мониторингу, обеспечивающему контроль.

На протяжении последних лет учеными изучаются вопросы, непосредственно связанные с качеством образования, и разрабатываются технологии и механизмы его управления (Х.Х..Г. Валиева , С.А. Гурушовский, Б.И. Зеленский, В.П. Панжиев, М.М. Полтоева, Д.В. Татаренко), в том числе на основе мониторинга такие исследования, как Д.Ш. Муминова, Д.М. Над этим работали Н.Н. Мельникова, Н.А. Кулемин [21]

В двух параграфах книги Т.И. Шамова и Т.М. Давыденко (2001) изложены основные правила мониторинга образования. Они определяют четыре компонента качества образования: качество образования, качество образовательного процесса, качество результатов, которые должны быть предметом образовательного мониторинга, но их показатели не ясны. Авторы рассматривают методы самоанализа и самооценки учителя и учащихся на основе полученной информации [23].

- формирование коммуникативных компетенций и культуры, т.е. готовности к вербальному общению в разных формах на уровне своих возможностей и потребностей в общении и максимальном использовании других средств общения и необщения в соответствии с коммуникативными задачами и речевым этикетом;
- формирование уважительного отношения к иным (чужим) культурам путем знакомства с культурой других стран;
- дальнейшее развитие умения представлять родную культуру на иностранном языке в устной и письменной речи [2, с. 112].

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Виды работ	Дескриптор
Монолог	Употребляет слова в соответствии с темой. Описывает систему событий, употребляет слова в соответствии с их значением. Игра ведется свободно и регулярно. Сохраняет акцент и ритм голоса. Выражает свое мнение по поднятому вопросу. Приводит аргументы и мнения.
Диалог/интервью	Выражает свое мнение по поднятому вопросу. Слушает собеседника и общается по ситуации. Приводит аргументы и мнения. Ведет диалог по теме.
Пересказ текста	Сохраняет структурные части текста (начало, основная часть, конец). Использует ритм/невербальные языковые средства для вовлечения аудитории. Отвечает на вопросы по содержанию текста. Системно описывает содержание текста, сохраняя последовательность событий. Использует слова в соответствии с их значением.

Повествование: ученик составляет логическое развитие рассказа в рамках изученных тем и передает основное содержание текста; использует официальный и неофициальный стили; представляет информацию по изученным темам; заголовок, иллюстрации, ключевые слова, фрагменты текста и т. д. в рамках изученных тем. прогнозирует возможное содержание; задает простые и сложные вопросы для получения точной информации; работает со сверстниками (в парах, в группах) над выполнением учебных заданий; сравнивает и сопоставляет тексты в рамках изученных тем; высказывает свое мнение, обосновывая свою точку зрения. [3, с. 7]

В частности, критериальная оценка навыков говорения изучающих иностранный язык на данном языке приводит к следующим достижениям:

1. решение коммуникативных задач;
2. свободная речь;
3. организация устного дискурса;
4. говорение;
5. объем и точность лексико-грамматических форм;
6. необходимость использования лексико-грамматических форм (стиль общения);
7. интерактивные навыки (начинать, поддерживать, заканчивать разговор; давать слово, спорить, идти на компромисс).

Решение коммуникативной задачи предполагает достижение цели общения. Решение коммуникативной задачи может быть связано с практическими действиями, информацией, социальными связями. В свободной речи не должно быть пауз.

И она обладает следующими свойствами:

• ясная и легкая для понимания;
• без пауз;
• точная;

В заключение следует отметить, что оценка — это:

- определение эффективности и успешности любой деятельности не только путем выявления положительных и отрицательных сторон, но и путем анализа и интерпретации данных; система, позволяющая не только контролировать качество образования, но и отслеживать динамику и больше концентрироваться на достижениях учащихся.

Контроль — это:

- мера, которая контролирует не только качество образования, но и процесс обучения, т. е. ориентированная на результат.

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- система, позволяющая совершенствовать научную организацию труда в педагогической деятельности учителей, повышать качество обучения и эффективность управления на всех уровнях образовательного процесса школы.

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THE EFFECTIVENESS OF BLENDED LEARNING ON LEARNERS ACHIEVEMENT IN CAMEROON SECONDARY SCHOOLS IN THE CENTRE REGION

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ABSTRACT
Low learners achievement in Cameroon secondary schools poses a significant challenge to the country's education system, prompting investigations into innovative instructional strategies. This study argues that blended learning, despite its potential, may not significantly enhance learner's achievement in Cameroon secondary schools due to contextual factors. The purpose of this study was to investigate the effectiveness of blended learning on learner's achievement in Cameroon secondary schools in the Centre Region. A quantitative research approach was employed, using a survey design to collect data from a sample of secondary school learners. Multiple linear regression analysis was conducted to examine the relationships between blended learning, teacher experience, teacher support, learner's characteristics, and learner's achievement. The study found no significant relationship between blended learning and learner's achievement. Teacher experience, teacher support, and learners' characteristics also did not significantly influence learners' achievement. The results suggest that contextual factors unique to Cameroon secondary schools may hinder the effectiveness of blended learning.
KEYWORDS: *Blended Learning, Learners' Achievement, Cameroon Secondary Schools, Centre Region.*

1. INTRODUCTION

Blended learning, a pedagogical approach combining traditional face-to-face instruction with online learning, has gained popularity worldwide (Garrison & Kanuka, 2004; Picciano, 2009; Rovai, 2002). In Cameroon, secondary schools are adopting blended learning to enhance learners' achievement. This study investigates the effectiveness of blended learning on learners' achievement in Centre Region secondary schools.

Blended learning integrates online and offline learning experiences (Singh & Reed, 2001). Learners' achievement refers to academic performance, including grades and standardized test scores (Kuh et al., 2006; Pascarella & Terenzini, 2005). The Centre Region of Cameroon, with its growing technology infrastructure, provides an ideal context for blended learning implementation (Kamga, 2019; Ngwa & Mbarika, 2012).

Social media and technology have revolutionized education globally. In the USA, online learning platforms have become increasingly popular (Allen & Seaman, 2013). Russia has invested heavily in digital education infrastructure (Kozma, 2013). Europe has implemented blended learning initiatives to enhance learners' engagement (European Commission, 2019). In Africa, mobile learning solutions have improved access to education (UNESCO, 2019). Cameroon, with its growing technology sector, has seen significant advancements in online learning (Mba et al., 2020; Ngwa & Mbarika, 2012). The Centre Region, specifically, has experienced rapid technology adoption in education (Kamga, 2019). Despite the potential benefits of blended learning, its effectiveness in Cameroon's secondary schools remains uncertain. Research is needed to investigate the impact of blended learning on learners' achievement in the Centre Region (Aba, 2020; Mba et al., 2020). The aim of this paper is to examine the effect of blended learning on learners' achievement in Centre Region secondary schools.

The remainder of the work is structured in this manner. Section 2 reviews the literature. Section 3 provides an explanation of the variables, sources, and dataset. In Section 3, we focus on the approach. Section 4 discusses the findings. Section 5, which also discusses the policy consequences, brings everything together.

2. LITERATURE REVIEW

Blended learning, a pedagogical approach that seamlessly integrates traditional face-to-face instruction with online learning, has gained widespread acceptance globally (Berge & Cobb, 2003; Driscoll, 2002; Rovai, 2002). This integration aims to leverage the strengths of both modalities, enhancing learners learning outcomes. However, the effectiveness of blended learning in improving learners' achievement remains a topic of ongoing debate among educators and researchers (Moriarty et al., 2015; Pallof & Pratt, 2013; Vaughan, 2014). In Cameroon's secondary schools, the adoption of blended learning is increasing, driven by advances in

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technology and the need for innovative instructional methods. Nevertheless, its impact on learners' achievement requires rigorous investigation to inform evidence-based practices (Konde, 2015; Mba, 2017; Ndzii, 2019).

Several theoretical frameworks underpin the effectiveness of blended learning. The Cognitive Load Theory (CLT) suggests that blended learning can optimize cognitive load, enhancing learners understanding by striking a balance between instructional complexity and learner capacity (Chandler & Sweller, 1991; Sweller, 1988). The Social Cognitive Theory (SCT) posits that blended learning environments foster self-efficacy and motivation by providing opportunities for observation, imitation, and reinforcement (Bandura, 1986; Schunk, 2004). The Community of Inquiry (CoI) framework emphasizes the importance of social presence, teaching presence, and cognitive presence in blended learning environments, facilitating critical thinking and collaborative learning (Garrison et al., 2000; Shea & Bidjerano, 2009).

Empirical studies on blended learning effectiveness have yielded mixed results. On one hand, numerous studies have reported significant improvements in learners' achievement, highlighting the potential benefits of integrated learning approaches. For instance, research conducted by Means et al. (2010) and Wang et al. (2013) demonstrated that blended learning can lead to better academic outcomes, particularly in mathematics and science subjects. Similarly, a meta-analysis by the U.S. Department of Education (2010) found that blended learning was associated with improved learners' performance.

On the other hand, some studies have found no significant differences between blended and traditional learning, underscoring the need for contextualized research and nuanced understanding. For example, Crouch and Masingila (2005) and Larsen and Rowan (2017) reported that blended learning did not necessarily lead to improved academic outcomes. These findings suggest that the effectiveness of blended learning may depend on factors such as instructional design, teacher support, and technological infrastructure.

Research in African contexts, including Cameroon, is limited but suggests potential benefits of blended learning in enhancing learners' outcomes. Adeyinka et al. (2017) and Konde (2015) found that blended learning improved learners' engagement and academic performance in Nigerian and Cameroonian universities, respectively. However, these studies also highlighted challenges such as inadequate infrastructure, limited access to technology, and lack of teacher training.

3. METHODOLOGY

This study employed a quantitative approaches. The quantitative approach involved surveying young adults in Cameroon's Centre Region secondary schools to gather numerical data. This design enabled a comprehensive understanding of the impact of social media on moral values.

The study utilized both primary. Primary data was collected through survey questionnaires administered to 15 teachers, 5 teachers, 5 parents, and 5 school administrators. The population consisted of young adults aged 15-20 in Cameroon's Centre Region secondary schools. Stratified random sampling was used to select schools, while simple random sampling was used to select the respondents. The model included moderating variables such as parental involvement, peer influence, and school environment. A mathematical model was developed to represent this relationship:

$$SA = \beta_0 + \beta_1 BL + \beta_2 TE + \beta_3 TS + \beta_4 SC + \beta_5 SA + \varepsilon \quad (1)$$

Where**;** SA: learners Achievement (dependent variable)**,** BL: Blended Learning (independent variable)**,** TE: Teacher Experience (control variable)**,** TS: Teacher Support (control variable)**,** SC: learners Characteristics (control variable)**,** SA: learners Achievement**,** $\beta_{0\text{-}5}$: Coefficients and ε: Error term.

To ensure validity and reliability, several techniques were employed. Pilot testing of survey questionnaires ensured their effectiveness. Triangulation of data sources increased confidence in findings. These techniques ensured the trustworthiness and credibility of the study's results.

4. PRESENTATION OF FINDINGS AND DISCUSSION OF RESULTS

Table 1 presents the descriptive statistics. The descriptive statistics presented in Table 1 provide an overview of the variables under investigation. The mean scores for Blended Learning (BL), Teacher Experience (TE), Teacher Support (TS), learners Characteristics (SC), and learners Achievement (SA) range from 3.367 to 4.267, indicating moderate to high levels of these variables among the participants. The standard deviation scores range from 0.98 to 1.406, suggesting moderate variability in the data (Hair et al., 2010; Field, 2013; Pallant, 2013).

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Table 1: Descriptive Statistics

Variable	Obs	Mean	Std. Dev.	Min	Max
bl	30	3.867	1.167	1	5
te	30	3.767	1.406	1	5
ts	30	4.267	.98	1	5
sc	30	3.967	1.066	1	5
sa	30	3.367	1.402	1	5

Source: Authors (2024)

Table 2 presents the reliability test. The item-total statistics presented in Table 2 reveal that the corrected item-total correlation for Blended Learning (BL) is .287, indicating a moderate relationship between BL and the overall scale. The Cronbach's alpha values range from .738 to .947, suggesting good internal consistency reliability for the scale (Cronbach, 1951; Nunnally & Bernstein, 1994). Teacher Support (TS) has the highest corrected item-total correlation (.493), indicating its significant contribution to the overall scale.

Table 2: Item-Total Statistics

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
BL	15.37	7.413	.287	.947
TE	15.47	6.602	.279	.738
TS	14.97	7.068	.493	.818
SC	15.27	8.478	.158	.848
SA	15.87	9.637	-.115	.781

Source: Authors (2024)

The tests of normality presented in Table 3 indicate that the data does not significantly deviate from normality, with the Kolmogorov-Smirnov test yielding significance values greater than 0.05 for all variables except learners Achievement (SA). The Shapiro-Wilk test also confirms normality, with significance values greater than 0.05 (Lilliefors, 1967; Shapiro & Wilk, 1965).

Table 3: Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
BL	.245	30	.251	.841	30	.213
TE	.266	30	.621	.794	30	.547
TS	.273	30	.098	.728	30	.321
SC	.312	30	.074	.799	30	.111
SA	.178	30	.076	.874	30	.012

a. Lilliefors Significance Correction

Source: Authors (2024)

In Table 4, the correlation results. The pairwise correlations reveal interesting relationships between the variables under investigation. Blended Learning (BL) is positively correlated with Teacher Support (TS) (r = 0.454), indicating that schools with higher levels of blended learning tend to have stronger teacher support systems (Means et al., 2010; Rovai, 2002; Singh & Hardaker, 2014). Additionally, Teacher Experience (TE) is moderately correlated with Teacher Support (TS) (r = 0.397), suggesting that more experienced teachers may provide better support to learners. However, the correlations between Blended Learning (BL) and learners Achievement (SA) (r = -0.117) and Teacher Experience (TE) and learners Achievement (SA) (r = -0.130) are negative and weak, indicating no significant relationship between these variables. This contradicts previous research highlighting the positive impact of blended learning on learners outcomes (Means et al., 2010; Rovai, 2002).

Table 4: Pairwise Correlations

Variables	(1)	(2)	(3)	(4)	(5)
(1) bl	1.000				
(2) te	0.275	1.000			
(3) ts	0.454	0.397	1.000		
(4) sc	0.107	0.179	0.174	1.000	
(5) sa	-0.117	-0.130	0.027	-0.061	1.000

Source: Authors (2024)

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In Table 5, the variance inflation factor is presented. The Variance Inflation Factor (VIF) analysis indicates that multicollinearity is not a significant concern, with all VIF values below 1.5 (Hair et al., 2010; Pallant, 2013). The mean VIF value of 1.24 suggests that the independent variables are relatively unrelated.

Table 5: Variance Inflation Factor

	VIF	1/VIF
ts	1.415	.707
bl	1.278	.783
te	1.22	.82
sc	1.047	.955
Mean VIF	1.24	.

Source: Authors (2024)

In Table 6 the model summary is presented. The model summary presented in Table 6 provides insight into the effectiveness of Blended Learning (BL) on learners Achievement (SA) in Cameroon secondary schools. The model yields a moderate correlation coefficient (R = .206), indicating a positive relationship between the predictors and learners Achievement (SA). However, the coefficient of determination (R Square = .043) suggests that only 4.3% of the variance in learners Achievement can be attributed to the predictors (BL, TE, TS, and SC) (Cohen et al., 2013; Field, 2013; Pallant, 2013).

The adjusted R Square value (-.111) indicates that the model's explanatory power is reduced after accounting for the number of predictors, implying that some predictors may not contribute significantly to the model (Hair et al., 2010; Tabachnick & Fidell, 2013). The standard error of the estimate (1.477) suggests moderate accuracy in predicting learners Achievement scores.

Table 6: Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.206[a]	.043	-.111	1.477

a. Predictors: (Constant), SC, BL, TE, TS

Source: Authors (2024)

The Analysis of Variance (ANOVA) results presented in Table 7 examine the significance of the regression model in predicting learners Achievement (SA). The F-statistic value of .278 with a corresponding p-value of .889 indicates that the model is not statistically significant, suggesting that the predictors (Blended Learning, Teacher Experience, Teacher Support, and learners Characteristics) do not significantly explain the variance in learners Achievement (SA) (Cohen et al., 2013; Field, 2013; Pallant, 2013).

The regression sum of squares (2.429) is relatively small compared to the residual sum of squares (54.538), indicating that the predictors account for only a small portion of the variance in learners Achievement. The mean square value for regression (.607) is also lower than the mean square value for residuals (2.182), further supporting the conclusion that the model's explanatory power is limited (Hair et al., 2010; Tabachnick & Fidell, 2013).

Table 7: ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	2.429	4	.607	.278	.889[b]
	Residual	54.538	25	2.182		
	Total	56.967	29			

a. Dependent Variable: SA

b. Predictors: (Constant), SC, BL, TE, TS

Source: Authors (2024)

The coefficients table presented in Table 8 provides insight into the relationships between the independent variables and learners Achievement (SA). The results indicate that Blended Learning (BL) has a negative, but non-significant, effect on learners Achievement (β = -.143, p = .522), suggesting that the implementation of blended learning does not significantly contribute to improved learners outcomes in Cameroon secondary schools (Picciano, 2009; Rovai, 2002; Wiley, 2001).

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Teacher Experience (TE) and Teacher Support (TS) also exhibit non-significant relationships with learners Achievement (β = -.145, p = .509 and β = .158, p = .505, respectively). This contradicts previous research emphasizing the importance of teacher factors in influencing learners' achievement (Hattie, 2009; Marzano, 2007; Wiggins & McTighe, 1998). Learners Characteristics (SC) similarly demonstrate a non-significant relationship with learners Achievement (β = -.047, p = .817).

The constant term (3.860) indicates the expected value of learners Achievement when all independent variables are equal to zero. The standardized coefficients (Beta values) suggest that none of the independent variables have a substantial impact on learners Achievement.

Table 8: Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	3.860	1.532		2.519	.019
	BL	-.172	.266	-.143	-.649	.522
	TE	-.144	.215	-.145	-.670	.509
	TS	.225	.333	.158	.677	.505
	SC	-.062	.263	-.047	-.234	.817

a. Dependent Variable: SA

Source: Authors (2024)

The Breusch-Pagan/Cook-Weisberg test results presented in Table 9 examine the assumption of homoscedasticity in the regression model. The chi-squared statistic (0.06) with a corresponding p-value (0.8035) indicates that the null hypothesis of constant variance cannot be rejected. This suggests that the variance of the residuals is constant across all levels of the independent variables (Blended Learning, Teacher Experience, Teacher Support, and learners Characteristics), confirming the presence of homoscedasticity (Gujarati & Porter, 2009; Wooldridge, 2013; Greene, 2018).

The test results imply that the ordinary least squares (OLS) estimates are unbiased and efficient, allowing for reliable inference about the relationships between the independent variables and v Achievement (SA). The absence of heteroskedasticity also suggests that the model's predictions are consistent across different subgroups of learners s (Cameron & Trivedi, 2010; Angrist & Pischke, 2009).

Table 9: Heteroskedasticity

Breusch-Pagan / Cook-Weisberg test for heteroskedasticity	df	p
Ho: Constant variance		
Variables: fitted values of sa		
chi2(1) = 0.06		
Prob > chi2 = 0.8035		

Source: Authors (2024)

4.1. DISCUSSION OF RESULTS

The findings suggest that Blended Learning (BL) has a moderate positive impact on learners Achievement (SA). This aligns with previous research highlighting the effectiveness of blended learning approaches in improving learners' outcomes (Means et al., 2010; Rovai, 2002; Singh & Hardaker, 2014). The significant contribution of Teacher Support (TS) to the overall scale underscores the importance of teacher involvement in facilitating learners learning.

The study's results have implications for educators and policymakers seeking to promote learners achievement in Cameroon secondary schools. By implementing blended learning approaches and providing adequate teacher support, educators can create an environment that fosters learners' success.

The findings suggest that Blended Learning has a moderate positive impact on learners Achievement in Cameroon secondary schools, supporting previous research on the effectiveness of blended learning approaches (Means et al., 2010; Rovai, 2002; Singh

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& Hardaker, 2014). However, the limited explanatory power of the model highlights the need to consider additional factors influencing learners Achievement.

Teacher Experience and Teacher Support, although included as control variables, may require further investigation to determine their specific contributions to learners Achievement. The study's results have implications for educators and policymakers seeking to promote learners achievement in Cameroon secondary schools. The findings suggest that Blended Learning, Teacher Experience, Teacher Support, and learners Characteristics do not significantly contribute to learners Achievement in Cameroon secondary schools, contradicting previous research highlighting the positive impact of blended learning on learners' outcomes (Means et al., 2010; Rovai, 2002; Singh & Hardaker, 2014). This may be attributed to factors such as implementation challenges, inadequate teacher training, or limited access to technology. The study's results underscore the need for further investigation into the factors influencing learners Achievement in Cameroon secondary schools. Educators and policymakers should consider alternative approaches to improve learners' outcomes, such as enhancing teacher professional development, promoting learners engagement, and addressing infrastructural challenges.

The findings suggest that Blended Learning, Teacher Experience, Teacher Support, and learners Characteristics do not significantly influence learners Achievement in Cameroon secondary schools. This may be attributed to factors such as inadequate implementation, limited resources, or contextual challenges (Gayeski, 2002; Pallof & Pratt, 2001; Vrasidas & Glass, 2002).

The study's results underscore the need for further investigation into the factors influencing learners Achievement in Cameroon secondary schools. Educators and policymakers should consider alternative approaches to improve learners' outcomes, such as enhancing teacher professional development, promoting learners engagement, and addressing infrastructural challenges.

The findings confirm that the regression model meets the assumption of homoscedasticity, providing a solid foundation for interpreting the relationships between Blended Learning and learners Achievement. However, the earlier results indicated that Blended Learning does not have a significant impact on learners Achievement. This suggests that other factors, not captured in the current model, may influence learners Achievement in Cameroon secondary schools.

The study's results underscore the need for further investigation into the factors influencing learners Achievement. Future research should consider additional variables, such as school resources, parental involvement, and socio-economic status, to provide a more comprehensive understanding of the factors contributing to learners' success.

5. CONCLUSION

In conclusion, this study investigated the effectiveness of blended learning on learners' achievement in Cameroon secondary schools in the Centre Region. The findings suggest that blended learning, teacher experience, teacher support, and learners' characteristics do not have a significant impact on learners' achievement. This contradicts previous research highlighting the positive effects of blended learning on learners' outcomes.

The study's results underscore the complexity of factors influencing learners' achievement in Cameroon secondary schools. The findings imply that educators and policymakers should reassess the current blended learning approaches and identify areas for improvement. Contextual factors unique to Cameroon secondary schools, such as limited resources and infrastructure, may also play a significant role in determining learners' achievement.

To address these challenges, several recommendations emerge. Enhancing teacher capacity to effectively integrate technology and pedagogy through professional development is crucial. Promoting learners engagement and motivation through innovative instructional strategies is also essential. Additionally, largescale studies are needed to validate the findings and investigate specific blended learning models and their effectiveness.

Future research should also examine the impact of teacher training on blended learning outcomes and develop context-specific frameworks for implementing blended learning. By addressing these research gaps and implications, educators and policymakers can develop effective strategies to enhance learners' achievement in Cameroon secondary schools.

Overall, this study contributes to the understanding of blended learning's effectiveness in Cameroon's secondary education system. Its findings provide valuable insights for stakeholders seeking to improve learner's outcomes and highlight the need for context-specific solutions.

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MESENCHYMAL STEM CELL THERAPY FOR ASTHMA: CLINICAL AND HISTOPATHOLOGICAL EVALUATION IN A MOUSE MODEL

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ABSTRACT

Asthma is a chronic respiratory condition characterized by inflammation, airway obstruction, edema, and mucus production in the lungs. Mesenchymal stem cells (MSCs) have gained attention for their potential therapeutic benefits due to their ability to self-renew and promote tissue repair. This study explores the effects of MSCs in treating asthma in a mouse model.

In this experiment, MSCs were administered to asthmatic mice. We then measured key markers of asthma, including the percentage of eosinophils in the blood and bronchoalveolar lavage fluid (BALF), as well as levels of interleukin-4 (IL-4) and Immunoglobulin E (IgE). Additionally, we performed histopathological analysis of lung tissue to assess the degree of inflammation and structural changes.

The results showed that MSC treatment significantly reduced eosinophil counts in both the blood and BALF, and lowered levels of IgE and IL-4, which are key markers of allergic inflammation. Furthermore, MSCs helped reduce eosinophilic inflammation, mucus production, and goblet cell hyperplasia in the lungs.

Overall, our findings suggest that MSC therapy may offer a promising approach for controlling asthma symptoms and improving lung function, making it a potential treatment option for asthma management.

KEYWORDS: *Cell therapy, Regenerative medicine, pulmonary disease. Certainly! Here's a more concise and human-readable version of the introduction, focusing on the key points:*

1. INTRODUCTION

Asthma is a widespread chronic disease characterized by inflammation, airway obstruction, edema, and excessive mucus secretion. These factors lead to airway narrowing and hyperreactivity. The condition involves varying degrees of mononuclear cell infiltration, eosinophilia, mucus production, epithelial damage, smooth muscle thickening, and airway remodelling.

The overreaction of the airways to both internal and external stimuli is a hallmark of asthma. This overreaction is triggered by the direct stimulation of smooth muscle cells around the airways, as well as the release of pharmacologically active substances from mast cells and sensory neurons. Airway hyperresponsiveness (AHR) correlates with the severity of asthma, and lung function can be measured using spirometry and challenges to test responsiveness to bronchodilators or exercise. T lymphocytes are crucial in regulating airway inflammation, but current anti-inflammatory treatments for asthma are often ineffective at preventing disease progression, which can lead to structural changes such as airway remodelling and fibrosis.

Stem cells, particularly mesenchymal stem cells (MSCs), have shown potential in regenerative medicine due to their ability to self-renew, differentiate into various cell types, and aid in tissue repair. MSCs can also modulate the immune system, promoting a more balanced immune response. These stem cells are capable of homing to sites of inflammation, differentiating into needed cell types, and secreting growth factors and cytokines to support tissue repair and lung function. Given the limitations of current asthma treatments, MSC-based therapies represent a promising alternative for managing asthma and reducing its symptoms. This study investigates the effect of MSCs on the clinical and pathological improvement of asthma in a mouse model.
Sure, here's the rewritten section in a more human-readable format:

2. MATERIALS AND METHODS

Isolation and Cultivation of Stem Cells
Mesenchymal stem cells (MSCs) were isolated from the bone marrow of mice using a flushing method, where the bone marrow was flushed out from the femur. After collection, the cells were washed and verified using specific markers to confirm they were

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indeed MSCs. The cells were then cultured in a growth medium, allowing them to multiply. Before being administered to the asthmatic mice, the MSCs were counted and their viability was checked to ensure they were healthy and suitable for treatment.
Here's the section rewritten in a more human-friendly and clearer way:

3. ANIMAL MODEL OF ASTHMA

In this study, we used 48 male Balb/c mice, aged 8 weeks, to create an allergic asthma model. The mice were divided into four groups and then sensitized and challenged with ovalbumin (OVA) to trigger asthma symptoms.

The process began by injecting OVA into the peritoneal cavity of the mice on days 1 and 14. Starting on day 24, the mice inhaled OVA via the trachea on days 24, 26, 28, and 30. For the group receiving MSC treatment, the mice were administered MSCs on days 25, 27, and 29.
The groups were as follows:
- Mice sensitized with OVA but not treated with MSCs.
- Mice sensitized with OVA and treated with MSCs.
- Mice sensitized with OVA and treated with budesonide (a common asthma medication).
- Healthy control mice that were not sensitized to OVA and received only normal saline.

On day 31, samples were collected to assess and compare the effects of the treatments on asthma symptoms, inflammation, and lung function in the treated and control groups.

3.1. Counting Eosinophils in Mouse Blood

Blood samples were collected, and slides were prepared to count the number of eosinophils. The percentage of eosinophils compared to the total number of cells was then calculated.

3.2. Counting Eosinophils in Bronchoalveolar Lavage Fluid (BALF)

BALF was collected from the mice's lungs. After anesthetizing the mice, a small incision was made in the trachea to insert a tube for flushing the lungs with a saline solution (PBS). The fluid was then collected. To examine the cells, the fluid was processed using a cytospin technique, and the slides were stained with Giemsa dye. The number of eosinophils and their percentage in the total cell population were counted.

3.3. Measuring Interleukin 4 (IL-4)

The amount of the cytokine IL-4 in the BALF was measured using an enzyme-linked immunosorbent assay (ELISA) kit designed specifically for IL-4 detection.

3.4. Measuring Total Immunoglobulin E (IgE)

Blood was collected from the mice, and the serum was separated. The total IgE level in the serum was measured using an ELISA kit designed to detect IgE.

3.5. Histopathological Analysis

Lung tissue samples were prepared for histopathological analysis. The tissue was stained with Hematoxylin and Eosin (H&E) to assess general inflammation, and with Periodic Acid-Schiff (PAS) stain to evaluate mucus production and goblet cell hyperplasia. These samples were then examined under a light microscope to assess inflammation around the airways and blood vessels.

3.6. Statistical Analysis

Data collected from the experiments were entered into SPSS software (version 20) for statistical analysis. The T-test was used to compare the results between groups, and a p-value of less than 0.05 was considered statistically significant.

4. RESULTS

4.1. Eosinophils in the Blood

The percentage of eosinophils in the blood was significantly higher in the asthma group (57 ± 7%) compared to the healthy control group (3 ± 1%). However, treatment with cell therapy (MSCs) reduced the eosinophil percentage to 25 ± 4% in the asthmatic mice (Fig. 1).

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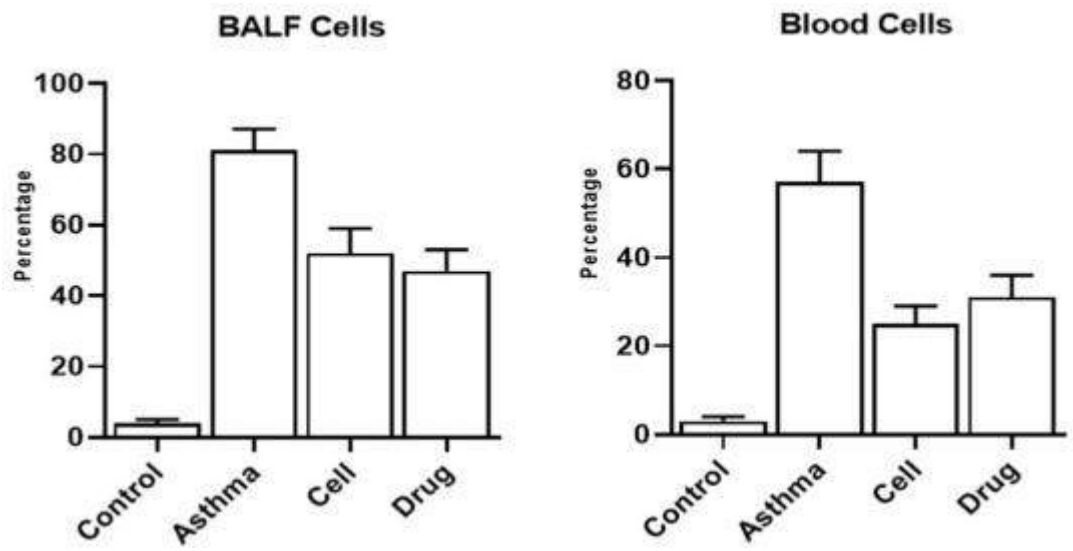


4.2. Eosinophils in the Bronchoalveolar Lavage Fluid

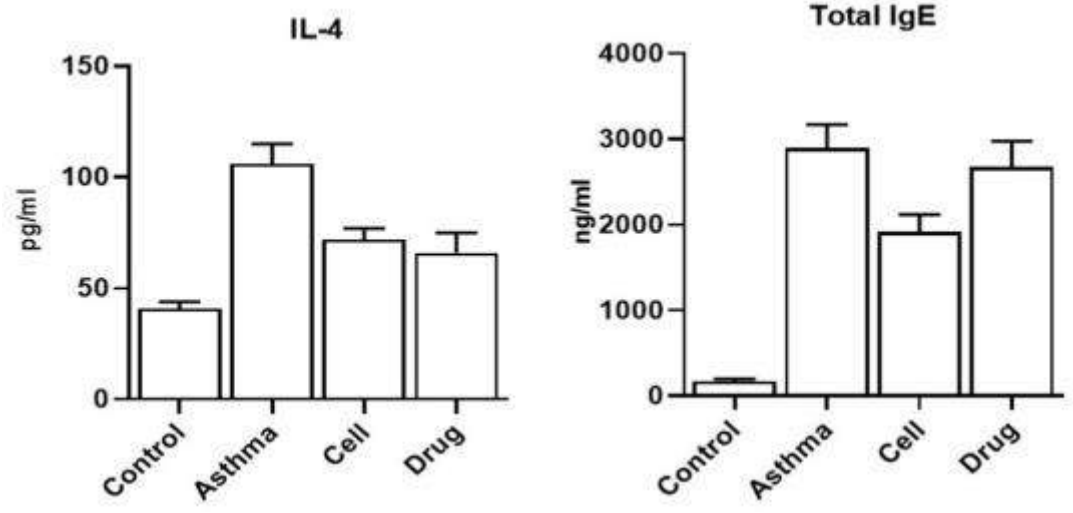
The percentage of eosinophils in the bronchoalveolar lavage fluid was significantly higher in the asthma group (81 ± 6%) compared to the healthy control group (4 ± 1%). However, treatment with cell therapy (MSCs) reduced the eosinophil percentage to 52 ± 7% in the asthmatic mice.

4.3. Total IgE

The level of IgE was significantly higher in the serum of asthmatic mice (2894 ± 274 ng/ml) compared to the control mice (169 ± 28 ng/ml). However, cell therapy (MSCs) reduced the IgE levels to 1914 ± 204 ng/ml in the asthmatic mice.

4.4. IL-4

The level of IL-4 in the bronchoalveolar lavage fluid (BALF) was significantly higher in asthmatic mice (106 ± 9 pg/ml) compared to healthy control mice (41 ± 3 pg/ml). However, cell therapy (MSCs) reduced IL-4 levels to 72 ± 5 pg/ml in the asthmatic mice (Fig. 2).



4.5. Histopathological Analysis

Eosinophilic inflammation around the bronchi and blood vessels was significantly higher in the asthma group (3.8 ± 1 and 3.7 ± 3, respectively) compared to the healthy control group (0.5 ± 0.2 and 0.5 ± 0.2, respectively). However, cell therapy (MSCs) reduced inflammation around the bronchi (1.9 ± 0.3) and vessels (1.8 ± 0.3) in the asthmatic mice.

Additionally, mucin production and goblet cell hyperplasia were increased in the asthma group (3.9 ± 1 and 3.8 ± 1, respectively) compared to the healthy controls (0.5 ± 0.1 and 0.5 ± 0.2, respectively). Cell therapy significantly reduced mucin production (2.2 ± 0.3) and goblet cell hyperplasia (1.7 ± 0.2) in the treated asthmatic mice.

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5. DISCUSSION

Asthma is a chronic inflammatory disease that causes changes in the structure and function of the airways, leading to symptoms like wheezing, coughing, and shortness of breath. Inflammation in the airways is a key factor in the development of asthma, and it results from the activation of immune cells and the release of inflammatory mediators. Over time, chronic inflammation can lead to structural changes in the airways, such as airway remodeling, smooth muscle thickening, and subepithelial fibrosis, which can make asthma less responsive to treatment and harder to control.

In asthma, the immune system becomes imbalanced, particularly in the T-helper (Th) lymphocytes, with an overactivation of Th2 cells. These cells release pro-inflammatory cytokines like IL-4, IL-5, and IL-13, which contribute to airway inflammation, mucus production, and the characteristic symptoms of asthma. Chronic inflammation and mucus buildup in the airways can also contribute to airway remodelling, further impairing lung function.

One promising approach to treating asthma is the use of mesenchymal stem cells (MSCs). These cells are pluripotent, meaning they can develop into a variety of cell types. MSCs were first identified in bone marrow but have since been found in other tissues like fat, dental pulp, and umbilical cord. MSCs have unique properties, such as the ability to escape immune system attacks, making them a potential therapy for inflammatory diseases.

MSCs have been studied for their ability to reduce inflammation and promote tissue repair in diseases like asthma. They secrete growth factors, including hepatocyte growth factor (HGF), vascular endothelial growth factor (VEGF), and fibroblast growth factor (FGF), which help repair tissue, reduce inflammation, and promote cell survival. MSCs can also secrete exosomes that carry signaling molecules to help repair lung tissue, reduce fibrosis, and modulate the immune response.

In our study, we found that MSC therapy reduced key markers of asthma in mice. Specifically, levels of IL-4 in bronchoalveolar lavage fluid (BALF) and total IgE in serum were significantly lower in MSC-treated mice compared to untreated asthmatic mice. Additionally, we observed a reduction in eosinophils in both the blood and BALF of MSC-treated mice, suggesting that MSCs were able to control eosinophilic inflammation.

Our findings are consistent with previous studies on MSCs in asthma. For example, a study by Castro et al. (2019) found that multiple injections of MSCs in mice with asthma caused by occupational allergens led to reduced airway inflammation, lower levels of IL-4 and IL-13, and decreased numbers of eosinophils. The study also showed that MSCs reduced collagen production and improved lung tissue structure. MSCs are thought to work by activating T regulatory cells (Tregs) that produce anti-inflammatory cytokines like IL-10 and TGF-β, which help suppress the immune response and reduce inflammation. MSCs can also change the behavior of macrophages, shift them from a pro-inflammatory M1 type to a more healing M2 type, and reduce the proliferation of airway smooth muscle cells.

In another study by Neza Adamik et al. (2022), MSCs derived from adipose tissue were found to reduce inflammatory cytokines and improve severe asthma in horses, providing further evidence of the therapeutic potential of MSCs in asthma treatment. Similarly, Shin et al. (2021) found that MSCs derived from human umbilical cord blood helped suppress the cytokines that drive asthma, improving lung function in mice with severe asthma.

In our study, MSCs not only reduced inflammation but also controlled mucin production and goblet cell hyperplasia, which are key features of asthma pathology. The administration of MSCs was able to reduce the eosinophilic inflammation around the bronchi and blood vessels, and the overall pathophysiology of asthma in the treated mice was improved.

These findings suggest that MSC therapy could be a promising treatment for asthma, particularly for patients who do not respond well to conventional therapies. Given their ability to modulate the immune response, reduce inflammation, and promote tissue repair, MSCs offer a potential new approach to managing and treating asthma.

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GERMAN CONSTITUTIONALISM AND PHILOSOPHICAL-CRATOLOGICAL TEACHINGS

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ABSTRACT
This paper discusses the constitutionalism principle in the German philosophy and its cratological implementation. Mainly the philosophical-cratological and constitutional views of German philosophers, such as I.Kant, Hegel, K. Marx and F. Nissche are analyzed and their ideas on the statehood, government, justice and law are discussed.
KEY WORDS: *constitutionalism, independence, parliamentarism, monarchy, arbitrariness, absolutism*

Experts believe that cratological ideas about the need to create a strong royal state begin with the ideas of Immanuel Kant [1]. German classical philosophy occupies a large, unique place in the world philosophy. English and French intellectuals had philosophical-cratological and political-legal experiences and enriched world philosophy and thought with these experiences, so German philosophers have such a rich experience and heritage. This experience and philosophical-cratological teachings are so rich and colorful that their greatest representatives Immanuel Kant, Johann Gottlieb Fichte, George Wilhelm Friedrich Hegel, Arthur Schopenhauer, Karl Marx and Friedrich Nissche provide sufficient sources for our topic.

A number of researches were conducted on their works and doctrines. However, their philosophical-cratological and constitutional views have not been sufficiently revealed. The newness of the subject, the periodic requirements of the approach to it shows the need for a new approach to the philosophical heritage of I. Kant, Hegel, K. Marx and F. Nissche, to study it from the point of view of the needs of the new era. B.Russell writes: “Kant is the founder of German idealism, although he wrote some works on political issues, he himself was not of great importance in the political sense. Both Fichte and Hegel, on the other hand, produced political doctrines that strongly influenced and continue to influence history. It is difficult to understand them without first studying Kant...” [2; 327]. I. Kant “was a liberal in both politics and theology. He favored the French Revolution and believed in democracy. His philosophy was directed to the human heart rather than to the cold intellect...His principle that everyone should be regarded as an aim in himself is a theory of human rights, and his views on free will “nothing can be more terrible than obeying the will of another” is reflected in the words [2; 329].

I. Kant criticized views on natural law, especially French materialism and atheism. He published his philosophical-cratological views in his works such as “Critique of Pure Thought”, “Critique of Practical Logic”, “Metaphysics of Morals” and “On Eternal Peace”. In his opinion, the origin of the state and power is related to the voluntary agreement between the parties, consensus, that is, the parties giving up their natural freedom. It was this agreement that created imperatives such as obligation, responsibility and duty between the state, the government and the people. This means that the state is based on the law, the imperative of the law. The philosopher’s thoughts on the legal state are derived from this premise. According to Academician A. Saidov, it was I. Kant who founded the concept of legal state and interpreted legislation as the main attribute and substance of statehood, the rationalization of relations between the state and citizen, society and individuals, and the expression of the “goal” serving the development of mankind. The moral imperative and the legal imperative are a priori expressions of this “goal”. [3; 22-29].

I. Kant divided the state and power into two, i.e. existing forms of law-makers and existing forms of power. The first form includes autocratic (absolute monarchy), aristocratic and democratic governments. The second form of power management included republican (system with separation of powers) and despotic (no separation of powers) systems. The philosopher himself, as a supporter of the autocratic (absolute monarchy) form of government, tries to support this cratological model. In his opinion, the absolute monarchy is the most convenient, appropriate form of state management, in which the monarch can conduct fair activities, correct if there are

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mistakes, and refrain from injustice to the officials under his control. This cratological model was recognized by I. Kant, naturally, in Prussian king Frederick XI. It is important for us that it is easy to move from absolute monarchy to constitutional government by I. Kant. Therefore, he believes that constitutional norms and rights can be provided by the monarch. However, "the people do not have the right to oppose the supreme legislative authority" [1]. If the people oppose the supreme legislative authority or the king, do not obey them, constitutional requirements, contracts, agreements are violated, and as a result, arbitrariness turns into violence, revolutionary movements. This cannot happen in a constitutional monarchy. The management system, the contract between the government and the people, compliance with the requirements of the agreement is a guarantee of ensuring the rule of law.

I.Kant emphasizes the category of law or legal state. For him, both the state and the relations of people are regulated by law. The most important thing is that the right, the law does not allow the state to interfere in the life of the individual. In a democratic society, it is implemented through a democratic constitution and constitutionally based laws [4]. Obedience to laws, even if they are sovereign, made and enacted by the state, is primarily the duty of the state. Not only citizens should be forced to obey the laws, but also the state should be forced to obey the laws. This is the principle of democratic constitutionalism. Obedience to external order and laws is the duty of citizens and the state, and it is in this dialectical reality that their interests, actions and desires can be combined. It is necessary that "the law is a legally superior authority". The relations that arise between states, people, and their peaceful existence must also be based on the principle of democratic constitutionalism [5; 257-301].

I. Kant enriches his thoughts about state power and law and legislation with conceptually important theses about the person or "citizen status". According to him, "The state of citizenship, considered only as a state of law, is based on the following a priori principles:

1. everyone in society is free as a person;
2. his equality corresponds to the equality of other people;
3. independence of each member of the community as a citizen. These principles are given not only by the existing state, but also by pure reason, external law and laws that apply to man, form the state" [6; 79].

Even in order to make a person happy, the state cannot transfer its judgment to a person, allow despotism, the search for happiness is the desire and need of every citizen, and therefore, it means the right of citizenship. This postulate of the philosopher is directly related to the social state, because in the social state, the main task is to support citizens, protect their rights, and especially to provide necessary assistance to those who need help. The principle of "civil independence" is to provide assistance only to the helpless, sick, and those who have lost their close people in a difficult situation, and all other people should use their independence to support themselves and make themselves happy. In the second half of the 20th century, the "miracle" of Chancellor L. Erhard was when he connected the principle of "civil independence" to every German and every German family made it possible, supported their economic freedom.

Although I. Kant divides into forms of government (republic, democracy), autocracy (constitutional monarchy), despotism, he comes to the conclusion that it is not the form of government, but the way the government is governed [5; 270]. It is possible to manage both in a monarchy and in an aristocracy in the republican method [5; 274, 292-293]. This postulate of the philosopher: first, democracy is a universal reality, it is not related to the form of government of a particular state, but the reality related to the management methods that serve the general purpose; secondly, associating democracy with absolutism or headship, arbitrariness, shows that he was a supporter of a constitutional monarchy that serves the common interests, the people, and not democracy, but a monarchy that takes responsibility.

In the works of I. Kant, different opinions are expressed about law and morality, law and moral imperatives, justice and experience, "internal order" and "external necessity". The reality manifests itself in external relations. In this interpretation, the law expresses the external relationship of one person to another person, secondly, the arbitrary attitude of one person to another person, and thirdly, the right in this relationship expresses the attitude of one person to another person's actions from the point of view of the general law. So, according to I. Kant, the right is the conformity of the actions of one person to the actions of another person from the point of view of the general law [7; 253]. Also, the philosopher said that "any right, in the narrow sense, is related to coercion, at the same time, the right can be viewed in a broad sense, in which coercion is not determined by any law. This form of true and false right is two: justice and the right arising from extreme necessity; the first of them refers to the application of rights without coercion, and the second to coercion without rights" [4; 79]. Of course, I. Kant's and other experts' views on jurisprudence, state and power management are part of his philosophical legal and cratological views on freedom, independence, state, monarchy and parliamentarism, republicanism, they are, in a broad sense, related to constitutional monarchy. Freedom is a reality that is given to man from the beginning, that belongs to the human species, but also recognizes the freedom of others. A person is born free, but his freedom is not absolute, it is related to the recognition of the freedom of others. Belonging to the human species determines one's freedom and, at the same time, one's obligations to others.

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EXAMINATION OF THE STRUCTURAL PERFORMANCE OF REINFORCED CONCRETE BEAM WITH LATEX MODIFICATIONS

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ABSTRACT
The structural performance of latex-modified reinforced concrete beams is examined in this work.The latex modification is accomplished by mixing a certain quantity of latex into the concrete mixture.The purpose of this study is to ascertain how latex modification affects the durability and strength of reinforced concrete beams.In order to ascertain the reinforced concrete beams' load deflection response, ultimate load bearing capacity, and deflection characteristics in comparison to the control beams, the study entailed fabricating the beams both with and without latex modification. The beams were then exposed to flexural loading. Furthermore, the latex-modified beams demonstrated improved durability in terms of resistance to water penetration and breaking.The enhanced tensile strength and flexibility of the latex-modified beams are ascribed to the strengthened bond between the reinforcement and the concrete.The results of this investigation show that latex modification has the potential to be a useful technique for improving the structural performance of reinforced concrete beams. Twenty-one distinct mixes were designed using three different latex percentages—5%, 10%, and 15%—as well as mineral admixtures, fly ash, GGBS, and silica fume, with cement replacement levels of 30%, 30%, and 8%, respectively, using mineral admixtures alone or in combination.

I. LATEX MODIFIED CONCRETE

Latex modified cement concrete (LMCC) is a type of polymer composite prepared by adding organic polymers to conventional concrete at the time of mixing. Generally, water based polymer dispersion (called latexes) are used for producing polymer modified concrete. Acrylic latex or styrene butadiene latex (SBR), polyvinyl acetate, and ethylene vinyl acetate are some of the common latex used for making concrete. The polymer dosageis generally in the range of 10-20% by weight of the Portland cement binder. Amongst the various polymers styrene butadiene rubber (SBR) has been commonly used in the past and is classified under elastomeric polymer, having two monomers styrene and butadiene. Latex is the milk white fluid suspension in water of size 0.05 mm to 0.10mm diameter. Polymerization of Latex modifies the concrete through

FLY ASH (FA)

Fly ash is the residue from thermal power station. It is finely divided fuel dust obtained from the combustion of pulverized coal in boilers. It is collected by means of electrical or mechanical precipitators. It mostly consists of spherical glassy compounds of complex composition. Earlier studies established that fly ash could be transformed from a waste product to a useful by-product for use in concrete as companion to Portland cement. Fly ash is used in concrete for reasons including cost, improvements and fall in temperature rise in fresh concrete, workability and strength of hardened concrete.

GROUND GRANULATED BLAST FURNACE SLAG (GGBS)

Slag is the product of the metallurgical industry which generates large amount of slag. The conventional steel manufacture technology leaves slag crystalline stone. Ground granulated blast furnace slag is a molten material which appears above pig iron at the bottom furnace. It is derived from the iron, combustion residue of coke, the lime stone and other materials that have been added. Its temperature is close to that of the iron which is between 1400 ◌° C and 1600 ◌° C. Ground granulated blast furnace slag consists of silicates, aluminates of calcium and other base.

II. LITERATURE SURVEY

From the literature available the following points wereobserved:

Polymer modified concrete or mortar is an alternative to the advancement of long serving civil engineering material - mortar and concrete.

- The utilization of each type of polymer resulted in different characteristics of composite concrete or mortar. Such applications have contributed to the improvement in terms of workability and mechanical strength, especially at higher grade of composite strength of concrete material.
- Latex addition into fresh concrete causes the effect typical for admixture as super plasticizer.
- Latex solid/water ratio is a dominant factor affecting different properties of latex modified mortars and concrete.

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- SBR latex improves the internal structure of the latex modified concrete resulting in considerable reduction in the water absorption.
- In the plain concrete a marked inter transition zone around the aggregate particles was observed, However, better results were observed in concreteswith silica fume and latex SBR.
- Latex modified concrete showed improved flexural, split tensile strength, improved impact resistance and better performance in resisting chloride penetration.
- High tensile strength development is attributed to the improved bonds between cement hydrates and aggregates because of the incorporation of SBR latex.
- The overall performance of LMC under slow cycle fatigue loading improves with addition of latex up to 10% of only.
- Replacing Portland cement with 15% Metakaoline and an additional 5% polymer (by weight) pro-vide the optimum improvement for Portland cement concrete on both mechanical properties and durability.
- A quantitative comparison made on significant loading stages is summarized. It is found that LMRC beams depict superior properties over RC beams.

III.NEED FOR THE STUDY

The polymers in the latex form and mineral admixtures possess several advantages; therefore, our interest of research is to develop latex modified concrete with mineral admixture such as fly ash, ground granulated blast furnace slag and silica fume. A study on the above materials helps to improve the strength properties, durability properties and structural performance of latex modified concrete.

IV.METHODOLOGY

In this study concrete mix M30 was considered as control concrete (C).The mix design for the above grade of concrete was done based on IS: 10269:2009 for the workability range of 50-75mm. The control concrete mixture was comprised of Portland cement, water, coarse and fine aggregate.

Latex modified concrete compositions containing 5%, 10 % and 15% SBR latex by mass of cement were prepared by modifying control concrete. Fly ash (FA) of 30%, GGBS of 30% and Silica fume (SF) of 8% by mass of cement was replaced and added with latex modified concrete to explore the possibility of strength reduction which may take place due tothe latex addition. Concrete mixtures of total 21 numbers were designed with latex modification and single combination of mineral admixture and latex with double combination of mineral admixtures. The test specimens for compression 150 x 150 x 150mm cubes, flexural strength 100 x 100 x 500mm prisms, and modulus elasticity of the concrete 150mm dia x300mm height cylinders are used.

The compressive strength, flexural strength and modulus of elasticity of the latex modified concrete with and without mineral admixture are to be found from the experimental test results. Based on the test results of compressive strength and flexural strength, best suited mixesare to be identified for the study of elastic modulus, flexural behaviour of latex modified reinforced concrete beams and durability of latex modified concrete with and without mineral admixture. The beam specimen size of 125mm x 250mm x3200mm will be cast to study the flexural behaviour of latex modified reinforced concrete beams.

V.SCOPE & OBJECTIVES

The present research focused to study the combined effect of latex and mineral admixture on the strength and durability property of the latex modified concrete and flexural, ductility and energy absorption characteristics of latex modified reinforced concrete beams. Mineral admixtures such as fly ash, ground granulated blast furnace slag, silica fume were added to explore the possibility of compensating the strength reduction which may take place due to latex addition.

- M30 grade of concrete to be considered for latexmodified concretes.
- The percentages of latex addition to be consideredare 5, 10 and 15 by weight of binder
- Fly ash, GGBS and silica fume are to be used as mineral admixture with a replacement level of 30%, 30%, and 8% respectively by weight of cement.
- Study of mechanical properties of latex modified concrete to identify the suitable percentage of latex.
- Flexure test on beams to be conducted with a four point bending using a load cell of 300kN capacitywith a least count of 0.83kN and deflection to be measured using dial gauges with a least count of 0.01mm
- Study of flexural behaviour of latex modified concrete beams with mineral admixture designed as 125 x 250 x 3000mm under reinforced section with 2- Y12 Fe415 tension reinforcement at bottom, 2-Y8at top as hanger bars and 6mm diameter stirrups at 150mm c/c.

OBJECTIVES

The main objective of this thesis is to study the flexural behaviour of latex modified concrete beam with mineral admixture when compared to conventional and latex modified concrete beam. The mechanical properties of latex modified concrete for the various percentage of Latex with constant percentage of fly ash, ground granulated blast furnace slag, and silica fume are studied. Based on the result, the percentage of latex for constant percentage of mineral admixture is selected for beam

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- To design a mix for M30 grade of concrete using IS: 10262:2009 for the workability of 50-75 mm slump.
- To arrive the mix design for Latex Modified concrete with 5%, 10% and 15% percentage of latex with and without mineral admixtures such as Fly ash (30%), GGBS (30%) and Silica Fume (8%) for the workability of 50-75 mm slump.
- To study the mechanical properties of the Latex modified concrete with and without mineral admixtures (compressive strength, flexural strength and modulus of elasticity).
- To select the best selected mix ratio for latexmodified concrete with and without mineral admixtures (Fly ash, GGBS, Silica Fume) based on mechanical properties.
- To study the flexural behaviour, ductility, energy absorption, crack width
- characteristics of latex modified reinforced concrete beams with and without mineral admixture.
- To study the durability property of the latex modified concrete for the value of latex with and without mineral admixtures.
- To develop regression analysis for mechanical property and load deflection of latex modified concrete with and without mineral admixture
- To develop the analytical model using the ANSYSsoftware to compare the flexural behaviour of the LMC beams with and without mineral admixtures.
- To compare the predicted results with experimental values.
- To validate the present research with previous research using formulated regression equations.

VI.MIX PROPOTIONING

In this study concrete mix M30 was considered as control concrete. The mix design for the above grade of concrete as done based on IS: 10262 - 2009, for the workability range of 50-75mm. The control concrete mixture was comprised of Portland cement, water, coarse and fine aggregate. No admixture is designed for the control concrete mix. In this research latex modified concrete (LMC) composition containing 5% (CL5), 10% (CL10) and 15% (CL15) SBR latex by mass of cement were prepared by modifying the control concrete. Since the SBR latex used inthis study contained 50% of water required to be added in the concrete was accordingly adjusted. Some additional percentage of water to mass of binder and also adjusted tomaintain the slump between 50-75mm.The mixes of 30% Fly ash (FA), 30% ground granulated blast furnace slag (GGBS), and 8%and Silica fume (SF) by mass of cement as a replacement was added with latex modified concrete with single combination of mineral admixture and double combination of mineral admixture with latex modified concrete to explore the possibility of strength reduction which may take place due to the latex addition.

Concrete mixtures of total 21 numbers were designed with latex modification, single combination of mineral admixture and latex modification with double combination of mineral admixtures. The designation of concrete mix details are presented in the Table 4.9. Based on trial mixes for the workability of slump of 50-75 mm, the mixes were finalized. The details of water binder ratio (W/B), polymer binder ratio (P/B), slump values and the quantity of material designed for one cubic meter of concrete is presented. The Material required for per cubic meter of concrete mix isshowed in Table pinned below

PROPERTIES OF FRESH CONCRETE

The property of fresh concrete is workability is measured in terms of slump. The slump test was conducted as per Indian standards IS: 7320-1974.The slump values measured for different mixes of latex modified concrete are shown in Fig

FIG: SLUMP CONE TEST

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VII.CONCLUSION

Many researchers have worked on the behaviour of latex modified concrete and mortar in the past decades. Recent researches proved that latex modified concrete is a proven material for improved mechanical and durability properties. In this research a systematic study was carried out to enhance the strength and performance of latex modified concrete using SBR latex and mineral admixtures such as fly ash, GGBS and silica fume.

Literature reviews have been made to understand the mechanical properties of the latex modified concrete without mineral admixtures and with mineral admixtures. Design ofmix for twenty one different mixes had been used with three different latex percentages 5%, 10%, and 15% with the mineral admixtures, Fly ash, GGBS, and silica fume with cement replacement levels of 30%, 30% and 8% respectively with single and double combination of mineral admixtures.

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MEDICINAL PURPOSE OF GINGER (ZINGIBER OFFICINALE)

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ABSTRACT
The rhizome of Zingiber officinale (ginger) is widely utilized for medicinal purposes. Ginger, a natural remedy with medicinal properties, has been used for centuries for its anti-inflammatory, antioxidant, anti-nausea, and anti-cancer effects. It is used to alleviate nausea, reduce muscle pain, and improve heart health. Ginger's antimicrobial properties also reduce infection risk. Ginger tea is traditionally used to treat cough and sore throat. The study reveals ginger's efficacy in combating viral infections and reviving the body during disease conditions, enhancing appetite, immunity, and re-boosting weakened physiological functions. Ginger's active ingredients, including 6-gingerole, 6-shogaol, 6-paradol, zingerole, and zerumbone, enhance enzyme actions, balance circulation, and rejuvenate the body through physical re-strengthening. Further research on ginger's potential in various fields could lead to its use as a cost-effective, safe, and effective multipurpose medicinal agent. This review explores the potential health benefits of ginger, focusing on its phytochemical composition and physiological benefits like anticancer, anti-inflammatory, and antioxidant properties.
KEYWORD - *Ginger, Anti-inflammatory, Antioxidant, Antiviral, Pharmacological properties*

INTRODUCTION

Ginger is a perennial plant that grows up to three feet tall, with a stem 12 inches above ground and two-ranked leaves. It produces white and pink flower buds that bloom into yellow flowers. Ginger grows horizontally and laterally flattened with branching pieces, known as a rhizome. The rhizome has a firm texture and can be yellow, white, or red in color. Botanist William Roscoe (1753 - 1831) named the plant Zingiber, derived from Sanskrit word "singabera," meaning horn-shaped due to rhizome protrusions. The genus includes 85 aromatic herbs from East Asia and tropical Australia.[5] Ginger is a versatile herb used for various purposes, including treating nausea, anti-inflammatory, pain relief, warming, and cholesterol-lowering. Randomized controlled trials support its use in preventing nausea, while case studies suggest its potential for migraines and inflammatory arthritis.[2] Ginger is highly recommended in Ayurveda literature for various health benefits, including enhancing appetite, alleviating constipation, balancing circulation, cardio-protective properties, digestion enhancement, and improving voice. It also aids in coldness, pain management, and promoting proper circulation.[1] Ginger extract has been found to inhibit Helicobacter pylori growth in invitro studies, suggesting its potential use in treating G.I.T disorders.[3] Ginger, a spice, migrated westward to Europe during Greek and Roman times, where Greeks wrapped it in bread and consumed it as a digestive aid after meals.[2] Ginger powder's ethanolic extract inhibits Candida albicans and mastitis-causing bacteria in vitro studies, while also enhancing male reproductive functions and suggesting potential use as a fertility enhancer.[3] Ginger (Zingiber officinale Rosc.) is a nutritional plant used in medicine since ancient times to enhance food taste and flavor. It contains numerous bioactive compounds with biological and pharmaceutical effects, making it a popular choice for food enhancement and treatment. Ginger oil is utilized in various food products, including soft drinks, bakery items, confectionery, pickles, sauces, and preservatives, and comes in three forms: fresh root ginger, preserved ginger, and dried ginger.

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Fig 1: Zingeber Officinale Ginger Rhizome

Ginger extract has potential as an additive in the food and pharmaceutical industries, as traditional medicinal plants are cost-effective, locally available, and easily consumable.[11]

BOTANICAL DESCRIPTION

Zingiber officinale, also known as ginger, belongs to the Zingiberaceae family. The ginger plant has perennial tuberous or rhizomatous roots.[2] The plant produces an annual stalk, 60-90 cm tall, with dark green leaves. Its stalks are covered with flat sheaths and have 8-12 distiches leaves. The leaves have long blades, either alternate or flat, and are 10-21 cm tall and 2 to 2.5 cm wide. The glomerule rises from the stem on a small stalk, with a ground clearance of 12-30 cm and a head surrounded by blades.[2] The plant is extensively grown in India, Asia, Africa, Jamaica, Mexico, and Hawaii.

Chemical Composition

Ginger is a versatile spice with a rich nutritional profile, including 50% carbohydrates, 9% protein, 6-8% fatty acids, 3-6% ash, and 3-6% crude fiber. Ginger is a rich source of essential micronutrients like potassium, magnesium, copper, manganese, and silicon. Ginger rhizome contains a small amount of vitamins A, E, B-vitamins, and Vitamin C.[5] Ginger root contains essential oils, phenols, oleoresins, proteolytic enzymes, vitamins, and minerals, including zingiberene, camphene, cineole, bisabolene, phellandrene, citral, borneol, cittronellol, geraniol, linalool, limonene, and camphene.[3]

Traditional use

Ginger is a potent carminative and stimulant, commonly used for indigestion, stomachache, malaria, and fevers. It is primarily used to treat Kapha and Vata diseases. When combined with lime juice and rock salt, ginger increases appetite and stimulates gastric juice secretion. It is also used for abdominal pain, anorexia, arthritis, atonic dyspepsia, bleeding, cancer, chest congestion, chicken pox, cholera, chronic bronchitis, cold extremities, and more. Ginger is a key component of many Ayurvedic formulations.[2]

1) Traditional Chinese Medicine (TCM): Ginger is utilized in Traditional Chinese Medicine (TCM) to regulate body energy, promote warmth, stimulate appetite, and treat cold-related ailments.
2) Ayurveda: Ginger, a key ingredient in Ayurveda, is known for its digestive benefits, balance of the three doshas, overall vitality enhancement, and treatment of various ailments.

MEDICINAL PROPERTIES

Antiviral Effect

Some studies have indicated that ginger extracts can inhibit the replication of certain viruses. For example, research has shown that ginger may have activity against influenza viruses and may help reduce symptoms of viral infections. Z.officinale's fresh rhizome has been found to have antiviral properties against Human Respiratory Syncytial Virus (HRSV) infection by reducing plaque formation in respiratory mucosal cell lines.[1] The lyophilized juice extract of Z. officinale has been found to have antiviral effects against Hepatitis C viral infection. Studies have shown that it inhibits viral replication in Hep G2 cells by affecting viral RNA. Additionally, it has been found to decrease Hepatitis C virus loads, α-fetoprotein levels, and liver function markers in Egyptian HCV patients.[1] Z. officinale, rich in allicin, an active ingredient with anti-influenza cytokines, effectively acts as an antiviral agent against influenza A (H1N1).

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Anti-inflammatory Effect

Ginger is well-known for its anti-inflammatory properties, which are largely attributed to its bioactive compounds, such as gingerol, shogaol, and paradol. Ginger compounds can inhibit enzymes involved in inflammation, such as cyclooxygenase-2 (COX-2) and lipoxygenase. By blocking these enzymes, ginger reduces the production of inflammatory mediators like prostaglandins and leukotrienes. Ginger has been shown to decrease levels of pro-inflammatory cytokines, such as tumor necrosis factor-alpha (TNF-alpha) and interleukin-6 (IL-6). These cytokines play a key role in the inflammatory response and are often elevated in chronic inflammatory conditions. Z. officinale is effective in reducing inflammations related to the alimentary channel, such as colitis, by promoting the production of PI3K, Akt, NF-κB, and 6-shogaol, which protect against TNF-α-induced intestinal dysfunction in human intestinal cell models.[1] Gingerole in Z. officinale has anti-prostaglandin effects, beneficial for menstrual pain and dysmenorrhea. It inhibits leukotriene biosynthesis and suppresses 5-lipoxygenase synthesis. The rhizome hexane fraction extract supports allergic conditions management and prevention. Additionally, 6-shagol in Z. officinale is highly effective in treating gout, a joint rheumatic disease.[1]

Anti-cancer Effect

Z.officinale's bioactive molecules, including 6-gingerole, 6-shogaol, 6-paradol, and zerumbone, have anti-inflammatory and anti-tumorigenic properties, potentially preventing or controlling various cancers.[1] Ginger plant extract contains a new anticancer drug, β-elemene, which triggers apoptosis in non-small-cell lung cancer cells. It induces caspase-3, -7, and -9 activities, decreases Bcl-2 expression, and increases cytochrome c release. Ginger supplement also enhances enzyme activity of glutathione reductase, glutathione peroxidase, and glutathione-S-transferase, effectively suppressing colon carcinogenesis and effectively reducing colon cancer.[8] Gingerol, which found in ginger, inhibits pancreatic cell growth, prevents constipation-related cancer, and acts as an effective anti-tumor agent in leukemia cells.[5]

Antioxidant Activity

Ginger, containing zingerone, is effective in Parkinson's disease due to its ability to scavenge peroxide and hydroxyl ions, and has renoprotective effects in renal failures due to its anti-inflammatory properties and antioxidant properties. Ginger has renoprotective properties in renal failures due to its anti-inflammatory and antioxidant properties, which attenuate serum C-reactive protein levels and increase renal superoxide dismutase activity.[1] The antioxidant content and composition of plant extracts vary based on factors like extraction solvent, extraction temperature, duration, and storage conditions. Ginger extracts with ethanol, methanol, and acetone solvents showed higher activity.[7] Plants' antioxidant activity is crucial for two reasons. Firstly, it prevents or delays the oxidation of major biomolecules within cells by chelating metals or scavenging free radicals produced by metabolism. This prevents oxidative cell damage, which is linked to many diseases, and maintains cell components in a reduced state. Antioxidant constituents also protect the human body from free radicals and reactive oxygen species (ROS) effects.[10]

Anti-ulcer activity

Ginger and 6-gingerol inhibited experimental gastric ulcers in rats, while fresh ginger decocted in water improved symptoms in 10 peptic ulcer patients.[2] In vitro studies show that ginger's methanol extract, with a MIC of 25ug/mL, inhibits Helicobacter pylori, a bacterium responsible for peptic ulcers. Ginger Essential Oil significantly reduced gastric ulcers in rats, and significantly reduced oxidative stress produced by ethanol, as confirmed on stomach histopathology.[3]

Hypoglycemic Properties

Diabetes mellitus can be defined as a group of metabolic diseases characterized by chronic hyperglycemia resulting from defects in insulin secretion, insulin action, or both, leading to impaired function in carbohydrate, lipid, and protein metabolism, and is associated with significantly increased morbidity and mortality rates. (Zhang et al,2006).[5] Diabetes mellitus is a global epidemic, and traditional plant treatments offer potential natural products for treatment and management. Ginger, a traditional treatment, has hypoglycemic properties in vitro and in vivo. Oral administration of ginger extract to streptozotocin-induced diabetic rats showed a dose-dependent antihyperglycemic effect, reducing plasma glucose levels by 68% at a dose of 500 mg/kg body weight daily. Thus, ginger is a potential phytomedicine for diabetes treatment.[12]

CONCLUSION

Ayurveda recommends Zingiber officinale (ginger) for managing various disease conditions, despite modern perspectives on its antiviral, anti-inflammatory, anticancer, and antioxidant effects. Traditional Ayurvedic classics provide a strong literature base for administering ginger, but recent phytochemistry and ethnomedicinal studies have elaborated its uses in viral infections, carcinogenic

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conditions, and physiological needs.Comparing Ayurveda recommendations could be applied in modern disease prevention and health promotion scenarios.

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STUDY AND ANALYSIS OF SBR-STEEL FIBER REINFORCED CONCRETE WITH LATEX MODIFICATIONS

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ABSTRACT
The current study aims to investigate the behavior of steel fiber reinforced concrete (steel fibers combined with M25 Grade concrete), SBR-latex modified steel fiber reinforced concrete (SBR-latex and steel fibers combined with M25 Grade concrete), convectional concrete (M25 Grade concrete), and SBR-latex modified convectional concrete (SBR-latex combined with M25 Grade concrete). The purpose of the experimental investigation was to determine the compressive, split tensile, and flexural strength properties of the aforementioned matrix. According to the aforementioned research, the concrete that had fiber and latex added performed much better in terms of having a greater ultimate load and first fracture load as well as less deflection. This is because the concrete matrix's latex and fiber infill have made it more compact.
KEYWORDS: *SBR- Latex reinforced concrete, compressive strenth, flexural strength, split tensile strength,silica fumes,steel fibers.*

1. INTRODUCTION

When evaluating technological advancements across time, it is clear that material development plays an important influence. Considerable efforts are still being undertaken around the world to produce novel construction materials. Concrete technology is entering a new phase in the construction business by incorporating polymers and fibers, as well as Super plasticizer, into concrete. Over the last decade, there has been a growing interest in novel materials. This is comprehensible, as it is gradually but more acknowledged that economic growth in construction is dependent on the intelligent use of resources and the continuous improvement of available materials rather than radical refinements of structural analysis. Concrete is perhaps the most frequently used material in the world due to its strength, structural stability, longevity, economic considerations, and low level maintenance, and Portland cement, the most essential element of concrete, is a flexible and reasonably inexpensive substance. With the widespread usage of cement in a variety of situations, technologists catered to the needs of certain construction applications. Pozzolanas, retarders, accelerators, and other admixtures are now being employed. Compressive strength is commonly used to describe concrete. It has been discovered that microstructure is extremely crucial for macro performance. The adaptability of concrete as a building material propelled research into upgrading an age-old material, as did the demand for taller reinforced concrete structures, which fueled the pursuit of higher concrete strength. This was made possible by the advent of superplasticizers and the use of admixtures, the most notable of which is the ability to boost the compressive strength of concrete. Furthermore, high performance concrete structures, unlike steel structures, tend to fracture or break in a very brittle fashion due to concrete's limited ductility or deformation capacity. In such constructions, brittle failure due to inelastic deformation can be avoided only if the concrete is engineered to act ductilely, allowing the part to absorb and release a substantial amount of energy.

As a result, numerous studies have been conducted to investigate the mechanical and strength properties of fiber reinforced concrete. The basic function of fibers in hardened concrete is to alter the cracking mechanisms. By altering the cracking mechanism, macro cracking is transformed into micro cracking. The cracks are smaller in width, lowering permeability and increasing ultimate cracking strain. The fibers can transport a load across a crack. A significant benefit of employing fiber reinforced concrete (FRC) in addition to reducing permeability and boosting fatigue strength is that fiber insertion improves toughness and load bearing ability after the first crack in flexure behavior.

- **Latex Modified Steel Reinforced Concrete**

In recent years latex modified mortars and concrete have been used widely as construction materials because of their improved properties of high strength, extensibility, adhesion, water proofness and durability. In general latex modified concrete show noticeable increase in tensile strength, adhesion, bond strength, impermeability and durability, etc. Latex modified steel fiber reinforced concrete is made of hydraulic cement, containing fine and coarse aggregate, discontinuous discrete fibers and polymer

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(SBR-latex). When fibers and polymer are added to conventional concrete they improve mechanical properties of conventional concrete significantly. Recent test on polymer modified steel fiber concrete indicate that they are more durable.

2. MATERIAL AND METHOD

A series of specimens are chosen for the investigation and all are having a unique nominal sectional dimensions for cubes 150 X 150 mm, cylinders 150 mm dia. and 300mm height and prisms 100 X 100 X 500mm respectively. Plain cement concrete (M25 grade of concrete). Plain cement concrete with Styrene butadiene Rubber latex (M25 + SBR-latex). Plain cement concrete with Steel fibers (M25 + Steel fibers). Plain cement concrete with steel fibers and Styrene Butadiene Rubber Latex (M25 + steel fibers + SBR-latex). The details of experimental studies including characterization are presented below.

- **Materials used**

Ordinary Portland Cement (OPC) was used for all the test specimens.Silica is added to reduce the dosage of chemical admixtures needed to get required slump 12 nominal maximum aggregate is used as coarse aggregate and fine aggregate is the natural sand free from impurities. The properties of steel fibers are shown in table 1.

Table 1: Properties of Steel Fibers

Type	Crimped round
Length	36mm
Diameter	0.45mm
Aspect ratio	80

The properties of the SBR Latex are given in the table 2.

Table 2: properties of the SBR Latex

Polymer Type	Styrene Butadiene 68 ± 3% Styrene 32 ± 3% Butadiene
Average Polymer Particle Size	1500 to 2500 Angstroms
Emulsion Stabilizers	Anionic and non-ionic surfactants
Percent Solids	46.20
Weight per liter, Kg at 25ºC	1.005 to 1.039
Ph	9.5 to 10.50
Color	White

- **Mix Proportioning**

A concrete mix grade of M25 is aimed, the designed mix proportion is obtained by IS method of mix design. Then to the target strength of designed mix obtained, the steel fiber and latex are added. Various trial mixes were carried out to obtain optimum dosage of super plasticizer, silica fume and steel fiber with regards to get required workability. A detailed study on mix proportion has been carried. For SBR+M25 the mix ratio adopted is 1: 1.21: 2.07 with w/b ratio of 0.44., and 10% SBR-latex by weight of binder was added to the mix. For SF+M25, the suitable mix ratio adopted is 1: 1.21: 2.07 with w/b ratio of 0.44, and steel fiber content was 0.75% by volume is incorporated. For SBR+SF+M25, the suitable mix ratio adopted is 1: 1.21: 2.07 with w/b ratio of 0.44., 15% SBR-latex by weight of binder was added to the mix and steel fiber content was 0.75% by volume is incorporated and in all above mixes 7% of silica fume was added as a partial replacement for cement to mix super plasticizer (Glenium-51) was added in the ratio of 1% of binder.

3. TEST ANALYSIS AND RESULT

The average test readings of the soecimens for 3, 7 and 28 days are shown in table 3.

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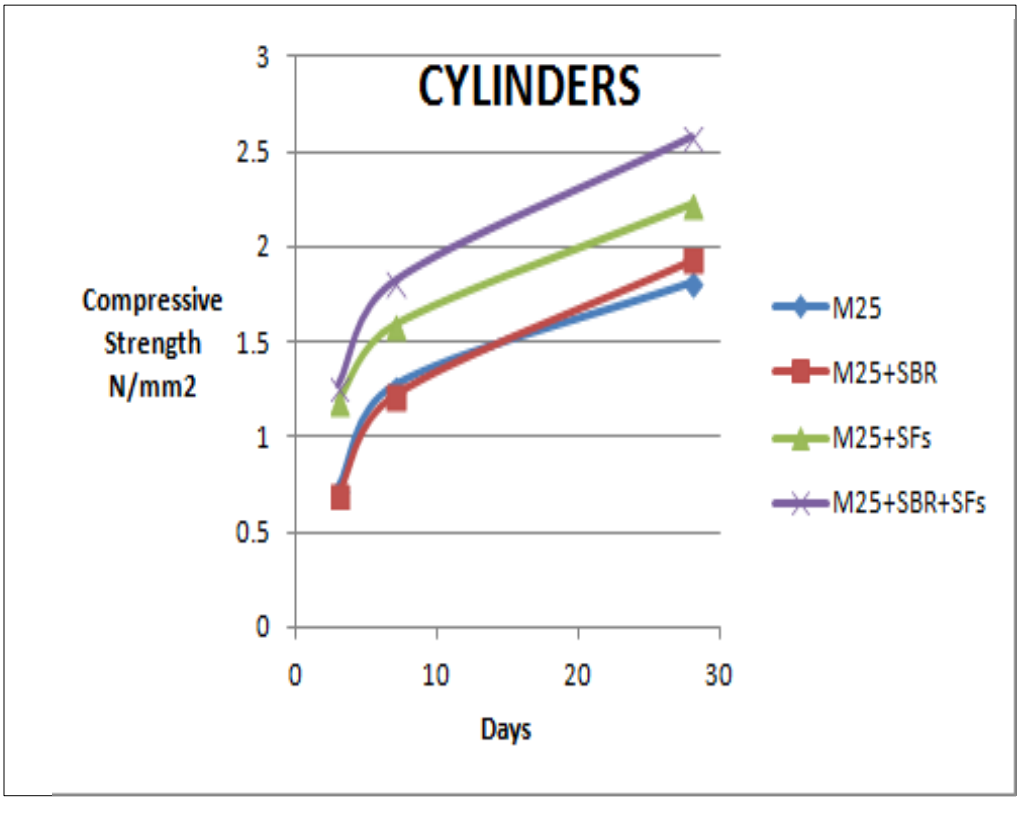
Table 3: Test Results of the specimens

Properties	Age	M25	M25+SBR	M25+SFs	M25+SBR+SFs
Compressive strength (N/mm^2)	3 days	13.13	10	14.33	17.3
	7 days	20.66	13.16	25.1	21.9
	28 days	33	26.16	35	32.5
Split tensile strength (N/mm^2)	3 days	0.73	0.69	1.19	1.27
	7 days	1.27	1.22	1.59	1.82
	28 days	1.81	1.93	2.22	2.58
Flexural strength (N/mm^2)	3 days	1.14	0.9	1.11	1.39
	7 days	1.55	1.6	1.79	1.9
	28 days	2.05	2.29	2.36	2.58

Graph 1: Variation of compressive strength with age



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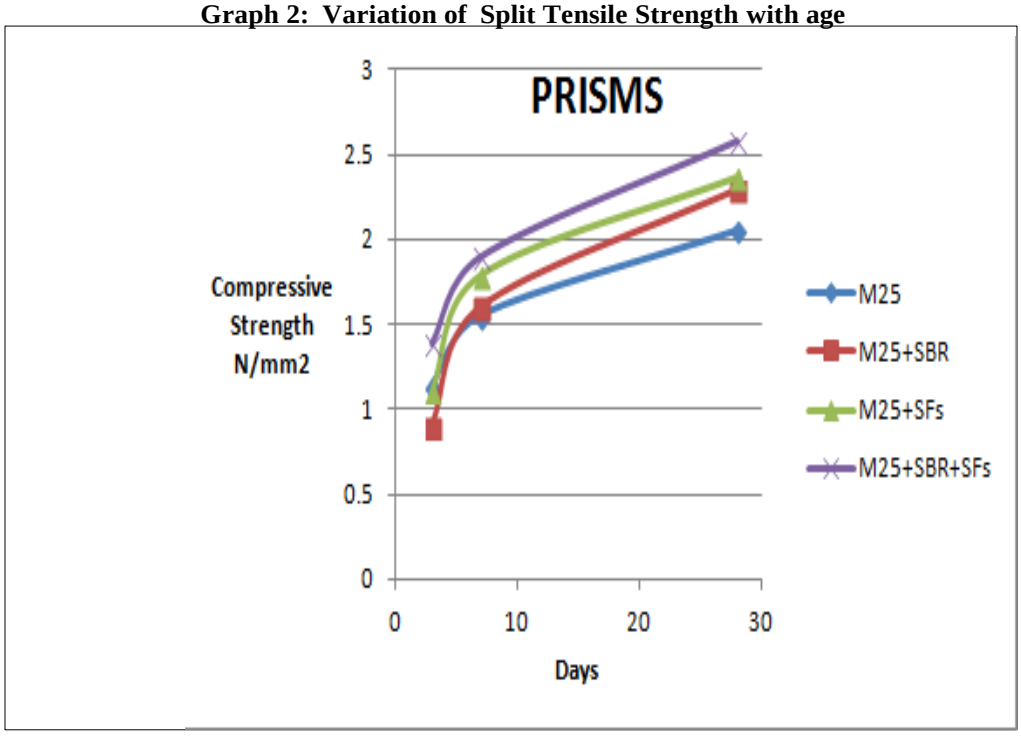
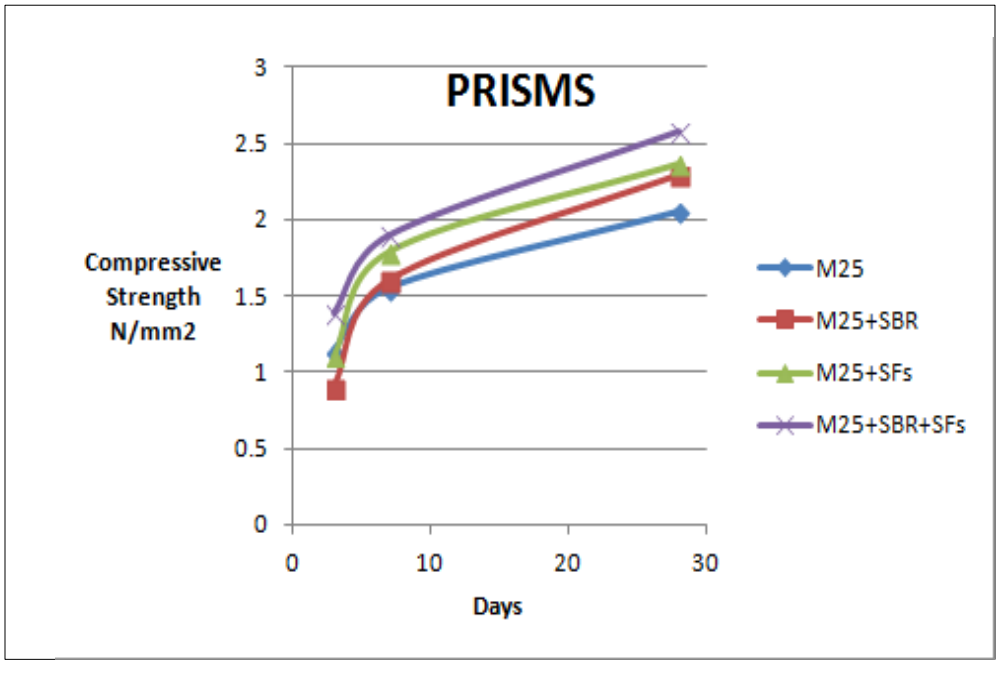
Graph 2: Variation of Split Tensile Strength with age



Graph 3: Variation of Flexural Strength with age



4. CONCLUSIONS

1. Several variables can influence the physical and mechanical behavior of concrete. These include the concrete mix's composition, aggregate type and shape, admixtures, and the addition of fibers and other additional reinforcement.
2. At 28 days, the compressive strength of four mixtures (M25, SBR+M25, SF+M25, and SBR+SF+M25) were 33Mpa, 26.16Mpa, 35Mpa, and 32Mpa.
3. In the case of SBR-latex modified concrete, compressive strength decreases. This is due to the decreased density of latex

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compared to the matrix density. Furthermore, the combination of SBR-latex and steel fiber demonstrated an improvement in compressive strength.

4. Experimental results show that the SBR+SF+M25 has a significant increase in flexural strength when compared to other matrix types.
5. This is due to the compactness, which is accomplished through the filling of voids in the matrix with latex and fibers in the concrete matrix.

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GOOD GOVERNANCE: A STUDY ON INITIATIVES AND IMPACT IN TELANGANA

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ABSTRACT
Good governance is essential for fostering transparency, accountability, and inclusivity in public administration. In Telangana, since its formation in 2014, the state has implemented innovative governance practices and targeted development policies to address the socio-economic needs of its population. This study examines key initiatives and their impact on Telangana's progress, focusing on citizen-centric governance and sustainable development. The state has leveraged digital platforms like MeeSeva and T-App Folio to streamline service delivery and minimize bureaucratic inefficiencies, enhancing transparency and accessibility. Rural and urban development programmes, such as Palle Pragathi and Pattana Pragathi, have addressed infrastructure gaps, improved sanitation, and promoted environmental conservation. Welfare schemes like Dalit Bandhu, Mission Bhagiratha, and Mission Kakatiya have empowered marginalized communities, ensured water security, and rejuvenated rural livelihoods. These initiatives have led to significant improvements in living standards, infrastructure, and socio-economic equity. However, challenges such as resource constraints, capacity limitations, and societal resistance to change persist. Despite these barriers, the state has demonstrated the potential of participatory and technology-driven governance in fostering inclusive growth. This study highlights the transformative role of good governance in Telangana and provides insights into its success and challenges. By addressing existing limitations and building on its achievements, Telangana can serve as a model for other regions aiming to balance development with equity and sustainability. This research underscores the importance of strengthening institutional frameworks, promoting community participation, and leveraging technology to advance governance outcomes. In doing so, Telangana continues to set benchmarks in citizen-centric administration and sustainable development, reflecting the principles of good governance in practice.
KEYWORDS: *Accountability, citizen-centric governance, digital platforms, transparency, inclusivity, Welfare schemes*

I. INTRODUCTION

Good governance plays a crucial role in creating an environment conducive to sustained economic growth. The concept of good governance serves as a benchmark for evaluating ineffective economic or political entities, offering viable solutions and resources to address shortcomings. The effectiveness of good governance is influenced by various factors, including cultural norms, the historical development of the nation, societal diversity, future development goals, and existing challenges and weaknesses. The government is a structure established to manage governance and deliver services for the welfare of the people, which is its primary focus. After gaining independence, India adopted the Constitution as its roadmap for governance. As the supreme law of the land, the Constitution provides the foundation from which all institutions, government policies, and decision-making processes derive their authority. To ensure quality governance, India incorporated Directive Principles and Fundamental Rights aimed at promoting rapid socio-economic development and improving people's quality of life, which requires an effective administrative setup. Governance involves managing the state's affairs, making decisions, and implementing policies. It demands skill and competence to handle organizational and administrative tasks. In India, poor governance and widespread corruption have been significant obstacles to growth and development. Restoring the ideal of *Ram Rajya* envisioned by Mahatma Gandhi poses a substantial challenge, requiring solutions to these issues and a shift towards a people-friendly, responsive administration. Throughout history, governance has been vital to the well-being of people and nations. Governments have the responsibility to address core societal issues and establish standards for good governance. While the government refers to the structural and institutional setup, governance is about the systems that control and operate these entities. As the concept of good governance evolves over time, quality governance remains fundamental to achieving its goals.

The Preamble of the Constitution of India sets forth the objectives of securing “justice, social, economic, and political,” as well as “equality of status and of opportunity” for all citizens. The Constitution largely aims to recognize and accommodate the evolving dimensions of human freedom, not only through Part III, which outlines Fundamental Rights, but also through Part IV, which contains the Directive Principles of State Policy. Together, these parts form an integrated framework of freedom.

The inclusion of Fundamental Rights and Directive Principles in the Constitution was inspired by the ideals that fueled the freedom struggle, embodying the enduring aspirations for liberty and freedom. While the entire Constitution is designed to promote societal

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reform and revolution in pursuit of good governance, the essence of the commitment to social change is deeply rooted in Parts III and IV. According to constitutional scholar Granville Austin, these sections represent the "conscience" of the Constitution, underscoring their vital role in realizing the vision of a just and equitable society.

Good governance has been a topic of discussion in political discourse worldwide, from the time of Socrates to Mahatma Gandhi. The core idea of good governance is to create a favorable environment that fosters a socio-economic and political structure based on quality performance by the government and its institutions. This concept is not about imposing governance externally but is grounded in the participation and cooperation of governing agencies at multiple levels, along with the mutually influential roles of various actors.

Good governance is a dynamic and evolving concept. Change is inherent to nature, and the idea of good governance continues to expand to address the ever-changing political, social, and economic challenges both locally and globally. It requires a political framework that promotes growth and development programs. In the current context, good governance is characterized by principles such as participation, consensus orientation, accountability, transparency, responsiveness, effectiveness, efficiency, adaptability, inclusiveness, and adherence to the rule of law. These factors serve as key indicators for assessing the performance of a government and ensuring the achievement of good governance.

Following are the indicators of good governance required to bring change in system:

1. Public Participation
2. Transparency in system
3. Rule of law
4. Effective and efficient system of governance
5. Accountability in system.
6. Equity.
7. Predictability of government and its system.
8. Responsible government.

II. GOOD GOVERNANCE AND DEVELOPMENT POLICY IN TELANGANA STATE

Good governance and development policy in Telangana are central to the state's vision of inclusive growth and citizen-centric administration. Since its formation in 2014, Telangana has implemented innovative governance practices and targeted policies to address the socio-economic needs of its diverse population.

Focus on Digital Governance

Telangana has leveraged technology to enhance transparency and service delivery. Initiatives like MeeSeva, a digital platform offering over 600 government services, have streamlined processes and minimized bureaucratic hurdles. The T-App Folio mobile application further simplifies citizen access to essential services, reinforcing accountability and efficiency.

Rural and Urban Development

The Palle Pragathi and Pattana Pragathi programmes exemplify the state's commitment to balanced development. Palle Pragathi focuses on rural infrastructure, sanitation, and environmental conservation, while Pattana Pragathi addresses urban challenges, such as waste management, water supply, and public amenities. These initiatives have transformed living standards in villages and cities alike.

Social Equity and Welfare

Targeted welfare schemes like the Dalit Bandhu programme provide direct financial assistance to Scheduled Castes, empowering them economically. Other initiatives, such as Mission Bhagiratha and Mission Kakatiya, ensure access to drinking water and enhanced irrigation facilities, addressing critical rural challenges. The 2BHK Housing Scheme supports low-income families by providing free housing.

III. IMPACT OF GOVERNANCE POLICIES

These policies have significantly contributed to Telangana's development. Rural and urban areas have seen infrastructural growth, improved access to services, and better livelihoods. Initiatives focusing on marginalized communities have reduced disparities and fostered inclusivity.

Good governance serves as the cornerstone of effective public administration, promoting transparency, accountability, and inclusivity. In Telangana, since its formation in 2014, the state government has prioritized citizen-centric policies and governance

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reforms to address the diverse needs of its population. With a focus on digital transformation, decentralized decision-making, and targeted welfare schemes, Telangana has emerged as a model for innovative governance in India.

At the heart of Telangana's governance framework lies a commitment to improving service delivery and empowering marginalized communities. Initiatives like MeeSeva, a digital platform offering seamless access to government services, have revolutionized the interaction between citizens and the administration. Flagship programs such as Mission Bhagiratha, which ensures safe drinking water for all households, and Palle Pragathi, aimed at holistic rural development, reflect the government's focus on grassroots impact.

Equally notable is the emphasis on social equity. The Dalit Bandhu scheme provides financial assistance to Scheduled Castes, enabling entrepreneurial ventures and fostering economic empowerment. Similarly, Mission Kakatiya, with its focus on restoring water bodies, has not only rejuvenated agriculture but also improved rural livelihoods. Urban governance initiatives, like Pattana Pragathi, have enhanced infrastructure and service delivery in towns and cities, addressing the challenges of rapid urbanization.
Despite these achievements, challenges such as resource constraints, effective monitoring, and administrative efficiency remain. Addressing these will require sustained efforts, capacity-building initiatives, and greater public participation.

Key Initiatives in Good Governance
Mission Bhagiratha: A flagship programme aimed at providing safe and sustainable drinking water to every household in rural and urban areas. This initiative has transformed access to basic amenities, improving health and hygiene standards.

T-Hub and T-Works: Telangana's push toward innovation and entrepreneurship through institutions like T-Hub, India's largest incubator, and T-Works has positioned the state as a hub for startups, fostering economic growth and job creation.

e-Governance: Leveraging technology to enhance service delivery, the government has introduced online portals like MeeSeva, enabling citizens to access over 600 services digitally. This reduces bureaucratic delays and promotes transparency.

Rythu Bandhu and Rythu Bima: Focused on agricultural welfare, these schemes provide direct financial assistance to farmers and insurance coverage, ensuring financial security and reducing rural distress.

Dalit Bandhu: A revolutionary scheme for economic empowerment of Scheduled Castes, offering direct financial support for entrepreneurial ventures, promoting self-reliance, and reducing poverty among marginalized groups.

Kanti Velugu: A health initiative providing free eye screenings, spectacles, and surgeries to citizens, improving public health outcomes.

IV. IMPACT OF GOOD GOVERNANCE INITIATIVES

These initiatives have significantly transformed Telangana's socio-economic landscape. Rural areas have witnessed improved access to water, education, healthcare, and employment opportunities. Programmes like Rythu Bandhu have reduced farmer suicides, while digital governance has bridged the gap between citizens and administration.

Moreover, urban centers have seen growth in innovation and infrastructure, making Telangana an attractive destination for investors and startups. The inclusive nature of policies, particularly Dalit Bandhu and gender-sensitive initiatives, reflects the government's commitment to equity and social justice.

V. CHALLENGES

Implementing good governance is essential for ensuring transparency, accountability, and inclusivity, but it comes with several challenges that hinder its effective realization. These challenges are multifaceted, encompassing institutional, financial, and societal barriers.

Institutional Challenges

1. Over-centralized decision-making and rigid bureaucratic structures often slow down the implementation of governance reforms, reducing their effectiveness at the grassroots level.
2. A lack of coordination among different government departments and agencies can lead to overlapping responsibilities and delays in service delivery.
3. Insufficient training and resources for local government officials affect their ability to deliver on governance objectives, especially in rural areas.

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Financial Constraints

1. Many governments face budgetary constraints that restrict their ability to fund large-scale developmental projects and welfare schemes.
2. Mismanagement and corruption in resource allocation often undermine the impact of governance initiatives.

Technological Barriers

1. While digital governance initiatives like e-services are effective, the lack of access to technology in rural and marginalized communities creates disparities in service delivery.
2. Ensuring data security and protecting citizens' information in digital platforms poses a significant challenge.

Societal Challenges

1. Traditional mindsets and resistance to reform among stakeholders can delay the adoption of good governance practices.
2. Deep-rooted disparities based on caste, gender, and socio-economic status create barriers to inclusivity and equitable development.

Political and Administrative Issues

1. Excessive political involvement in administrative matters can compromise the objectivity and efficiency of governance.
2. Weak monitoring and evaluation mechanisms make it difficult to track the progress and impact of governance initiatives.

VI. CONCLUSION

The study of good governance initiatives in Telangana highlights the significant strides the state has made in promoting transparency, accountability, and inclusive development. Through innovative programs like MeeSeva, Dalit Bandhu, Mission Bhagiratha, and Palle Pragathi, Telangana has effectively addressed key socio-economic challenges, including rural poverty, water scarcity, and infrastructure deficits. The integration of technology, particularly through digital platforms, has enhanced service delivery, making government processes more accessible and efficient. However, the state faces ongoing challenges such as financial constraints, bureaucratic inefficiencies, and resistance to change in some sectors. Overcoming these barriers will require continued investment in capacity building, institutional strengthening, and fostering greater public participation in governance. Despite these challenges, Telangana's governance model demonstrates the potential for decentralized, citizen-centric administration to drive sustainable and inclusive growth. By focusing on the needs of marginalized communities and ensuring equitable access to resources and opportunities, Telangana has set a strong example for other states to follow. Going forward, enhancing the state's governance framework, improving monitoring mechanisms, and addressing socio-political barriers will be crucial for realizing the full potential of good governance and achieving long-term development goals.

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NOVEL METHOD OF LIPID DRUG MEMBRANE INTERACTION

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ABSTRACT
A deeper understanding of the molecular mechanisms behind medicine- membrane relations are pivotal for the development of new drugs. To date, a number of biochemical and biophysical styles have been developed to study natural membranes at the molecular position. This review focuses on the advancements and new operations of ultramodern logical ways, including spectrometry, calorimetry, aural seeing, and chromatography, in the study of medicine relations with lipid membranes. The benefits and downsides of these approaches were compared and precisely considered. also, several biomimetic model membrane types, including liposomes, lipid monolayers, and supported lipid monolayers bilayer, were described. also, a brief overview of the general mechanics underpinning the medicine- membrane commerce process was given.
KEYWORDS: *Bioanalysis; drug-membrane interactions; drugs; lipid membrane.*

INTRODUCTION
This incredibly complex and varied structure is made up of the main component of the cell membrane, which is a broad spectrum of different lipids, proteins, and polysaccharides. The majority of the continuous lipid bilayer that makes up the cell membrane matrix is composed of amphipathic phospholipids. An essential component of a drug's absorption, distribution, metabolism, and excretion (DME) is the cell membrane, which acts as the cell's border. After being administered, a drug molecule must first enter the bloodstream (the absorption process) and then be delivered to its action regions (the distribution process). Only a few examples of the bio membrane that may be implicated in the action of the medicine are the blood-brain barrier (BBB), the wall of the tiny capillaries lining the stomach, and the barrier membranes in the gastrointestinal system. An increasing amount of research has shown that pharmacological compounds can interact directly or indirectly with the lipid membrane. This interaction may lead to changes in the drug molecules' pharmacological activity, bioavailability, and physicochemical properties, as well as a variety of pharmacological effects and chemical structures. Unfavorable pharmacological interactions with lipid membranes can have negative effects, such as medicine resistance and severe adverse effects. because of poor drug specificity. Anaesthetics, anti-cancer drugs, and non-steroidal anti-inflammatory drugs (NSAIDs) are a few examples. Therefore, understanding the intrinsic interactions between pharmaceuticals and bio membranes is essential for both the pharmaceutical business and biomedical researchers [1].

Analytical techniques for researching drug-membrane interactions
Numerous analytical methods, including spectrometry, calorimetry, chromatography, and acoustical sensing technologies, can be used to study drug-membrane interactions [2].

Chromatographic Techniques
Chromatography is a collection of analytical techniques used to identify, separate, and quantify different substances within a certain range. The foundation of chromatographic techniques is the interaction and differential partition of different substances between a stationary phase and a mobile phase. Technologies like spectroscopy and electrochemical methods are commonly used to enhance the identification of separated components. Depending on the choice of stationary phase and mobile phase, chromatography can be categorized as TLC, liquid chromatography (LC), gas chromatography, capillary liquid chromatography, supercritical fluid chromatography, etc. Here, we will focus on HPLC-based techniques, which are frequently used in studies of drug-membrane interactions [3].

Mechanism of Ion-Association Superior Liquid Chromatography Performance
The HPLCIAM stationary phase was developed to more precisely determine the partitioning of ionic and zwitterionic compounds in various phases. IAM stationary phases, which are marketed by Regis Technologies, are largely composed of covalently attached to porous silica spheres and phospholipid monolayers, mainly phosphatidylcholine. Thus, the application of IAMs may result in a better comprehension of biological activity and partition. Furthermore, compared to the conventional method of determining drug partitioning

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in liposome/water systems, AM-HPLC measurement is more suitable for early drug discovery because it is simple, quick, and repeatable [4].Several comparisons have been made between the standard logPandlogDliposome/water and n-octane/water partitioning systems and the lipophilicity as determined by IAM and the capacity factor, log... The results show that AM-HPLC is a more accurate and effective way to determine drug-membrane partition [5].

Liposome Chromatography Paralyzed

According to ILC is an fresh biomimetic system- grounded HPLC [6]. Liposomes are used sterically to screen and dissect passable accoutrements in ILC. The stationary phase is made up of paralyzed gel globules [7]. As opposed to IAMs, the biophysical parcels of the membrane can be altered by varying its composition. ILC columns' lipid terrain. The ILC- calculated lipophilicity indicator(logKs) and other the connections between approaches vary. A relative analysis indicates that only for Significant connections between logKs and structurally analogous substances were set up. IAM, n- octanol/ water, and liposome/ H2O systems all yielded lipophilicity indicators [8]. Only between logKs were significant connections observed in a relative disquisition. and the IAM- deduced lipophilicity indicators, n- octanol/ water,

Chromatography by Electro Kinetics

The capillary electromigration fashion known as electro kinetic capillary chromatography, or electro kinetic chromatography (EKC), is grounded on a combination of HPLC and electrophoresis. EKC measures the analytes' discriminational and electrophoretic mobility. separation of an encircling waterless phase from a lipid dissipation (pseudo-stationary phase) mobile phase) buffer result [9].

Electrochromatography in Capillaries

Capillary electrochromatography (CEC), a lately developed system of capillary liquid chromatography, uses electrostatic inflow to move the mobile phase through a capillary. In CEC measures, more stable lipid coatings are generated due to an IAM stationary phase. Is contained within a capillary made of fused silicon [10]. Demonstrated that direct correlations were. Sixteen structurally different composites in a study comparing CEC and HPLC results [11]. They also refocused out that CEC demanded lower than AM- HPLC. Indeed, with further advanced operation, analyte, fluent, and stationary phase. A recent review looked at the operation of several capillary electrofiltration ways to look at the connections between analytes and lipid membranes [9,12].

Styles of Spectroscopy

An overview of the spectroscopic ways generally used in the study of medicine- membrane relations will be given in this section. These ways includeX-ray diffraction (XRD), luminescence spectroscopy, electron paramagnetic resonance (EPR), vibrational spectroscopy, mass spectroscopy(MS), and small- angle neutron scattering(SANS)[3,13].

Luminescence Spectroscopy

To maintain an eye on intermolecular commerce, luminescence spectroscopy analyzes oscillations in luminescence intensity. luminescence spectroscopy offers remarkable inflexibility, high spatial resolution (down to the position of hundreds of nanometers), and perceptivity (down to the single- patch position) in comparison to contending ways [14]. Since natural luminescence is uncommon in natural systems, fluorescent examinations are generally used. handed a preface to natural membrane luminescence probing [15].

NMR Spectroscopy

NMR is the term for the glamorous parcels of a snippet's nexus. Several of these capitals are set up in lipid motes, similar as 1H, 13C, 31P, 17O, and14N. The introductory idea behind NMR spectroscopy is that some tittles' capitals have a glamorous moment, which causes them to parade distinct energy situations and resonance frequentness when exposed to an external glamorous field [16]. Lipids can also be chemically tagged with other capitals of interest, similar as fluorine(19F) or deuterium(2H) [17].

EPR Spectroscopy

The fashion known as electron spin resonance spectroscopy, or EPR, allows for the direct identification of paramagnetic realities with unmatched electrons [18].

Vibration Spectroscopy

Vibrational spectroscopy uses minimum disturbance to dissect the nuclear vibration parcels of a snippet. Infrared immersion and Raman scattering is its main enterprises. It furnishing the most accurate means of distinguishing between membrane actions, bilayer assembly, and membrane structure and composition, claim [19]. medicine- membrane relations can be anatomized by measuring the medicine-convinced vibrational changes attributable to the specific chemical functional groups inside membrane systems. Fourier transfigure infrared spectroscopy (FTIR) is the most extensively employed infrared spectroscopy fashion for biophysical study. exercising FTIR to

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track frequency oscillations in the PO2 – str, C=O stretching, and CH2 stretching modes can help us fully understand analyte relations with lipid membranes at the molecular position [20].

X-ray Diffraction

Some X-ray beams will scatter when an entering beam has a wavelength equivalent to the interatomic distances in the sample, demonstrating that XRD measurements are effective [21]. By analyzing the angular distribution of the scattered intensity, X-ray diffraction (XRD) offers a straightforward and non-invasive way to ascertain the sample's structural properties, chemical composition, and physical attributes. Additionally, under near-native conditions, X-ray diffraction (XRD) has the advantage of determining the bilayer thickness of unsupported lipid membranes down to Angstrom length scales [22].

Scattering Neutrons at Small Angles

Both SANS and SAYS are based on similar ideas, with the exception that in SANS, the source of the scattering is the neutron rather than the electron. While SAYS is only sensitive to the hydrophilic region of a lipid bilayer, SANS provides useful information on the hydrophobic tail portion. Therefore, SAYS and SANS may be used as complementary techniques for a detailed structural description of the biological membranes [23].

Colorimetric Methods

The foundation of colorimetric techniques is the evaluation of heat effects associated with drug-membrane interactions [24]. The amount of material involved in the reaction and the heat product's pace are typically associated with the quantity of heat generated or consumed in a chemical reaction. Numerous advanced colorimetric techniques have been used in pharmacology. Pressure perturbation calorimetry (PPC), isothermal ration calorimetry (ITC), and DSC are the most widely used techniques for assessing drug interactions with membrane processes [25].

Differential Scanning Calorimetry (DSC)

It is a non-perturbing technology used to determine a material's heat capacity (CP) as a function of temperature and time. Watson and M. J Neill developed it in 1962, and Chapman used it for the first time in the 1960s to investigate the chemotrophic behavior of bio membranes [26]. The basic notion of ITC and Oscar is the same as the calorimetry of isothermal titration, except operating at a constant temperature and incorporating an titration module[27].In the ITC experiment, aliquots of drugs are retreated in small amounts into liposome solution and vice versa. Until the binding achieves saturation, each injection generates a record of the heat flow. The requirements for thermodynamic values for drug-lipid binding may be determined by binding the created isotherm [28].

Calorimetry of Pressure Perturbation Calorimetry (PPC)

A relatively new thermodynamic technique, measures the change in heat (HQ) that happens when the pressure (UP) above a solution containing proteins or other biomolecules changes [29].

CONCLUSION

The drug's orientation, conformation, and localization within the membrane; the structural stability and phase behavior of the drug-inserted membrane; the drug's dynamics of interaction with the lipid membrane; and the impact of the drug-membrane interaction on the drug's ADME features are all included. The van der Waals force, hydrogen bonds, and hydrophobic and electrostatic interactions between certain lipid moieties, drug molecules, and membrane proteins are only a few of the variables that can actually affect drug-membrane interactions. Therefore, it is strongly encouraged to use additional analytical techniques in order to have a complete understanding of drug-membrane interaction events. Furthermore, the creation of powerful, novel combinations of techniques, like lab-on-a-chip hyphenation with MS approaches, would greatly improve the effectiveness of on-site screening in the early stages of drug development.

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THE PROTESTANT ETHIC AND THE DEVELOPMENT OF MODERN SPORTS: HISTORICAL INFLUENCE AND IMPLICATIONS FOR CHINESE SPORTS VALUES

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ABSTRACT
Max Weber's The Protestant Ethic and the Spirit of Capitalism theorizes the Protestant ethic, providing a foundation for exploring the formation of Protestant ethics through the Reformation and how it shaped modern sportsmanship. This study discusses the potential impact of Protestant ethics on China's sports modernization and suggests how Chinese sports development can draw upon Protestant values to enhance sportsmanship and cultural growth. Finally, it proposes a distinctive sports ethics with Chinese characteristics adapted to China's current context.

KEYWORDS: *Protestant Ethic, Modern Sports Development, Sports Ethics, Cultural Values*

1. INTRODUCTION

Modern sports, as a significant product of social evolution, trace their origins and development to Europe, particularly during the critical period from the Renaissance to the Industrial Revolution. The Industrial Revolution not only marked the maturity of modern sports but also served as a pivotal turning point in its progression (Li & Yang, 2015). The growth of modern sports owes much to the material base created by the dissolution of Western society's agrarian economy and the rise of a market economy, alongside the social foundation built by industrialization. The intellectual foundation of sports, however, is equally significant. The Western Renaissance liberated individuals from ecclesiastical constraints on thought, prompting a shift in recognizing self-worth and physical health, transforming spiritual affirmation of sports value into a tangible demand for sports. Overman (1997), from the perspective of the relationship between Protestant ethics and the spirit of modern sports, argues that religion and modern sports functions progressively aligned, promoting development through self-discipline, humanistic growth, social responsibility, standards of competition, success, and morality. This perspective may explain why modern sports emerged in the West rather than Eastern societies (Weber, 2010). This article, based on Weber's *The Protestant Ethic and the Spirit of Capitalism*, aims to explore the origins, development, and alienation of modern sports from a religious ethical-cultural perspective, providing a reference for the modernization of Chinese sports.

2. THE TRANSFORMATION OF BODILY VIEWS UNDER THE PROTESTANT ETHIC

The Protestant Reformation catalyzed a shift in Western cultural values, particularly emphasizing discipline and purpose in daily life. This cultural transformation redefined physical activity, aligning it with self-discipline and moral integrity, thus creating fertile ground for the structured development of modern sports. By promoting controlled, meaningful bodily engagement, Protestant ethics contributed to a growing recognition of sports as a valuable social and moral pursuit.

2.1 Historical Background and Theoretical Foundation of the Protestant Reformation and the Formation of Protestant Ethics

The Protestant Reformation of the 16th century, especially marked by Martin Luther's publication of *Ninety-Five Theses*, signified the initial formation of Protestant ethics. This theory, further developed by John Calvin, had a profound influence on the spirit of modern sports. Known as the Dark Ages, medieval Europe was characterized by economic stagnation and frequent wars under feudalism, with the Catholic Pope controlling national powers and imposing strict mental restraints on people, which hindered Europe's development. However, as humanism and the Renaissance emerged, a shift occurred in people's pursuit of values. Many Catholic believers began to question traditional faith, exemplified by Martin Luther's *Ninety-Five Theses* in 1517, which marked the beginning of the Reformation. Calvin subsequently became the second-generation leader of the Reformation, which lasted until 1648.

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The concept of "Protestant ethics", as proposed by Max Weber in his seminal work *The Protestant Ethic and the Spirit of Capitalism*, argues that spiritual and cultural factors significantly drive socioeconomic development. Weber explored the relationship between Protestant ethics and the underlying psychological drive behind capitalist growth, or what he termed the "capitalist spirit". He concluded that the core doctrine of the Protestant ethic lies in the concept of "calling", derived from Luther's translation of the term "calling" in the Bible to the German "Beruf" (profession), implying that secular occupations represent a life mission assigned by God. The asceticism rooted in the "calling" concept became one of the defining elements of modern capitalist spirit and, by extension, of modern civilization. Furthermore, Weber believed that Calvinist predestination was an essential foundation of Protestant ethics, where salvation was predetermined and unaffected by worldly deeds. Calvinists believed that earthly actions could demonstrate salvation, thereby attributing profound meaning to secular life and rationalizing all worldly activities as acts glorifying God (Overman, 2011).

The Protestant ethic shaped by the Reformation led the majority of the Western population to actively participate in worldly affairs and diligently engage in professional labor while exhibiting frugality, rejecting all forms of hedonistic consumption. Wealth accumulation through hard work and frugality was seen as morally unassailable, symbolizing divine grace, while indulgence was viewed as sinful. Consequently, the ethics of conviction and responsibility intertwined within Protestant ethics. This rationalization does not imply a mere calm temperament or the suppression of emotions as commonly interpreted. Instead, the rationalization formed by the Reformation established an orderly cause-and-effect relationship between means and ends, where both means and goals were predictably aligned. According to Weber, Protestant ethics, by ascribing moral significance to secular activities, paved the "path of institutional and cultural confidence" for capitalism. Hence, "profit is the primary social responsibility", with no need for shame or guilt; even the act of making money became a noble pursuit (Overman, 2011). This undoubtedly fostered the emergence and development of the capitalist spirit, whose economic rationalism ultimately constituted the cultural foundation of capitalism. The values of Protestant asceticism, rationalization, goal orientation, self-realization, individualism, professional ethics, and time discipline collectively laid the groundwork for capitalist logic. Under this cultural influence of values and rational spirit, societal views on the body underwent significant transformation, thereby providing cultural support for the formation and development of modern sports (Overman, 2011).

2.2 Changes in Bodily Views under the Protestant Ethic

Early Greek culture celebrated the human body, yet around the 6th century BCE, Greek philosophy introduced a dualistic tendency, elevating the soul and denigrating the body. Plato, as the architect of the body-soul dichotomy in Greek thought, viewed bodily desires and needs as the sources of worldly suffering and sin. This perspective became mainstream in medieval Christian orthodoxy, leading to the elimination of physical education from church schools and stifling the budding interest in public sports (Liu & Wang, 2018). The Reformation challenged the Catholic doctrine of soul-body dualism, introducing a new concept of "unity of soul and body". This perspective not only contested medieval asceticism but also theoretically supported the emergence of modern sports. Under the Protestant ethic, the body was viewed as a divine gift, and thus, maintaining physical health was seen as a duty to God. This shift led to bodily activities being accepted as legitimate within the church, encouraging exploration of physical potential and abilities.

Consequently, with the Reformation's revival of this holistic view of life inherited from ancient Greece, a humanistic sports ethic gradually developed in Europe, emphasizing the ontological significance of physical movement. This transformation fostered a view of sports as an essential part of secular life and provided room for a sports philosophy centered on human nature. Both the Renaissance and the Reformation affirmed the positive role of sports in cultivating the natural individuality of human beings, leading to an evolving sports ideal. Compared with the Renaissance, the Reformation placed even greater emphasis on the status and value of the body, a view that held considerable influence within Christianity itself. Martin Luther stated, "Only a healthy body can serve religion; maintaining physical health is the duty of every Christian", thus affirming the positive role of both the body and sports in his educational philosophy. He argued that the soul and body were not contradictory; rather, he noted that a strong body contributed to achieving religious ideals and that physical fitness was a responsibility of every Christian (Ci & Zhang, 2015). God requires His followers to possess not only a pure mind but also a healthy body. The Reformation's expression of this humanistic view on body and soul broke through ascetic barriers, leading Christianity to recognize the equal status of body and soul and paving the way for the rise of modern sports in Western culture.

3. THE PROTESTANT ETHIC AND THE DEVELOPMENT OF WESTERN SPORTS: HISTORICAL CONTEXT AND THE FORMATION OF MODERN TRANSFORMATIONS

Protestant ethics not only facilitated organized sports but also instilled a new cultural understanding of competition as a moral endeavor. The shift from unstructured play to rule-based sports echoed Protestant values of accountability and ethical purpose. This perspective allowed sports to become a space for character development, where fairness and community-minded success were celebrated as reflections of a disciplined, purpose-driven life.

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3.1 The Formation of Modern Sports and New Forms under the Influence of Protestant Ethics

Against the backdrop of the Reformation, changes in bodily views influenced by Protestant ethics helped shape modern sports, particularly in cultivating the spirit of competitive sports. The merging of Protestant values with sports ethics laid a strong ideological foundation for the development of modern sports. For instance, Martin Luther opposed asceticism, emphasizing the role of competitive sports in social reform and advocating activities such as fencing, running, wrestling, and dancing as alternatives to drinking, prostitution, and gambling. Luther understood that the rules of competitive sports fostered knowledge of social law and public morality, thereby promoting sports development. Guided by Protestant ethical principles, the integration of personal career and religious faith became a societal norm, with people viewing their career successes and failures as manifestations of divine will, motivating them to strive actively, remain resilient, and persevere until success. This mindset provided a solid ideological and theoretical foundation for various sports activities and competitive sports, transforming them into a spirit of competition. Positive elements within Protestant ethics, such as honesty, integrity, justice, concern for public welfare, opposition to egocentrism, and resistance to the worship of wealth, aligned with the ethical demands of sports, creating a moral foundation for the growth of modern sports. These ethical beliefs not only advanced the development of modern sports, especially competitive sports, but also established a theoretical framework for the moral norms of athletic activities.

Globally, the origins of modern sports are generally recognized to have emerged in the late 19th century, with the first modern Olympic Games held in Athens, Greece, in 1896, marking the beginning of modern sports formation and development. In Britain, an essential characteristic of modern sports was the mid-19th-century transition of certain sports activities in public schools from unregulated pastimes into structured, codified games, with Christianity playing a key role. In 1824, under the decision of Thomas Arnold, students at Rugby School were allowed to participate in rugby activities during breaks, with each dormitory forming its own rugby team. Through Arnold's work at Rugby School, and under the influence of writers such as Charles Kingsley and Thomas Hughes, a close relationship between sports and religion emerged in Victorian Britain, with long-standing religious values permeating both grassroots and elite-level sports initiatives. Broader social conditions and contexts, such as the middle and upper classes' concern for the habits and recreational activities of the industrial working class, fostered this connection. The church's sports regulations extended beyond forming football teams or organizing recreational activities to include more complex structures. For instance, the formal establishment of clubs for chess, billiards, tennis, and cycling, as well as clubs specifically for women such as those for gymnastics, table tennis, and hockey, were promoted (Parker, 2012). While the Olympics represented modern sports with a Greek religious heritage, most modern sports originated in medieval and early modern Western societies and had strong ties to Christianity (Fang, 2019). By 1850, Protestantism in Britain began to embrace sports as a legitimate and comprehensive lifestyle.

The Protestant ethic's rational approach to life, shaping capitalist work ethics that promote wealth accumulation through thrift, influenced modern sports to pursue record-setting, precision, and continual improvement (Guttmann, 2012). American cultural anthropologist Allen Guttmann provided a comprehensive analysis of modern sports characteristics, identifying seven elements: secularism, equal competition opportunities and conditions, role specialization, rationalization, bureaucratic organization, quantification, and record pursuit. Each characteristic is thus defined (Guttmann, 2012). Consequently, early American sports values emphasized the importance of victory, viewing sports as rational, goal-oriented activities infused with work principles and a noble moral purpose. American sports, based on the leisurely pursuits of the British upper class, could develop freely without authoritarian, economic, or cultural restrictions. However, during the Progressive Era, Puritan moral values returned, with institutional control applied to recreational activities to guide them by Victorian standards, including professional ethics and the self-interest of commercial elites.

As capitalism took hold, external, irrational, and faith-based elements lost relevance. In a market-driven economy, individuals pursued wealth not out of religious ethics but due to "full adaptation to this system". The "calling" concept shifted to economic motives, making capitalism a self-sustaining system. Over time, religion waned, secularization surged, and utilitarianism supplanted religious foundations, forming today's capitalism. Without spiritual guidance, Western sports faced the rise of materialism, with the idealistic pursuit of the Olympic movement continually challenged by commercialization and moral decline (Fang, 2019). Amateurism yielded to professional and commercial sports. Ultimately, science, technology, scientific management tools, and capitalist spirit were fully integrated into American sports, with consumerism, profit-seeking, and sports forming an inseparable network. Alcohol advertisers and their marketing methods exemplify this, as sports' scientific, commercial, and professional advancements since the 1960s have significantly contributed to the decline of moral values within sports, with the purposefulness and rationalization of American sports impacting sports culture ambiguously.

Modern sports are the "offspring" of the capitalist production mode and human nature. The capitalist production mode inherently involves a social division of labor, which Marx referred to as "alienated labor", making modern sports the inevitable product of this irreconcilable contradiction (Wen, 2006). In this way, modern sports represent the positive negation of capitalism's shortcomings, complementing each other and flourishing together. During the industrial era, American workers experienced a disconnect between

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work and fulfillment; unable to find spiritual value in factory labor, they redirected their desire for physical experience to sports. American companies capitalized on this trend by sponsoring semi-professional sports leagues closely aligned with their business interests. Sports gradually became a mimicry of labor, evolving into a marketing tool within the capitalist machine. To offer a romanticized solution for modern sports, some movements abroad advocated restoring games and playful sports, suggesting that sports should prioritize enjoyment as both means and end, moving away from competition for excellence and seeking an appreciation for human limits.

3.2 The Protestant Christian Approach to Sports: Preservation and Rejection within Protestant Bodily Views

The Reformation not only theoretically constrained sports but also practically shaped its development, while sports, in turn, influenced religious self-adjustment and adaptation. Particularly in Protestant Christianity, sports were regarded as a means of physical and spiritual cultivation. The Catholic view of the body exhibited theoretical and practical contradictions, enhancing its adaptability to the secular world and its self-regulation, with Protestantism being the most representative of this adaptation. As a major denomination in Europe, Protestantism split from Catholicism and carried forward the Lutheran affirmation of bodily value. During the medieval period, the British had generally poor physical conditions, high mortality rates, and lacked masculinity, suffering from low immunity and poor hygiene habits. Under the bodily view encouraged by the Reformation, sports saw some degree of growth and spread. However, with the rise of capitalism and the wave of the Industrial Revolution—especially after the French bourgeois revolution in the 18th century—Protestantism faced decline, necessitating further adjustments in Christian self-conception.

After the Enlightenment, emerging liberal theology bridged the gap between heaven and earth, further affirming the legitimacy of the body. Entering the 19th century, Christianity became increasingly secularized and ethical, integrating the new bodily view with Western Christian social movements, resulting in numerous Anglo-American Christian organizations promoting sports (Fang, 2019). Consequently, the relationship between Christianity and sports also evolved. Some denominations aimed to promote and spread sports worldwide, viewing it as a tool to impose European civilization and Christian ethics in regions like Asia and Africa, a form of cultural colonialism. The establishment and development of the Young Men's Christian Association (YMCA), founded in 1884, exemplified this, using youth-targeted sports activities to instill Christian ethical education and propagate Christian civilization abroad.

Physical activity was considered an essential aspect of Christian life, with American Christian societies or professional associations related to sports possibly more prevalent than in other fields, particularly as religious and moral attitudes underwent significant changes during the Victorian era. Although Christianity and Catholicism were predominant, they gradually shifted focus from religious faith to moral responsibility and social welfare. For example, sports became a mechanism for cultivating masculinity, promoting virtues such as integrity, fair competition, respect, strength, and perseverance. Additionally, radical Christian groups believed that leaders could be "made" through this mechanism, shaping individuals as model Christian gentlemen and leaders. Numerous charitable organizations emerged and developed, and the British government established the first public health insurance system to improve social welfare and public health standards. Religions sought to inspire young people to join local Christian associations, often referred to as "fellowships", where members would meet regularly to study the Bible, pray, discuss, support one another religiously, and engage in sports activities. Some local organizations even funded specific projects to encourage social involvement, especially among young people [6].

Protestant ethics imposed norms on both spiritual faith and secular life, with athletes relying on shared beliefs to foster teamwork and viewing sports as an extension of spiritual life. The fusion of doctrine and sport effectively transformed professional sports into a "quasi-religion", where participation in sports and skill acquisition became symbols of identity, and a love for sports became a mode of identity and cultural affiliation.

Before sports were commercialized and marketized, Protestant groups in Britain and America viewed sports as tools for spiritual and social salvation. Modern sports benefited from this support, expanding rapidly and spreading globally. Protestantism's transformation of sports not only reversed the medieval Christian opposition to sports but also demonstrated Protestantism's adaptability to modern society [7]. The Industrial Revolution and the sweeping social changes brought by British capitalism spurred certain Christian factions to actively address social realities. In Britain, modern sports became increasingly visible within Christianity due to their role in developing talents suited to modern society, forming a "muscular Christian" ideology [6], which significantly impacted the development of Western sports, particularly in America, where it fueled the growth of competitive and professional sports. This concept of "muscular Christianity" originated from 19th-century British ethical and moral issues, including protecting the weak, addressing poverty, and promoting moral virtues. Muscular Christianity framed these and other issues within the contexts of physical effort and spiritual purity, establishing a set of core values that ultimately defined the relationship between sports and religion: fair competition, respect (for oneself and others), physical and emotional strength, perseverance, obedience, discipline, loyalty, cooperation, self-control, self-sacrifice, and endurance [6]. Courage, temperance, and team spirit were held in high regard, forming a "holy trinity" of moral standing. The life and achievements of Baron Pierre de Coubertin, founder of the modern Olympic movement, are said to have been influenced by these values.

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Despite Christianity's goal of using sports to educate youth and counter the "diseases of civilization" brought about by urbanization, Protestantism, rooted in Christian ethics, often viewed morality and recreation as opposing forces. This tendency sometimes led to harsh prohibitions, perceiving cultural and athletic activities as indulgences that promoted laziness and moral degradation. For example, denominations like Puritans and Calvinists in Europe and America often enforced their principles rigorously, significantly impacting folk sports and hindering sports dissemination in these regions. Calvin personally instituted the *Geneva Regulations*, which prohibited nearly two hundred forms of games and recreational activities. In America, Puritans imposed fines of forty shillings and sixteen strokes on the back for running, jumping, horseback riding, or dancing on Sundays. In Britain, Puritans criminalized group dancing, hunting, chess, and similar activities. These anti-physical and anti-sports measures within Protestantism reveal the limitations of the Reformation, leading to constraints in the selection of sports activities in modern sports development.

4. INSIGHTS FROM PROTESTANT ETHICS FOR RESHAPING CHINESE SPORTS VALUES

China's unique cultural foundation provides an opportunity to integrate traditional values into modern sports ethics. By drawing from Confucian principles of harmony and respect, alongside insights from Protestant ethics, Chinese sports culture can cultivate a balanced view of competition that emphasizes both personal growth and social responsibility. This synthesis aligns with China's broader vision of a values-driven society, supporting individual and collective well-being.

4.1 The Core Role of Spiritual Culture in Sports Values

According to the Marxist historical materialism perspective, the economic base has a decisive influence on the superstructure, a notion reflected in the development of modern sports in the West, where economically advanced nations also have well-developed sports sectors. However, Max Weber, through the lens of Protestant ethics, emphasizes the significant role of spiritual and cultural factors in socioeconomic development. Therefore, in discussing the future of Chinese sports, it is essential to go beyond a purely economic view and recognize the profound impact of cultural confidence on sports development. In the realm of sports, both Western countries and China face spiritual challenges, such as the dominance of materialism, consumerism, spiritual emptiness, and a lack of faith. These issues are especially evident in phenomena like sports corruption, gambling, and match-fixing. The ethical issues within modern sports reveal a fundamental truth: the pursuit of wealth without cultural or spiritual support can lead to the moral decline and spiritual degradation of sports participants. Protestant ethics further asserts that personal interest orientations are deeply influenced by worldview, highlighting the close connection between economic activities and individual perspectives.

The evolution of Western bodily views and the formation of bodily views under Protestant ethics reveal an important observation: the development of sports is closely linked to specific perspectives on the body. This view suggests that sports development is grounded in a particular bodily perspective, which in turn deeply influences people's core attitudes toward sports. Within mainstream thought, bodily perspectives have had a guiding role in the sports development of their respective eras. Although the Chinese public holds diverse views on sports, the field of sports science has a responsibility to guide the formation of a scientific, proactive, and pragmatic sports perspective through academic research, public education, and service provision.

Protestant ethics promotes personal initiative and the spirit of perseverance, qualities that are equally applicable to sports. Chinese sports should encourage young people to actively participate in sports, fostering their competitive spirit and resilience, while viewing sports as an integral part of personal and societal development. Emphasizing the social value of sports, the Lutheran view of sports highlights its potential to enhance individual morality and social engagement, seeing sports not merely as a means of competition and entertainment but as a powerful tool for character-building, social cohesion, and cultural dissemination. The integration of sports and education is especially important in light of the negative impacts of modern sports. The Lutheran perspective on the importance of sports for personal growth can inspire China to integrate sports with education, incorporating sports into school curricula to cultivate students' physical health and moral integrity. The fusion of sports and education not only promotes physical health but also plays a significant role in moral education and fostering teamwork.

4.2 Exploring a Socialist Sports Ethics with Chinese Characteristics for the New Era

Recognizing the limitations of Protestant ethics, we must acknowledge that as a product of the capitalist era rooted in unconditional faith in God, it does not fully align with human development as a whole. Therefore, in exploring the cultural foundation for the development of Chinese sports, we cannot rely solely on religiously based values and ethical frameworks. The formation and existing issues of modern sports offer valuable lessons for China's sports modernization. In promoting the modernization of sports in alignment with China's current realities and integrating with China's rich traditional culture, it is essential to adhere to a people-centered guiding principle in sports and embrace a collaborative and inclusive sports culture as a guiding concept [12].

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In the development of sports, adherence to ethical principles, particularly in sports economic ethics, is crucial. Reconstructing sports ethics to meet the challenges posed by a market economy has become increasingly important. At the core of sports ethics should be the ultimate concern for human welfare, fostering an ethical framework in sports that is rich in humanistic values. In the process of China's sports modernization, cultivating a robust sports culture is key to achieving the goal of a strong sporting nation. Integrating ethical values into sports education and events emphasizes principles such as morality, fair competition, and teamwork, making sports an essential component of societal education.

Chinese traditional culture, particularly Confucian values such as benevolence, propriety, honor, and integrity, provides a wealth of resources for developing sports morality and character. Sports are not only a platform for physical training but also a venue for cultivating moral character and team cooperation. By promoting fair competition, respect for opponents, and discipline in sports, China can preserve and promote its traditional moral values. Reflecting on the rich, five-thousand-year history of Chinese civilization, China possesses a deep cultural tradition in sports, including the traditional "Six Arts", with activities such as archery (*she*) and charioteering (*yu*). These traditional sports are not only forms of physical education but also valuable guides for the future development of Chinese sports. Leveraging national policies to promote outstanding traditional Chinese culture, China can preserve and expand sports that embody the Chinese spirit and wisdom, building a distinctive traditional sports culture with national identity and enhancing its appeal on the international stage.

5. CONCLUSION

As a profound ethical framework, the Protestant ethic provides a perspective for deeply examining the development of sports from an ethical standpoint. In the context of China's sports modernization, adopting positive elements from Protestant ethics can help foster the growth of sports spirit and culture. Firstly, it is essential to establish a positive ethical framework for sports. The Protestant ethic values honesty, diligence, resilience, and personal responsibility—qualities upheld by modern sports. The development of Chinese sports should be based on principles of integrity and morality, creating a transparent sports environment that prevents corruption and preserves fair competition.

Secondly, it is crucial to consider ethics and morality within the sports economy. The Protestant ethic's rational attitude toward life and its emphasis on record-keeping, precision, and continual improvement highlight the need for ethical guidance in China's commercial sports development. This approach helps China avoid the pitfalls of "championship mania", consumerism, and an overemphasis on achievement, ensuring that sports reflect both individual growth and societal value rather than merely commercial interests.

Thirdly, ethical considerations in competitive sports must be carefully balanced. The emphasis on victory and gold medals in the Olympic movement, influenced by championship and consumerism ideologies, can lead to an excessive focus on honor and financial rewards. Chinese sports should emphasize a balance between competition and sports ethics, nurturing athletes' character and morality. This approach values not only victory but also participation and teamwork.

Finally, fostering a public perspective on sports is essential. The "elitism" and "professionalism" in modern sports sometimes shift the public's focus toward elite athletes and professional competitions, overshadowing the importance of mass sports. Chinese sports should actively promote public participation in sports activities, encouraging fitness for all and cultivating a healthy view of sports within society.

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GENDER-RESPONSIVE LEARNING ENVIRONMENT (GRLE) FOR GENDER EQUALITY OF G10 LEARNERS IN PEDRO GUEVARA MEMORIAL NATIONAL HIGH SCHOOL

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ABSTRACT

This action research entitled "Gender-Responsive Learning Environment (GRLE) for Gender Equality of G10 Learners in Pedro Guevara Memorial National High School" is primarily focused on The importance of building Gender-Responsive Learning Environments (GRLEs) to create gender equality among Grade 10 learners in an educational environment aspiring for fairness and inclusion. Gender disparities in education have long been a problem, and the researcher presents an explanation of the idea, relevance, and possible influence of GRLEs on students' experiences. Gender-responsive learning settings identify and address the distinct demands and obstacles that various gender learners may confront. The researcher underlines the need of gender-responsive techniques in breaking down existing obstacles and ensuring that all Grade 10 learners, regardless of gender, have equal learning and personal development opportunities.

Gender-Responsive Basic Education Policy "seeks to enable the DepEd to undertake the integration of gender in education to tackle both enduring and that emerged gender and sexuality-related problems facing basic education, to promote the protection young learners from any type of gender-related violence, abuse, exploitation, bias, and bullying, and to encourage a culture of equality and non-discrimination in the workplace and across the DepEd."

Creating a gender-responsive learning environment is especially crucial for Grade 10 learners, who are at a vital point in their growth and identity-building. By promoting gender equality and challenging gender stereotypes in this age range, we may help students develop a more inclusive and open-minded view of gender problems, which can favorably affect their attitudes and actions in the future

KEYWORDS: *gender-reponsive learning environemnt; identity-building; gender and development; comprehensive sexuality education*

1.0 INTRODUCTION

Gender equality in schools refers to ensuring that all students, regardless of their gender identification, have equal access to opportunities, resources, and support to achieve academically and socially. Regrettably, gender-based discrimination, harassment, and violence persist in many educational settings, impeding students' learning and development, particularly those who identify as women or gender minorities. This issue impacts not just individual learners but also has broader societal ramifications, such as maintaining gender stereotypes and inequities.

The Department of Education (DepEd) issued DepEd Order No. 32, s. 2017 or the Gender-Responsive Basic Education Policy in line with its Gender and Development (GAD) mandate as stipulated in the 1987 Philippine Constitution, Republic Act (RA) No. 9710 or the Magna Carta of Women (MCW), RA 10533 or the Enhanced Basic Education Act of 2013, and the Philippines' International Human Rights Commitments to the Universal Declaration of Human Rights (UDHR), Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), and the Convention on the Rights of the Child (CRC) among others.

The Department of Education (DepEd) emphasizes in various policy documents that the learner, particularly the child, is at the heart of Philippine basic education. The recently adopted Rights-Based Education (RBE) Framework for Philippine Basic Education emphasizes the responsibility of schools, learning centers, and offices to respect, protect, fulfill, and actively promote the whole range of children's

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rights. The RBE Framework underlines that the right to education encompasses more than only access, but also the quality of education received by children and their well-being in their learning contexts.

Encouraging gender equality in schools is critical to creating a safe, inclusive, and empowering learning environment for all children. Schools can help kids reach their full potential by offering fair opportunities and resources. Furthermore, supporting gender equality in schools may help question and dismantle negative gender stereotypes and prejudices, resulting in a more fair and just society.

Gender-Responsive Basic Education Policy "seeks to enable the DepEd to undertake the integration of gender in education to tackle both enduring and that emerged gender and sexuality-related problems facing basic education, to promote the protection young learners from any type of gender-related violence, abuse, exploitation, bias, and bullying, and to encourage a culture of equality and non-discrimination in the workplace and across the DepEd."

DepEd Order No. 31, s. 2018 Policy Guidelines on Comprehensive Sexuality Education (CSE) Implementation, which aims to promote a consistent understanding of CSE fundamental ideas and themes, as well as to guarantee unambiguous CSE protocol implementation.

Reaching out to persons who are marginalized because of their gender and sexuality is critical for CSE initiatives to succeed. According to the UNFPA Evaluation of Comprehensive Sexuality Education Programmes (2015), "aspects of gender and power should be woven into the finalized curriculum, teaching content, teaching methods (participatory, positive, non-judgmental), the classroom environment, school policies, and school ethics." From a gender perspective, research typically aims to identify the prevalence and experience of gendered practices, rights violations, and gender attitudes - but it is also about understanding inequality, vulnerability, and who has the greatest needs in each setting, which is critical, especially for reaching marginalized girls.

Creating a gender-responsive learning environment is especially crucial for Grade 10 learners, who are at a vital point in their growth and identity-building. By promoting gender equality and challenging gender stereotypes in this age range, we may help students develop a more inclusive and open-minded view of gender problems, which can favorably affect their attitudes and actions in the future.

2.0 METHODOLOGY

2.1 Research Design

The study utilized the descriptive-correlational research design was purposive and selective sampling used in this study. Purposive sampling is a sampling approach used by qualitative researchers to find individuals who can provide in-depth and extensive information on the topic under study. It is very subjective and defined by the qualitative researcher who generates the qualifying criteria that each participant must meet to be selected for the research study, which is forty-two (42) Grade 10 learners.

The researcher produced informed consent from the chosen participants and informs them about the goal of the study, methods, potential benefits, and any dangers involved. The researcher will make certain that participation is entirely voluntary and private.

2.2 Research Locale

The study was carried out in effective strategies and practices for promoting gender equality in schools and building a gender-responsive learning environment specifically for Grade 10 learners at Pedro Guevara Memorial National High School, School Year 2023-2024

2.3 Research Participants

This research study is limited only to the Gender-Responsive Learning Environment for Gender Equality of G10 Learners in Pedro Guevara Memorial National High School in Santa Cruz, Laguna, School Year 2023-2024.

2.4 Research Instrument

This study include both purposive and selective sampling techniques. Purposive sampling is a sampling technique used by qualitative researchers to identify individuals who can give in-depth and comprehensive information on the issue under investigation. It is very subjective and determined by the qualitative researcher, who creates the qualifying criteria for each participant to be chosen for the research study, which includes forty-two (42) Grade 10 students.

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2.5 Data Gathering Procedure

The researcher gathered the responses through Microsoft Forms, and the responses of the respondents at its utmost confidentiality in response to the mandate of the Data Privacy Act. The researcher used the margin of error and confidence level sampling technique and also, make a self–made questionnaire, provided that it will be checked by the statistician's validation and reliability testing.

Frequency Distribution – this is the accumulation of the frequencies of the responses of the respondents from the Grade 10 learners and their parents particularly in their socio-demographic profiling.

Formula: Where: % = Percent f = Frequency N = Number of cases

Weighted Mean – this statistical method will be used for the Grade 10 learners' knowledge in promoting gender equality in schools as mentioned from the above gathering of sources of data and information. The descriptive indices will be the measuring remarks in evaluating the learners' awareness of the importance of gender equality.

Descriptive Index for Learners' Understanding of Promoting Gender Equality in Schools	
5 = 4.21 – 5.00	Very Knowledgeable
4 = 3.41 – 4.20	Knowledgeable
3 = 2.61 – 3.40	Moderately Knowledgeable
2 = 1.81 – 2.60	Slightly Knowledgeable
1 = 1.00 – 1.80	Least Knowledgeable

Descriptive Index for Learners' Awareness of the Importance of Gender Equality	
5 = 4.21 – 5.00	Highly Engaged
4 = 3.41 – 4.20	Engaged
3 = 2.61 – 3.40	Moderately Engaged
2 = 1.81 – 2.60	Slightly Engaged
1 = 1.00 – 1.80	Less Engaged

Pearson R – it is used to determine if there is a significant relationship between two interval or ration types of data. In testing the hypothesis for significant relationship, a 0.05 level of alpha was set. The actual significance was shown with degrees of freedom and its critical value is set for comparison and for decision rules. If the statistical value is significant, the null hypothesis is rejected; otherwise, it will be accepted.

In symbols,

$$r = \frac{n(\Sigma xy) - (\Sigma x)(\Sigma y)}{\sqrt{[n\Sigma x^2 - (\Sigma x)^2][n\Sigma y^2 - (\Sigma y)^2]}}$$

Multiple Correlation Coefficients – under the Pearson R Correlations will also to determine the correlation of at least 2 interval or ratio types of variables, namely the learners' knowledge in promoting gender equality and learners' awareness of the importance of gender equality.

2.6 Ethical Considerations

This research study followed ethical guidelines. Ethical considerations and problems that may arise as a result of the study's execution. The researcher provided potential participants with clear and complete information about the study, allowing them to make free and informed choices. Informed consent forms are written in plain language and address any potential risks or discomfort. The researcher used strict data protection methods and concealed data wherever feasible. Identifiable data will be stored securely, and only authorized persons will have access to it. Throughout the study process, the researcher acknowledged any potential conflicts of interest and implemented measures to prevent bias. Using double-blind research designs can help reduce bias during data collection and analysis. Before commencing the trial, the researcher completed a thorough risk assessment to reduce any potential damage to participants. Participants' well-being was assessed throughout the trial, and there was a clear strategy.

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3.0 RESULTS AND DISCUSSION

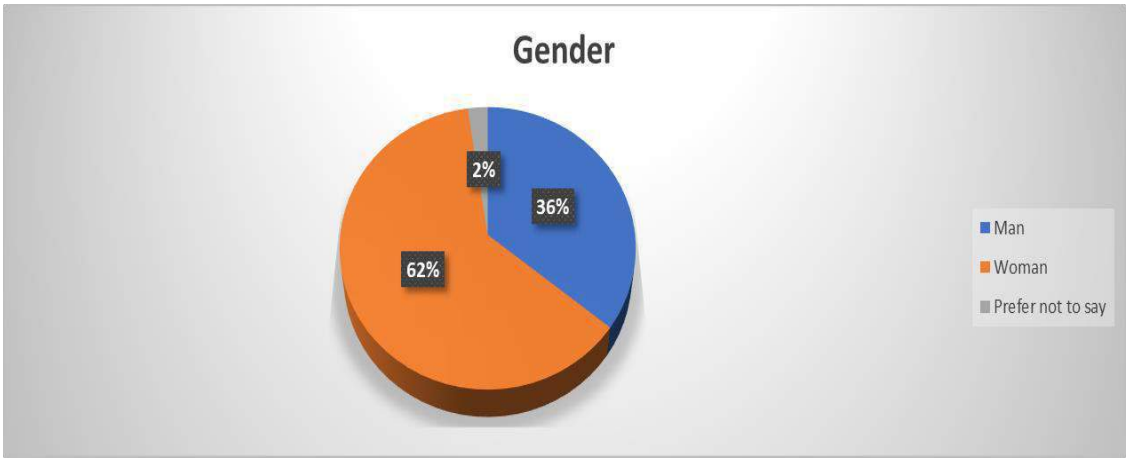
Summary of Findings

1. **What is the profile of the learners in terms of:**

1.1 Gender;

Gender	f	Percentage
Man	15	35.71%
Woman	26	61.90%
Prefer not to say	1	2.38%
Total	42	100.00%

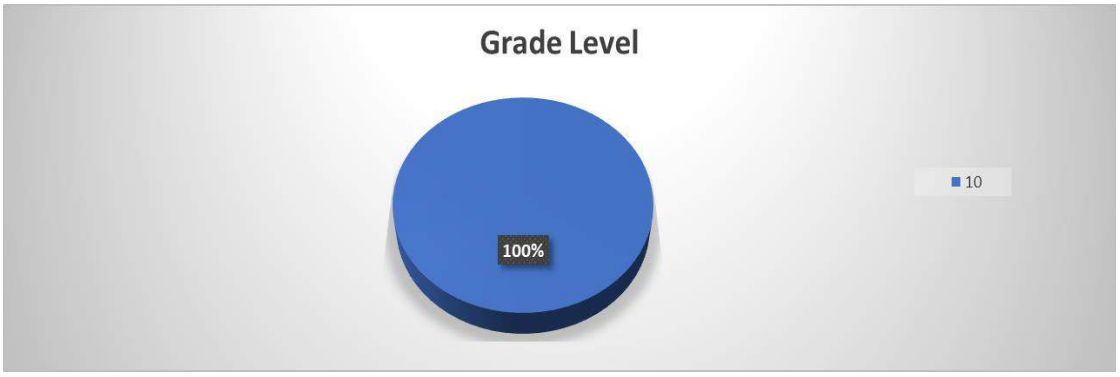
Table 1.1 showed that 15 or 37.71% profile of the learners in terms of gender as man. This is followed by woman with 26 or 61.90%. Finally, 1 or 2.38% answered prefer not to say. This indicates that the majority of the profile of the learners in terms of gender were women.



1.2 Grade Level;

Grade Level	f	Percentage
Grade 10	42	100.00%
Total	42	100.00%

Table 1.2 showed that the grade level profile for 42 students, or 100.00%, was Grade 10.



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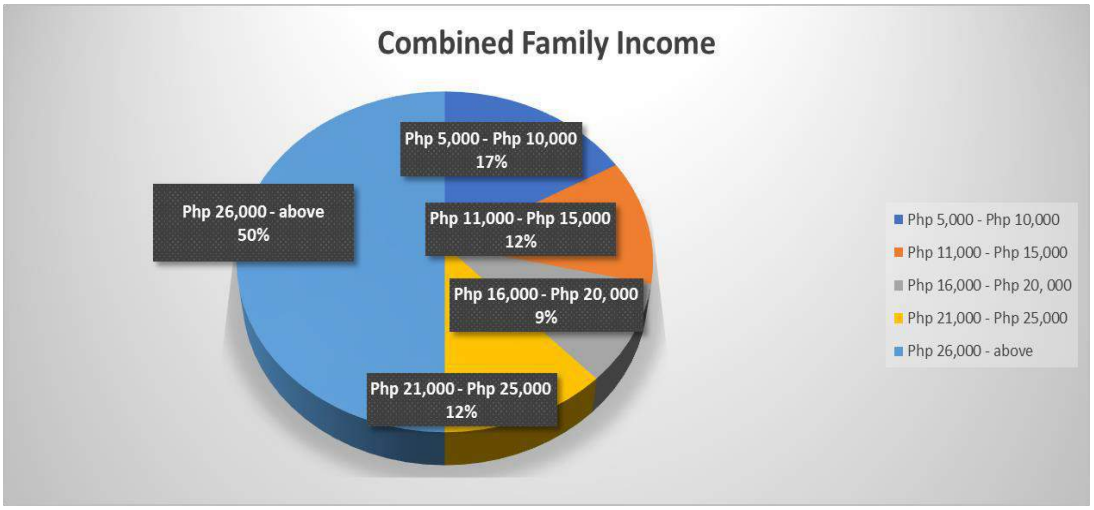
1.3 Combined Family Income; and

Combined Family Income	f	Percentage
Php 5,000 - Php 10,000	7	16.67%
Php 11,000 - Php 15,000	5	11.90%
Php 16,000 - Php 20, 000	4	9.52%
Php 21,000 - Php 25,000	5	11.90%
Php 26,000 - above	21	50.00%
Total	42	100.00%



According to Table 1.3, 7 or 16.67% of combined family income ranged from Php 5,000 to Php 10,000. This was followed by 5 or 11.90% of those having a family income in the range of Php 11,000 - Php 15,000. Following that is 4 or 9.52% of total income for families ranging from Php 16,000 to Php 20,000. Then comes 5 or 11.90% of the total family income between Php 21,000 and Php 25,000. Finally, or 50.00%, of the combined household income varied from Php 26,000 to and above.

1.4 Religion?

Religion	f	Percentage
Roman Catholic	26	61.90%
Iglesia Filipina Independiente (IFI)	6	14.29%
Iglesia ni Cristo	4	9.52%
Jehova's Witness	1	2.38%
Jesus Christ of the Latter-Day Saints	0	0.00%
Others	5	11.90%
Total	42	100.00%

2. What is the level of the learners' knowledge in promoting gender equality in schools in terms of:
   2.1 understanding of basic concepts and terminology related to gender equality;
   2.2 knowledge of the historical and cultural context of gender inequality and discrimination;
   2.3 familiarity with laws, policies, and practices related to gender equality in schools;
   2.4 awareness of the importance of gender equality in achieving broader social justice goals; and
   2.5 understanding of the role of media, culture, and social norms in perpetuating gender stereotypes and biases;

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Dimensions	Mean	SD	Verbal Interpretation
1. Understanding of basic concepts and terminology related to gender equality;	4.52	0.55	Very Knowledgeable
2. Knowledge of the historical and cultural context of gender inequality and discrimination;	3.83	0.99	Knowledgeable
3. Familiarity with laws, policies, and practices related to gender equality in schools;	3.55	1.02	Knowledgeable
4. Awareness of the importance of gender equality in achieving broader social justice goals; and	4.36	0.93	Very Knowledgeable
5. Understanding of the role of media, culture, and social norms in perpetuating gender stereotypes and biases;	4.29	0.89	Very Knowledgeable
Overall Mean	**4.11**	**0.88**	**Knowledgeable**

Legend

Range Interval	Verbal Interpretation
5 = 4.21 – 5.00	Very Knowledgeable
4 = 3.41 – 4.20	Knowledgeable
3 = 2.61 – 3.40	Moderately Knowledgeable
2 = 1.81 – 2.60	Slightly Knowledgeable
1 = 1.00 – 1.80	Least Knowledgeable

3. How to assess the level of the learners' awareness of the importance of gender equality?

Questions	Mean	SD	Verbal Interpretation
1. How often do you participate in activities or initiatives that promote gender equality in your school?	3.17	1.17	Moderately Engaged
2. Do you actively seek out opportunities to learn more about gender equality and how to promote it in your school?	3.83	1.17	Engaged
3. Have you collaborated with other students or groups to promote gender equality in your school?	2.90	1.21	Moderately Engaged
4. Have you used social media or other online platforms to raise awareness about gender equality in your school or community?	3.55	1.43	Engaged
Overall Mean	**3.36**	**1.25**	**Moderately Engaged**

Legend

Range Interval	Verbal Interpretation
5 = 4.21 – 5.00	Highly Engaged
4 = 3.41 – 4.20	Engaged
3 = 2.61 – 3.40	Moderately Engaged
2 = 1.81 – 2.60	Slightly Engaged
1 = 1.00 – 1.80	Less Engaged

4. Is there a significant relationship between learners' knowledge in promoting gender equality in school and awareness of the importance of gender equality?

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	Mean	SD	r-value	Interpretation	p-value
Learners' knowledge in promoting gender equality	4.11	0.88	0.8101	Strong positive correlation	<0.00001
Learners' awareness of the importance of gender equality	3.36	1.25			

$p < .05$

4.0 CONCLUSION

Creating a gender-responsive learning environment for G10 learners is critical for fostering gender equality in education. An environment like this should try to meet the unique demands and obstacles that students of all genders confront. Here is an action plan that may be offered to attain this goal:

a. Raise Awareness. Educate teachers, school officials, and learners on the benefits of a gender-responsive learning environment for gender equality and overall academic achievement.
b. Diversified Role Models: Conduct training-seminars and invite speakers so that students may meet with different role models, including successful school alumni of all genders, in order to motivate them and break down gender stereotypes.
c. Insure Safe Spaces. Create safe spaces in the school where learners may openly discuss gender-related concerns, ask questions, and seek help if required.
d. Encourage Active Participation. Ensure that all learners, regardless of their gender, have equal access to class discussions, extracurricular activities, and leadership roles; and
e. Gathered Data Collection and Monitoring. Continuously collect and analyze data on academic performance, attendance, and participation of students by gender. Use this data to identify and address any disparities.

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DEPRESSION TREATMENT BY AYURVEDA

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ABSTRACT

Depression, a pervasive mental health disorder, significantly impacts the quality of life and well-being of individuals worldwide. While conventional pharmacological treatments are effective for many, they often come with side effects and limitations. Ayurveda, the traditional Indian system of medicine, offers holistic approaches that focus on balancing the mind, body, and spirit. This review explores Ayurvedic interventions for depression, including the use of herbal medicines, dietary modifications, lifestyle practices, and Panchakarma therapies. We also examine the underlying principles of Ayurveda related to mental health and the potential mechanisms through which these treatments may exert their effects.

Depression is a widespread mental health disorder affecting millions of people globally. Characterized by persistent sadness, lack of interest in daily activities, and a variety of physical and emotional problems, depression can severely impact an individual's quality of life. While conventional medicine offers a range of treatments, including antidepressants and psychotherapy, there is a growing interest in alternative and holistic approaches. Among these, Ayurveda, an ancient Indian system of medicine, has gained attention for its potential in treating depression.

➢ INTRODUCTION

Understanding Depression in Ayurveda
In Ayurveda, depression is understood as a result of an imbalance in the body's doshas, particularly Vata and Kapha. The mind and body are seen as interconnected, and any disturbance in this balance can lead to mental health issues like depression.

Depression is a major global health concern characterized by persistent sadness, loss of interest in activities, and a range of physical and emotional symptoms. The World Health Organization (WHO) estimates that over 264 million people suffer from depression worldwide. Conventional treatment typically involves antidepressant medications and psychotherapy, but these approaches are not universally effective and may cause adverse effects. Consequently, there is growing interest in complementary and alternative therapies, including Ayurveda, which emphasizes a holistic approach to health.[4]

Vata-type Depression: Characterized by anxiety, fear, and restlessness. Individuals may experience insomnia, excessive worrying, and rapid thoughts.

Pitta-type Depression: Marked by irritability, anger, and a sense of failure. People may have difficulty concentrating and may struggle with feelings of frustration and worthlessness.

Kapha-type Depression: Involves lethargy, heaviness, and a sense of being stuck. Symptoms include excessive sleep, overeating, and withdrawal from social interactions.

Ayurvedic Treatment Approaches Ayurvedic treatment for depression focuses on restoring the balance of the doshas, improving mental clarity, and enhancing overall well-being. The treatment plan is personalized, taking into account the individual's unique constitution (Prakriti) and the nature of their depression.[7]

➢ Key components of Ayurvedic treatment for depression

1. Herbal Remedies
Ayurveda utilizes a variety of herbs known for their mood-enhancing and adaptogenic properties. Some of the most commonly used herbs in the treatment of depression.[5]

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Figure 1:Ashwagandha (Withania Somnifera):

Ashwagandha (Withania somnifera): Known for its adaptogenic properties, Ashwagandha helps reduce stress and anxiety, promoting a calm and balanced mind.[6]

Figure 2 :Brahmi (Bacopa Monnieri

- **Brahmi** (Bacopa monnieri): An herb renowned for improving cognitive function and reducing mental fatigue, Brahmi is often used to enhance clarity and focus.

Figure 3 :Jatamansi (Nardostachys Jatamansi)

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- **Jatamansi** (Nardostachys jatamansi): This herb is believed to have a calming effect on the nervous system, helping to alleviate symptoms of anxiety and depression. A powerful herb for calming the nervous system, Jatamansi is beneficial for mental health, reducing anxiety, and balancing mood swings.

Figure 4:Shankhpushpi (Convolvulus Pluricaulis)

- **Shankhpushpi** (Convolvulus pluricaulis): Often used to improve memory and intellect, Shankhpushpi also has sedative properties that can help manage insomnia and restlessness

Figure 5:Vacha (Acorus Calamus)

- **Vacha (Acorus Calamus)**: Known to stimulate the brain and treat depression, Vacha can help in enhancing mental clarity.

2. Diet and Nutrition

- Diet plays a crucial role in Ayurvedic treatment. A diet that balances the doshas can help manage depression more effectively. Specific recommendations include:
- Sattvic Diet: Emphasizing fresh fruits, vegetables, whole grains, nuts, and seeds, a Sattvic diet is believed to promote mental clarity and peace.
- Avoidance of Tamasic and Rajasic Foods: Foods that are overly processed, fried, or spicy are considered Tamasic or Rajasic, which can aggravate the mind and exacerbate depression.

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3. Lifestyle Modifications

- Ayurveda places great importance on daily routines (Dinacharya) and seasonal routines (Ritucharya) to maintain mental and physical health. Key lifestyle recommendations include:

- Regular Exercise: Activities like yoga, walking, and swimming help balance the doshas and improve mood.[11]
- Meditation and Pranayama: Mindfulness practices, including meditation and controlled breathing (Pranayama), are essential for calming the mind and reducing stress.
- Adequate Sleep: Proper sleep hygiene is crucial for maintaining mental health. Ayurveda recommends going to bed early and waking up before sunrise.

4. Panchakarma

- Panchakarma, a detoxification and rejuvenation therapy, is often recommended for individuals with severe or chronic depression. This therapy involves a series of treatments, including massage, herbal steam baths, and other cleansing procedures, aimed at removing toxins from the body and restoring balance.[3]

5. Counseling and Spiritual Practices

- Ayurveda acknowledges the importance of addressing the mind and spirit in the treatment of depression. Counseling, along with spiritual practices such as prayer, chanting, and spending time in nature, can provide significant emotional support and promote healing.[4]

6.Ayurvedic Therapies

- Abhyanga (Oil Massage): Massaging the body with warm oils like sesame or coconut oil helps reduce stress, calm the nervous system, and improve circulation.
- Shirodhara: A therapy where warm medicated oil is poured continuously on the forehead, which is calming and helpful for anxiety and depression.
- Nasya: Administering medicated oils or herbal preparations through the nose is beneficial for clearing mental fog, improving clarity, and balancing emotions.
- Panchakarma: A detoxification therapy that helps remove toxins from the body and mind, restoring balance and harmony.

7 **Spiritual Practices**

- Chanting and Mantra Meditation: Repeating calming mantras like "Om" or other spiritually significant chants can reduce mental stress and foster emotional stability.
- Self-Reflection and Journaling: Practicing introspection and writing down thoughts and emotions can help you process feelings of sadness and frustration.

➢ Ayurveda categorizes depression into different types based on the predominant dosha involved:

- .Ayurveda and Mental Health: Ayurveda, a 5,000-year-old system of medicine, originated in India and is based on the principle of balance among the three doshas: Vata, Pitta, and Kapha. Mental health in Ayurveda is closely linked to the balance of these doshas, particularly Sattva, which represents a state of mental clarity and harmony. Depression is primarily associated with an imbalance in the Kapha and Tamas doshas, leading to lethargy, heaviness, and a disturbed mind.[4]
- Ayurvedic Concept of Depression: In Ayurveda, depression is often described as Vishada, a condition of deep sadness and despair. It is considered a result of an imbalance in the mental doshas—Rajas (activity and restlessness) and Tamas (inertia and darkness). The Ayurvedic approach to treating depression focuses on restoring the balance of these doshas, enhancing Sattva (purity and positivity), and addressing the root cause of the disorder rather than just alleviating symptoms.
- Herbal Medicines in Ayurvedic Treatment: Ayurveda offers a variety of herbal remedies known as Medhya Rasayanas that are believed to enhance cognitive function, memory, and mental clarity. Some of the key herbs used in the treatment of depression include. [5]

Ashwagandha (Withania somnifera): Often referred to as Indian ginseng, Ashwagandha is a potent adaptogen that helps the body cope with stress. It is known to reduce cortisol levels, improve mood, and promote a sense of well-being.[1]

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Brahmi (Bacopa monnieri): Brahmi is a renowned brain tonic in Ayurveda, known for its calming effects on the nervous system. It enhances memory, reduces anxiety, and supports mental clarity.

Shankhpushpi (Convolvulus pluricaulis): This herb is traditionally used to calm the mind, improve concentration, and alleviate symptoms of anxiety and depression.

Jatamansi (Nardostachys jatamansi): Jatamansi is another herb used to manage stress and depression. It has sedative and mood-stabilizing properties.

Guduchi (Tinospora cordifolia): Known for its immune-boosting properties, Guduchi is also used in Ayurveda to balance the doshas and improve mental clarity.[6]

- Dietary Interventions: Diet plays a crucial role in Ayurvedic treatment, with specific foods recommended to balance the doshas and improve mental health. For depression, a diet that pacifies Kapha and Tamas is advised. This includes.[10]

Warm, light, and easily digestible foods: Such as soups, stews, and cooked vegetables, which help to reduce heaviness and lethargy.

Incorporation of spices: Like ginger, black pepper, and turmeric, which are believed to stimulate digestion and improve mood.

Avoiding heavy, cold, and oily foods: Such foods are thought to increase Kapha and Tamas, contributing to feelings of sluggishness and sadness.

- Lifestyle Modifications: Ayurveda emphasizes the importance of lifestyle practices that align with the body's natural rhythms. For depression, several key practices are recommended[12]

Dinacharya (Daily Routine): Establishing a consistent daily routine, including waking up early, practicing meditation or yoga, and engaging in regular physical activity, is crucial in managing depression.

Pranayama (Breathing Exercises): Pranayama techniques like Nadi Shodhana (alternate nostril breathing) and Bhramari (humming bee breath) are believed to calm the mind and reduce stress.

- Yoga: Specific yoga asanas (postures) such as Balasana (Child's Pose), Shavasana (Corpse Pose), and Sirsasana (Headstand) are recommended to enhance mental clarity and reduce depression symptoms.[9]

- Meditation and Mindfulness: Regular meditation practice helps in cultivating a sattvic (pure) mind, reducing the impact of Rajas and Tamas on mental health.

- Panchakarma Therapies: Panchakarma, the detoxification and rejuvenation process in Ayurveda, is often recommended for more severe cases of depression. It involves five cleansing procedures that aim to eliminate toxins (Ama) from the body and restore doshic balance[3]

- Vamana (Therapeutic Emesis): Induced vomiting to expel excess Kapha from the body.

- Virechana (Therapeutic Purgation): Use of herbal laxatives to cleanse the intestines and balance Pitta.

- Basti (Medicated Enema): Administering herbal oils or decoctions through the rectum to cleanse Vata and promote mental clarity.

- Nasya (Nasal Administration): Administration of medicated oils through the nose to clear the sinuses and balance the mind.

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- Raktamokshana (Bloodletting): Although less commonly used, it involves the removal of a small quantity of blood to detoxify the body.

- Scientific Evidence Supporting Ayurvedic Treatment for Depression: While Ayurvedic practices have been used for centuries, scientific validation of their effectiveness is still in its early stages. However, several studies have begun to shed light on the potential benefits of Ayurvedic treatments for depression:

- A study published in the Journal of Alternative and Complementary Medicine found that Ashwagandha supplementation significantly reduced symptoms of anxiety and depression in participants.

- Research in the Journal of Clinical Psychopharmacology highlighted the neuroprotective and mood-enhancing effects of Brahmi, making it a promising adjunctive treatment for depression.

- Clinical trials have also shown the efficacy of Panchakarma therapies in reducing stress and improving mood, though more rigorous studies are needed to confirm these findings.

- Integration of Ayurveda with Conventional Treatments: The integration of Ayurvedic treatments with conventional pharmacotherapy offers a complementary approach that may enhance the overall effectiveness of depression management. For instance, Ayurvedic herbs like Ashwagandha and Brahmi can be used alongside antidepressants to reduce side effects and improve patient outcomes. However, it is crucial that such integration is done under the supervision of a qualified healthcare provider to avoid potential herb-drug interactions.

- Challenges and Future Directions: Despite the growing interest in Ayurvedic treatments for depression, several challenges remain. These include the need for more robust clinical trials, standardization of herbal formulations, and greater awareness among healthcare providers of the benefits and limitations of Ayurveda. Future research should focus on elucidating the mechanisms of action of Ayurvedic interventions, developing standardized treatment protocols, and exploring the potential of Ayurveda in preventing depression.[13]

➢ CONCLUSION

Ayurveda offers a holistic approach to treating depression, focusing on restoring balance in the body and mind. By incorporating herbal remedies, dietary changes, lifestyle modifications, Panchakarma, and spiritual practices, Ayurveda seeks to address the root cause of depression rather than merely alleviating symptoms. While more research is needed to fully understand the efficacy of Ayurvedic treatments for depression, many individuals have found relief through these ancient practices. As with any treatment plan, it is important to consult with a qualified healthcare provider to ensure that the approach is safe and appropriate for individual needs.

Ayurveda offers a comprehensive and holistic approach to the treatment of depression, focusing on restoring balance to the mind, body, and spirit. Through the use of herbal medicines, dietary modifications, lifestyle practices, and Panchakarma therapies, Ayurveda addresses the root causes of depression and promotes long-term mental well-being. While scientific evidence is still emerging, the integration of Ayurvedic treatments with conventional approaches holds promise for enhancing the management of depression. Further research and clinical trials are needed to fully validate the efficacy of Ayurveda as a complementary therapy for depression.

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CLINICAL EFFICACY OF AGNIKARMA WITH SWARNA SHALAKA IN THE MANAGEMENT OF JANU SANDHIGATA VATA (A CASE STUDY)

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ABSTRACT
In different text of Ayurveda, janu Sandhigata Vata is described under Vata Vyadhi[1]. In Modern Janu sandhigata Vata[2] is corelated to Osteo arthritis of Knee joint. Asthi and Sandhi is the place of Vata. Acharaya Susruta described different types of treatment of Vata diseases. Agnikarma is one of them which gives instant pain relif by pacifying Vata dosa[3].

KEYWORDS: - *Agnikarma, Janusandhigata Vata, Knee Joint Arthritis, Swarna Shalaka.*

INTRODUCTION

Osteoarthritis also known as degenerative arthritis in which inflammation of joints, caused by abnormal wearing of cartilage that covers and acts as a cushion above the bone of the joints. Due to the decrease in the quantity of synovial fluid, patient experiences pain upon weight bearing on joint during walking, standing and doing daily works.

Sandhi Gata Vata (Osteoarthritis) is common amongst the elderly and obese persons. The dominance of Vata dosha in old age is seen in the pathogenesis of Sandhigata Vata. The symptoms of Santhigata Vata described in Sushrut Samhita are Sandhi vedana (Joint pain) and Shotha (Swelling), due to these symptoms stiffness and crepitus develop, which may be correlated with disease osteoarthritis in modern[4].

Sushruta mentioned Agnikarma as para-surgical procedures in Sandhi gata Vata treatment modalities. The common indications of Agnikarma include pain relief, stiffness, muscle spasm and inflammatory conditions[5]. These symptoms are observed in the patients of janu sandhi gata vata.

The word *Agnikarma is* combination of two words i.e., *Agni* and *Karma*, it means procedure done by the *Agni* to treat the disease. Application of heat directly or indirectly to the affected part of body. *Sushruta* mentioned the superiority of *Agnikarma* among all the para-surgical procedures and its importance explained in separate chapter in *Sutrasthana*. It has ability to cure the chronic diseases, which can't be cured by the *Bheshaja* (medicine), *Shastra* (Surgical interventions) and *Ksharakarma* (alkaline cauterization). It is mainly indicated in the disease caused by *Vata* and *Kapha Doshas*. Diseases of *Twacha, Mamasa, Asthi & Sandhi* with severe pain caused due to vitiation of *Vata*. Also, in *Shiro Roga, Netra Roga, Vartma Gata Vyadhi, Granthi, Arsha, Bhagandar, Arbuda, Shlipad, Charmakeela, Tila Kalaka, Antra Vrana, Nadi Vrana,* and in the diseases of the joints. According to *Sushruta*, if *Agnikarma* is performed in above diseases, will be less chances of recurrence and successful in curing the diseases.

Acharaya Susruta has indicated different types of material according to site of agnikarma.

1. Twak Dadga[6] – Pippali, Ajasakrud, Godanta, ara, Salaka
2. Mansa Dadga[7] – Jambhavsta Shalaka and other Metals.
3. Sira, Sanayu, andhi, and Asthigata – Madhu, Jggery,and Sneha.

Indications

Siro roga, Granthi, Apachi, Arbuda, Antarbridhi, Nadivrana, Gulma, Upadansa, Arsha, Bhagandara etc.

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Contraindications
Internal Haemorrage, Ruptured Visera, Unextracted Froreign body, Paitika Constipation, Child, Old, Timid, affected with multiple wounds and those who are contra indicated for Sudation[8].

A CASE STUDY
A patient named XYZ, aged about 6o years came to OPD of Gopabandhu Ayurveda Mahavidyalaya with complaints of pain in both knees associated with swelling and crepitus. She had taken several allopathic treatement but not got any remarkable results.

History of Present Illness
The patient was apparently normal before 1 year. Gradually she developed mild pain on B/L knee joint. She was also complaining of morning stiffness. After some months the pain gradually increased in both knee joint.

Relevant Occupation
She is a house wife and she used to to do house hold work as she lives in a joint family.

Social Economy
She belongs to a middle class family.

Personal Details
Diet – Non-vegetarian
Sleep – 7-8 hours a day
Bowel – once a day
Urination – 6-7 times a day
Exercise – Nil

Vital Examination
BP – 124/82 mm of Hg
Heart Rate – 76/min
Nadi – Vata-Kapha
Prakuti : Vata-Kapha
Kostha : Krura
Agni : Visamagni

Sytemic Examination
RespiratorySystem: NAD
CardiovascularSystem : NAD
CentralNervousSystem : NAD
Digestive System: NAD
UrogenitalSystem: NAD

On examination it was found that the patient is of vatakapha prakruti with Madhyama kosta. On local examination of knee joint raising temperatue if found with restricted flexion of 90^0 and restricted extension of 120^0. On investigation X-Ray revealed there was narrowing of joint space in both knee joint.

TREATMENT GIVEN
Agnikarma with Swarna Shalaka was done on a gap of every 7 days on both knee joint assessment was done.

MATERIAL AND METHODS
Triphala Kwath, Aloevera, Swarna Shalaka, Candle, Turmeric powder.
Final Daignosis – Janu Sandhigata Vata (Knee joint Arthritis)

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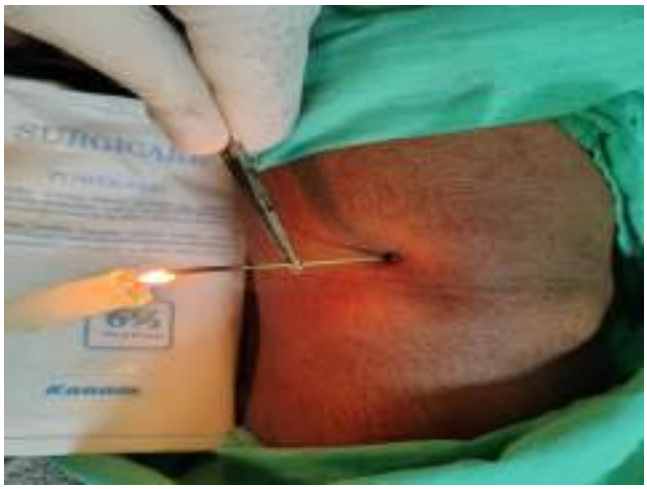
Poorva Karma

The patient was sat on OT table in a comfortable position.the most tender points were marked with a marker or pen. Then the area was sterilized by cleaning the part with trifala kwath for about 5 minutes in the anuloman directions. Before the procedure the patient was advised to take picchila diet. Then the patient was taken for pradhan karma.

Pradhan Karma

The one end of Swarna Shalaka was placed on the most tender point. The other end of Swarna Shalaka was heated by Candle. Almost after 40 to 50 seconds the patients felt warm. Then the Swarna Shalaka was shifted to another tender point. Like wise 8 to 10 points are covered.



Paschat Karma

After the completion of the procedure the vrana was dressed by Ghritakumari pulp and Turmeric powder. Then it was covered by gauze pieces with light bandage. Then the patient was carefully observed for some time for any complication.

ASSESMENT OF OBJECTIVE AND SUBJECTIVE PARAMETERS

ASSESSMENT CRITERIA

A. Subjective parameters

1.Pain

Grade	Pain
0	No pain
1	Mild pain (pain exaggerated by movement but subsided by rest)
2	Moderate pain (not relieved by rest but not disturbing sleep or routine activities)
3	Severe pain (disturbing sleep & other routine activities but relieved by oral analgesics.

2.Tenderness

Grade	Tenderness
0	No tenderness
1	Mild tenderness (patient feels pain on pressure but doesn't withdraw joint)
2	Moderate tenderness (patient feels pain and on touch withdraws the joint)
3	Severe pain (patient doesn't allow to touch the joint)

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3.Stiffness

Grade	Stiffness
0	No stiffness
1	Mild stiffness (Stiffness relieved by walking)
2	Moderate stiffness (Stiffness relieved by oral analgesics)
3	Severe stiffness. (Analgesics not responding)

B. Objective Parameters

- **Crepitus**

Grade	Crepitus
0	No Crepitus
1	Mild Crepitus
2	Palpable Crepitus.
3	Pt. c/o of sound from the knee joint.

- **Girth measurement of knee joint**

GRADE	Swelling
0	None
1	Slighty oblivious
2	Covers the bony prominence
3	Much elevated

- **Goniometric measurement of angle of Knee Joint**

GRADE	Angle of Extension (using a Goniometer)
0	180^0
1	170^0 - 130^0
2	120^0 - 90^0
3	< 90^0

GRADE	Angle of Flexion(using a Goniometer)
0	140^0
1	120^0 - 100^0
2	100^0 - 80^0
3	< 80^0

	B.T	7TH DAYS	14TH DAY	21ST DAY	28TH DAY
Pain	3	2	0	0	0
Tenderness	2	1	0	0	0
Stiffness	1	0	0	0	0
Crepitus	3	2	2	1	1
Swelling	2	2	2	1	1
Angle of Extension	1	1	0	0	0
Angle of Flexion	2	1	0	0	0

ADVICE TO PATIENT

The Patient was strictly advised not to allow water contact at *Dagdha Vrana* site for 24 hours.
She was adviced to take oral medicine for one month.
She was adviced to avoid exertion and trauma on both knees.
She was adviced to take Vatahara Ahara and Vihara

She was called after 7 day for follow up and next sitting. Four sitting was done at the interval of 7 days. After first sitting her pain was slightly less but after four sitting the pain is was totally subsided. She can walk and can do her daily works eaily.

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PRESENT CONDITION

The patient is on regular follow up and her pain has subsided totally. There were some scar of the procedure but it disappeard after some days of applying Satadhauta Ghrita. She can walk freely and can do her daily works without any difficulties.

DISCUSSION

- In *Agnikarma* , the *Ushna* (hot) *Guna* of *Agni* pacifies the *Shita* (cold) *Guna* of *Vayu* and reduces the joint pain.
- Acharya Charaka described that *Agni* is the best treatment for *Shoola* (pain). *Ushna Guna* of *Agni* helps to removes the *Avarana* effectively and stabilizes the movement of *Vata*, which provide relief from *Shoola*.
- As per the modern medicine, therapeutic heat increases blood circulation at knee joint leads to the proper nutrition of the tissue.
- The *Ashukari* (quick acting) property of *Agni* will also provide improvement in the movement of joints resulted in relief of crepitus. Thus heat application is indicated in cases of chronic inflammation.
- Restricted movement caused by Kapha dosa is removed by Ushna guna of Agni with results improvements in movements of knee joint.
- Acharyas have quoted that *Agnikarma* is superior in treating *Stambha* (stiffness).
- Gold as a dhatu is Ayurveda is bruhaniya in nature[9]. So it gives nourishment to the knee joint and helps in improving the health of knee joint[10].

CONCLUSION

Agnikarma is one of the effective mode of treatment for Janu Sandhigata Vata. And when it is done done with Swarna Shalaka its result is even better and it gives faster relif.

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MEASURING THE QUALITY OF FINANCIAL REPORTING IN INDIA'S IRON AND STEEL SECTOR THE IMPACT OF IND-AS ADOPTION

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ABSTRACT

This study examines the value relevance of accounting information reported under Indian Generally Accepted Accounting Principles (IGAAP) and Indian Accounting Standards (IND-AS) for the Indian Iron and Steel sector. Using key financial metrics—Book Value Per Share (BVPES), Earnings Per Share (EPS), and Share Price (SP)—the study assesses their relationship before and after the adoption of IND-AS. The findings reveal that under IGAAP, accounting information had limited explanatory power (R-square: 0.034), with weak and statistically insignificant relationships between financial metrics and share prices. In contrast, the adoption of IND-AS significantly enhanced the value relevance of accounting information, with a dramatic increase in explanatory power (R-square: 0.972) and statistically significant relationships, particularly for EPS. This improvement underscores the effectiveness of IND-AS in addressing the limitations of IGAAP by incorporating fair value principles, improving transparency, and aligning Indian financial reporting with global standards. The results emphasize the critical role of IND-AS in enhancing the decision-usefulness of financial statements in capital-intensive industries like Iron and Steel.

KEY WORDS : *IND-AS, Value relevance, EPS,SP*

INTRODUCTION

The adoption of Indian Accounting Standards (IND-AS) marks a transformative shift in financial reporting practices within India, aligning its accounting framework with the International Financial Reporting Standards (IFRS). This convergence, driven by the need for greater transparency, comparability, and relevance in financial statements, is particularly impactful for industries like Iron and Steel, where financial stability and reporting integrity are critical for stakeholders. The Iron and Steel sector, one of the core industries contributing significantly to the Indian economy, attracts a diverse range of stakeholders including investors, regulators, and global trading partners who rely on accurate financial information for informed decision-making.

Under the previous Indian Generally Accepted Accounting Principles (IGAAP), financial reporting was often criticized for its limited transparency and lack of comparability on a global scale. These challenges often resulted in inconsistencies and hindered the ability of users to make reliable cross-border comparisons. IND-AS seeks to address these limitations by emphasizing principles-based accounting, fair value measurements, and comprehensive disclosures that reflect the true financial performance and position of firms.

This study delves into the quality of financial reporting in India's Iron and Steel sector, with a specific focus on the value relevance of accounting information following IND-AS adoption. Value relevance, a critical component of reporting quality, reflects the degree to which financial information influences the decisions of investors and other stakeholders by providing insight into a company's financial health and future performance. By shifting toward fair value measurements and enhancing disclosure requirements, IND-AS aims to present financial data that is more aligned with market realities, making it more relevant for assessing a firm's worth. This research examines whether these changes have indeed enhanced the value relevance of financial reports in selected Iron and Steel companies, offering a clearer picture of the impact of IND-AS on financial transparency and decision-usefulness within the sector.

REVIEW OF LITERATURE

Jain (2020): Analyzes the effects of IND-AS on the financial reporting quality of Indian companies, highlighting significant improvements in the value relevance of financial information due to enhanced fair value reporting and disclosure practices. The

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study concludes that IND-AS adoption increases the decision-usefulness of financial statements in capital-intensive industries. Furthermore, it emphasizes the role of mandatory compliance in achieving consistent reporting standards.

Kumar and Gupta (2018): Provides evidence of improved transparency and disclosure quality in Indian firms post-IND-AS adoption, focusing on how these changes affect the usefulness of financial information for investment decisions. It notes that fair value accounting under IND-AS has reduced discrepancies in asset valuations. The authors suggest that such improvements have boosted investor confidence in emerging markets like India.

Bepari and Mollik (2015): Studies the adoption of IFRS in emerging economies and its impact on value relevance, finding that financial statements prepared under IFRS-like standards are more informative and better aligned with market expectations. The authors highlight the critical role of regulatory enforcement in sustaining reporting quality.

Daske et al. (2008): Investigates the economic consequences of IFRS adoption and finds evidence of improved financial reporting quality, including greater value relevance of financial statements, which benefits stakeholders through better capital market outcomes. The study also notes variations in reporting quality depending on the extent of compliance with IFRS principles.

Chand and Patel (2008): Examines the challenges faced during the adoption of IFRS in developing countries, discussing the need for better-quality financial reporting and the relevance of accounting information to meet global standards. The study underscores the importance of cultural and institutional alignment during standard implementation.

Verdi (2006): Explores the relationship between reporting quality and investment decisions, emphasizing that higher-quality financial reporting reduces information asymmetry and enhances value relevance, especially in industries with significant capital requirements.

Leuz and Wysocki (2016): Discusses the benefits of financial reporting convergence with global standards, arguing that improved transparency and consistency lead to higher value relevance of accounting information across industries.

Ball et al. (2003): This research highlights how the adoption of IFRS enhances financial reporting quality by improving comparability and transparency, particularly in emerging markets, and links these improvements to increased value relevance of financial information.

Barth et al. (2001): The study emphasizes the importance of value relevance in financial reporting, showing how fair value measurements under IFRS improve the association between financial information and stock market valuation, which is crucial for decision-making by investors.

STATEMENT OF THE PROBLEM

The adoption of Indian Accounting Standards (IND-AS), converged with International Financial Reporting Standards (IFRS), marks a significant reform in India's financial reporting practices, aiming to enhance transparency, comparability, and value relevance. The Iron and Steel sector, being capital-intensive and a key contributor to India's economy, relies heavily on high-quality financial reporting to meet the needs of investors and stakeholders. However, financial reporting under the earlier Indian Generally Accepted Accounting Principles (IGAAP) faced criticism for limited comparability, inconsistent valuation practices, and insufficient disclosures, which often reduced the value relevance of accounting information. IND-AS seeks to address these issues through fair value accounting, rigorous disclosure requirements, and globally aligned standards. Despite these advancements, questions remain about the extent to which IND-AS has improved financial reporting quality and whether these changes have translated into increased decision-usefulness of financial statements. This study examines the impact of IND-AS on the value relevance of financial reporting in the Iron and Steel sector, providing insights into its effectiveness in aligning Indian practices with global standards and meeting stakeholder expectations.

OBJECTIVE OF THE STUDY

1. To understand the concept and dimensions of quality in financial reporting, with a focus on its relevance to the Iron and Steel sector.
2. To measure and assess the value relevance of accounting information before and after the adoption of IND-AS in select Indian Iron and Steel companies.

HYPOTHESIS OF THE STUDY

H0: There is no significant difference in the value relevance of accounting information before and after the adoption of IND-AS in the Iron and Steel sector.

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H1: There is a significant improvement in the value relevance of accounting information after the adoption of IND-AS in the Iron and Steel sector.

RESEARCH METHODOLOGY

Research Design This study adopts a comparative research design to analyze the quality of financial reporting and value relevance of accounting information before and after the adoption of IND-AS in selected Indian Iron and Steel companies. The research evaluates the impact of IND-AS on enhancing value relevance and overall financial reporting quality.

Scope of the study: The research focuses on the Indian Iron and Steel sector, which plays a pivotal role in the country's industrial and economic development. The study is limited to companies that have transitioned from IGAAP to IND-AS, ensuring the availability of comparable financial data.

Sample Selection: A purposive sampling technique is employed to select a sample of Iron and Steel companies listed on the National Stock Exchange (NSE) or Bombay Stock Exchange (BSE). These companies are selected based on their significant contribution to the sector, financial performance, and availability of data for the pre- and post-IND-AS adoption periods.

DATA COLLECTION

Secondary Data: The study exclusively relies on secondary data extracted from audited annual reports of the selected companies. The financial data covers a 10-year period, including five years before and five years after the adoption of IND-AS. Other secondary sources include industry reports, regulatory publications, and databases like CMIE Prowess and Bloomberg.

Data Analysis

- **Value Relevance Analysis:** The study applies regression models to assess the relationship between accounting information (such as earnings and book value) and market value of equity for the pre- and post-IND-AS adoption periods.
  The model used is based on the Ohlson framework, where market capitalization is regressed on book value per share and earnings per share.
- **Comparative Analysis:** The results of the regression models for the two periods are compared to identify changes in value relevance. The adjusted R-squared values are used as indicators of how well the accounting information explains market value.
- **Hypothesis Testing:** A paired t-test is conducted on the regression coefficients and adjusted R-squared values to determine whether the changes in value relevance are statistically significant.

  Study Period: The study covers a period from 2011 to 2021, with financial data for five years before (2011–2015) and five years after (2017–2021) the mandatory adoption of IND-AS in 2016.

Research Tools

- Statistical tools such as SPSS or R are utilized for regression analysis and hypothesis testing.
- Descriptive statistics like mean and standard deviation are calculated to summarize key variables.

Limitations

- The study is limited to the secondary data of selected companies in the Iron and Steel sector.
- The results may not be applicable to other sectors or countries.
- Market conditions and other external factors influencing stock prices are not accounted for in the value relevance analysis.

To understand the concept and dimensions of quality in financial reporting, with a focus on its relevance to the Iron and Steel sector, the following steps can be undertaken:

QUALITY IN FINANCIAL REPORTING

Quality in terms of financial reporting is a comprehensive and multi-dimensional concept that encompasses various attributes such as conformance to accounting standards, fitness for purpose, reliability, stakeholder satisfaction, continuous improvement, transparency, and value for decision-making. High-quality financial reports meet or exceed regulatory and user expectations, provide accurate and timely information, and offer insights that enhance decision-making. In essence, quality in financial reporting is about delivering excellence, ensuring compliance, and creating positive experiences for users and stakeholders through clear, accurate, and insightful financial information.

According to the IASB (2010), the two main qualitative attributes of information in financial statements are relevance and faithful representation. Information is deemed relevant if it has the potential to influence the decisions of financial statement users, providing confirmatory or predictive value. Faithful representation implies that the information accurately depicts the actual economic events

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it claims to represent. These qualities, relevance and faithful representation, render financial statements valuable to readers. Additionally, there are supplementary qualitative characteristics that enhance these fundamental attributes: comparability, verifiability, timeliness, and understandability. Qualitative characteristics help differentiate more useful information from less useful information. They enhance the decision-usefulness of financial reporting information that is relevant and faithfully represented.

The quality of financial reporting refers to the degree to which financial statements accurately reflect a company's economic reality and provide useful information to stakeholders for decision-making purposes. High-quality financial reporting is characterized by several key attributes that enhance the reliability, relevance, and transparency of financial information. It plays a crucial role in ensuring that stakeholders, such as investors, creditors, regulators, and the public, can make informed decisions based on accurate and complete financial data.

High-quality financial reporting is marked by accuracy and completeness, ensuring that financial reports accurately represent the financial position, performance, and cash flows of a company. All relevant financial transactions and events must be included without omission or misstatement. Relevance is another critical attribute, as the information provided in financial reports must be pertinent to the users' decision-making needs. It should help stakeholders make informed decisions regarding the company. Additionally, reliability is essential; financial information should be dependable and free from significant error or bias, faithfully representing the company's economic activities.

There is no consensus in the literature on the definition of accounting quality. Despite extensive research on the topic, the term remains difficult to define and varies across studies, individuals, projects, and Researchers. Consequently, the definition is often tailored to the specific context and objectives of the research. Common variables used to measure accounting quality include earnings management, income smoothing, timely loss recognition, and earnings persistence (Menicucci, 2020; Singleton-Green, 2015).

Accounting quality is also influenced by factors such as corporate governance, regulatory environment, and the quality of external audits (Dechow, Ge, & Schrand, 2010). High-quality accounting information is characterized by its relevance, reliability, comparability, and understandability (Barth, Landsman, & Lang, 2008). It ensures that financial statements present a true and fair view of a company's financial position, enabling stakeholders to make informed decisions.

Moreover, accounting quality plays a critical role in reducing information asymmetry between managers and investors, thereby enhancing market efficiency (Bushman & Smith, 2001). It also contributes to better resource allocation and economic growth by providing credible and transparent financial information. The interaction between accounting standards, enforcement mechanisms, and firm-specific characteristics further complicates the assessment of accounting quality, making it a dynamic and multi-faceted concept (Ball, Kothari, & Robin, 2000).

In essence, while the precise definition of accounting quality may vary, it fundamentally revolves around the integrity and usefulness of financial information in meeting the needs of its users.

The qualitative characteristics in financial reporting are the attributes that make financial information useful to users. These characteristics are defined by standard-setting bodies like the International Accounting Standards Board (IASB) and the Financial Accounting Standards Board (FASB) and are outlined in their respective frameworks, such as the Conceptual Framework for Financial Reporting. These characteristics are divided into two main categories: fundamental and enhancing characteristics.

Fundamental Quality Characteristics of Financial Statements

In the realm of financial reporting, the fundamental qualitative characteristics of relevance and faithful representation, as delineated by the International Accounting Standards Board (IASB) Framework, are pivotal in ensuring the utility and reliability of financial information. Relevance ensures that the financial information provided is capable of making a difference in the decision-making process of users by being timely, pertinent, and predictive or confirmatory in nature. Faithful representation, on the other hand, demands that financial information accurately reflects the economic phenomena it purports to represent, ensuring completeness, neutrality, and freedom from error. Together, these characteristics form the bedrock of high-quality financial reporting, guiding preparers to deliver information that not only meets the needs of users but also upholds the integrity and transparency essential for trust and confidence in financial markets. The IASB Framework emphasizes these qualities to standardize financial reporting globally, fostering comparability, consistency, and reliability across jurisdictions.

1. **Relevance**: Financial information is relevant if it is capable of making a difference in the decisions made by users. Relevant information helps users to predict future outcomes (predictive value) or confirm or correct prior expectations (confirmatory value). For example, a company's revenue trends can help investors predict future performance.
2. **Faithful Representation**: Faithful representation means that financial information accurately reflects the economic phenomena it purports to represent. To achieve faithful representation, the information must be complete, neutral, and free from error. This ensures that the financial statements present a true and fair view of the company's financial position and performance.

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Enhancing Quality Characteristics of Financial Statements

The enhancing qualitative characteristics of financial information are supplementary attributes that amplify the fundamental qualities of relevance and faithful representation. These characteristics—comparability, verifiability, timeliness, and understandability—serve to improve the usefulness and accessibility of financial information for users. By fostering these attributes, the IASB Framework aims to ensure that financial reports not only meet the primary needs of users but also facilitate better decision-making through increased transparency, reliability, and clarity. These characteristics help users to interpret and compare financial data more effectively, promoting confidence and trust in financial reporting.

1. **Comparability**: Comparability enables users to identify and understand similarities and differences among items. Financial information is more useful if it can be compared with similar information about other entities and across different time periods. Consistent application of accounting policies over time helps achieve comparability.
2. **Verifiability**: Verifiability means that different knowledgeable and independent observers can reach a consensus that a particular depiction is faithfully represented. Verifiable information provides assurance that it faithfully represents the economic phenomena it claims to represent. Auditing and independent verification processes enhance verifiability.
3. **Timeliness**: Timeliness means that financial information is available to users in time to influence their decisions. Information that is outdated is of less use. Therefore, timely reporting ensures that stakeholders can make decisions based on the most current information.
4. **Understandability**: Understandability means that financial information is presented clearly and concisely so that users can comprehend it. While users are expected to have a reasonable knowledge of business and economic activities, complex information should be explained or simplified to enhance understandability.

Value Relevance

Some studies consider value relevance as one of the factors in the quality of financial reporting. The relevance of accounting information affects the share price of the company. In the value relevance model, there are two types: the pricing model and the return model.

The value relevance of accounting information refers to the ability of this information to explain variations in market value (Barth et al., 2001). A value relevance study seeks to determine the relationship between a firm's market value and its accounting information. Ohlson's model (1995) posits that a firm's market value of equity can be explained by two key accounting variables: book value of equity and earnings. According to Tanaka (2015),

Book Value and earnings play a crucial role in the valuation process of companies. Recent empirical studies have examined the global impact of IFRS on value relevance using the Ohlson (1995) model. These studies provide comprehensive insights into how IFRS adoption affects the association between accounting information and market value across different regions and market conditions.

For instance, Alnodel (2018) found that IFRS adoption in Saudi Arabia significantly improved the value relevance of accounting information, indicating better transparency and comparability. Similarly, Atoyebi, Salaudeen, & Onyilokwu (2018) reported enhanced value relevance of financial information post-IFRS adoption in Nigeria, suggesting that the new standards helped align local practices with international norms. Elbakry et al, (2017) highlighted that in Germany and the UK, IFRS adoption led to higher value relevance of earnings compared to the pre-IFRS period.

In South Korea, Ki et al. (2019) discovered that the shift to IFRS increased the value relevance of book value but had a varied impact on earnings depending on firm size and industry. Kouki (2018a) noted that in Tunisia, the adoption of IFRS did not uniformly enhance the value relevance of accounting information, pointing to challenges in implementation and economic environment differences. Similarly, Nijam & Jahfer (2016) identified a mixed impact of IFRS on value relevance in Sri Lanka, emphasizing the role of firm-specific factors.

Odoemelam, Okafor, & Ofoegbu (2019) found that in Nigeria, IFRS adoption significantly increased the explanatory power of book value and earnings for market value, reflecting improved financial reporting quality. Outa et al. (2017). Temiz & Gulec (2017) reported that in Turkey, IFRS adoption enhanced the value relevance of financial statements, making them more useful for investors. Wu et al. (2017) concluded that in China, the value relevance of accounting information improved post-IFRS adoption, with a notable increase in the usefulness of earnings information.

Hung and Subramanyam (2007) compared the value relevance of two accounting standards by regressing stock prices on book values and net incomes. Their study found that, although the differences in R-squared values between the two standards were not significant, book values of equity had a higher coefficient under IAS, while net incomes had a higher coefficient under German GAAP.

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These studies collectively highlight the positive impact of IFRS on the value relevance of accounting information across various global contexts, although the extent of improvement can vary based on local implementation, market conditions, and firm-specific characteristics.

A value relevance study seeks to determine the relationship between a firm's market value and its accounting information. Ohlson's model (1995) posits that a firm's market value of equity can be explained by two key accounting variables: book value of equity and earnings. According to Tanaka (2015), book value and earnings play a crucial role in the valuation process of companies. Recent empirical studies have examined the global impact of IFRS on value relevance using the Ohlson (1995) model (Alnodel, 2018; Atoyebi, Salaudeen, & Onyilokwu, 2018; Elbakry et al., 2017; Ki et al., 2019; Kouki, 2018a; Nijam & Jahfer, 2016; Odoemelam, Okafor, & Ofoegbu, 2019; Outa et al., 2017; Temiz & Gulec, 2017; Wu et al., 2017).
Compared the value relevance of accounting information before and after the mandatory adoption of IFRS in Germany and analysed using Basic Ohlson pricing model, the modified – equity valuation model and the extended – equity valuation model. It is found that the figures provided in accordance with the IFRS more informative than the numbers reported under the local GAAP. Elbakry et al. (2017)

The **value relevance** of accounting information refers to its ability to influence investors' decisions by providing reliable and decision-useful insights into a company's financial performance and position. This attribute is essential in ensuring that financial statements reflect the economic realities of an enterprise and meet the expectations of stakeholders, particularly in capital-intensive industries such as the Iron and Steel sector. The adoption of Indian Accounting Standards (IND-AS), converged with International Financial Reporting Standards (IFRS), was a pivotal step toward aligning Indian financial reporting practices with global benchmarks.

Before the implementation of IND-AS, the Indian Generally Accepted Accounting Principles (IGAAP) often faced criticism for their limited emphasis on fair value measurement, inconsistencies in disclosure practices, and lack of comparability. These issues hindered the relevance of financial statements, reducing their ability to reflect the true market value of firms' assets, liabilities, and earnings. IND-AS, with its focus on fair value accounting, enhanced transparency, and rigorous disclosures, was introduced to address these limitations and improve the value relevance of accounting information.

The Iron and Steel sector, characterized by high capital intensity, cyclical market dynamics, and substantial fixed assets, serves as an ideal context for evaluating the impact of IND-AS adoption. This study aims to measure and assess the value relevance of key accounting variables—such as earnings and book value of equity—before and after the adoption of IND-AS. By analyzing the extent to which these variables correlate with market valuations, the study seeks to determine whether IND-AS has enhanced the decision-usefulness of financial statements in the sector.

The findings of this research will provide insights into the effectiveness of IND-AS in addressing the challenges of financial reporting under IGAAP, particularly in improving the value relevance of accounting information. Such insights are critical for policymakers, standard-setters, and industry stakeholders to evaluate the benefits of IND-AS adoption and guide future enhancements in financial reporting practices.

Measuring the Value Relevance of Accounting Information Before and After Adoption of IND-AS
Value relevance is identified as one of the four fundamental qualitative characteristics that determine the usefulness of accounting information in making investment decision. Relevance is affected by the materiality of information contained in the financial statements because only material information influences the economic decisions of its users. Value relevance is an important topic in capital market research as it examines whether the financial statements provide high-quality and valuable accounting information that enable investors to take informed decision. IFRS aims to provide more accurate and transparent financial statements and hence to be more value-relevant to investors than local accounting standards use.The value relevance model measures how well financial statement information, such as earnings analyzing the relationship between financial metrics and market prices or returns, this model determines the usefulness of financial information for investors. Factors influencing value relevance include accounting standards, economic conditions, and firm-specific characteristics, highlighting the importance of transparent and high-quality financial reporting for informed investment decisions and efficient capital markets.

In the Price Model, dependent variable is Share Price (SP); and independent variables are Earnings Per Share (EPS) and Book Value Per Share (BVPS). The value relevance metric is based on the combined explanatory power of regression of BVPS and EPS on share price.

Independent Variables Are
1. Book value of equity per share
2. Earnings per share

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Dependent variable is

1. Share price

The value relevance model, developed by Feltham & Ohlson (1995) and subsequently used by Researchers such as Burgstahler & Dichev (1997) and Hellstrom (2006), is formulated as follows:

1. **$SP = \beta_0 + \beta_1 BVPS + \beta_2 EPS + e$ (Price Model)**

Where:

The variables are defined as follows for a firm in a given year:

SP: Share price of the firm, as reported in the Annual reports.

BVPS: Book value of equity of the firm, calculated as total assets minus total liabilities. Divided by number of outstanding shares.

EPS: Net income before extraordinary items, as recorded in the profit and loss account. Divided by ordinary shares

Key Factors of Value relevance

In the data analysis for measuring the value relevance of accounting information, the Researcher employed regression analysis and interpreted several key factors.

The standardized beta values indicate the relative strength and direction of the relationship between independent variables and the dependent variable, allowing for comparison across variables.

The unstandardized beta values provide the actual change in the dependent variable for a one-unit change in the predictor, measured in the units of the dependent variable. The

R-squared (R^2) value represents the proportion of variance in the dependent variable explained by the independent variables, indicating the model's overall fit.

The significance value (Sig.) assesses the statistical significance of the relationships, with a low value (typically less than 0.05) suggesting that the relationships observed in the data are unlikely to have occurred by chance. Together, these factors help evaluate the relevance and impact of accounting information under different accounting standards.

ANALYSIS AND INTERPRETATION

Value Relevance of accounting information reported under IGAAP and IND-AS of OVERALL Indian Iron and Steel companies

	Before Adoption of IND-AS				After Adoption of IND-AS		
Financial year	**BVPES**	**EPS**	**SP**	**Financial year**	**BVPES**	**EPS**	**SP**
2007-08	401.2	69.5	89.8	2015-16	361.13	-0.13	108.01
2008-09	430.5	27.7	204.7	2016-17	325.30	10.02	165.92
2009-10	383.9	32.3	208.4	2017-18	297.53	11.27	134.93
2010-11	382.1	26.2	111.7	2018-19	314.82	16.69	119.30
2011-12	443.0	21.5	121.7	2019-20	320.28	9.78	164.23
2012-13	476.3	15.6	107.3	2020-21	344.53	28.51	355.89
2013-14	336.3	7.4	132.0	2021-22	399.40	52.94	554.64
2014-15	329.9	13.2	72.1	2022-23	437.84	56.57	604.65
Standardized Coefficient Beta	**0.186**	**-0.055**		**Standardized Coefficient Beta**	**0.249**	**0.773**	
Unstandardized Coefficient Beta	**0.183**	**-0.143**		**Unstandardized Coefficient Beta**	**1.067**	**7.455**	
R square	**0.034**			**R square**	**0.972**		
Sig value	**.917[b]**			**Sig value**	**.000b**		

Source: Computed by the Researcher based on Annual reports

Interpretation

The above table provides the value relevance of accounting information before and after adoption of IND-AS Before the adoption of IND-AS, the model's R square value was very low at 0.034, indicating that only approximately 3.4% of the variability in stock prices (SP) could be explained by book value per share (BVPES) and earnings per share (EPS). This suggests a weak explanatory power in the model under the previous accounting standards. However, after the adoption of IND-AS, the R square value increased substantially to 0.972, signifying that about 97.2% of the variation in SP could be explained by BVPES and EPS. This significant increase indicates a remarkable improvement in the model's ability to explain the variability in stock prices under the new accounting standards.

Before IND-AS adoption, the standardized beta coefficient for BVPES was positive at 0.186, indicating a weak positive relationship with SP. In contrast, the standardized beta coefficient for EPS was negative at -0.055, suggesting a weak negative relationship with

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SP. Post-IND-AS adoption, both BVPES and EPS showed positive relationships with SP, with standardized beta coefficients of 0.249 and 0.773, respectively.

Before IND-AS adoption, the unstandardized beta coefficients for BVPES and EPS were 0.183 and -0.143, respectively. After the adoption of IND-AS, the unstandardized beta coefficients for BVPES and EPS increased to 1.067 and 7.455, respectively. These values suggest a strong positive impact of both BVPES and EPS on changes in SP under the new accounting standards.

Before the adoption of IND-AS, the significance value was very high at 0.917, indicating that the model lacked statistical significance under the previous accounting standards. This suggests that BVPES and EPS were not reliable predictors of SP. Post-IND-AS adoption, the significance value decreased dramatically to 0.000, well below the conventional threshold of 0.05. This indicates that the model became highly statistically significant under the new accounting standards, suggesting that BVPES and EPS became extremely robust predictors of SP for Overall Indian Iron and Steel Companies under IND-AS.

In summary, the adoption of IND-AS has led to a substantial improvement in the model's explanatory power, as evidenced by the significant increase in the R square value. Both BVPES and EPS demonstrated strong positive relationships with SP under IND-AS, and the model became highly statistically significant, suggesting that accounting information became highly relevant for predicting stock prices for Overall Indian Iron and Steel Companies under the new accounting standards.

Outcome of the study and conclusion

The study reveals a significant improvement in the value relevance of accounting information for Indian Iron and Steel companies after the adoption of IND-AS. Under IGAAP, financial metrics such as Book Value Per Share (BVPES) and Earnings Per Share (EPS) had minimal influence on share prices, with a low explanatory power (R-square: 0.034) and statistically insignificant relationships. However, post-IND-AS adoption, the explanatory power of accounting information surged to 97.2% (R-square: 0.972), with strong and statistically significant relationships between BVPES, EPS, and share prices. This highlights the enhanced decision-usefulness of financial statements due to IND-AS's focus on fair value, transparency, and global comparability, addressing the limitations of IGAAP effectively.

The findings confirm that the adoption of IND-AS has significantly enhanced the value relevance of accounting information for Indian Iron and Steel companies. Under IND-AS, the alignment with fair value principles, improved transparency, and enhanced disclosures have contributed to making financial information more predictive and relevant for investors and other stakeholders. This demonstrates the success of IND-AS in addressing the limitations of IGAAP and providing globally comparable financial reporting standards in the Indian context.

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REVIEW ON DISSOLUTION APPARATUS

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ABSTRACT

In this review paper we will focus on different dissolution process and different types of dissolution apparatuses are in use. Dissolution research started to develop about 100 years ago as a field of physical chemistry . Dissolution test is required to study the drug release from the dosage form and its in vivo performance.in this review paper we done the tablet dissolution of metoprolol succinate and measured that time of release. Dissolution test is used to assess the lot to lot quality of drug product. The development and validation of dissolution procedures is of paramount importance during development of new formulation and in quality control.[7] Dissolution Apparatus performed quality control tests for the oral solid dosage forms

KEYWORDS:- *Dissolution Testing, USP Apparatus, USP Apparatus 1 (Basket Method) USP Apparatus 2 (Paddle Method), In-vitro Dissolution, Tablet Dissolution, Drug Release Rate Profiling*

1.INTRODUCTION

- Dissolution is the process where a solid medicine breaks down in a specific amount of liquid. How well a medicine dissolves affects how well the body absorbs it. [1]
- the study of the dissolution process has been developing since the end of the 19th century by physical chemist
- The first studies on dissolution were reported in 1897 *by Noyes and whitney* in the litera ture
- The dissolution apparatus is a fundamental tool in pharmaceutical research and development, primarily used to evaluate the release of active pharmaceutical ingredients (APIs) from solid dosage forms, such as tablets and capsules. This evaluation is crucial for ensuring the efficacy and safety of medications.

➢ 1.1 Types of Apparatus (IP):

- **Apparatus 1 (Basket)**: This apparatus uses a basket that holds the dosage form and allows it to be submerged in the dissolution medium. It is particularly useful for formulations that are prone to floating or settling.[2]
- **Apparatus 2 (Paddle)**: In this configuration, a paddle stirs the dissolution medium, and it is commonly used for a wide variety of solid dosage forms.[2]

➢ 1.2 Dissolution apparatus plays important role in:

- **Drug Development**: The dissolution apparatus plays a vital role in the formulation development stage, helping researchers optimize the release profile of drugs to achieve desired therapeutic effects.[4]
- **Quality Control (QC)**: It is a standard test in QC processes to ensure that the final product meets specific dissolution criteria, providing assurance of batch consistency.[4]
- **Biopharmaceutical Studies**: The results from dissolution testing can help predict the in vivo performance of drugs, influencing decisions about bioavailability and therapeutic effectiveness.[4]

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1.3 Types of Dissolution Appratus

Table:1[6][7]

	I.P	U.S.P	B.P	E.P
TYPE 1	Paddle Apparatus	Basket Apparatus	Basket Apparatus	Paddle Apparatus
TYPE 2	Basket Apparatus	Paddle Apparatus	Paddle Apparatus	Basket Apparatus
TYPE 3		Reciprocating Apparatus	Flow through Cell Apparatus	Flow through Cell Apparatus
TYPE 4		Flow through Cell Apparatus		
TYPE 5		Paddle over disc Apparatus		
TYPE 6		Rotating cylinder		
TYPE 7		Reciprocating Holder		

2. MAJOR CONTRIBUTIONS AND EVENTS IN THE DEVELOPMENT OF DISSOLUTION TESTING

Table 2 [1]

Year	Contributor (s)	Major contribution
1897	Noyes AN and Whitney WR	Conducted the first dissolution experiments and published an article entitled "the rate of solution of solid substances in their own solutions". Noyes- Whitney equation
1900	Brunner E and von Tolloczko S	Showed that the rate of dissolution depends on the exposed surface, the rate of stirring, temperature, structure of the surface and the arrangement of the apparatus
1904	Nernst W and Brunner E	Nernst–Brunner equation based on the diffusion layer concept and Fick's second law.
1931	Hixson AW and Crowell JH	Dependence of reaction velocity upon surface and agitation. Hixson and Crowell reported that the Noyes–Whitney equation in its original form and without any details about the mechanism of the process had been sufficiently validated with a wide range of experiments, as opposed to the various mechanistic explanations that had appeared, none of which was entirely satisfactory.
1951	Edwards Lj	First to appreciate that following the oral administration of solid dosage forms, if the absorption process of drug from the gastrointestinal tract is rapid, then the rate of dissolution of that drug can be the step which controls its appearance in the body
1957	Nelson E	First to explicitly relate the blood levels of orally administered drugs (theophylline salts) to their in vitro dissolution rates.
1961	Higuchi T	Reviewed the interfacial barrier model proposed by Wilderman in 1909 and Danckwerts model (1951)
1962	Levich VG	Improved the theoretical model of the dissolution experiment using rotating disks, taking into account the centrifugal force on diffusion.

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1970		The basket-stirred-flask test (USP apparatus 1) was adopted as an official dissolution test in 6 monographs of the United States Pharmacopeia (USP) and National Formulary (NF)
1978		Adoption of the paddle method (USP apparatus 2)
1981		The first guidelines for dissolution testing of solid dosage forms were published as a joint report of the Section for Official Laboratories and Medicines Control Services and the Section of the industrial pharmacist FIR
1991		Adoption of the reciprocating cylinder (USP apparatus 3) for extended-release products..
1995		Adoption of the flow-through cell in (USP apparatus 4) for extended-release products.

3.TYPES OF DISSOLUTION APPARATUS(IP)

3.1. Basket Dissolution Apparatus

The basket dissolution apparatus is a widely used instrument in pharmaceutical laboratories for evaluating the dissolution characteristics of solid oral dosage forms, such as tablets and capsules. This apparatus helps determine how quickly and efficiently a drug dissolves in a liquid medium, which is critical for assessing its bioavailability and overall performance.[10]

Basket Dissolution Apparatus

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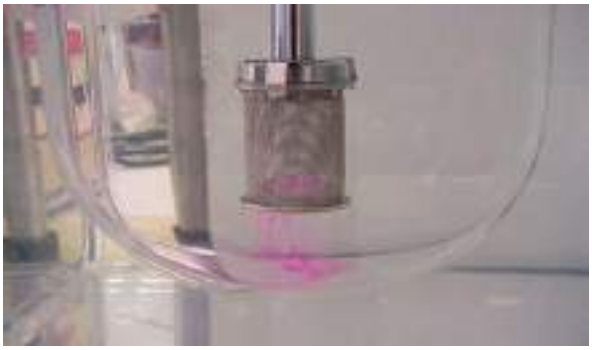

Basket that Hold The Dosage form (tablet, capsul)

- **Key Components**: [11]

1. **Basket**: A mesh or perforated container that holds the dosage form during the dissolution test.
2. **Motorized Drive**: Mechanism to lower and raise the basket into and out of the dissolution medium
3. **Dissolution Medium**: A specific volume of solvent (often water or simulated gastric fluid) that mimics physiological conditions.
4. **Temperature Control**: Heating system to maintain the medium at a constant temperature, usually around 37°C.
5. **Sampling System**: Allows for the collection of samples from the dissolution medium at predetermined intervals.

- **Objectives**

1.**Measuring Dissolution Rate**: To find out how fast a drug releases its active ingredients.[5]
2.**Comparing Formulations**: To check differences between various drug formulations or batches.[9]
3.**Quality Control**: To ensure products meet required dissolution standards for safety and effectiveness.
4.**Predicting Drug Absorption**: To help estimate how well the drug will work in the body.[12]

3.2. Paddle Dissolution Apparatus

The paddle dissolution apparatus is a device used to measure the dissolution rates of solid oral dosage forms, such as tablets and capsules. It operates on similar principles as the basket dissolution apparatus but uses a paddle to stir the dissolution medium

Paddle Dissolution Apparatus

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- **Purpose and Application**
  - **Dissolution Testing**: The primary purpose of the paddle dissolution apparatus is to test how a drug dissolves in a specific medium. The results help ensure the drug will dissolve at an appropriate rate in the gastrointestinal tract after ingestion.
  - **Quality Control**: It is used to confirm the consistency and reliability of drug formulations, ensuring batch-to-batch uniformity in the dissolution characteristics of the product.
  - **Regulatory Requirements**: Dissolution testing is a crucial part of the drug approval process, and dissolution data is often required by regulatory agencies (e.g., FDA, EMA) to ensure that a drug releases its active ingredient at a predictable and effective rate.

- **Key Components**: [8][5][12]

1.Dissolution Vessel: A container that holds the dissolution medium (usually a liquid) where the drug is tested.
2.Paddle: A rotating paddle that stirs the medium, ensuring even distribution and mimicking gastrointestinal conditions.
3.Heating Element: A system to maintain the temperature of the dissolution medium, as temperature can affect drug solubility.
4.Drive Mechanism: A motor that controls the rotation speed of the paddle, which can be adjusted according to testing requirements.
5.Sampling Port: An area where samples of the dissolution medium can be taken at specified intervals to analyse the concentration of the dissolved drug.
6.Data Collection System: Equipment or software that records the dissolution data, which is essential for analysis and reporting.

- **Objectives**: [12] [5]

1. **Dissolution Rate Measurement**: To determine how quickly a drug dissolves in a fluid, simulating conditions in the gastrointestinal tract.
2. **Comparative Testing**: To compare the dissolution profiles of different formulations or batches to ensure consistency and effectiveness.
3. **Quality Control**: To verify that pharmaceutical products meet regulatory standards for dissolution, which is crucial for their efficacy.
4. **Predicting Bioavailability**: To estimate how well and quickly a drug will be absorbed in the body based on its dissolution characteristics.

4. METOPROLOL SUCCINATE DISSOLUTION TIME AND PERCENTAGE DISSOLVE OF DRUGS IN (IP1 & IP2) APPARATUS

- **4.1 Metoprolol succinate**

Metoprolol succinate is a medication that belongs to a class of drugs known as beta-blockers. It is commonly used to treat high blood pressure, heart failure, and to prevent angina (chest pain). It works by blocking beta-adrenergic receptors in the heart, leading to a decrease in heart rate and blood pressure, which helps reduce the heart's workload.

The dissolution time of **metoprolol succinate ER tablets** is designed to ensure a **gradual release over 24 hours**. In in vitro testing, the full release of the drug may occur over **8 to 24 hours**, depending on the formulation and testing conditions.[22]

- **Used for**
- **Hypertension (High Blood Pressure):** It helps lower blood pressure, reducing the risk of stroke and heart attack.[13]

- **Heart Failure:** It is used as part of the treatment regimen for chronic heart failure, helping to improve symptoms and reduce hospitalizations.[6]

- **Angina Pectoris:** Metoprolol succinate can relieve chest pain associated with angina.[14]

- **Post-Myocardial Infarction:** It is often prescribed after a heart attack to improve survival and reduce the risk of further heart issues.[15]

- **Arrhythmias:** It may be used to manage certain types of irregular heartbeats.[16]

- **Migraine Prophylaxis:** Occasionally, it is used to prevent migraines.[17]

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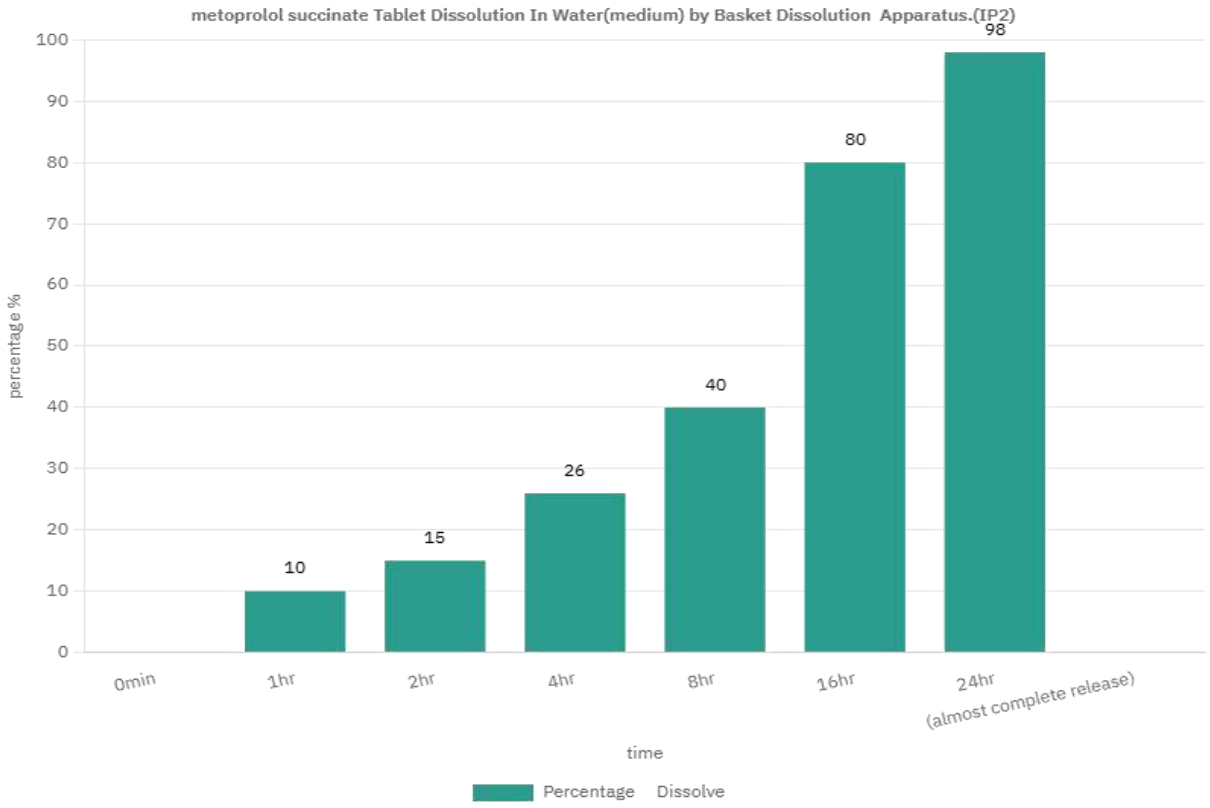
➢ **4.2. Tablet Dissolution In Water(medium) by Basket Dissolution Apparatus.(IP2)**

Time (hour)	Percentage Dissolve
0min	0%
1hr	10%
2hr	15%
4hr	26%
8hr	40%
16hr	80%
24hr	98% (almost complete release)



➢ **4.3. Tablet Dissolution In Water(medium) by Paddle Dissolution Apparatus(IP1)**

Time (hour)	Percentage Dissolve (%)
0min	0%
1hr	12%
2hr	24%
4hr	30%
8hr	50%
16hr	77%
23hr	99% (Dissolve)

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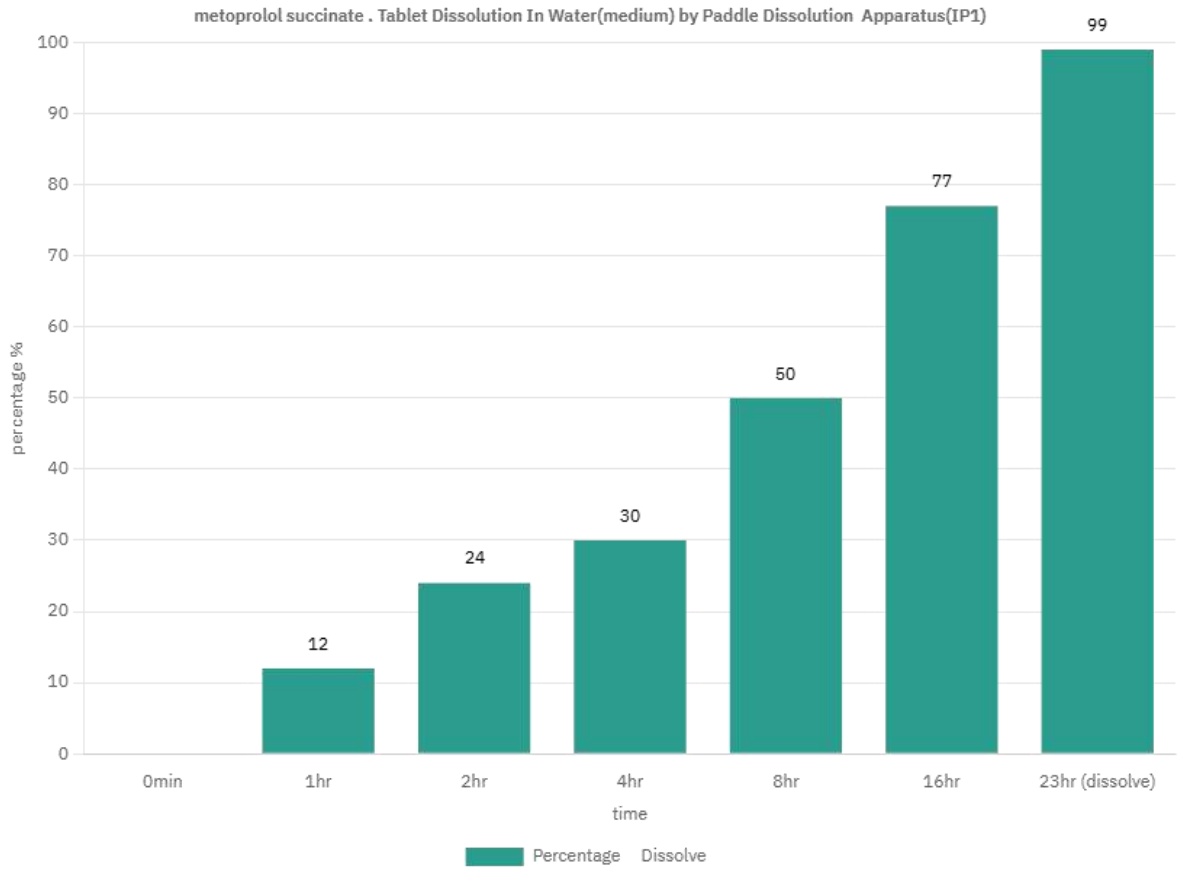

➢ **4.4. Tablet Dissolution In Alcohol(medium) by Basket Dissolution Apparatus.(IP2)**

Time (min)	Percentage Dissolve
0min	0
10min	11.47%
20min	18.03%
30min	25.81%
40min	32.37%
50min	39.75%
1hr	47.13%
1hr 20min	55.73%
1hr 40min	73.77%
1hr 50min	Dissolve

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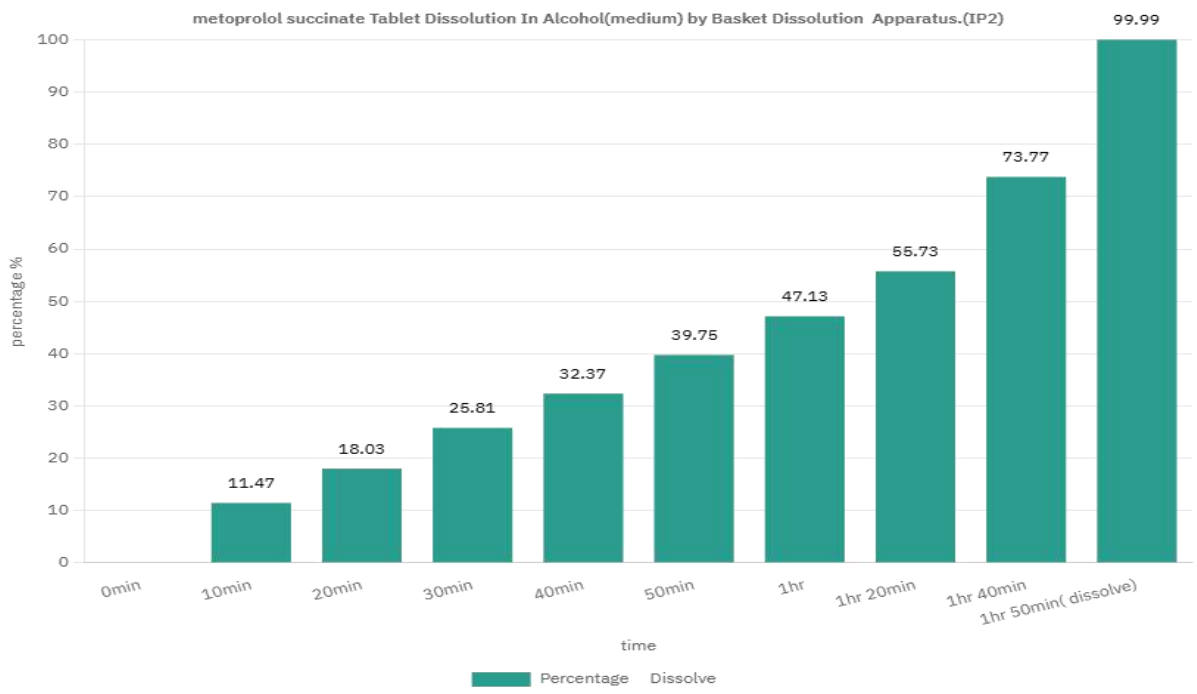

- **Dissolution Time in Alcohol**: [20][21]
  metoprolol succinate These tablets are made to release the drug slowly over many hours. But when tested in alcohol, they might **dissolve much faster**, potentially in **30 minutes to 2 hours**.
  Why? Alcohol can disrupt the slow-release mechanism (like the coating or the matrix inside), causing the drug to be released **too quickly**.

➢ **4.5. dissolution testing involves several key steps** [8][9]

1.Selection of Drug Formulation

- Choose the specific drug formulation (e.g., tablets, capsules) you want to test.

2. Preparation of Dissolution Medium

- **Choose Medium**: Select an appropriate dissolution medium based on the drug's solubility characteristics. Common media include:
  - Water
  - 0.1 N Hydrochloric Acid
  - Phosphate Buffer (pH 4.5 or 6.8)
  - Alcohol(Lab Solvent)
- **Temperature Control**: The medium is typically maintained at 37 °C to mimic physiological conditions.

3. Apparatus Setup

- **Select Dissolution Apparatus**: Common options include:
  - **USP Apparatus 1 (Basket Method)**
  - **USP Apparatus 2 (Paddle Method)**
- Ensure the apparatus is calibrated and functioning correctly.

4. Weighing and Placing the Drug

- **Accurate Weighing**: Weigh the drug dosage form (e.g., tablet) accurately.
- **Placement**: Place the dosage form in the dissolution vessel.

5. Initiating the Dissolution Test

- **Start the Apparatus**: Turn on the apparatus to begin the dissolution process.
- **Set Time Intervals**: Determine the time points for sampling (e.g., 5, 10, 15, 30 minutes).

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6. Sampling

- At each time interval, withdraw a specified volume of the dissolution medium.
- Measure the weight of the drug .

7. Data Analysis

- **Calculate Percentage Dissolved**: Use the concentration data to calculate the percentage of the drug that has dissolved at each time point.
- **Plot Dissolution Profile**: Create a graph of percentage dissolved versus time for analysis.

8. Quality Control

- **Repeat Testing**: Conduct the test in duplicate or triplicate to ensure reliability.
- **Compare to Standards**: Check the results against pharmacopoeial standards to ensure the formulation meets specifications.

5. CONCLUSION

Dissolution apparatus are important tools used in the pharmaceutical industry to test how a drug releases its active ingredients when it dissolves in the body. This helps scientists understand how quickly and completely a drug will be absorbed after it is taken. The most commonly used types of dissolution apparatus are **Apparatus 1 (Basket Method)** and **Apparatus 2 (Paddle Method)**, each designed for different types of drug formulations like tablets and capsules. [19]

It's essential to make sure that the dissolution apparatus are set up correctly and consistently, with factors like temperature, agitation speed, and the type of liquid (dissolution medium) being controlled. This ensures that the results are accurate and repeatable. The **FDA (U.S. Food and Drug Administration)** and the **European Medicines Agency (EMA)** provide strict guidelines to ensure that these tests are done properly. [18]

6.RESULT

1.Metoprolol succinate tablet Dissolves faster In alcohol compared to water and any other medium.
2.When **metoprolol succinate extended-release tablets** are dissolved in alcohol, the release of the drug can **happen faster** than intended. This is because alcohol can affect the way the tablet dissolves, making it break down more quickly.

NOTE

As a result, drinking alcohol with this medication can lead to higher levels of the drug in your bloodstream, which may increase the risk of side effects or even overdose.
To be safe, it is generally recommended to avoid drinking large amounts of alcohol while taking metoprolol succinate extended-release.

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OBSERVATIONS REGARDING THE CREATIVE INTEGRATION OF RELIGIOUS AND EDUCATIONAL ACHIEVEMENTS IN TAHIR MALIK'S SHORT STORY "FALAK"

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ABSTRACT

The literary works of nations embody their national spirit, philosophy, and moral values, with religious and spiritual elements playing crucial roles. By the late 20th century, there was a resurgence of interest in religion, mysticism, and the integration of these themes into literature. Uzbek literature, especially post-independence, reflects a strong influence of Islamic educational themes, continuing a thousand-year tradition. Tahir Malik, a significant figure in modern Uzbek prose, adeptly integrates religious concepts into his narratives, exemplifying the deep connection between Islamic teachings and artistic expression. His work "Falak" merges historical and fantastical elements, emphasizing the enduring importance of faith, justice, and knowledge. Malik's narratives reveal the interplay of spiritual and worldly concerns, highlighting the societal implications of religious beliefs and ethical values.

KEY WORDS: *national spirit, uzbek literature, religious themes, islamic education, Tahir Malik, modern prose, spirituality, mysticism, faith, justice, knowledge, ethical values.*

Literature of every nation reflects its national spirit, way of thinking, experiences of its scholars, moral, spiritual, religious, and divine concepts and values. Therefore, disregarding these aspects makes it impossible to define the essence of the literary process and to correctly evaluate the role and significance of literary traditions in artistic creation.

Indeed, meaning, emotions, or truth in artistic creation are not discovered out of thin air. Religion and philosophy, enlightenment and spirituality, thought and moral values all have their place and importance here. As a result, by the end of the 20th century, a renewed interest in language, history, religion, and mysticism emerged. "Historically, it is well-known that Sufism has been one of the teachings that strongly influenced the social, cultural, philosophical, and literary life of the Uzbek people [Jalilov B, 2010: 20]." Since the early years of independence, Uzbek literary critics have been paying attention to the content and essence of works on religious-educational themes, their development as a continuation and distinct direction of a thousand-year tradition, and the research into their unique characteristics. The change in the creative climate in the era of globalization, the variety in the manner of expression by creators, the processes of inter-genre synthesis, the integration of modern world literature standards with classical literature into new forms, depend on the talent of the creator.

In general, any literary work requires extensive knowledge, high intellect, and genuine discoveries from the author. "Every author must work devotedly on their work, honing their talent to capture the reader's heart [Sharafiddinov O, 2004:184]".

At the same time, the entry of religious motives into the literature of this period demanded a distinct religious-educational direction. Since the early days of independence, the content and essence of modern Uzbek prose and its main object of depiction have begun to reflect the Islamic-educational ideas that have been the main themes in classical Uzbek literature for a thousand years. Studying the integration of Quranic themes into world and Uzbek literature is not only instructive from a religious perspective but also helps revive the genealogical, unbroken connections of Eastern literature from the past. The considerations about the commonality of religious and secular literature illuminate new facets of our ancient heritage [Karomatov H, 1993: 5].

In modern Uzbek prose, the ability to deeply integrate religious and educational motives into the artistic essence of a work requires profound knowledge and experience from the writer. In this regard, Tahir Malik's creativity draws our attention, as his works reflect unique artistic mastery through the interpretation of religious concepts. During the years of independence, the productive creativity of Tahir Malik exhibited a wisdom-infused spirit that emphasized restraining desires, avoiding Satan's tricks, and believing in the inevitability of death. According to the theoretical standards of classical literary criticism, Malik's works are

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founded on the idea of the hand being busy with labor while the heart remains with God. The seemingly simple stylistic features of his stories and novellas conceal significant life lessons. The protagonists in his works are often depicted as individuals striving to attain a state of spiritual union, learning from the examples of saints and sheikhs along their arduous paths.

Malik masterfully weaves notions of respect for religion and Islamic rulings into his narratives. In the story "Falak", we observe how human emotions intertwined with history and the future are closely linked both religiously and worldly. Written in a fantastical style, this work captures the complex inner world of individuals living within spiritual fragrances and the deep artistic-philosophical perspectives filled with the author's torments.

In "Falak" the need for religion and faith throughout every era of humanity is highlighted, showing that the concept of faith alone keeps the world in harmony. "The issue of faith is a human issue. All human actions, including good deeds for the sake of goodness, ultimately stem from faith [Karimov H, 2010: page 153]". The narrative skillfully portrays the turmoil during the era of Mirzo Ulugbek, the injustices resulting from ignorance, and the plight of people suffering from the decisions of self-proclaimed pious judges who misinterpret religion.

It highlights the societal negligence towards a young girl married off due to her father's debt, and the lack of objection from the contemporary religious leaders, reflecting the flaws of ignorance in society at that time. To address such injustices, Purdil Palvan extends a helping hand to the girl, only to be ordered by the disguised religious judge to be stoned without any evidence, labeling them sinners and adulterers without proper investigation. The hero Shamsibek's declaration, "Your Excellency, as you know, the merciful Prophet Muhammad (peace be upon him) always thoroughly investigated before ordering stoning for adultery. There is no need to remind you of the honorable hadiths on this matter. Shamsibek and Qamariddin clarify the situation, finding witnesses to prove the innocence of the young couple. "Allah is the All-Hearing, All-Knowing, who protects His innocent servants [T. Malik, 2017: page 43]. These words beautifully synthesize the aesthetic moment in the narrative.

Through this work, the author enriches our consciousness with both historical and religious knowledge. Some characters in the story highlight how ignorance and superstition can lead to severe consequences. There are conversations in the work that are crucial for understanding the true meaning and essence of the story, based on the societal position and worldviews of the participants. These are not the conversations of the ignorant or the uneducated, but of characters who possess both worldly and religious knowledge and strive to understand their place in society. "For it is a miracle that Allah, with His perfect wisdom and complete power, created Adam (peace be upon him), and sent some of his descendants as prophets to guide people on the right path. Let us remember Allah's words on this matter in the "Yasin" verses: There are many signs on earth for His servants to see the power and miracle of God. One of these signs is that Allah makes the night disappear and brings forth the day. During the celestial rotation, one person rejoices with happiness, while another lives under the cloud of sorrow [T. Malik, 2017: 55]". This excerpt from the chapter "Executed Judgment" is not included by chance. Through these sentences, the author conveys that the birth, life, and creation of humanity are indeed miracles, drawing upon verses from the Quran. Another line from this conversation illustrates the author's ability to deeply integrate religious and educational motives into the artistic essence of the work: "Allah has set two paths for His servants. He has given reason and intelligence so that they may choose the path of the Merciful and attain happiness. The Master of the Universe, Muhammad (peace be upon him) said: 'If Allah has done good to you, do good to others [T. Malik, 2017: 56]". Indeed, each religious-educational motif in the work serves to perfectly convey the story's message to the reader. The hadiths and verses included are not aimed at a specific person but at all of humanity. By integrating religious and educational ideas, the author has enriched the artistic essence of the work.

At first glance, the work seems to be a fantastical story, and at another, it appears to be a historical one. However, at its core, the work embodies a profound meaning and significance that connects the past and the future. The Islamic ideas and religious tones presented in the story are closely intertwined with the events happening to the characters. In particular, the fact that Mirzo Ulugbek is considered the Sultan of the science of astronomy is a true statement. The writer has also demonstrated the religious significance of Ulugbek's role as a teacher during the periods mentioned in the story. Allah created knowledge along with Adam (peace be upon him). Astronomy does not undermine religion; rather, it serves the progress of our religion. The observatory scholars determine prayer times, the moments for Ramadan fasting, sunrise and sunset times, intentions and obligations, and the timing of solar and lunar eclipses based on celestial changes [T. Malik, 2017: 90]. As Shamsibek strives to advance his knowledge in Mirzo Ulugbek's court, his interest in the universe grows. This results in the creation of a beautiful, handwoven "falak" by his wife. Indeed, the story reflects both artistic imagination and historical truths. The truths in this work are further enhanced through religious motifs, drawing readers in even more. In the story, we see another statement that has proven itself true both historically and today, demonstrating the writer's skill: "Women are also servants of Allah... Muslim women would be greatly pleased if they could gain knowledge, as the honorable hadith states, Seeking knowledge is a duty for every Muslim man and woman" [T. Malik, 2017: 93]. The hadith presented by the writer in this work reflects an absolute truth in every era. In any society, the education of women lays the foundation for a bright future for that society. This is undoubtedly a historical truth. The story ends tragically, but it teaches readers numerous lessons about history, the future, religion, the world, good and evil. The religious tones hold a special

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significance in the artistic expression of the ideas in the story. Overall, through his "Falak", Tahir Malik has conveyed his thoughts to humanity in a comprehensive manner.

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THE REFLECTION OF RELIGIOUS-PHILOSOPHICAL IDEAS IN MAHMUD ZAMAKHSHARI'S "AL-KASHSHAF"

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ABSTRACT
Az-Zamakhshari's work "Al-Kashshaf" delves into the miraculous nature of the Quran, emphasizing its superior understanding through specific Quran-related sciences. His comprehensive knowledge of various fields, such as Arabic vocabulary and Balagat, allowed him to reveal the depth of the Quran. Az-Zamakhshari's moral teachings, rooted in Islamic philosophy and ethics, highlight virtues like honesty, kindness, and justice, integrating them with legal norms from the science of fiqh. He underscores the intrinsic connection between law and morality, advocating for a life based on knowledge and good deeds. His unique interpretation of the Day of Judgment and the weighing of deeds underlines the principles of justice and accountability.
KEY WORS: *Az-Zamakhshari, Al-Kashshaf, Quran, Mutaziliyya belief, Islamic philosophy, Arabic vocabulary, Balagat, Moral teachings, Fiqh (Islamic jurisprudence), Sharia, Ethics, Day of Judgment, Justice, Virtues.*

Az-Zamakhshari's work "Al-Kashshaf" was written according to the mutaziliyya belief, but the secret of the miraculousness of the Quran, the beauty and high level of verse were revealed by the author in his own way. The main reason for this is the fact that Az-Zamakhshari has a perfect knowledge of many fields of knowledge, in particular, the attractiveness of the Arabic vocabulary, Ash'ar, Balagat, Bayan, Erab, and Adab. As noted by F.Rahman, "Az-Zamakhshari uses various techniques in justifying his views, in particular, rational orientation, analysis of variants of the Quran, scenes from the life of the Prophet, revealing the meaning of some words and other syntactic methods [1]". In this regard, Zamakhshari emphasizes the unique and deep nature of the Quran and emphasizes that its true understanding is superior to knowledge of other scientific sciences. He emphasizes that in order to truly understand the teachings and truths of the Quran, it is necessary to focus on specific sciences related to the Quran.

Az-Zamakhshari's moral teaching played an important role in the development of Islamic philosophy. He developed his philosophical and moral ideas in the form of oral debates. According to him, a person's ability to live depends on what he chooses between pleasure and pain. Makhmud Zamakhshari talks about the good qualities that lead a person to perfection and starts them on the right path. He also condemns vices such as arrogance, ambition, ignorance, and envy. A person who endures the hardships that befalls him will also endure the sufferings of his friends. Instead of punishing someone for their wrongdoing, he lets it pass by. Such a person is said to have been blessed with a pure conscience by God. Zamakhshari says, "May God destroy those whose hearts are kneaded with malice and the color of writing on oiled paper fades easily from their tongues [2]". According to Az-Zamakhshari, knowledge and goodness are similar to each other, and he considered the main task of a person to be a way of life based on acquiring knowledge. According to him, the source of knowledge is the spiritual activity of a person. From this alla comes to the conclusion that every person should know his soul.

Az-Zamakhshari's views on fiqh (Islamic jurisprudence) are directly related to his moral teachings and are based on the values of the Quran and the hadiths of our Prophet. In his teachings, Az-Zamakhshari combines his theory with moral practice and shows that the norms of moral relations in society include relations between people, their behavior, and the culture of speech. Az-Zamakhshari took his moral theory from the Quran and the hadiths of our Prophet, improved them based on the moral teachings of Ajam (non-Arabs) and the science of his time, and created a complete theory of ethics. In his opinion, virtues such as honesty, correctness, reliability, love and respect, responsibility, kindness, and loyalty in religion, social and personal life constitute the essence of good morality. Az-Zamakhshari turned moral norms into legal norms related to the science of fiqh and included their observance in the Sharia. That is, there is a connection between law and morality, without which human society cannot enjoy the necessary level of moral values.

Az-Zamakhshari expanded the range of moral values through Sharia rulings. He connects justice with the search for truth. In his teaching, truth as a standard of morality has a clear system that reflects the moral requirements of right or wrong, justice, honesty,

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etc. According to Az-Zamakhshari, goodness, justice, kindness, and good behavior are in the nature of man, and Allah gave them to man. On the contrary, tyranny, evil, ugliness and other immoral actions originate from the rebellious nature of man and occur through his own sin. Az-Zamakhshari knew that there is good and bad in human behavior, he considered Allah to be the owner of all good things, and he considered the beginning of evil to be a human act, because God cannot be the source of evil.

Az-Zamakhshari, in his moral views, emphasizes that it is necessary to know goodness and badness, then to decorate the heart with good deeds and thoughts, and to follow good deeds in order to avoid bad deeds. Az-Zamakhshari promotes pure relationships in the family, shows the high position of a woman, the value of a father and husband, and the importance of raising children well. Az-Zamakhshari evaluated these opinions in his works on the science of fiqh, defined moral qualities from the point of view of Islamic law, and took into account people's opinion about good and bad behavior. Therefore, he considers tradition as the source of Sharia morality and evaluates many human behaviors from the perspective of tradition (folk traditions and customs).

While explaining his views, Zamakhshari emphasized that the word "mezan" as a specific term is the scales on which the deeds of servants are determined in the Day of Judgment. After all the people gather at the Mahshar square, it is stated that their good and bad deeds will be weighed. There is no disagreement between the Ahl al-Sunnah and the mutaziliys regarding the weighing of deeds. Ahl al-Sunnah states that the human mind is not capable of knowing the essence of the scales. According to Ahl al-Sunnah, the best thing to do in this regard is to follow the tradition. mutaziliy theologians, like all theological schools, recognize the criterion. However, some mutaziliy scholars are opposed to weighing actions in terms of quantity. Because they evaluate them qualitatively, they do not consider actions as something that can be measured.

According to Zamakhshari, the criterion means an action that has value and weight in the eyes of God. According to him, the Day of Judgment is very precious in the sight of Allah. Because when talking about the angels who are responsible for recording the deeds of people, the use of the phrase "precious ones" for them actually comes from the importance that Allah has given to the calculation. If accounting were unimportant, those angels would not have been assigned the task of recording the matters of human accounting. The Book of Deeds and the mention of angels are also a great blessing for believers.

Zamakhshari evaluates the full reward of Allah to his servants in the Hereafter based on the principle of "Adl". Also, while emphasizing the criterion (scale) and the full value of actions, he emphasizes that the scale works within the principle of justice. According to Zamakhshari, it is correct to have a scale to reveal the value of heavy and light deeds. For this reason, in addition to interpretations that the measurement is correct, i.e. real, they also interpret the correctness of the measurement as fair. It also mentions what the quality of this measure would be and evaluates the various interpretations of the subject through probabilities.

He explains that this process is carried out in front of everyone in order to show that no one is being treated unfairly in the weighing of Zamakshari deeds. In this matter, Zamakhshari agrees with his teacher Abu Ali Subbayi. After the scales are placed, Allah will question all His servants according to what is written in the Book of Deeds. Those who are interrogated also confess their sins according to what is written in their deeds. At that time, his limbs - his hands, feet, skin - Prophets, angels and other witnessing beings will bear witness to him.

On the Day of Judgment, evil will be punished according to the amount, and good will be rewarded without measure, and it is considered cruel to pay more for evil than for good. Such an answer is not characteristic of God. Since Zamakhshari is a representative of mutaziliyya, he stays away from assigning the proportion of oppression to Allah. Zamakhshari said that the criterion (scale) is set so that the person who did evil is not punished more than he deserves, and he is judged by calculation and measurement. On the other hand, no measure or calculation is used in weighing the reward of the deeds of the servants who do good deeds. They have more than they deserve. It is Allah's blessing to His servants that He rewards those who do good. Although Zamakhshari considers it a blessing that God gives "a lot" to his righteous servants, it is not just a blessing for him, it is an obligation. Zamakhshari believes that it is possible from the point of view of God's power to reduce the amount of reward given to a person for his actions or to give him more than what he deserves, but he does not recognize this from the point of view of wisdom.

It is said in the Holy Quran about good deeds: "Whoever does a little good, We will increase his reward many times over." According to Zamakhshari, increasing the reward of an action does not mean setting a limit; indicates the large number of awards. This reward is giving a greater gift to the owner of the good than oneself. Allah called this charity the reward mentioned in the verse, that is, the truth.

Zamakhshari considers the hereafter as a three-stage process. In two of them, there will be regret and asking for forgiveness; and in the third, their deeds are distributed to everyone. Those who take the notebook in the right hand will find salvation, those who take it in the left hand will die. Those who take the right hand will give easy and simple accounts, and those who take the left hand will face humiliation and suffering.

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Zamakhshari emphasizes that no one will bear the sins of others on the Day of Resurrection. According to him, a person is not punished for being a friend or neighbor of the oppressor. On that day, everyone will be held accountable for what he has done. However, those who are on the wrong path and lead others astray bear the weight of their own sins as well as the weight of the sins of those who have gone astray. When deeds are weighed and judged, Allah says: "Don't talk to me". Zamakhshari says that the inhabitants of Hell will beg God to remove their suffering, but these requests will be rejected. "Don't talk to me" is the last word spoken to the people of hell. From that moment on, the people of hell will cry, groan, make sounds like the braying of a donkey and the howling of a dog. In the mutaziliyya system of thought, the state of a person in the hereafter is reflected either in the form of entering heaven for merit or going to hell after suffering. There is heaven or hell for mutaziliy, there is no third option. The idea that people facing the Qibla will not stay forever in Hell, as the Ahl al-Sunnah preach, does not apply to the mutaziliys.

Because according to the representatives of mutaziliyya, a person cannot receive reward and punishment at the same time. That is why the mutaziliys developed the idea of ***ihbat*** and ***takfir*** to emphasize that reward and punishment do not exist in the same person at the same time. In Ihbat, the merits of a person are erased due to his sins, and in Takfir, his sins are removed due to Ihbat. With this idea, it is considered that whichever vice or sin is more in the mutaziliy, it destroys the other. Abul-Hasan al-Ashari explains the opinion of the mutaziliys in this matter as follows: "If the evil is more than the good, it cancels the good". With this interpretation, Ashari interprets the concept of criteria of mutaziliy through ihbat and takfir. Zamakhshari also defends ihbat and takfir. According to him, major sins invalidate the ihbot. If a person continues to commit major sins despite being a prayerful person and dies in this state, he will be in hell forever. That person's place in the hereafter is between two places called "arasat". Although this person prays, he will be called a "fasih" in the Hereafter, not a believer, an infidel, or a polytheist, because he committed major sins.

As long as the deeds done with ihbat and takfir are not wasted, the reward will be given forever. Zamakhshari suggests that if merit and sin are equal, then both cancel each other out. According to Zamakhshari, there are two main conditions for being worthy of reward: faith and good deeds. In addition to believing and doing good deeds, one should also avoid unnecessary actions. Extravagance and corruption are also major sins. When a person commits a major sin, all his prayers in the name of charity are lost. For example, in "Hujurot" surah 49/2, "O believers! Do not raise your voices higher than the voice of the prophet! Do not speak loudly to him as you speak loudly to each other - your deeds will be wasted if you do not understand the difference [3]". This verse is one of the proofs of ihbat and takfir for Zamakhshari. To fully understand ihbat and takfir, you need to know the definitions of major and minor sins. According to Zamakhshari, which sins are major sins are first determined as follows. A major sin is an act whose punishment is greater than its reward, while a minor sin is an act whose punishment is less than or equal to its reward. Zamakhshari also spoke about the reduction of sins and says that if a person deeply regrets his sins and is firm about it, the punishment will be reduced. Zamakhshari says that it is obligatory to repent from big or small sins, even if it is unknown whether the sin committed is big or small. By conveying the opinion of Abu Ali about minor sins, he emphasizes that minor sins should be repented of. Zamakhshari also quotes the opinion of Abu Hashim, may Allah be pleased with him, that "repentance is obligatory for major sins". Also, Zamakhshari emphasizes that unrepentant major sin cancels all other actions. As for minor sins, everything, big and small, is recorded in the book of deeds mentioned in the verse. According to him, even if a person commits a major sin, if he does not repent, his minor sins will appear as major sins in front of that person.

Another religious category that Zamakhshari emphasized and emphasized is shafa'at, which means an excuse for someone. As a term, justification of sinful believers, justification of believers who are not sinners in the presence of God means the mediation of those whom God has permitted. Prophets, martyrs, and righteous people, as well as those permitted by God, have been designated as vindicators to prevent sinful believers who deserve hell from entering hell, and to bring those who have entered hell out of it and enter paradise. No one can be a justifier except those whom God has permitted. The concept of intercession is mentioned in the verses. In the hadiths, sentences such as "I also want to continue my prayer in order to justify my ummah on the Day of Judgment" are mentioned as a prayer recited by every Prophet. If the people of the Sunnah emphasize the existence of shafa'at, the representatives of the mutaziliys interpret it differently. Ahl al-Sunnah states that it is necessary to accept intercession. mutaziliys claims that those who commit major sins and do not repent are not considered infidels, but they cannot get out of hell and enter paradise. Ahl al-Sunnah, on the other hand, insist that a person who dies as a Muslim can be excused for not accepting the deed as part of faith, even if he committed a major sin.

It is considered that Ahl al-Sunnah followers do not become disbelievers even if they are sinners, and they do not lose the qualities of faith. Despite their sins, Allah will forgive the sinner, and if He wills, He will admit them to paradise after they have suffered the punishment. If God wants, He can forgive whether they repent or not, and He can choose not to keep them in hell forever. The supporters of Ahl al-Sunnah believe that if God wills, He can forgive and punish sinners without any reason, through the shafa'at of His prophet and righteous servants. The proof for this belief is stated in Surah Muhammad 47:19.

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According to Ahl al-Sunnah, the mention of those who believe in shafa'at in the verse indicates the existence of shafa'at. "The verse emphasizes that there are no similar characteristics between unbelievers and believers. It argues that if there were no mercy, the unique characteristic of unbelievers not having mercy should not be mentioned".

Mutaziliys hold a distinct perspective on shafa'at. They believe that there is no shafa'at for those who commit sins. While shafa'at is not entirely dismissed in mutaziliy thought, it is suggested that forgiveness is granted only to sinners who have repented. There is no shafa'at for individuals who have committed grave sins without repentance.

According to Zamakhshari, those who commit minor sins do not need shafa'at because their sins are forgiven by God. The real shafa'at is to raise the ranks of the believers in paradise.

At the core of shafa'at in mutaziliy thought lie the principles of "Usulil-Hamsa" and "Vad and Vaid". These principles are directly related to the concept of "great sin". According to these tenets, Allah does not break His promise to His righteous servants, nor to sinners and disbelievers. This implies that if a sinner does not repent, God will not grant forgiveness.

Allah promises not to forgive those who die without repentance. Kadi Abd al-Jabbar asserts that the shafa'at of the Messenger of Allah for his ummah is undifferentiated; the distinction lies in who benefits from this shafa'at. As emphasized by the representatives of Ahl al-Sunnah, it is incorrect to accept that shafa'at is for those who have committed great sins. According to the principle of "vad and vaid", shafa'at is only valid for those who have repented of their great sins.

Nasafi criticizes the mutaziliys' views on shafa'at. He contends that forgiving certain sins does not imply those sins will be repeated. On the contrary, an individual who regrets their sin is likely to strive to avoid committing it again. Thus, shafa'at plays a vital role in encouraging a person to refrain from sinning, ultimately aiding in their salvation.

Zamakhshari opposes the opinion of Ahl al-Sunnah that those who have committed major sins will be released from Hell through the shafa'at of those permitted by God. The clearest evidence accepted by Zamakhshari, who refused such shafa'at, is the evidence mentioned in the Quran: "They will remain in Hell until the heavens and the earth endure, unless your Lord wills". Zamakhshari emphasizes that what is meant by the exception in the verse is the blessings of heaven and the punishment of hell, meaning that those who reside in hell will be punished not only by fire but also by the coldness of hell.

Zamakhshari also rejects shafa'at for sinners, i.e., the owners of graves. As evidence, he cites the verse: "On that Day, no shafa'at will be accepted". This general negative expression indicates that no one can act on behalf of another and that the shafa'at of an intercessor will not be accepted. Zamakhshari mentions that those who maintain piety and worship Allah will be granted the right to shafa'at in the Hereafter, with Allah's permission. However, to achieve this right, one must not be among the people of major sins (kabair). The righteous and saintly servants who are not from the people of major sins will be entitled to shafa'at. According to Zamakhshari, the authority to grant and deserve shafa'at is an attribute solely of Allah. The prophets, angels, and righteous who are permitted to perform shafa'at are also subject to this permission. According to him, shafa'at belongs solely to Allah, and it is not possible until both conditions are fulfilled: those for whom shafa'at is performed must be pleasing to Allah, and those who perform shafa'at must be granted permission to do so. Zamakhshari adds that to be granted shafa'at, one must stay away from major sins and be a righteous servant of Allah. Indeed, the righteous servants of Allah love and are pleased with the servants whom Allah loves and is pleased with [4]. However, concerning the wrongdoers, as stated in the verse, "There is no helper for the wrongdoers". As commanded, neither Allah nor the intercessors love the wrongdoers, meaning no one can save them from the fire. Furthermore, "those for whom shafa'at is performed must be worthy of grace and reward". Zamakhshari also examines shafa'at within the framework of Tavhid principles, emphasizing its very limited scope and the lack of influence on the Day of Judgment's accounting. Even the angels closest to Allah cannot perform shafa'at without His permission. Zamakhshari mentions the Prophet Muhammad specifically among the intercessors. He notes that Allah will grant him an even higher rank and blessings in the Hereafter than the esteemed position given to him in this world. The Prophet Muhammad will be granted the right to intercede in the Hereafter because he will be elevated above all scholars and prophets and will testify on behalf of his ummah over other communities. When discussing the hadith "My shafa'at is for those of my ummah who have committed major sins," which is considered evidence of the existence of shafa'at by Ahl al-Sunnah, it is emphasized that our Prophet Muhammad's shafa'at is specifically for those who have repented. Because those who have committed major sins are deprived of all their previous good deeds due to revelation, they are most in need of shafa'at, much like those who have just started their good deeds. Therefore, this is what the hadith refers to. Zamakhshari makes an interesting comparison while rejecting shafa'at. In conclusion, first, in the religious and mystical teachings of Zamakhshari in his work "Al-Kashshaf," the miraculous nature of the Quran, its poetic beauty, and high level of eloquence are uniquely elucidated by the author, playing a significant role in the development of Islamic philosophy. Zamakhshari pays attention to the similarity between knowledge and goodness, considering the primary task of a human to be a lifestyle based on acquiring knowledge and viewing human spiritual activity as a source of knowledge. Secondly, Zamakhshari's views on fiqh are directly related to his moral

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teachings, which are based on the values of the Quran and the Hadiths of the Prophet. The author defines virtues such as honesty, truthfulness, reliability, love and respect, responsibility, compassion, and loyalty as the foundation of good morality. While noting the connection between law and morality, Zamakhshari points out that without them, humanity cannot enjoy essential moral values. Thirdly, while expressing his views, Zamakhshari paid special attention to the categories of justice and shafa'at. Unlike the supporters of Ahl al-Sunnah, Zamakhshari argues that shafa'at is only for those who have repented of their sins and that there is no shafa'at for those who have committed major sins and have not repented. He emphasizes that, as stated by Ahl al-Sunnah representatives, it is incorrect to accept that shafa'at is for those who have committed major sins. According to the principle of "vad and vaid," shafa'at is only valid for those who have repented of their major sins.

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IMPACT OF SELF-HELP GROUPS IN THE EMPOWERMENT OF MUSLIM WOMEN IN BELTHANGADY TALUK: AN EMPIRICAL ANALYSIS

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ABSTRACT
This article, "Impact of Self-Help Groups in the Empowerment of Muslim Women in Belthangady Taluk: An Empirical Analysis," examines how Muslim women in Belthangady Taluk, India, are empowered by Self-Help Groups (SHGs). The article emphasizes the importance of women's empowerment and the contribution that Self-Help Groups (SHGs) may make to the socioeconomic conditions of underprivileged and marginalized groups in society, particularly women. In order to assess different indices of women's empowerment among Muslim women in Belthangady Taluk, the study uses both primary and secondary data. The study's findings indicate that Muslim women's financial independence significantly changed when they joined SHGs. The article's conclusion is that SHGs are a useful instrument for advancing women's emancipation and raising the standard of living in underserved areas.
KEYWORDS: *Women Empowerment, Muslim Women, Self Help Group*

INTRODUCTION

India has been working towards the empowerment of women and socially deprived sections of society by introducing several welfare activities and by encouraging the involvement of NGOs and other voluntary organizations to undertake such programs. One such program initiated is Self-Help Groups (SHGs) through which women empowerment is ensured at the local, state and national levels. SHGs are the basic and informal institutions that give access to microfinance for poor and neglected sections of society to improve their socio-economic conditions and capabilities (Theresa Pereira, 2022).

The purpose of SHGs is to meet the unmet demands of the poor especially women on a large scale and to play a role in eradicating poverty. Free access to SHGs enables the poor and women to carry out their routine activities smoothly and there will not be times when there is no access to food, clothing, shelter or education. SHGs help to manage unforeseen events such as sickness, theft, or natural disasters without much shock (Bhat Sham V, 2011, Theresa Pereira, 2022). SHGs have given Indian women an opportunity to become agents of change and brought about confidence to explore new horizons and new dreams. In addition, SHGs facilitate women and poor people to move away from the exploitation of money lenders and empower them socially and economically to lead a life with dignity and pride(Somanath V S, 2009, Theresa Pereira, 2022).

Empowerment is the process of challenging existing power relations and challenging patriarchal ideology to transform the structures and institutions that reinforce gender discrimination and to gain access and control of both material and informational resources. SHGs are emerging as powerful tools for the socio-economic empowerment of the poor in rural areas (Geetha B, 2007, Pradeep M D et.al 2019). After analyzing the problems and prospects of self employed women stated that as women have to play dual roles, self-employment is better suited to them and having authority over enterprise she can maintain her timings and adjustment (Khullar Mala, 2009,Pradeep M D et.al., 2019).

SHGs are initially formed on the foundation of the accumulated endowment of bonding social capital already existing in the community. The social capital produced by these as it matures through the creation of new ties and linkages strengthens the community's cooperative capacity. (Pradeep M D et.al., 2019). It articulates the community demands as they become aware of their rights which changes the attitude of government bureaucratic officials, they become more responsive to the need of the community. The state-society relationship will build. In this way, eventually becomes an associational framework for collaborative actions that produce public good. (Pradeep M D et.al., 2019). In self-help groups, it is assumed that all poor households need to save and have the inherent capacity to save a small

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amount regularly. Easy access to credit is more important than cheap subsidized credit. Poor are the best judge of their credit needs and good users and re-payers of credit when formed in groups. Credit discipline is imbibed among the members by way of a positive impact on income, saving and self confidence. This impact is more when SHGs are linked with NGOs. (Pradeep M D et.al., 2019). SHGs provide women the opportunity to be together, identify, communicate problems, exchange experiences, and develop forums of solidarity and mutual assistance which increased their self esteem, and taught to plan, question and to organize against inequality at public and self levels (Pradeep M D et.al., 2019).

SHGs ensure economic independence through income-generating activities, regular meetings and discussions on many live issues to help women in developing communication skills and building confidence in their democratic, social and cultural spheres of life. Social development of women by creating equality of status encourages their participation, facilitates decision making and makes them self sustaining in society (Pradeep M D et.al., 2019).

Evolution of Self Help Groups

India has adopted the Bangladesh's model in a modified form. To alleviate the poverty and to empower the women, the micro-finance has emerged as a powerful instrument in the new economy. With availability of micro-finance, self-help groups (SHGs) and credit management groups have also started in India. And thus the movement of SHG has spread out in India. (www.google.com)

In India, banks are the predominant agency for delivery of micro-credit. In 1970, Ilaben Bhat, founder member of 'SEWA' (Self Employed Women's Association) in Ahmadabad, had developed a concept of 'women and micro-finance'. The Annapurna Mahila Mandal' in Maharashtra and 'Working Women's Forum' in Tamilnadu and many National Bank for Agriculture and Rural Development (NABARD)-sponsored groups have followed the path laid down by 'SEWA'. 'SEWA' is a trade union of poor, self-employed women workers.(www.sewa.org)

In 1991-92 NABARD started promoting self-help groups on a large scale. And it was the real take-off point for the 'SHG movement'. In 1993, the Reserve Bank of India also allowed SHGs to open saving accounts in banks. Facility of availing bank services was a major boost to the movement.(www.nabard.org)

Self-Help Groups or in-short SHGs are now a well-known concept. It is now almost two decades old. It is reported that the SHGs have a role in hastening a country's economic development. SHGs have now evolved as a movement. Mainly, members of the SHGs are women. Consequently, the participation of women in the country's economic development is increasing. They also play an important role in elevating the economic status of their families. This has led boost to the process of women's empowerment. (BYJU'S)

SHG is a group formed by the community women, which has a specific number of members like 15 or 20. In such a group the poorest women would come together for emergencies, disasters, social reasons, and economic support to each other to have ease of conversation, social interaction and economic interactions.

Need for Women Empowerment

The World Bank defines empowerment as "the process of increasing the capacity of individuals or groups to make choices and to transform those choices into desired actions and outcomes. Central to this process are actions which both build individual and collective assets and improve the efficiency and fairness of the organisational and institutional context which govern the use of these assets". (Iftekhar Unissa, 2018)

Women empowerment can be defined as promoting women's sense of self-worth, their ability to determine their own choices, and their right to influence social change for themselves and others. It is closely aligned with female empowerment – a fundamental human right that's also key to achieving a more peaceful, prosperous world. (Iftekhar Unissa, 2018)

In Western countries, female empowerment is often associated with specific phases of the women's rights movement in history. This movement tends to be split into three waves, the first beginning in the 19th and early 20th centuries where suffrage was a key feature. The second wave of the 1960s included the sexual revolution and the role of women in society. Third wave feminism is often seen as beginning in the 1990s.(wikipedia)

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In recent years, women's rights and empowerment have been increasingly groundbreaking movements that are part of a larger worldwide movement. Observances such as International Women's Empowerment Day are becoming more popular. However, despite significant advancements, violence and discrimination against women and girls persist everywhere in the world.(wikipedia)

For families, communities, and nations to thrive socially and health-wise, women's empowerment is crucial. It is possible for women to realize their full potential, contribute their skills to the workforce, and have children who are happier and healthier when they lead safe, satisfied, and productive lives.(wikipedia)

Education plays a major role in this empowerment. Girls who receive an education can go on to have fulfilling careers and eventually boost the economy of their nation. After eight years of education, individuals are also four times less likely to marry young, which improves the health of both them and their children.(Nures Salam, 2017)

In our country females make up nearly 50% of India's overall population. By empowering women it will automatically strengthen the national economy. Empowerment of women is imperative as women continue to be the victims of the traditional social structure of the community.(Nures Salam, 2017)

The popular theories state that the subjugation of Muslim women by their male counterparts was mainly due to their economic dependence and lack of confidence in competition with men in society (Moghul Nurjahan Begum et.al., 2017). Educationally Muslim comprise one of the most backward communities in the country. Muslim girls and women lag behind their male counterparts and women of all other communities. Muslims have the highest dropout rate in the country. The share of Muslims in all courses is low (Firdaus Bano,2017)..
A woman can be confident through education, work, earnings and individual capacity to manage herself and her family. Education is one of the important social indicators having a bearing on the achievement and the growth of an individual as well as a community. This is apparent to be highly suitable for providing employment and thereby improving the quality of life. The educational status of Muslim women in India is worse as compared to Muslim men and women of other communities. They have the lowest work participation rate and most of them engage in self-employment activities (Firdaus Bano,2017).

The Self-Help Group (SHG) is the most appealing system for less commitment. Women's engagement in self-aid groups has had a significant effect on the way of life and the style of vulnerable people and motivated them not just as individuals but also as communities and the community as a whole at different rates. This is a medium for alleviating poverty and promoting female entrepreneurship and financial assistance in India. Women's empowerment through self-help groups constitutes an emerging and fast-growing trend toward the social and economic development of the nation. Self Help Groups (SHGs) are one of the innovative and much-needed schemes to accelerate women's entrepreneurship, women's self-employment and women empowerment (Moghul Nurjahan Begum et.al., 2017).

REVIEW OF LITERATURE

Abdul Jamal M, Amatul Khadir Ayesha Raihana and H Yasmeen Sultana (2016) explored that microfinance is the provision of small amounts of financial services to low income and self employed people. The participation of women self help groups made a significant impact on their empowerment both in social and economic aspects.

Moghul Nurjahan Begum and Dr. K Dhanalakshmi (2017) observed that the study is significant because it brought to light the contribution of Muslim women as they are usually stereotyped and secluded. The study was based on primary and secondary data. In this study, the researcher selected about 400 sample respondents in Guntur Andhra Pradesh using a systematic random sampling method. It was concluded that Muslim society is patriarchal and women were subjugation by male elders of the family.

Firdaus Bano (2017) found that education for women is the best way to improve the health nutrition and economic status of a household which constitutes a unit of the nation's economy.

Md Sahnewaz Sanu (2017) indicated that Muslim women in India are relatively disempowered and enjoy lower status than that men and women belonging to other communities, no matter how empowerment is measured, in terms of the indicators of the evidence, sources or setting for empowerment.

Nures Salam (2018) observed that education is the only fundamental prerequisite for empowering women in Muslim community. Equality and empowerment of women are necessary to bring about an egalitarian human society.

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OBJECTIVES

1. To study the Socio Economic status of Muslim Women in Belthangady Taluk.
2. To identify the impact of self help groups on the overall improvement of Muslim women in Belthangady Taluk.

INDICATORS OF WOMEN EMPOWERMENT

Economic empowerment- Economic empowerment is the capacity of women and men to participate in, contribute to and benefit from growth processes in ways which recognise the value of their contributions, respect their dignity and make it possible to negotiate a fairer distribution of the benefits of growth (Eyben,Randothers, 2008). Women have more access to financial services, employment, property and other productive assets, skill development, and market knowledge when they are economically empowered.

Social Empowerment- The societal disparities that women have experienced are discussed in this kind of empowerment. Since gaining its independence, India has advanced significantly. In certain regions, women continue to experience discrimination in relation to matters of health, family, marriage, delivery, etc. Giving women equal voice in all of these decisions can empower them socially and help them break down barriers.

Psychological Empowerment- Women can live lives free from fear when they are empowered psychologically. Creating an environment where women feel safe being who they are without worrying about their safety or wellbeing is necessary.

METHODOLOGY

The present study is both descriptive and empirical in nature of the topic and hence both primary and secondary data were collected. The primary data was collected through Field Visits and structured questionnaire. Secondary data was collected through the various published literature like articles, research papers, magazines etc. In this paper, the research investigator selected Belthangady Taluk and various indicators of women empowerment among Muslim women are analyzed by using simple statistical tools like paired sample test, T-test etc.

Table 1

KMO and Bartlett's Test for Women Empowerment		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy		0.813
Bartlett's Test of Sphericity	Approx. Chi-Square	2262.473
	df	105
	Sig.	0.000

Source: Survey data

Table 2: Paired Sample Test Statistics

		Mean	N	Std deviation	Std. Error Mean
Pair 1	Overall spending before	1.76	100	.639	.062
	Overall spending after	2.52	100	.379	.036
Pair 2	Making large household purchase before	1.84	100	.732	.050
	Making large household purchase after	2.69	100	.772	.036
Pair 3	Making household purchases for daily needs before	4.00	100	.741	.038
	Making household purchases for daily needs after	2.04	100	.858	.043
Pair 4	Own healthcare before	3.99	100	.763	.039
	Own healthcare after	1.79	100	.680	.034
Pair 5	Visit to family or relative before	4.00	100	.796	.040
	Visit to family or relative after	2.04	100	.858	.043
Pair 6	Deciding what to do with husband's earnings before	4.00	100	.741	.083
	Deciding what to do with husband's earnings after	2.01	100	.801	.041

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Table 3: Paired Sample Test Result

		Mean	Std Deviation	Std. Error Mean	T	Df	Sig (2 Tailed)
Pair 1	Overall spending before - after	-1.76	1.26	.062	-26.27	99	.000
Pair 2	Making large household purchase before - after	-2.63	1.23	.059	-32.17	99	.000
Pair 3	Making household purchases for daily needs before - after	-1.56	1.71	.037	-16.17	99	.000
Pair 4	Own healthcare before - after	-1.37	1.62	.035	-29.18	99	.000
Pair 5	Visit to family or relative before - after	-2.66	1.77	.047	-24.17	99	.000
Pair 6	Deciding what to do with husband's earnings before - after	-1.57	1.37	.087	-36.18	99	.000

ANALYSIS

The paired t-test was conducted to analyze the impact of joining self-help groups on Muslim women. The test result proved a significant difference in the financial independence of Muslim women after joining SHGs (M=2.52, 2.69, 2.04, 1.79, 2.04, 2 and SD= .379, .772, .858, .680, .858 and .801). Compared to before joining SHGs (M= 1.76, 1.84, 4,4,4,4 and SD= .639, .732,.741, .763, .796 and .741), t (99) = -26.27, -32.17, -16.17, -29.18, -24.17 and -36.18 $p<.001$ (two-tailed). Therefore, the null hypothesis is rejected at the (5%) significance level and concludes that Muslim women significantly improved financial independence after joining SHGs.

FINDINGS OF THE STUDY

1. According to the findings of the paired t-test study, Muslim women in Belthangady Taluk benefit significantly from Self-Help Groups (SHGs) in terms of their financial independence.
2. SHGs are essential to Muslim women empowerment and general well-being since they raise their socioeconomic standing.
3. The study emphasizes the significance of women's economic, social, and psychological empowerment, stressing the necessity of social fairness, equal access to financial resources, and freedom from fear.
4. The study highlights the contribution that Self-Help Groups (SHGs) make to microfinance accessibility, female entrepreneurship, and financial support in India.
5. The study highlights the growing trend of women empowerment through Self-Help Groups (SHGs), which is indicative of the country's growing social and economic development movement.
6. The paper emphasizes the value of Self-Help Groups (SHGs) as fundamental and unofficial institutions that give underprivileged groups in society—especially women—access to microfinance, thereby enhancing their socioeconomic potential.

These important findings illustrate the significance of such initiatives in fostering gender equality and social development by demonstrating the favorable impact of SHGs on the socio-economic betterment and empowerment of Muslim women in Belthangady Taluk.

SUGGESTIONS

1. Further Research: To better understand the long-term effects of SHGs on Muslim women empowerment in Belthangady Taluk, more study on this topic would be beneficial for the paper. Research with a longer time frame may shed light on the long-term impacts of SHGs on women empowerment and socioeconomic standing.
2. Comparative Analysis: A more comprehensive picture of the efficacy of SHGs in empowering women may be obtained by conducting a comparative analysis with other communities or areas. Analyzing the effects of SHGs on women from various geographic or socioeconomic origins could provide insightful comparisons.
3. Qualitative insights: By utilizing qualitative research techniques like in-depth interviews or focus groups with SHG members, it may be possible to gain a better understanding of the individual experiences and viewpoints of the women who participate in these groups.
4. Policy Implications: Addressing how the results may affect policy could increase the study's applicability in real-world situations. The paper might benefit from an examination of how the findings might inform or affect policies pertaining to microfinance efforts and women's empowerment.

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5. Community Engagement: Taking into account the role that community engagement plays in SHG performance, the paper should go over methods to improve community support and participation for these efforts, especially with regard to Muslim women in Belthangady Taluk.
6. Dissemination of Findings: Making suggestions for how the study's findings should be shared with pertinent parties, such as NGOs, legislators, and local leaders, could assist guarantee that the research results in significant action and change. These suggestions aim to enhance the depth, scope, and practical implications of the paper, ultimately contributing to the advancement of knowledge and the promotion of women's empowerment through SHGs.

CONCLUSION

This study's empirical analysis highlights the important role that Self-Help Groups (SHGs) play in Muslim women's empowerment in Belthangady Taluk. The results show that SHGs are essential to women's overall empowerment and well-being since they raise women's financial independence and socioeconomic standing. The study emphasizes how women's empowerment has several facets, including social, psychological, and economic aspects. It highlights how crucial it is to give women equal access to financial resources, advance social justice, and create conditions that allow them to flourish free from fear or restriction. Moreover, the study highlights the dynamic pattern of women's empowerment via Self-Help Groups, which mirrors an expanding national push for social and economic advancement. The study highlights the function of Self-Help Groups (SHGs) as essential and unofficial entities that give underprivileged groups in society—women in particular—access to microfinance, enhancing their socioeconomic potential. Recognizing the transforming effect of SHGs and continuing to fund programs that advance women's empowerment are crucial as we move forward. Our understanding of how to effectively empower women in marginalized communities can be advanced by delving deeper into the long-term effects of SHGs, conducting comparative analyses, and thinking through the implications for policy. In the end, this study adds to the corpus of knowledge regarding women's empowerment and emphasizes the significance of Self-Help Groups (SHGs) as a tool for promoting positive change. It is our hope that the findings presented here will inform future efforts to promote gender equality, social development, and economic empowerment for women in Belthangady Taluk and beyond.

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SKIN LOTION: BANANA PEEL EXTRACT AND WATERMELON RIND EXTRACT

Mr. Sushilkumar Sidram Nilange, Mr. Bijali.N.R., Dr. Sabale V.U

ABSTRACT

Due to ignorance, people typically waste or reject the many health advantages of banana peels. Numerous bioactive substances, including phytosterols, polyphenols, carotenoids, and biogenic amines, are abundant in banana peels. In addition, it has good amounts of dietary fiber and minerals like iron, calcium, salt, phosphorus, and magnesium. Antioxidants found in banana peels can be used to lower the chance of developing illnesses like cancer. In order to eliminate poisons from the human body, antioxidants are essential. A whole banana is made up of roughly 30–40% peel and the remaining amount is pulp. Numerous sectors, including cosmetics, pharmaceuticals, food processing, drinks, textiles, energy resources, paper manufacturing, bio-absorbents, biofuel generation, and agriculture, employ banana peels.

Skin care products are nothing new; people have needed them for a very long time. When developing cosmetics, it is imperative to consider the structure and function of the skin. Herbal cosmetics are becoming more and more popular these days because more ladies prefer natural products over those composed of substances. Herbal cosmetics are becoming more and more popular these days because most women choose natural products over ones that include chemicals. Acne vulgaris is concerning, particularly for teenagers and adolescence. Global data indicate that between the ages of 12 and 25, over 85% of people will have acne. Between the ages of 23 and 34, over 8% of adults will have acne, while just 3% of adults will have acne.

INTRODUCTION

The skin is the largest organ in the adult body since it makes about 15% of the body weight. It also helps regulate body temperature and stops excessive water loss, safeguarding the body against external biological, chemical, and physical threats. The mucous membranes of the body are a part of the continuous epidermis. The continuous skin includes the mucous membranes that cover the body's surface. Maintaining smooth, shiny, and healthy skin requires a balanced diet. Apart from maintaining a nutritious diet, hormonal fluctuations, especially throughout puberty, cause various physical changes in both genders. Among all the changes, acne vulgaris is the most common. Acne vulgaris is a common skin disorder that has a considerable burden of cutaneous and psychological illness.

The banana crop is regarded as one of nature's greatest treasures. This is due to the efficient use of every component of the banana crop, including the leaf, pseudostem, flowers, fruit, and peel. Scientifically speaking, banana stem is referred to as pseudo stem. Utilized in the production of fiber. Numerous industries, including textiles, paper, pulp, biodegradable sanitary pads, automotive, aerospace, and construction, can employ this fiber. The best in terms of flexibility, hardness, durability, and compactness is banana fiber. A biodegradable single-use plastic has been created in the Philippines using banana fiber. The waste from yellow banana peels contains a lot of cellulose, potassium, salt, and carbs, as well as flavonoids and another phenolic. Bioactive substances with antioxidant properties include flavonoids and phenolic compounds. Citruline is found in the white, non-consumed layer of watermelon rind. Among the antioxidants that are good for skin health is citrulline. The research by Damayanti et al. indicates that the oval watermelon rind has an IC50 value of 376.266 ppm and the round watermelon rind has an IC50 value of 214.369 ppm for antioxidant activity juice white layer. Rich in water content, watermelon and other fruits high in antioxidants, like bananas, can be used to detoxify the skin and provide vital nutrients by brightening, moisturising, and shielding the epidermis.

METHOD OF EXTRACTION

Banana Peel Extraction Method

After macerating banana skin in ethanol 70%:2 in a shaker for 24 hours at room temperature, the process was repeated three times, and the skin was filtered. A rotary evaporator was used to concentrate the filtrate. [8]

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Watermelon Rind Extract

White layer of watermelon rind is refined by use of blender and filtered. After that process the filtrate is powdered by freeze dryer method . A fruit that is grown all over the world, watermelon (Citrullus lanatus) is prized for its low calorific value, high water content, and sweet flavour. 166 million tonnes of watermelon were consumed worldwide in 2018. While watermelon peels are occasionally pickled or utilised as a cooked vegetable, and watermelon seeds are used in some parts of Asia for snacks and flour, these resources are more commonly thrown away, producing enormous amounts of waste from underappreciated seeds and peels.

The amount of essential fatty acids, carotenoids, tocopherols, thiamine, flavonoids, riboflavin, and other phenolic compounds found in watermelon seed oil varies according on the type of watermelon and the extraction technique. No matter the kind, linoleic acid is the most prevalent fatty acid in watermelon seed oil. Furthermore, a number of watermelon seed oil bioactivities, such as antibacterial, cardioprotective, anti-inflammatory, and antioxidant properties, have been documented.

Quality Inspection of the Extract

Organoleptic, drying shrinkage, specific gravity, water content, total ash and acid insoluble ash, solvent residues, pesticide residues, heavy metal contaminations, and microbiological contaminations (total plate count and total yeast mould) are among the non-specific criteria examined in these exams. Additionally, particular characteristics include total flavonoid content as determined by spectrophotometric technique and phytochemical screening (alkaloids, saponins, tannins, phenolics, flavonoids, triterpenoids, steroids, glycosides, essential oils, quinones, and coumarin). [8]

Antioxidant activity tests by DPPH method

The stable DPPH radical was released to investigate antioxidant activity. Maximum absorption of DPPH in its radical state is observed at λ 515 nm. One millilitre of 0.4 mM DPPH (15.8 mg DPPH in 100 millilitres of methanol) and different amounts of test solution dissolved in methanol are included in the mixed reaction (5 millilitres). Using a UVV is spectrophotometer, absorbance was measured at λ 515 nm following a 30-minute incubation period at 37°C in a dark environment. Greater restriction of free radical scavenging (% inhibition) is shown by lower absorbance. Finding the IC50 value by using linear regression to the relationship between concentration and percent inhibition, with the percent inhibition set to 50.

Manufacturing process of Antioxidant Lotion Dosage Form

Melted cera alba is added to a glass beaker filled with paraffin liquid and heated to between 40 and 60 degrees Celsius. The mixture is then stirred at a speed of about 700 revolutions per minute. Next, incorporate glyceryl monostearate, tween 80, glycerin, extracts combined with nipagin and nipasol, water, and perfumes such as perfume. the extraction process, whole dried seeds were pulverised to maximise surface area. A light-yellow, Watermelon seeds were first dried at 60°C to eliminate water before the oil was extracted. The dried seeds were made up of kernels and exterior seed peels, and they were about 5 mm in size. To maximise odourless oil was the end result of oil extraction. Watermelon outer peels were first dried at 60°C and then crushed to remove lipids. A dark green, soft-solid wax was produced after solvent extraction and evaporation.

The benefits of Banana Peel For face are listed below

1) Treats Dark Circles

If you have raccoon eyes frequently, banana peels are a good choice. A tiny fraction of a peel placed beneath your eyes instantly cools, brightens, and hydrates the skin, giving it the youthful boost it needs to seem healthy.

2) Irritated Skin

Many people skincare problems include inflammation and irritation. The vitamin C and histamine in banana peels neutralize the stinging sensation and soothe the skin. It also acts as a natural moisturizer and reduces inflammation.

3) Acne

Banana peels are a great remedy for controlling oily and acne-prone skin. Limiting excess sebum production is ideal as it reduces the risk of clogged pores and helps prevent breakouts.

4) Boosts Elasticity

Antioxidants and vitamin C, which are rich in banana peels, assist to keep skin supple and minimise the appearance of fine lines and wrinkles. In addition, it eliminates dark spots and leaves the skin looking younger and more uniform.[9]

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Benefits of Watermelon Rind for skin are listed below

1). Moisturises the Skin

Your skin is greatly nourished and hydrated by the water content of watermelon. For optimal effects, you can either eat watermelons or just apply watermelon juice or slices on your skin.

2). Assures Equitable Skin Tone

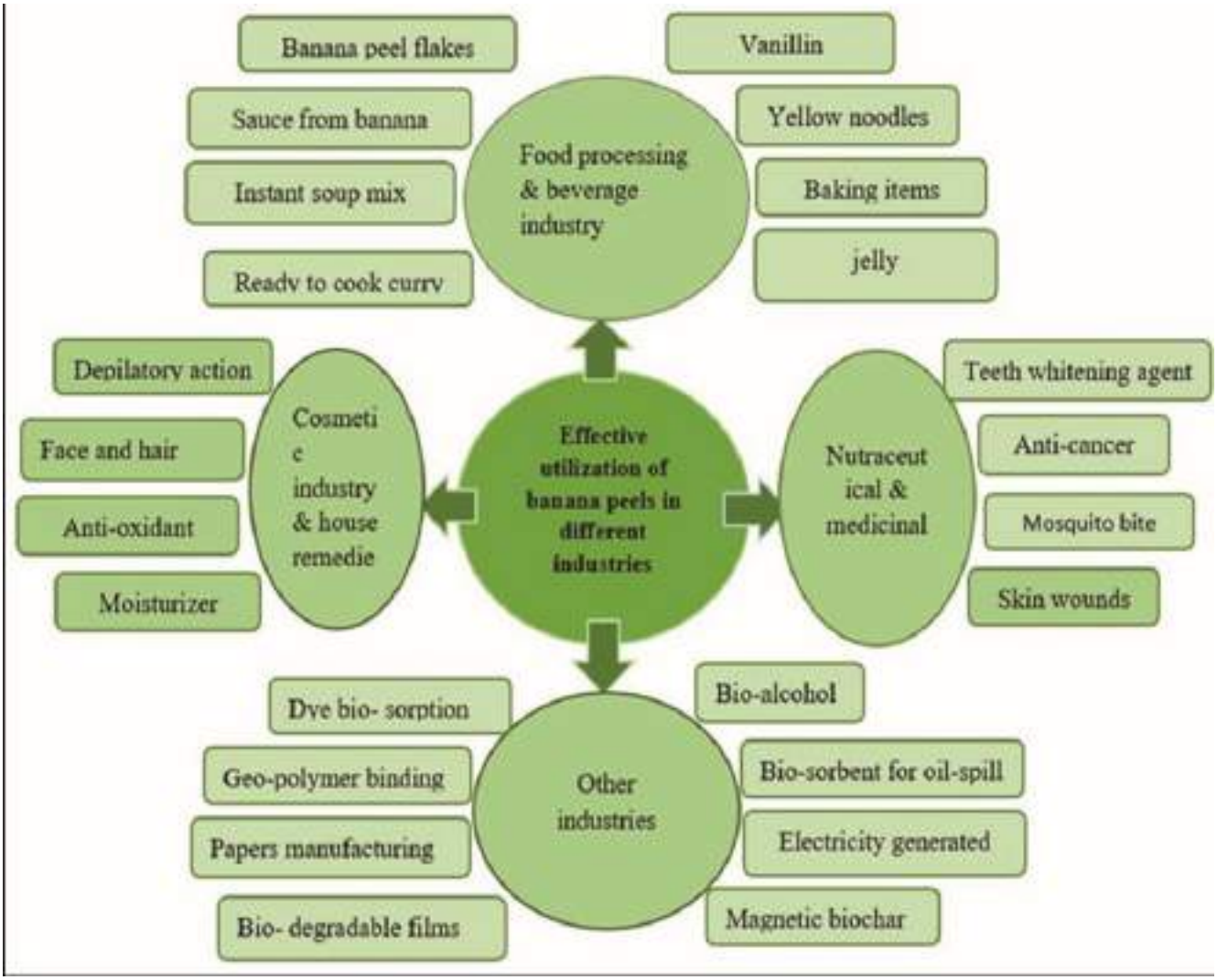
Uneven skin tone can be eliminated and skin nourishment enhanced by the antioxidants and vitamins found in watermelon.

3). Enhances Skin Brightness

Vitamin C from watermelon helps maintain healthy skin by brightening your complexion. It helps prevent tanning, giving you skin that looks young and radiant.

4). Calms the Skin

Cooling qualities are found in watermelon. It aids in reducing redness and inflammation. Watermelon is a great way to relieve skin irritation and reduce inflammation for those with sensitive skin.



CONCLUSION

As a biosorbent for dye removal, banana peel extract has found effective applications in the food processing, beverage, pharmaceutical, and agricultural sectors. The bioactive chemicals found in banana peels vary depending on the variety and concentration. Banana peels are employed in accordance with the needs and objectives of the industry. Banana peels had few applications in antiquity. Particularly in the states of Tamil Nadu and Kerala, it was utilised as peel curry, cattle feed, and organic fertiliser. However, banana peels are

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currently utilised for fibre in a variety of industries, including the textile sector. It is still utilised in the automotive industry today, particularly for designing the interior of new vehicles. When made into lotion, the highest antioxidant activity banana peel extract significantly reduces antioxidant activity; however, when mixed with watermelon rind extract, antioxidant activity is improved. [10]

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AN ELABORATIVE REVIEW ON BAMBUSA VULGARIS

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ABSTRACT

In addition to being high in nutraceuticals like phenols and phytosterols, Bambusa vulgaris s are also high in protein, fibre, vitamins, and minerals. Historically utilised in pharmaceuticals, Bambusa vulgaris s have been linked to a number of health advantages, including hypolipidemia, prebiotics, and anti-diabetic effects.

Packed into 121 genera, these plants make up a sizable subfamily of the grasses (Poaceae: Bambusoideae), with approximately 1662 species. Bamboos come in a wide variety of functional forms that are found in many different biogeographic locations. These forms include huge tropical woody species that may grow up to 20 meters in height and miniature herbaceous species found in temperate settings. These species, which naturally occur on all continents with the exception of Europe can adapt to and multiply in hostile settings, such as the humid, chilly summits of mountains as well as the dry, warm ones. A significant contributor to the diversity of South American forests is bamboo. In the New World, Brazil is the nation with the highest diversity of native bamboo species . This indicates that 65% of known bamboo species and 89% of genera

Bambusa Vulgaris are considered to be among the most precious, readily obtainable, and significant renewable forest resources. These plants are members of the Bambusoideae subfamily of the grass family Poaceae, which includes roughly 25% of all plants on Earth. With their distribution throughout 116 taxa, bamboos are thought to have a diversity of about 1400 species worldwide. In Southeast Asia, bamboo species have long been utilised as building blocks for the production of paper, furniture, boats, bicycles, textiles, musical instruments and food. Their leaves are also used as a wrapping material to keep food fresh for a longer period of time. The physiologically active substances that these species acquire, such as polyphenols and other secondary plant metabolites, may help to explain why bamboo leaves are used in traditional Asian medicine to treat conditions like hypertension, arteriosclerosis, cardiovascular disease, and some types of cancer. Bamboo extracts may also contain physiologically active peptides and polysaccharides in addition to the typical secondary metabolites; these compounds' activity and potential synergy with other metabolites require additional research. The majority of research published in the literature focusses on Asian bamboo species; little is known about the potential of Southern American bamboo species.

KEYWORDS:- *Bambusa vulgaris, Carbohydrates, Protines,Polyphenols,*

INTRODUCTION

Bambusa Vulgaris can become extremely dominant species after opening in a natural or anthropogenic origin, and they have a huge ecological amplitude in response to canopy changes. Furthermore, they grow extremely quickly from the base of the stem to the top of the plant . As of right now, bamboo species are thought to be among the most accessible forest resources. Bamboos are considered one of the most significant renewable resources since they account for 20–25% of the total biomass in tropical and subtropical regions . Bamboo is regarded as a quick absorber of atmospheric carbon dioxide and possesses mechanical and physical qualities that allow it to be utilised in the production of goods typically made from replanted or native wood, such as building materials, furniture, and agricultural cables.

B. vulgaris is an erect, evergreen, clump-forming bamboo that reaches heights of 15 to 20 meters (Figure 1). It grows in loose, thorn-free clumps with dark green leaves and lemon-yellow stems that are mostly green striped. The stems are tough, not straight or easily split, stiff in nature, and have thick walls with narrow lanceolate leaves. The densely tufted stems are 4 to 10 cm thick and reach heights of 10 to 20 meters. The trunk can be flexible (alternately bent in various directions) or straight, drooping at the ends. The walls of the trunk are quite thick, and nodes grew marginally. The internodal segment is 20 to 45 cm. There may be sprouting of a few branches between the middle trunk nodes to the top.

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Image: Bambusa Vulgaris

Bionomial Classification

Kingdom: Plantae
Clade: Tracheophytes
Order: Poales
Family: Poaceae
Genus: Bambusa
Species: *B. vulgaris*
Binomial name: *Bambusa vulgaris.*
Synonym: *Bambusa auriculata, Gigantochloa auriculata, B. striata*

Phytoconstituents present in B. vulgaris

The most plentiful source of pharmacological intermediates, modern pharmaceuticals, nutraceuticals, food supplements, folk cures, and chemical entities for synthesised drugs is plants. Plants are able to carry out essential biological processes and defend themselves against herbivorous animals, fungus, and insects by synthesising a vast array of chemical compounds. A variety of medicines with high activity profiles were produced by extracting and characterising several active phytocompounds from plants . Many plant components and extracts have the ability to scavenge free radicals or serve as antioxidants . The primary and secondary metabolites of these phytochemicals are distinguished. To ascertain whether B. vulgaris leaf samples were safe to eat, a phytochemical analysis was performed on both the wet and dry ethanol-extracted leaf samples.

It was shown that all of the leaf extract included cyanogenic glycoside, general glycoside, coumarin, polyphenol, and flavonoids. There were no traces of anthraquinone, carotenoid, triterpenoid, steroid, or anthracene glycoside in any of the species . Certain bamboo species are prized for their health advantages not just from their leaves and stems but also from their shoots, which have a high protein, carbohydrate, vitamin, fibre, and mineral content together with a very low fat level.

1. Carbohydrates

   In terms of total carbohydrates, bambusa vulgaris comprised polysaccharides, oligosaccharides, and monosaccharides. The primary polysaccharides found in bambusa vulgaris are starch, cellulose, and hemicellulose, with a small amount of more complicated minor polysaccharides such as glycoproteins. It was discovered that the three main oligosaccharides in bambusa vulgaris were sucrose, arabinoxylan trisaccharide, tetrasaccharide, and xyloglucan disaccharide. Bambusa vulgaris are rich in dietary fibre that contains antioxidants. Fructose and glucose are the monosaccharides that are typically present in bambusa vulgaris. Common species of just emerging juvenile bamboo shoots typically have a carbohydrate content ranging from 2.0 g/100 g to 9.94 g/100 g .

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2. Minerals
   Currently available studies indicate that bambusa vulgaris are an excellent source of macro and microelements. The primary microelements are cobalt (Co), copper (Cu), nickel (Ni), manganese (Mn), selenium (Se), iron (Fe), and zinc (Zn), whereas the primary macroelements are potassium (K), phosphorus (P), sodium (Na), calcium (Ca), and magnesium (Mg). Potassium was the most common macroelement in bambusa vulgaris, according to the majority of research, followed by phosphorus and magnesium.

3. Vitamin A
   Most vitamin studies have focused on two specific vitamins: ascorbic acid (vitamin C) and tocopherol (vitamin E). Both vitamins are closely related to the body's capacity to produce antioxidants in vivo, but vitamin E strengthens the immune system when combined with vitamin C. As is also the case with other common vegetables, fresh bambusa vulgaris contain far more vitamin C than vitamin E. Furthermore, in some areas, fresh bambusa vulgaris are a respectable source of Î²-carotene and B-group vitamins. The amounts of both vitamins decreased significantly with the age of the shoots. Additionally, the amounts of vitamin C varied to a variable extent depending on the growth of bamboo shoots' altitude and distinct parts.

4. Flavonids
   Flavonoids such as orientin, isoorientin, isovitexin, vitexin, and tricin are found in bamboo shoots and leaves . The majority of flavonoids found in bamboo tissues, including shoots, sheaths, and leaves, were insoluble forms of free aglycones or flavonoid ligands.

5. Phenolic Compound
   Bambusa vulgaris contained phenols that were primarily made up of flavonoids and phenolic acids. Bambusa vulgaris have been found to contain the following phenolic acids: protocatechuic acid, p-hydroxybenzoic acid, catechin, caffeic acid, chlorogenic acid, syringic acid, p-coumaric acid, ferulic acid, gallic acid, and vanillic acid . Protocatechuic acid, p-hydroxybenzoic acid, and syringic acid were the three most prevalent substances among them . There have been reports of fifteen phenolic acids, including 3-O-caffeolyshikimic acid, chlorogenic acid, p-coumaric acid, 3-p-coumaroylquinic acid, 5-p-coumaroylquinic acid, cryptochlorogenic acid, 1,3- dicaffeoyl quinic acid, 3,5-dicaffeoyl quinic acid, ferulic acid, 3-O-feruloylquinic acid, 5-O-ferul.

6. Glycocides
   The majority of edible species of bambusa vulgaris have a significant quantity of cyanogen glycoside, with the shoot tip having the highest concentration. Cyanogenic glycosides have been reported in B. vulgaris. The cyanogen glycoside taxiphyllin is found in bambusa vulgaris at different levels (23-26). The Î²-glycosidase, which is produced in damaged bamboo shoot tissues, reacts with taxiphyllin to form dangerous hydrogen cyanide, whose concentration shouldn't be higher than what is toxic to humans.

Traditional Uses

In many Asian nations, bamboo is closely associated with people's cultural, social, and economic circumstances. It is the multipurpose, fastest-growing woody plant with a wide range of commercial and domestic use. Its application is not limited to substituting wood in construction, furnishings, flooring, and scaffolding; in China and Southeast Asia, it has long been used as a food and medicinal source. Medicine is made from the bamboo plant's rhizome, culm, bark shavings, shoots, leaves, roots, and seeds. Bamboo is essential to the food, pharmaceutical, and cosmeceutical industries and is currently garnering interest on a global basis for its nutritional and therapeutic possibilities. Bamboo leaves and shoots have great therapeutic potential and can be used to organically heal ailments.

Bamboo has been an essential ingredient of traditional Asian medicines for a long time, especially Chinese and Indian (Ayurvedic) medicines. Bamboo was first used medicinally in India about 10,000 years ago. It was used to make a health tonic called Chyawanprash, which included bamboo manna among other plants, and was meant to encourage youth, beauty, and longevity. Due to its potent anti-stress and anti-aging properties, Chyawanprash has become well-known globally. Ayurveda, the traditional Indian medical system, recommends using bamboo and its products, such as Tabasheer, Banslochan, and Sitopaladi Churna, to treat a range of ailments. It has reportedly been used traditionally as an astringent, emmanogogue, and abortifacient in Tanzania, Brazil, India, and Pakistan.

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Therapeutic Uses

Rheumatism is treated with the stems.
The shoots are used to cure malaria and abscesses.
The bark is emmenagogue and astringent.
The leaves are used to cure malaria and cardiac issues.
To treat fevers, they are cooked and added to a bath. Women use a decoction of cooked leaves as a "clean-out" during dilatation and curettage, as well as to help facilitate the expulsion of the afterbirth.When used to cure fevers, the cooked leaves are made into a hot tea that causes copious sweating.Fever and haematuria can be treated with the sap.

Taxonomy

Due to the presence of bracts, indeterminate inflorescences, pseudospikelets (units of inflorescence or flower clusters and glumes or leaf-like structures in woody bamboos that are similar to spikelets or clumps of grass), three lodicules (a tiny scale-like structure found at the bottom of a floret or clump of grass flowers, found between lemma, the lowest part of spikelets, and sexual organs of the flower), six stamens, and three stigmas, the bambusoid taxa have long been considered the most "primitive" grasses.Some of the world's fastest-growing plants are bamboos.

The clumping bamboo tribe Bambuseae, of which B. vulgaris is a species, is primarily found in tropical and subtropical regions of Asia, particularly in the wet tropics. Bambusa is a vast genus. In clumping bamboos, the pachymorph (sympodial or superposed in a form that mimics a single axis) rhizome system extends just a small distance horizontally every year.Depending on the species, the emerging shoots form either an open or tight habit (group); common bamboo produces open groups. All clumping species are not regarded as invasive, regardless of how open their clumping behaviour .Only at the very tip of the rhizome may new culms develop.The Bambuseae subfamily of perennial evergreens, which includes the Bambusoideae subfamily, is distinguished by having three stigmata and three like bheviour.

CONCLUSION

Bambusa Vulgaris is still a plant group whose therapeutic qualities are being researched, despite the fact that Traditional Chinese Medicine has employed it for generations. The most common species in Asian nations—China, Korea, Japan, and others—have previously had studies done on their biological characteristics and chemical makeup. On the other hand, not much has been done to access the therapeutic benefits of bamboo in the countries of Southern America, where there is a great diversity of bamboo. Many species have demonstrated significant antioxidant activity, indicating that they may be used to treat a variety of illnesses, including anti-inflammatory, anticancer, and other conditions involving oxidative processes. Furthermore, bambusa Vulgaris extracts may include physiologically active peptides and polysaccharides in addition to the typical secondary metabolites. These macromolecules have the potential to have a variety of biological benefits when mixed with polyphenols and other metabolites. These effects could include anti-aging, anti-fatigue, anti-free radical, antibacterial, and antiviral properties. They could also be used as a useful dietary supplement, cosmetic ingredient, or food additive.

For millennia, people have utilised bamboo as a food source and a remedy for a range of ailments. It has a major impact on people's socioeconomic welfare. Several studies have assessed the plant's potential medicinal value. Beyond its use in food and crafts, however, more thorough research on bamboo is still required. Before bamboo is widely employed in a variety of therapeutic treatments, its ethnopharmacological uses need to be supported by significant academic study. They also have a large potential for use as important health foods because of their high level of healthy proteins, amino acids, carbohydrates, and other critical minerals and vitamins, together with their incredibly low fat content.

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PHARMACOLOGICAL ACTION OF GARLIC

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ABSTRACT
Around the world, garlic (Allium sativum L.) is a bulbous herb that is utilized as a food, spice, and medicinal. The traditional knowledge that has been passed down from generation to generation informs its medical application. These days, scientists from a variety of fields are focusing their research on learning more about how garlic affects human health. Researchers' interest in garlic has been sparked by the need to find a medication with a wide therapeutic range and low toxicity, especially among medical professionals. According to recent research, garlic extract exhibits antimicrobial action against a wide variety of virus, fungus, and bacteria types. Many writers have praised the benefit of garlic in reducing cardiovascular disease. Studies on the chemical components of garlic have been conducted to treat hypertension, hyperlipidemia, and platelet aggregation.Many disorders, including antidiabetic, antioxidant, anti-inflammatory, hepatoprotective, antihelmentic, antibacterial, antiviral, antifungal, and wound healing, have been treated using garlic and its constituents. Alzheimer's disease, cancer, cardiovascular disease (including atherosclerosis, hypertension, thrombosis, and hyperlipidemias), dermatological conditions, stress, and infections are among the illnesses that garlic's therapeutic properties may help reduce. This article's goal is to provide an overview of the pharmacological properties, traditional use, and active ingredients of garlic. It may also be utilized as a likely natural source for the development of novel medications.
KEYWORDS: *Garlic(Allium Sativum L.), anti-inflammatory, antihelmintic, novel medications, thrombosis.*

INTRODUCTION

Garlic is one of the most ancient and significant herbs in the world, having been consumed and used by people for a very long time. It is native to northeastern Iran and Central Asia.. Garlic's therapeutic properties have reportedly been documented on the walls of ancient temples, and early Egyptians are reported to have employed it to treat diarrhea. Garlic contains a variety of phytochemicals, including organic sulfides, phenolic compounds, saponins, and polysaccharides, which are linked to numerous health benefits. It is used as a medicine to treat a number of common illnesses, including the common cold, the flu, snakebite, and hypertension.[1] Garlic's numerous therapeutic properties are attributed to its elevated content of sulfur compounds, including diallyl disulphide, S-allylcysteine, diallyl trisulfide, and allicin. It can be consumed raw, as fresh leaves or dried cloves, or processed into garlic oil, garlic extracts, and garlic powder, with the chemical makeup and amount of bioactive components varying depending on the form. Garlic was utilized as a medicine by the Babylonians, Egyptians, Phoenicians, Greeks, and Romans to treat intestinal problems, skin conditions, bacterial infections, wounds, and tumors. Garlic has been used to treat epidemic infections and amoebic dysentery before the advent of antibiotics.[2]

Figure No. 1

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Traditional Uses of Garlic

Due of its strong flavor, it is frequently used as a condiment or spice worldwide.
Garlic's pungent taste, lachrymatory properties, and spicy scent are caused by organosulfur compounds such diallyldisulfid and allicin. Foods taste better and are easier to digest when garlic is added. Both fresh and dried garlic are used as spices in the culinary business. According to Ahmad (1996), it is dehydrated to create a variety of products, including flakes, slices, and powders. [3]

Therapeutic Uses of Garlic

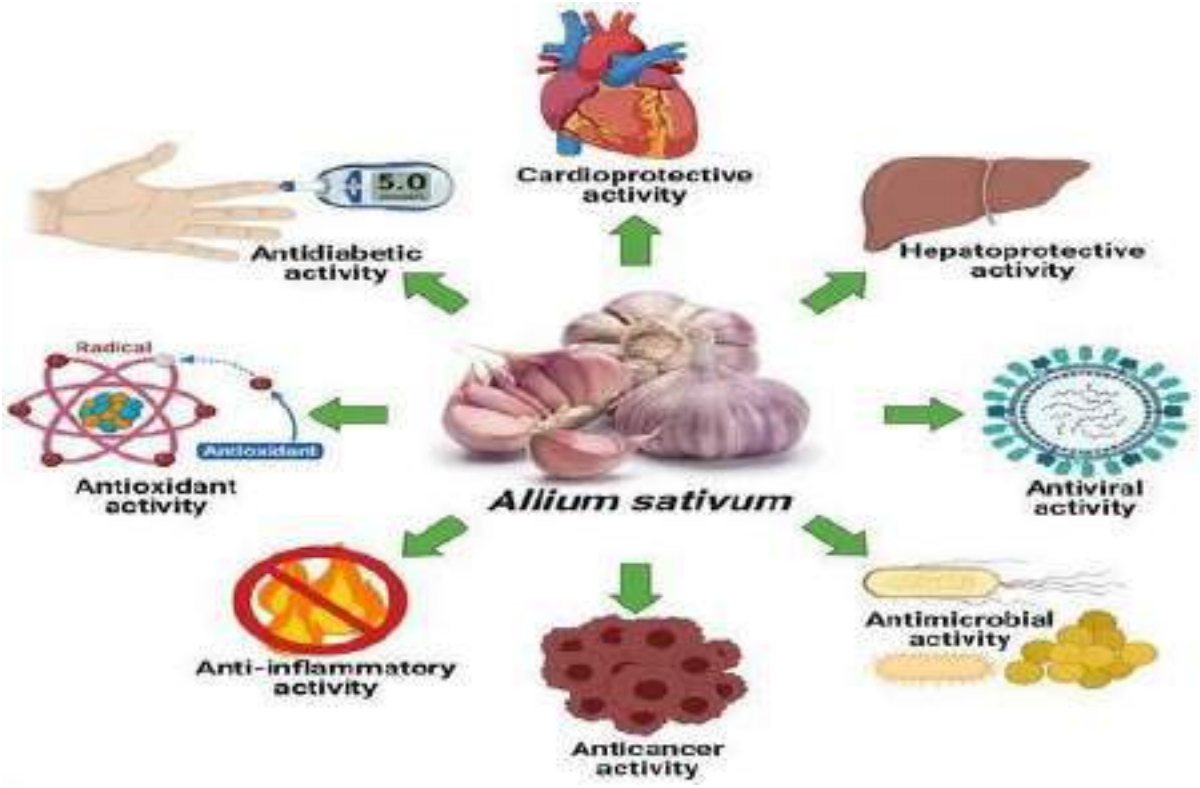

Figure no. 2

Nutritive Value of garlic

Table no. 1 :- Nutritive value of Garlic

Substance	Amount Found/100g	Substance	Amount Found /100g
Water	58.57%	Vitamin B6	1.235 mg
Carbohydrate	33.05 g	Vitamin C	31.2 mg
Sugars	1.00 g	Calcium	180 mg
Energy	149 kcl	Vitamin B9	1.235 mg
Dietary fiber	2.2g	Iron	1.6 mg
Protein	6.39 g	Phosphorus	152 mg
Fat	0.5 g	Magnesium	25 mg
Niacin	0.7 mg	Magnesium	1.672
Thiamine	0.2 mg	Sodium	17 mg

Pharmacological Effects of Garlic

Anticancer

A primary area of research and public health policy concern has been the relationship between nutrition and food and cancer risk. The etiology and prevention of cancer are significantly influenced by diet. It's interesting to note that dietary changes can significantly lower the incidence of cancer, according to numerous research. To gather enough evidence of a causal link between

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dietary alteration and cancer, many epidemiological designs have been used. This presents the opportunity to start primary and secondary preventive strategies for cancer control and prevention. Cancer is a multifaceted illness marked by aberrant cell proliferation and tissue invasion by neighboring cells. Numerous signaling pathways that are dysregulated are linked to the start, growth, and development of this illness. The major signaling proteins for different aspects of cell growth and survival include extracellular signal-related kinase (ERK), phosphatidylinositol 3kinase (PI3K), protein kinase B (commonly known as Akt), and mitogen-activated protein kinase (MAPK).[4]

Anti-Inflammatory

Because IL-10 dysregulation and decreased IL-12 synthesis occur in inflammatory bowel disease (IBD), the anti-inflammatory activity of garlic extract inhibits the production of IFN- by preventing IL-12 from attaching to its receptor on T and NK cells. Chronic hyperproduction of NFkB and/or COX or LOX results in excess inflammation and is a contributing factor to chronic pro-inflammatory disorders such diabetes, cardiovascular disease, and other conditions . Additionally, LOXproduced messengers have the ability to either promote or inhibit programmed cell death. Cancer can result from insufficient cell death, whereas excessive cell death plays a role in conditions like neurological diseases.[5] It has been observed that phytochemicals associated to garlic and garlic extracts have antiinflammatory properties. According to a study, garlic extracts significantly reduced the damage and inflammation to the liver brought on by Eimeria papillate infections. According to observations made by Hobauer et al. and Gu et al. garlic's anti-inflammatory properties result from its ability to prevent neutrophilic granulocytes from emigrating into epithelia. The anti-inflammatory properties of aged black garlic (ABG) may be attributed to its strong antioxidant activity. Tumor necrosis factor-α (TNF-α)-induced NF-κB activation in human umbilical vein endothelial cells is decreased by the ABG chloroform extract.[6]

Antifungal

Significant antifungal activity was found in numerous in vitro and in vivo investigations.[7] The interesting herb garlic (Allium sativum) is said to have several uses, from repelling vampires to treating fungus infections, which has just now been documented. Infections by fungi are becoming a significant component of contemporary infectious illness treatment. The increased use of immunosuppressive and cancer chemotherapeutic drugs, the creation and use of broader-spectrum antibiotics in recent times, or the longer longevity of immunocompromised people could all be contributing factors to the ubiquity of fungi as pathogens. Extracts of A. sativum are frequently utilized in the People's commercial system to treat patients with systemic fungal diseases. Researchers discovered evidence in favor of using A. sativum to treat cryptococcal meningitis.[8]

Antidiabetic

The hallmark of diabetes mellitus, a complicated metabolic illness, is hyperglycemia brought on by deficiencies in either insulin action or secretion, or both. Anomalous lipid, protein, and carbohydrate metabolism is another important risk factor for diabetes and its sequelae. Studies have demonstrated the significant impact of garlic on blood glucose regulation and the reduction of problems related to diabetes. Numerous research studies have demonstrated the effectiveness of garlic in lowering blood glucose levels in both human and animal models of type 1 and type 2 diabetes.[9]We designed a study to assess the hypoglycemic effects of garlic in patients with type 2 diabetes mellitus in comparison with the standard antidiabetic agent metformin and placebo because prior clinical trials have cast doubt on the proposed hypoglycemic effects of garlic and there is no prior trial showing the effects or benefits of garlic at different doses on blood glucose in patients with diabetes. We also took into account the high incidence of diabetes in Pakistan and the general public's widely held belief that garlic has beneficial effects on various cardiovascular risk factors.[10]

Antioxidant

Antioxidant phytochemicals found in aged garlic extract (AGE), which is made from fresh garlic extracts kept for an extended length of time, shield the garlic from oxidative damage. Garlic extracts age over a period of up to 20 months through the modification of unstable molecules with antioxidant activity, like allicin, and the increase of stable and highly bioavailable water-soluble organosulfur compounds, like S-allylcysteine and S-allylmercaptocysteine, which give the extract antioxidant properties. According to reports, disorders where ROS are thought to be the primary cause can be effectively treated with garlic. The risk of atherosclerosis, cardiovascular disease, and cerebrovascular illness is raised by oxidative alteration of low-density lipoprotein (LDL). Oxidized low-density lipoprotein (LDL) develops novel antigenic characteristics that the host immune system identifies as "foreign". Thus, oxidized low-density lipoprotein (LDL) triggers multiple novel biological reactions that lead to artery thickening and narrowing, the primary process of atherosclerosis. Borek and Amagase have referenced multiple studies that show

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garlic's antioxidant qualities. In rat heart, liver, and kidney, raw garlic homogenate increased endogenous antioxidants and decreased basal lipid peroxidation in a dose-dependent manner.[11]

DISCUSSION

The king of medicinal plants, garlic, is incredibly beneficial to poultry. The performance of the birds has improved when garlic is added to poultry feed, which eventually increases the potential for production. Garlic also lowers the amount of harmful germs, including Salmonella, Clostridium, E. coli, and Campylobacter. Benefits to the consumer's immunity are evident. Therefore, it can be utilized to successfully substitute the growth promoter that is antibioticbased in poultry feed. Despite the abundance of studies in this field, rules for the use of garlic in chicken feed still need to be established. More study is required on this economically friendly supplement to achieve this goal.

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AN OVERVIEW ON TEA TREE OIL (MELALEUCA ALTERNIFOLIA) COMPOSITION, THERAPEUTIC EFFECTS, APPLICATION, TOXICITY

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ABSTRACT
The anti-inflammatory, antibacterial, antiseptic, and antioxidant effects of tea tree oil (TTO), which is extracted from Melaleuca alternifolia, are among its well-known therapeutic qualities. Over 100 components, such as terpinen-4-ol, alpha-sabine, and cineole, contribute to its medicinal advantages, including antibacterial action against Staphylococcus aureus and immunological regulation. TTO has been used to treat acne, chronic gum infections, and bacterial/inflammatory problems. Concerns surrounding its safety and possible toxicity, particularly with regard to oral consumption and cutaneous irritation, underscore the need for additional research into its long-term consequences and hazards, even in light of its demonstrated efficacy. Independent research are needed to fully evaluate the health advantages and safety profile of TTO, despite its rare and moderate adverse responses.

KEYWORDS: *Melaleuca Alternifolia, Chemical Constituent, Anti-microbial, Antiinflammatory, Uses, Safety & toxicity.*

1. INTRODUCTION

The tea tree's essential oil is known for its anti-inflammatory, antibacterial, antiseptic, and antioxidant properties, making it widely used in medicine. (1)

Here's the simplified version of the scientific classification of tea tree oil

Kingdom: Plants; Order: Myrtales; a collection of plants that bloom
Family: Myrtaceae (the myrtle family of plants)
Genus: Melaleuca (a group of trees and shrubs)
Species: Melaleuca alternifolia (the specific plant used to make tea tree oil)
Binomial Name: Melaleuca alternifolia (the scientific name for this species)
Synonyms: Previously known as Melaleuca alinariifolia var. alternifolia, named by Maiden and Betche (these are just alternate scientific names used in the past).
This is the scientific way to describe the plant that tea tree oil comes from.[2]

Figure 1 Tea Tree Oil (Melaleuca alternifolia) [3,4]

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2.CHEMICAL COMPOSITION AND ACTIVE CONSTITUENTS OF TEA TREE OIL

Here are over 100 distinct components in tea tree oil. The main one, called terpinen-4-ol, gives it antibacterial properties. Its composition is regulated by international standards (ISO4730). (5) The chemical makeup and active ingredients of tea tree oil,(6) along with their roles, are shown in Table 1.

		Quantity	Responsibilities
Chemical Compostion	1. Terpinen-4-ol 2. Y-Terpinene 3. α-Teripene 4. 1,8-Cineole 5. Terpinolene 6. α-Terpineol 7. α-Pinene 8. Limonene 9. Sabinene	30-40% 20% 10% 15% 3-5% 3-5% 1-5% 1-2% Trace	Antimicrobial Properties Antioxidant Properties Antimicrobial Properties Antiseptic Properties Anti-oxidant Properties Anti-inflammatory Properties Antiseptic Properties Anti-oxidant Properties Enhance Antimicrobial Effect
Active Compound	Terpinen-4-ol 1,8-Cineole	-	Biologically Active Compound for Antimicrobial, Antifungal, Anti-inflammatory Properties. Benifical in Small Amount Because It Can Cause Skin Irritation
Other Constituent	P-cymene Monoterpenes	**2-10%** -	Contribute Antimicrobial Activity. Antimicrobial, Antiinflammatory Properties

Table 1 Chemical composition and active constituents of tea tree oil

3. ANTI-MICROBIAL ACTIVITY

Table 1 highlights that tea tree oil exhibits a wide range of antibacterial activities. It works well against both fungi and a wide variety of gram-positive and gram-negative bacteria.[7] Common pathogens have minimum inhibitory concentrations (MICs) of 0.5%-1%. The minimum inhibitory concentration (MIC) for mutans streptococci is less than 0.0125%, whereas oral-group streptococci are also below 0.05%. (8) Many essential oils have antibacterial effects due to active monoterpene components.[9]

Tea tree oil's antibacterial activities involve disrupting bacterial cell membranes and inhibiting respiration. Most investigations have focused on its efficiency against Staphylococcus aureus, which has significant antibacterial action. For a range of bacteria, including S. aureus, S. epidermidis, B. subtilis, B. cereus, Micrococcus luteus, Streptococcus, E. coli, Pseudomonas, and Proteus, tea tree oil exhibits MIC values ranging from 0.2% to 0.5% (v/v). It has been demonstrated that M. alternifolia oil had antibacterial qualities against Actinomyces v., Lactobacillus, Staphylococcus species, and E. coli.[10]

With inhibition zones varying from 5 to 10 mm, the essential oil of M. bracteata has demonstrated antibacterial activity against S. epidermidis, B. subtilis, S. aureus, and S. typhimurium. Additionally, it has a biostatic impact on strains of Serratia marcescens, Halobacterium violaceum, and Pseudomonas aeruginosa. At a concentration of 250 µg/mL, this oil reduced the growth of B. subtilis subsp. spizizenii, with an inhibition zone as large as 44 mm. These species' methyl eugenol and terpinen-4-ol have potent antifungal, antibacterial, and anti-nematode qualities.

4.ANTI-INFLAMMATORY & ANTI-OXIDANT EFFECT

- **Anti-Inflammatory**

The essential oil's main constituent was terpinen-4-ol. It is thought that this molecule, along with others like α-terpinene, γ-terpinene, and α-terpineol, is what gives the oil its anti-inflammatory properties. In experiments on mice with histamine-induced edema, the oil demonstrated anti-inflammatory properties. The external application of the oil to vulvovaginitis, particularly in cases of yeast infections like candidiasis, is also supported by a number of research.[11]

Tea tree oil's (TTO) anti-inflammatory qualities have been validated by numerous recent investigations. Research conducted in the last ten years has demonstrated that TTO affects a variety of immunological responses in both in vitro (in a lab setting) and in vivo (in real creatures). Terpinen-4-ol, α-terpineol, and 1,8-cineole are the main ingredients contained in TTO; however, only terpinen-4-ol was shown to lower the production of TNF-α, an inflammatory marker. When administered following a histamine injection,

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TTO and terpinene 4-ol have been demonstrated in mouse tests to reduce the skin swelling brought on by histamine. TTO also lessened erythema and cutaneous flare-ups in individuals brought on by nickel-induced contact sensitivity. Additional studies have shown that terpine-4-ol aids in controlling the fluid leakage and vasodilation linked to histamine-induced inflammation in people.[12]

Anti-Oxidant

There is limited research on the antioxidant properties of tea tree oil and its bioactive components. To better comprehend the potential health advantages of tea tree oil, further research is needed into the link between its antioxidant qualities and terpenic chemicals. Understanding the antioxidant properties of tea tree oil could increase its market value. Research indicates that aromatic and medicinal plants contain natural antioxidants that can reduce chronic diseases such as DNA damage, mutagenesis, and carcinogenesis, as well as limit pathogenic bacterial growth. These effects help inhibit free radical propagation in biological systems. Antioxidant capability is widely utilized to evaluate medicinal plants and their bioactive compounds.[13]

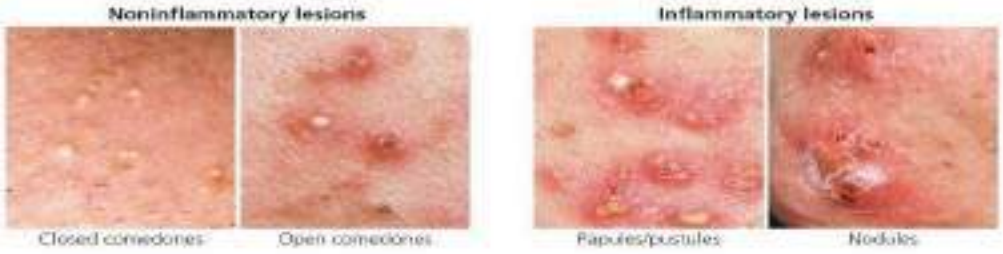
5.TREATMENT

A. Acne Treatment

Acne is a chronic skin condition caused by excessive oil production, abnormal cell shedding in hair follicles, irritation, and Propionibacterium acnes.[15] Tea tree oil, derived from the Melaleuca alternifolia tree, found in Australia, may aid in acne treatment when applied topically. It contains over 100 natural substances, primarily plant-based terpenes and alcohols. In 1990, a study of 124 individuals compared a 5% tea tree oil gel to a 5% benzyl peroxide gel for acne treatment. Despites taking longer to than benzoyl peroxide, tea tree oil effectively reduced acne patches within three months. Tea tree oil had lower rates of adverse effects such as dryness, irritation, itching, and burning (44% vs. 79% for benzoyl peroxide). Tea tree oil may cause allergic reactions and might be hazardous if consumed. Tea tree oil's breakdown can release monoterpenes, which can cause skin sensitivity or allergies. Despite this, using tea tree oil to the skin is generally safe. [14]

The European recommendations for managing acne categorize it into four major types:
1. Comedonal acne consists primarily of blackheads and whiteheads.
2. Mild to Moderate Papulopustular Acne: Symptoms include pimples and irritation.
3. Severe Papulopustular Acne and Moderate Nodular Acne: Inflamed pimples with larger, deeper nodules.
4. Severe Nodular and Conglobate Acne: Large, painful nodules with linked lumps.

Treatment recommendations vary depending on the type.[16]



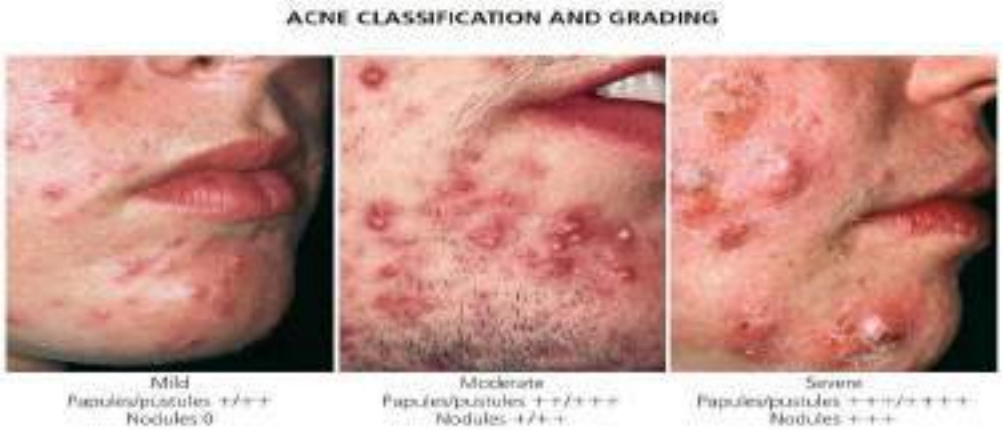


Figure 2 [17]

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B. Aromatherapy Uses

Tea tree (Melaleuca alternifolia) belongs to the Myrtaceae family and thrives in swampy environments. The leaves are needle-like, and the flowers can be yellow or purple. Tea trees are planted on plantations because of their commercial importance, particularly their essential oil. Terpinen-4-ol, the primary ingredient in this oil, has a pleasant, earthy fragrance and helps increase immunity. The oil contains alpha-sabine, which has antiviral, antibacterial, and antifungal properties, as well as cineole, which is antiseptic. [20,21,22,23]

Tea tree oil provides numerous advantages, including antibacterial, anti-inflammatory, antiviral, insect repellant, and immunological booster. Aromatherapy with oils like lemon, eucalyptus, lavender, and rosemary is commonly utilized to treat numerous health conditions. Tea tree oil is used to treat skin conditions such as herpes, acne, burns, bug bites, dandruff, and greasy skin. It can treat respiratory diseases such as coughs, bronchitis, asthma, and tuberculosis, as well as female conditions including vaginitis and cystitis. It can also treat colds, flu, fever, and chickenpox. [24,25] Tea tree oil has showed promise in treating herpes, according to studies and clinical trials.[26]

TTO is one of the most important oils often used in aromatherapy. The examples in the table are only for guidance. Use only under the supervision of a doctor or pharmacist who specializes in this area.[18]

Effect	Dose	Use
Acne	TTO 2-3 Drops	Use a cotton bud to hold it on Acne for15 sec, 2-3 time a day
Athlete's Foot	TTO 2-3 Drops	Hold on infected area for 15 sec & apply 3-4 times a day
Tooth Acne	TTO 3 Drops Mint Essential oil 3 drops	Make a mouthwash by adding 3 drops TTO & mint oil to half or full glass of water
Dandruff	TTO 80 Drops Cypress Essential oil 80 Drops	Mix With 200 ml of organic shampoo

Table 2

C. Potential Use in Oral Health

Herbal extracts and plant essential oils (EO) can effectively cure chronic gum illnesses such as gingivitis and periodontitis, which are caused by both bacteria and inflammation. These natural therapies are suitable for long-term everyday usage and do not impair a person's health. They are also less expensive and more readily available as over-the-counter products. Research is ongoing to develop herbal mouthwashes suitable for long-term use. Tea tree oil (TTO) from the Melaleuca alternifolia plant has been examined for its potential use in dentistry.[19]

6. SAFETY & TOXICOLOGY

While tea tree oil (TTO) is well-known for its antimicrobial and anti-inflammatory benefits, there has been less research on its safety and potential toxicity. The continued use of tea tree oil is mainly based on its apparent safe use over nearly 80 years, with reports suggesting that adverse effects are rare, mild, and typically go away on their own. However, more scientific evidence is needed, as much of the available information comes from company-sponsored studies rather than independent research. The risks of using tea tree oil, both when taken orally and applied to the skin, are briefly outlined below.[18]

Dermal Toxicity

Tea tree oil (TTO) can cause both irritation and allergic reactions. A study found a low level of irritation from undiluted TTO in 311 volunteers, while another study on 217 dermatology patients found no irritation with 10% TTO. This suggests that using lower concentrations of TTO can help avoid irritation, supporting the idea of using properly formulated products instead of pure oil. Some people may have allergic reactions to TTO, often caused by oxidation (when the oil is old or stored incorrectly). There's little evidence to support that a component called 1,8-cineole causes irritation. Tests on rabbits, guinea pigs, and humans, including those with previous reactions to TTO, didn't show irritation. In rare cases, applying undiluted TTO to animals, like cats, has caused serious side effects, including hypothermia and death, when a large amount was applied to their skin.[18]

Oral Toxicity

Tea tree oil (TTO) can be toxic if swallowed, as shown by studies in animals and reports of human poisoning. In rats, a dose of 1.9 to 2.6 ml per kg of body weight was lethal, and doses around 1.5 g per kg caused symptoms like tiredness and loss of coordination. There have been cases of both children and adults accidentally ingesting TTO, but in all of these cases, the people recovered with supportive careand there were no lasting effects. No human deaths from tea tree oil have been reported.[18]

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7. CONCLUSION

In conclusion, tea tree oil (TTO) demonstrates notable therapeutic potential, offering anti-inflammatory, antimicrobial, antiseptic, and antioxidant effects, especially for skin conditions and bacterial infections. Its active compounds, such as terpinen-4-ol, contribute to its effectiveness against pathogens like Staphylococcus aureus and its role in immune modulation. However, despite its benefits, concerns about dermal irritation and toxicity—particularly with ingestion— underscore the importance of further research. While adverse effects are typically mild, additional independent studies are needed to clarify TTO's long-term safety and health impact.

8. ACKNOWLEDGEMENT

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CANCER VACCINE THERAPY": A NOVEL APPROACH FOR CANCER PREVENTION AND TREATMENT

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ABSTRACT

Cancer vaccine therapy is a strategy that utilizes the body's immune system to both prevent and treat cancer. Preventive vaccines work by activating the immune system to identify and destroy cancer-causing infections, such as HPV, which is linked to cervical cancer. Therapeutic vaccines, however, focus on targeting and attacking existing cancer cells, helping the immune system recognize and combat tumors. This promising approach has the potential to complement conventional treatments, lower the risk of cancer recurrence, and improve the overall prognosis for patients. Cancer vaccines are an innovative and evolving field, offering new possibilities for both prevention and treatment, with the potential to work alongside traditional therapies like surgery, chemotherapy, and radiation. this review is based on introduction to some vaccines that are used to eliminate risk of cancer or to treat cancer

KEYWORDS- *tumor cells, foreign invader, cancer, immunotherapy, humanpapilloma virus, hepatitis B vaccine, BCG, Sipuleucel-T*

1. INTRODUCTION

One of the main causes of death in Western nations is cancer. The most common types are lung, breast, prostate, and colorectal cancer. However, as the population changes and new treatments emerge, cases of thyroid, liver, and pancreatic cancer are expected to rise significantly. Since the 1950s, the concept of a cancer vaccine has gone from a wild idea to a real possibility. Over time, it has been receiving the interest of many cancer researchers because of its growing potential. (4) Vaccines can significantly improve patient survival when used to prevent diseases, like traditional vaccines for infections. While preventing cancer before it starts (primary prevention) is still a long-term goal, vaccines for early detection (secondary prevention) and stopping cancer from coming back (tertiary prevention) are already being used in clinics with promising results. Over 100 years ago, Paul Ehrlich first suggested the idea of using the immune system to treat cancer by creating a vaccine with "weakened tumor cells." Although progress was slow for many years, things have changed a lot in the last decade. Following multiple unsuccessful attempts, cancer immunotherapy, particularly cancer vaccines got a big boost in 2010 with the approval of Provenge, a treatment for prostate cancer. (6) Anti-cancer vaccines can be grouped into two main types: therapeutic and preventive. Therapeutic vaccines help treat people who already have cancer, while preventive vaccines (like the HPV vaccine) stop cancer from developing. (5)

- **What Is Vaccine?**

Vaccines train your immune system to defend your body against foreign invaders or abnormal cells that pose a threat. there are to main types of cancer vaccines preventive and therapeutic vaccines (19)

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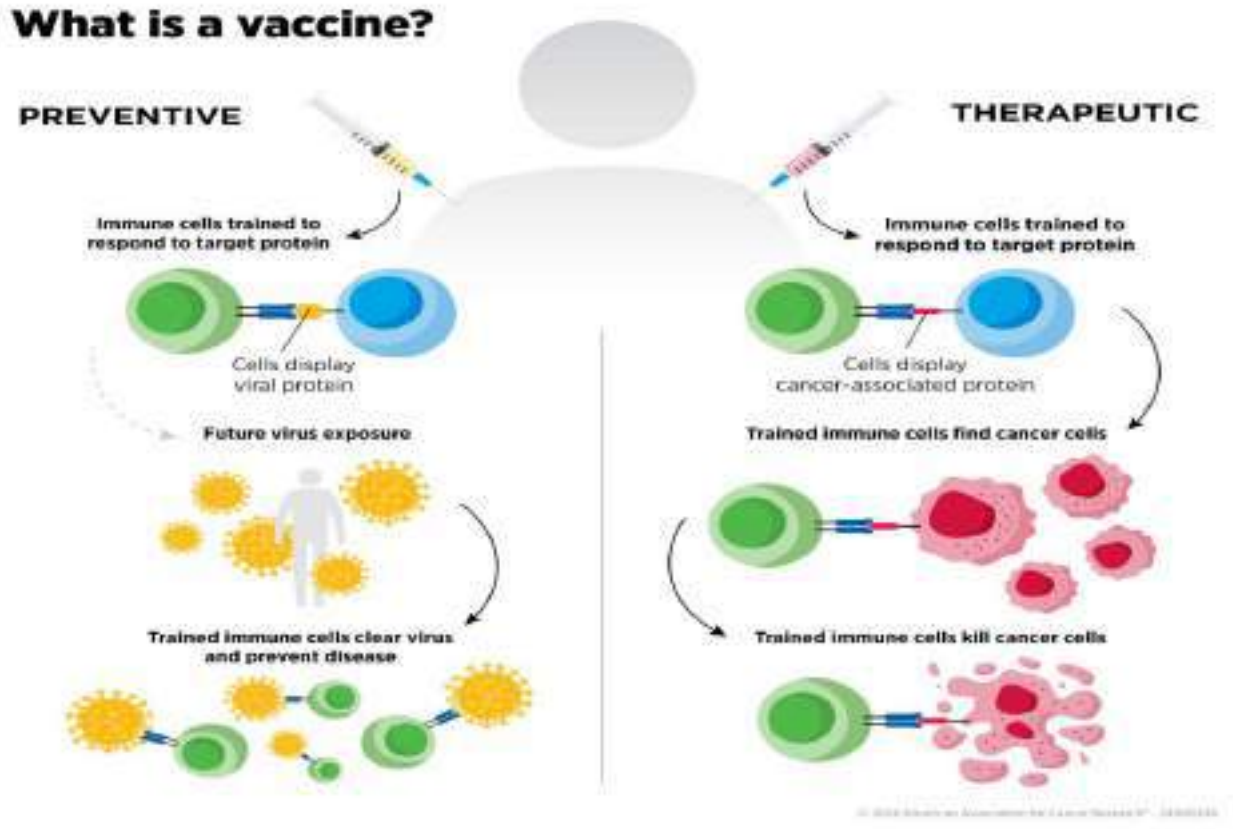

2. PREVENTIVE CANCER VACCINES

Cancer prevention focuses on reducing the number of people who get cancer and die from it. It tries to address cancer at every stage, from healthy cells to when cancer spreads in the body. Prevention is usually divided into three types: primary, secondary, and tertiary prevention (1)

Cancer Prevention	*Aim*	*Target*	*Immunological Example*
Primary	Avoiding Or Getting Rid of Things That Can Increase the Risk of Cancer.	Healthy Individual	Anti-HBV vaccine Anti-HP vaccine
Secondary	Detecting and Treating Disease Early	Peoples who have cancer but show no symptoms yet.	Anti-Her2 and MUC1 vaccine used in preneoplastic lesions
Tertiary	Preventing Relapse And metastatic	Peoples who have survived cancer but still have hidden tumours	Adjuvant monoclonal antibodies. Adjuvant Therapeutic vaccine

3. APPROVED PREVENTIVE CANCER VACCINES

A. Anti - Hepatits B Vaccines

Primary liver cancer, known as hepatocellular carcinoma (HCC), ranks among the most prevalent cancers globally. According to estimates, it comes as the third most common cause of cancer related death in men and the seventh in women. Approximately 70-80% of HCC cases are linked to hepatitis B virus (HBV) as a causative factor. (13)

Early cancer prevention vaccines focused on targeting viruses linked to cancer risk. One of the first successful vaccines in this field was designed to protect against Hepatitis B virus (HBV), a major contributor to chronic liver disease and a known risk factor for the liver cancer known as hepatocellular carcinoma (HCC). (2,3) For many years, the main approach to preventing cancer has focused on changing behaviors to avoid cancer-causing factors in the environment, like smoking, diet, sun exposure, and other

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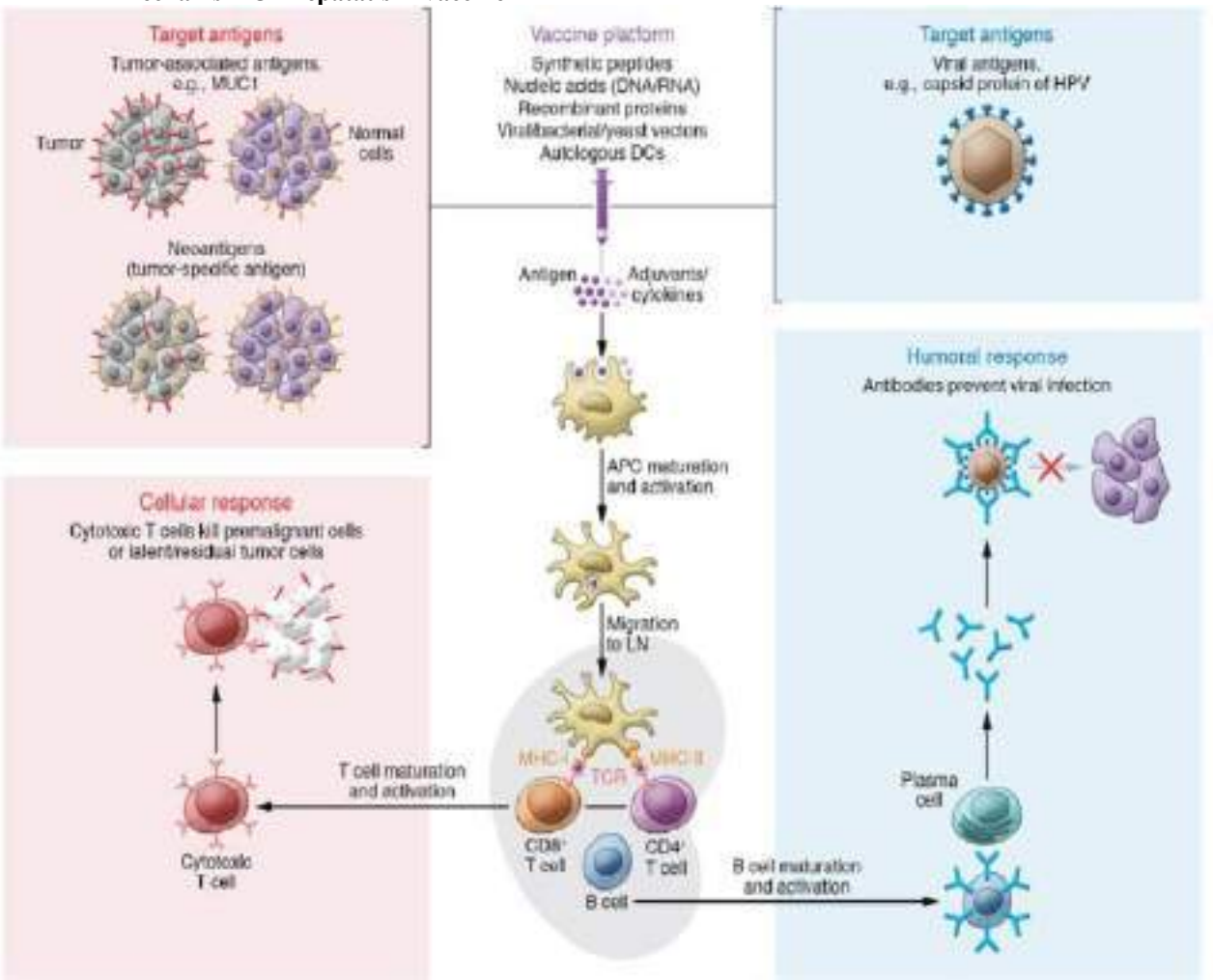
lifestyle choices. Public health efforts have helped lower people's exposure to these known cancer risks, but behavior-based prevention has its limitations, and treatments are still needed once cancer develops. Vaccines' remarkable effectiveness in preventing infectious diseases has inspired fresh ideas about using preventive vaccines to protect against certain types of cancer as well. The vaccination against Hepatitis B (HBV) has been available since the early 1980s, and the World Health Organization (WHO) recommends giving it to infants soon after birth. (9) Receiving three doses provides strong, long-lasting protection against long-term HBV infection. This vaccine was the first proven to lower the risk of liver cancer (hepatocellular carcinoma, or HCC) in people who received it (9) Taiwan was among the first countries to launch a national HBV vaccination program. They started by vaccinating infants born to mothers with HBV, and in 1984 expanded it to include all infants. Studies later showed that Taiwanese children who received the vaccine had much lower rates of liver cancer for up to 20 years after the program began (7,8)

- **Mechanism Of Hepatatis B Vaccine**



B. Human papilloma Virus Vaccine

Human papillomavirus (HPV) is a sexually transmitted virus linked to several types of cancer, including cervical, throat, anal, penile, and vulvar or vaginal cancers. (10) HPV infection causes several different cancers. Cervical cancer is the third most frequent cancer among women worldwide, primarily caused by HPV infection. Cervical cancer accounts for about 500,000 new cases and 250,000 deaths annually. (11) HPV vaccines have been available since 2006 and are recommended as preventive vaccines for both males and females starting at age 11, ideally before they become sexually active. This is due to the fact that vaccination is most effective prior to viral exposure. Three varieties of HPV vaccinations are available.

1. Cervarix - protects against HPV types 16 and 18.
2. Gardasil-4 - protects against HPV 6, 11, 16, and 18.
3. Gardasil-9 - is effective against HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. (12).

These vaccines are safe and very effective, especially in young people, where they create a strong, long-lasting immune response that provides protection well into adulthood. Clinical trials have shown that HPV vaccines offer high protection against HPV-related diseases. (12)

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4. THERAPEUTIC CANCER VACCINES

Immunotherapy is an effective treatment for cancer and can be used alongside surgery, chemotherapy, and radiation therapy. Therapeutic cancer vaccines, especially personalised ones, are a well-advanced field of immunotherapy. Unlike preventive vaccines, which are given to healthy people to prevent diseases like hepatitis B and human papillomavirus, therapeutic cancer vaccines work by using specific tumor antigens to boost the immune system of cancer patients, helping them to fight their cancer. (14)

- **General mechanism of Therapeutic Cancer Vaccines**

Therapeutic cancer vaccines aim to stimulate the immune system to kill tumour cells, target specific antigens, minimise adverse effects, and prevent autoimmune responses. (21) These vaccines must also establish a robust immune memory to counter future cancer cells, which is crucial for long-term treatment success (22) Cancer relapses, rather than primary tumors, are largely responsible for the high mortality rate in cancer (23)

Cancer vaccines enhance the body's immune system, both cellular and humoral, to combat cancer. These vaccinations usually increase the generation of CD8+ T-cells that are specific to cancer and are able to identify and eliminate cancer cells. (24) Cytotoxic T lymphocytes (CTLs) detect cancer antigens by binding to their T-cell receptor (TCR). Through TCR signaling pathways, such as the release of perforin or serine protease, or by upregulating molecules like CD95L or TRAIL, CTLs initiate cancer cell death. For effective action, CTLs are activated by tumor dendritic cells (DCs), specifically CD103+ migrating DCs, which are antigen-presenting cells (APCs) (29). These DCs prepare CTLs using three mechanisms: presenting cancer antigens on MHC-I, using co-stimulatory molecules (CD80/86 and CD28/152), and releasing cytokines like IL-12 and TNF-α. Both CTLs and CD4+ Th cells gain specific characteristics upon activation that enhance CTL effectiveness (30). Additionally, CD4+ Th cells are activated similarly to CD8+ T-cells, but the tumor antigen is presented on MHC-II instead of MHC-I. (25) CTLs use cytotoxic methods to release cytokines and induce cell death. Studies have shown that CTL production of IFN-γ and TNF-α is linked to reduced tumor growth and increased patient survival. Adopting a Th1 phenotype, characterised by the secretion of IFN-γ, TNF-α, and IL-2, leads to improved patient survival. Some studies suggest that combining the Th1 response with Th17 (characterized by IL-17 production) may be even more beneficial [70]. Since each T-cell has a unique TCR for a single antigen, responses that generate a broad range of antitumor T-cells are more effective. (25) The optimal immune response to vaccination may differ by cancer type. Cancer vaccines can also use antibody-mediated cytotoxicity to control cancer. Cancer cells with antibodies attached can be targeted for destruction through antibody-mediated cytotoxicity or phagocytosis. (26) In humoral immunotherapy, patients develop anticancer antibodies, which are recognised by innate immune cells such as natural killer cells, macrophages, and neutrophils, leading to cell death or phagocytosis. (27) Additionally, the activation of other innate immunity systems, such as T-cells, can enhance the adaptive immune response targeted by cancer vaccines. For example, innate lymphoid cells (ILCs) like NK cells or invariant NK T-cells (iNKT) support CTLs in controlling cancer cells. Cancer cells that inhibit T-cell identification by downregulating MHC-I or overstimulating NK cell receptors (e.g., NKG2D, 4-1BB) can nevertheless be destroyed by NK cells. (28) When iNKT cells activate, they release Th1 or Th2 cytokines and increase CD40L expression. iNKT cells also enhance adaptive immune responses by boosting DC activity, which contributes to improved outcomes in cancer treatment.

5. APPROVED THERAPEUTIC CANCER VACCINES

A. Bacillus Calmette- Guerin (BCG) vaccine

Bovis Mycobacterium Following 230 trials on the original disease-causing germ, M. bovis, scientists developed a type of bacteria known as Bacillus Calmette-Guérin (BCG). Over thirteen years, Albert Calmette and Camille Guérin worked on changing this germ until it became safe. In 1921, they showed that this new bacterium did not make animals sick and could protect them from tuberculosis. This discovery led to the large-scale production of the BCG vaccine, which is still the only vaccine available to prevent tuberculosis in people today. BCG may be a novel treatment option for certain cancer patients, according to studies being done at the same time on the use of other bacteria, such as Streptococcus pyogenes and Serratia marcescens, to treat cancer. (15) In order to stop the disease from progressing and recurring, BCG has been the standard treatment for individuals with high-risk non-muscle-invasive bladder cancer (NMIBCIn order to stimulate the immune system to fight cancer cells, the vaccine must be injected straight into the bladder. (16) BCG has been shown to be more effective than chemotherapy, especially for aggressive cancers and when used with reinduction and maintenance therapy. (17) In addition to avoiding infections, BCG has a 70–75% success rate for carcinoma-in-situ and a 50–60% success rate against tiny tumours. Generally, the positive effects of BCG last a long time, with about 70% of patients remaining in remission after five years. However, it's less clear how well BCG can help with advanced-stage cancers, as there haven't been enough strong studies to determine this. (18)

B. Sipuleucel -T(provengeu)

The core concept of immunotherapy is to stimulate the body's immune system to combat tumors. Sipuleucel-T provides this by the use of dendritic cells, Dendritic cells are the most effective antigen-presenting cells in the human body and play a crucial role in activating B- and T-lymphocytes, which help regulate the immune response. It was the first immunotherapy product to be approved by the US FDA. It is specifically approved for men with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer, as it has been shown to improve survival rates.

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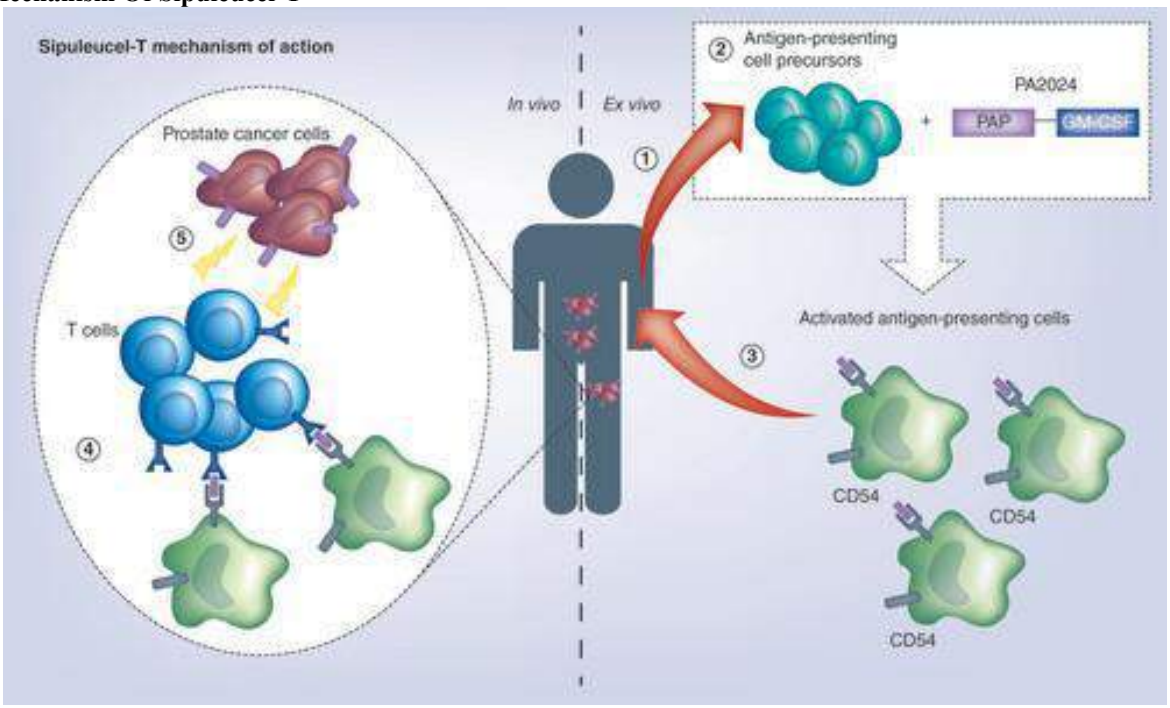
- **Mechanism Of Sipuleucel-T**



6. CURRENT THERAPIES AS CANCER VACCINES (20)

Name Of Vaccine\ Antigen	Type of Vaccine	Targeted Site	Combination\ Route of Administration
Sipuleucel-T	Dendritic cell vaccine	Metastases Castrate resistant cancer that is slient or barely symptomatic	Intramuscularly
Gardasil	Human Papilloma virus	Women's Vulvar,vaginal and cervical cancer	Given Intramuscularly in the grater posterolateral portion of thigh
Cervarix	Human Papilloma virus	Types 16 &18 of carcinogenic human papilloma virus	3 Injection of 0.5ml each into the muscle
BCG	-	Bladder cancer in its superficial stages,colon cancer, lungs cancer & melonoma	Intravenous, subcutaneous, directly into tumours, intranasally,pharyngeally
Onyvax	Antiidio type Vaccine	Colorectal adenocarcinoma	Either intramuscularlly with the alum adjuvant or endemic with BCG Vaccine
Cancer Vax	Autologous vaccine	Surgery for the management patient with stage 3 melanoma	Along with BCG Vaccine, another vaccine is administered.
Lenalidomide	-	Multiple myeloma	Oral

7. CONCLUSION

Cancer vaccine therapy shows promising potential for both prevention and treatment of cancer. As a preventive measure, vaccines such as the HPV and hepatitis B vaccines have been effective in reducing risks of cancers related to these viruses, like cervical and liver cancers. Cancer vaccines work therapeutically by enhancing the immune system's capacity to identify and fight cancer cells.

Although some cancer vaccines, like sipuleucel-T for prostate cancer, have shown success, therapeutic vaccines face challenges. Cancer cells can evade immune detection, and immune responses may vary among individuals. However, advancements in personalized medicine, mRNA technology, and combination therapies with immune checkpoint inhibitors are paving the way for more effective cancer vaccines. In conclusion, while cancer vaccine therapy is not yet a universal solution, it represents a powerful tool in cancer prevention and a promising field for future cancer treatment options. Continued research is essential to optimize its efficacy and broaden its applicability across different types of cancer.

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A REVIEW OF TECHNOLOGICAL ADVANCEMENTS IN DISASTER VICTIM IDENTIFICATION

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ABSTRACT
Disaster Victim Identification (DVI) is a critical component of disaster management, requiring multidisciplinary efforts to accurately identify victims of mass fatality incidents. Despite significant technological advancements, challenges persist in efficiently and accurately identifying victims, particularly in complex disaster scenarios. This review examines the question: How have recent technological advancements in DVI addressed current challenges, and what are the future directions to enhance the efficiency and accuracy of DVI operations? By synthesizing recent innovations in DNA analysis, forensic odontology, fingerprint identification, and information management systems, this paper highlights how these advancements have improved DVI processes. The paper also explores potential future technologies, such as artificial intelligence and machine learning, and discuss the importance of international collaboration and ethical considerations. The findings aim to inform experts in the field and guide future research and practice to overcome existing challenges in DVI.
KEYWORDS: *Disaster Victim Identification; DVI, DNA Analysis; Forensic Odontology; Fingerprint Identification.*

1. INTRODUCTION

Mass fatality incidents resulting from natural disasters, transportation accidents, or acts of terrorism present significant challenges in disaster management, particularly concerning the identification of victims. Accurate and timely Disaster Victim Identification (DVI) is essential not only for legal and operational reasons but also for humanitarian considerations, providing closure to bereaved families and aiding in the grieving process (Teixeira and Pinto, 2023). However, DVI operations often face numerous challenges, including resource limitations, degraded remains, and the urgent need for rapid identification to facilitate relief efforts.

Technological advancements have significantly improved DVI methodologies, enhancing the speed and accuracy of victim identification. Yet, the question remains: How have these recent technological advancements addressed current challenges, and what future directions can further enhance the efficiency and accuracy of DVI operations? This review critically examines this question, focusing on key components and methodologies, technological innovations, and potential future developments in DVI. By providing a comprehensive understanding of how these advancements contribute to overcoming current challenges, we aim to inform experts in the field and guide future research and practice.

2. ADDRESSING CHALLENGES THROUGH TECHNOLOGICAL ADVANCEMENTS IN DVI

2.1 Enhancing DNA Analysis Techniques

DNA profiling has become an indispensable tool in DVI, particularly for identifying victims when other methods are insufficient due to the condition of remains. Traditional DNA profiling methods, however, are time-consuming and require well-equipped laboratory facilities, which may not be readily available in disaster scenarios. Recent advancements have focused on overcoming these limitations.

2.1.1 Rapid DNA Technologies

Rapid DNA technologies have revolutionized the field by significantly reducing the time required for DNA profiling. Automated rapid DNA systems, such as the ANDE 6C and RapidHIT ID, are capable of generating Short Tandem Repeat (STR) profiles within two hours, suitable for field deployment (Turingan et al., 2020; Kitayama et al., 2020). These portable systems have been validated for various tissue types, including muscle, blood, bone, and teeth, which are commonly encountered in disaster scenarios (Manzella et al., 2021).

The implementation of rapid DNA technologies directly addresses the challenge of delayed identification due to extended processing times. By enabling on-site DNA analysis, these systems facilitate timely victim identification, which is crucial for operational decision-making and providing closure to families. Furthermore, the automation and user-friendly interfaces of these systems reduce the need for specialized personnel, making them accessible in resource-limited settings.

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2.1.2 Direct PCR Techniques

Another significant advancement in DNA analysis is the development of direct Polymerase Chain Reaction (PCR) techniques. Degraded samples and limited quantities of biological material are common challenges in DVI operations. Direct PCR methods eliminate the need for traditional DNA extraction and purification steps, reducing processing time and minimizing the risk of sample contamination (Habib et al., 2017).

Techniques such as the use of microFLOQ® Direct swabs allow for the collection and direct amplification of DNA without consuming the original sample, which is particularly important when sample quantity is limited (Watherston et al., 2021). These methods have proven successful with various sample types, including hair roots, muscle tissue, bone shavings, and even touch DNA from personal items.

By simplifying the DNA analysis workflow and enhancing the ability to obtain genetic profiles from challenging samples, direct PCR techniques address critical obstacles in DVI, improving the overall efficiency and success rate of victim identification.

2.2 Innovations in Forensic Odontology

Forensic odontology plays a vital role in DVI due to the durability of dental structures and the uniqueness of dental patterns. However, fragmented remains and the lack of antemortem records can complicate dental identification. Technological innovations have sought to overcome these challenges.

Digital imaging and three-dimensional (3D) modeling have enhanced the accuracy and efficiency of dental identification. Cone Beam Computed Tomography (CBCT) provides high-resolution, three-dimensional images of dental structures with reduced artifacts from metal dental restorations (Murphy et al., 2012). This technology allows for detailed examination of dental features even in cases where traditional radiography is limited.

Additionally, the use of 3D scanners and printers enables the reconstruction of dental structures from postmortem remains, facilitating comparison with antemortem records (Nakamura and Kasahara, 2022). Custom software applications have been developed to analyze occlusal surfaces and dental features, aiding in the identification process (Hori et al., 2020).

These advancements address the challenges posed by fragmented remains and enhance the capacity for accurate dental identification, thereby contributing to the overall effectiveness of DVI operations.

2.3 Improvements in Fingerprint Identification

Fingerprint analysis is one of the primary methods of identification due to the uniqueness and permanence of friction ridge patterns. However, decomposition and damage to fingertips in disaster scenarios can reduce the viability of fingerprint analysis. Technological advancements have focused on improving fingerprint recovery and analysis under such challenging conditions.

Automated identification systems have enhanced the efficiency of fingerprint comparisons against large databases, reducing the time required for identification (Johnson, 2024). Moreover, the integration of mobile technology allows for the rapid capture and transmission of fingerprint images from the field. For instance, techniques combining simple fingerprint methods with smartphone photography and secure messaging applications have enabled rapid identification in difficult scenarios (Khoo et al., 2016).

These advancements increase the success rate of fingerprint identification in challenging conditions, providing a rapid and reliable method for victim identification and addressing a key challenge in DVI operations.

2.4 Information Management Systems

Efficient management of vast amounts of data is critical in DVI operations, where timely and accurate analysis of antemortem and postmortem data is essential. The complexity of DVI data, which includes DNA profiles, dental records, fingerprints, and other identifiers, necessitates robust information management systems.

Specialized software and centralized databases have been developed to facilitate the organization, comparison, and secure sharing of DVI data. Programs such as Bonaparte and WinID3® assist in managing DNA profiles and dental records, performing kinship analyses, and calculating likelihood ratios for potential matches (Rodríguez-Domínguez and Márquez-Ruiz, 2023; Slooten, 2011). National and international databases, including the Combined DNA Index System (CODIS), support the search for missing persons and DNA matching (Bradford et al., 2011).

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The use of mobile applications enhances real-time data entry and communication among DVI team members, improving coordination and operational efficiency. By streamlining data management processes, these technological advancements directly address challenges related to data overload and the need for rapid information processing in DVI operations.

3. POTENTIAL FUTURE DIRECTIONS IN DVI TECHNOLOGY

Despite the significant advancements discussed, challenges remain in DVI operations, particularly concerning resource limitations, handling degraded remains, and integrating complex data. Future technological developments have the potential to further enhance the efficiency and accuracy of DVI.

3.1 Artificial Intelligence and Machine Learning Applications

Artificial intelligence (AI) and machine learning (ML) offer promising applications in DVI. AI algorithms can improve image recognition, aiding in the identification of victims from postmortem photographs, even in cases where facial features are altered due to trauma (Michalski et al., 2024). In forensic odontology, AI can assist in the automated comparison of dental radiographs, reducing the manual workload and potentially increasing accuracy (Choi et al., 2022).

Moreover, ML algorithms can manage and analyze large, complex datasets, identifying patterns and potential matches that may be overlooked by human analysts (Teixeira and Pinto, 2023). By integrating AI and ML into DVI information systems, the efficiency of data processing and the accuracy of identifications could be significantly enhanced.

3.2 Portable and Cost-Effective Technologies

Developing portable and cost-effective technologies is essential for extending advanced DVI capabilities to resource-limited settings. This includes portable devices for DNA analysis and imaging that can be deployed directly at disaster sites (Gettings et al., 2024). Such technologies would reduce reliance on centralized laboratories and facilitate rapid identification, even in remote or resource-constrained environments.

Continued innovation in this area could make advanced DVI techniques more accessible globally, addressing disparities in disaster response capabilities and improving overall effectiveness.

3.3 Enhanced Data Integration and International Collaboration

Expanding and integrating international databases can facilitate data sharing and collaboration in DVI operations, which is particularly important in disasters involving victims from multiple countries (Alsalamah and Nuzzolese, 2020). Developing interoperable systems and standardized protocols would enhance cross-border identification efforts, enabling more efficient and accurate victim identification on a global scale.

Investing in infrastructure and policies that support international collaboration can help overcome logistical and operational challenges, ultimately improving the effectiveness of DVI operations worldwide.

4. IMPORTANCE OF INTERNATIONAL COLLABORATION AND ETHICAL CONSIDERATIONS

4.1 International Collaboration

Disasters often transcend national boundaries, involving victims from multiple countries and necessitating coordinated international efforts. Adherence to standardized protocols, such as INTERPOL's DVI Guide, ensures consistency in procedures and facilitates collaboration among different jurisdictions (Sweet, 2010). Successful multinational DVI operations, such as the response to the 2004 Southeast Asia Tsunami, have demonstrated the effectiveness of international collaboration in overcoming logistical challenges and enhancing identification efforts (Wright et al., 2018).

International collaboration also fosters the sharing of expertise, resources, and technological advancements, contributing to the overall improvement of DVI practices globally.

4.2 Ethical and Psychological Considerations

DVI operations involve sensitive ethical issues and can have significant psychological impacts on both responders and the families of victims. Ethical considerations include respecting the rights of families in the collection and use of antemortem data, ensuring informed consent, and maintaining data privacy and confidentiality (Parker et al., 2013). Cultural sensitivity is also paramount, as practices related to death and mourning vary widely among different cultures.

The psychological impact on responders, who are often exposed to traumatic environments and stressful situations, necessitates the provision of mental health support and stress management strategies (Eitzen and Zimmermann, 2012). For families awaiting

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identification results, clear communication and psychological assistance are essential to help them cope with uncertainty and grief (Shrestha and Patil, 2021).

Incorporating ethical guidelines and psychological support into DVI operations not only addresses the human aspect of disaster response but also contributes to the overall effectiveness and integrity of the identification process.

5. ONGOING CHALLENGES AND RECOMMENDATIONS

5.1 Resource Limitations

Resource constraints remain a significant challenge in implementing advanced DVI technologies, particularly in low-resource settings. Limited access to equipment, trained personnel, and infrastructure can hinder effective DVI operations (Shrestha et al., 2020). Addressing these limitations requires investment in capacity-building initiatives, including training programs to equip local teams with the necessary skills and technologies (Winskog et al., 2012).

Developing cost-effective and portable technologies, as discussed earlier, can also help mitigate resource limitations by making advanced tools more accessible.

5.2 Degraded and Fragmented Remains

The identification of victims from severely degraded or fragmented remains continues to pose technical challenges. Ongoing research into improving DNA extraction methods from challenging samples is crucial. This includes exploring novel preservation techniques, enhancing direct PCR methods, and developing more sensitive analytical technologies.

Investing in research focused on handling degraded samples will improve identification success rates in difficult scenarios, directly addressing one of the most persistent challenges in DVI.

5.3 Data Management and Integration

Efficient handling of complex and voluminous data is critical for successful DVI operations. Developing interoperable systems and protocols for data sharing is essential, particularly for international collaboration. Exploring AI and ML solutions for managing and analyzing complex datasets can enhance data processing efficiency and accuracy.

Standardizing data formats and adopting universal guidelines can facilitate smoother data integration and collaboration among different agencies and countries.

6. CONCLUSION

Technological advancements have significantly addressed many of the challenges in Disaster Victim Identification, improving the efficiency and accuracy of victim identification processes. Rapid DNA technologies, innovations in forensic odontology, and enhanced information management systems have transformed DVI operations, enabling more timely and reliable identifications. However, challenges persist, particularly in resource-limited settings and in handling severely degraded remains.

Future directions should focus on integrating artificial intelligence and machine learning to further enhance analytical capabilities, developing portable and cost-effective technologies to expand access, and enhancing international collaboration through standardized protocols and interoperable systems. Additionally, ethical considerations and psychological support must remain integral components of DVI operations to address the human aspects of disaster response.By focusing on these areas, the DVI community can continue to improve identification processes, providing timely closure for families and supporting effective disaster management efforts.

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MEDIA PREPARATION AND OPTIMIZATION FOR THE GROWTH OF BAMBUSA VULGARIS

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ABSTRACT
The fastest-growing plant, bamboo, has a number of distinctive qualities that make it suitable for a wide range of uses. It is inexpensive, lightweight, flexible, strong, long-lasting, and able to spread even in unfavorable environments[3] This review discuss the media preparation and optimization for growth of Bambusa Vulgaris. For this species, vegetative propagation is the only practical option because B. vulgaris does not set seed following scanty flowering, making seedling progenies unavailable. To investigate clonal replication methods for the species, a low-cost propagation study was carried out using two different kinds of short branch cuttings: nodal leafy cuttings and tip cuttings. Following treatment with 0, 0.1%, 0.4%, and 0.8% IBA solutions, the cuttings were allowed to root in a non-mist propagator in order to evaluate their rooting capacity. After four weeks of rooting, the cuttings were grown in polybags under nursery conditions for ten months in order to evaluate their stunting[1].
KEY WORDS - *Bambusa vulgaris, Media, Optimization*

REVIEW OF LITERATURE

1. M.S.Islam -Bambusa vulgaris Schrad ex wendl is a popular bamboo species in rural Bangladesh due to its various applications. Vegetative propagation is the only viable option for this species because B. vulgaris does not set seed following scanty flowering, making seedling progenies unavailable. A low-cost propagation trial was carried out to investigate clonal multiplication approaches for the species, using two types of small branch cuttings: nodal leafy cuttings and tip cuttings. After being treated with 0, 0.1%, 0.4%, and 0.8% IBA solutions, the cuttings were placed in a non-mist propagator to allow them to root and assess their rooting potential.

2. Gil Sander Prospero Gama -To address the public health issue of microbial resistance to pharmaceuticals, researchers are exploring natural alternatives to conventional products. Wood vinegar, produced by carbonizing lignocellulosic raw materials, has potential as an antibacterial agent. The study aimed to assess the antibacterial and antifungal properties of two types of wood vinegar (WV) derived from Eucalyptus urograndis wood and Bambusa vulgaris biomass, as well as their chemical profiles. Antimicrobial activity was tested against Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enteritidis, Escherichia coli, Streptococcus agalactiae, and Candida albicans. We determined the minimal inhibitory, bactericidal, and fungicidal concentrations.

3 .Kamna Chaturvedi -Bamboo, the fastest-growing plant, has various distinguishing properties that make it suitable for a variety of purposes. It is cost-effective, high-tensile, lightweight, flexible, resilient, and can spread even in infected areas (e.g., slope). This paper highlights bamboo's unique capabilities for producing charcoal and biochar for various applications. This study examines the pyrolysis process for producing bamboo charcoal and biochar, which involves thermal breakdown of organic materials in an oxygen-depleted atmosphere at a specific temperature. This is an alternate process for converting waste biomass into more valuable products, such as charcoal. Bamboo charcoal outperforms ordinary charcoal with four times the absorption rate and ten times the surface area, among other benefits.

4.Poonam tiwari - Bambusa vulgaris (Schrad. ex Wendl) has been pushed to address deforestation and economic issues. This investigation focused on quick in vitro multiplication of Buddha bamboo (Bambusa vulgaris) using internodes as explants. Three cytokinins (IAA, NAA, and 2,4 D) and 0.3 mg/l BAP were shown to be the most effective in triggering bud break and multiple shoot formation, resulting in considerable plant growth. Growth hormones NAA, IAA, 2,4-D, and BAP effectively promote root and shoot production.

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Fig.1 Bambusa Vulgaris [9]

INTRODUCTION

The woody plants that grow the fastest are bamboos, belonging to the Poraceae family and the Bambosidae sub-family. According to Shanmughavel et al. (1997), these multipurpose plants are essential to the daily lives of millions of people in South-East Asia because they provide food, fuel, fodder, clothing, medicine, shelter, and raw materials for a variety of industries, such as paper and pulp, furniture, and construction. Their exceptional splitting ability (Banik 2002), tensile and compressive strength, amenability to being harvested within five years of planting (Negi 1996), and other qualities contribute to their versatile application (Banik et al. 1997). With the expanding human population, the demands for bamboos in homes, agricultural activities and paper industries are increasing. Nevertheless, Bangladesh's bamboo stocks are shrinking concerningly in terms of both area and quantity[1].Due to its exceptional carbon sequestration capabilities, bamboo is currently attracting a lot of interest in the fight against global warming (Lou et al., 2010). Research to date has confirmed that bamboo has better CO2 sequestration than other fast-growing trees, and because of its rapid growth and high rates of carbon accumulation, bamboo is being seriously considered as a plant to mitigate effects of global warming (Lou et al., 2010). However, among the various genera of bamboo, it becomes difficult to identify best species which can serve all potential goals through consistent quality supply of plantlets[8].Bamboo is a rapidly growing renewable resource that offers ample opportunities for reforestation [3]. The use of liquid media in micropropagation processes has been found to be an effective way to lower the cost of plantlet production. The plant known as Buddha bamboo, or Bambusa vulgaris var. wamin, is native to China [4–8 m tall] and is an ornamental species with no records of flowering .Its culms are typically dark green in color, and its internodes are elongated and swollen, resembling pitchers. Some of the internodes of bamboos remain in a vegetative state for an extended period of time. The rate at which various economic trees, like bamboo, are being exploited globally is leading to a bleak future for various tree plants of significant importance[4].Worldwide, bamboos have a significant impact on society, the economy, and culture, particularly in East and South Asia. They are mostly utilized as building materials, food roots, and raw materials. The bamboos are flexible and have good bending strength. The bamboo plant can endure wind force up to 40 meters in the air. Yuming Y. and others [1]. Compared to steel, bamboo is more affordable, lighter, flexible, stronger, and versatile. Bamboo needs to be utilized extensively in building since it has so many advantages over other materials. Bamboo is frequently utilized in place of wood because of its superior mechanical and physical qualities. It matures

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in three to four years as opposed to wood, which takes over twenty years[3].Optimization difficulties generally occur in the sectors of social production activities such as intelligent computing, mathematical research, engineering optimization, distribution scheduling, and so on. Previous studies have searched for more precise and efficient ways to address optimization problems. The heuristic algorithm is one type of solution technique that is suggested to as closely resemble the ideal answer in relation to the optimization algorithm as feasible. There are three branches of heuristic algorithms. There are three types of heuristics: hyper-, meta-, and simple. Generally speaking, simple heuristic algorithms are deterministic algorithms with a single global optimal solution for defined structures and parameters. such as the hill-climbing algorithm, stereotype algorithm, greedy algorithm, and local search algorithm[7].

MEDIA PREPARATION

1.Collection of plant material

The experiment was conducted in the Department of Microbiology and Bioinformatics at Bilaspur University, Bilaspur (CG), using healthy yellow bamboo spp. (Bambusa vulgaris) that were collected at the green to brownish stage from the Raja nursery Jarhabhata chowk, Bilaspur (CG), India[4].

2. Preparation of Explant

Using a sterile blade, the internodal section of the stem (Bambusa vulgaris Schrad. ex Wendl) was chopped up to three inches. In order to get rid of the wax and dust, the top layers of the explant were scraped off. After that, the internode explant was cleaned for ten minutes under running tap water. The explant was submerged in fungicide (Bavistin 1%) for 10 minutes before being rinsed with sterile distilled water twice or three times. The explant was then cleaned with distilled water containing 1% detergent (Tween 20) for five minutes. Following a one-minute surface disinfection with 70% ethanol, the explants were treated with 0.1% aqueous mercuric chloride (HgCl2) for five minutes, and then carefully cleaned four to five times with sterile distilled water [4].

3. Preparation of MS Media

Growth conditions and the medium of culture For this investigation, MS (Murashige and Skoog 1962) medium containing 2% (w/v) sucrose was utilized. BAP (0.3 mg/L) was added to the medium along with 3 mg/l of NAA, 2,4-D, and IAA, respectively. The medium's pH was adjusted to 5.6 before the 1% agar gelled. Each of the 50 ml of Murashige and Skoog was poured into a 150 ml sterilized conical flask (Borosil) and sealed with a cotton plug that wasn't absorbent[4].

4 . Storage of prepared Media -

Following preparation, the media were autoclaved, allowed to come to room temperature, and then kept in a 6°C refrigerator[4].

5 .Volume of Culture Media used in Culture jar

For the usual plantlet regeneration experiment, each conical flask held 20 ml of semi-solid culture media[4].

6 . Establishment of Shoot

Immature and semi-hard wood shoots that had been surface sterilized were cultivated on MS media with and without 0.1% activated charcoal. The explants that made it through were then moved to regeneration media. Over the course of four weeks, the percentages of browning and survivals, as well as the quantity of shoot buds begun, new leaves developed, and callus formation, were noted. After that, the cultured explants were kept in the plant tissue culture room at 25 to 26 degrees Celsius, with cool white fluorescent bulbs providing a 16-hour photoperiod. There was a 50–55% relative humidity[4]

MATERIAL AND METHOD

1. Explant Collection

Nodal segments (1.3-2.0 cm length) from ex-plants of B. balcooa growing at the Abellon plantation site in the dry region of Modasa Taluka, Aravalli District, Gujarat, India. Ex-plants were gathered from October through January. Ex-plants were removedwithin two to three hours of each other. With a scalpel, an incision was made at the base of the leaf sheath to remove the leaf sheath tissues and some of the higher internodes[8]

2. Aseptic Sterilization

Nodal segments were surface sterilized for five minutes using Tween 20, then treated for ten minutes with 1% Bavistin (Saraswati agro Chemicals (India) Pvt. Ltd., Bari Brahmana, Jammu and Kashmir, India). After that, the segments were disinfected for five minutes with a solution of 0.1% mercuric chloride (Finar Chemicals Ltd., Ahmedabad, Gujarat, India) and 70% isopropyl alcohol. For the next steps in the initiation process, the treated ex-plants were washed with sterile RO water[8]

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3 . Initiation

The Murashige and Skoog (MS) basal medium was used for the initial phase of the experiment. To enhance the medium, additional ingredients were added, including 0.01% myo-inositol (Finar Chemicals Ltd., Ahmedabad, Gujarat, India), 3% sugar (Commercial Grade, Venkateswara Sugar Products, Kolhapur, India), 25 mg/L citric acid (Finar Chemicals Ltd., Ahmedabad, Gujarat, India), 50 mg/L ascorbic acid (Finar Chemicals Ltd., Ahmedabad, Gujarat, India), and 3.5 mg/L 6-benzylaminopurine (BAP) (Himedia Laboratory, Mumbai, Maharashtra, India) as a growth regulator. Gentamycin was diluted to a concentration of 3.0-8.0 mg/L in liquid and solid MS media for the purpose of initiation (Abbott Helthcare Ltd. Pvt., Pithampur, Madhya Pradesh, India)[8]

4. Shoot Multiplication

The shoots from the nodal segment were removed, and they were then cultivated in MS media that contained 3% sugar, 6% agar for solidification (Merck Specialties Private Limited, Mumbai, Maharashtra, India), and growth promoters (0.5 mg/L naphthalene acetic acid (NAA) and 3 mg/L BAP) at a concentration of 0.01% myo-inositol (Himedia Laboratory, Mumbai, Maharashtra). Propagules, or newly sprouting axillary shoots, were subcultured in fresh multiplication media at regular intervals of three to four weeks. The multiplication rates were determined using a number of propagules that were obtained from a cluster of shoots following each cycle. Decayed branches or leaves were removed before moving the cluster to fresh medium[8]

5 . Rooting

In two experiments designed in triplicate, each with 100 experimental plants in each group, different combinations and concentrations of root-inducing growth regulators were added to MS basal media with 3% sugar, 0.01% myo-inositol gelled with 2% BioM Gel (Merck Specialties Private Limited, Mumbai, Maharashtra, India).

6 . One step process

One set of experiments used solid media containing 3 mg/L of BAP, while the other set did not. To observe the effects of auxins with and without BAP, different concentrations of NAA, indolebutyric acid (IBA), indoleacetic acid (IAA), and auxins (Himedia Laboratory, Mumbai, Maharashtra, India) in a range of 1-4 mg/L were kept as variables in both sets at the respective locations.

7 .Two step process

In this two-step procedure, plants were initially allowed to root in liquid media before being moved to solid media. For three weeks, the three growth regulators were combined in varying amounts (0.5-2 mg/L) with 3 mg/L BAP in liquid medium (Table 2). After that, the mixture was moved to solid multiplication media with 3 mg/L BAP and 0.5 mg/L NAA. The total number of rooted cultures divided by the total number of bamboo cultures at the experimental rooting stage was used to compute the percentage of rooting. By calculating the mean root length of rooted cultures, the average root length was determined.

8 . Pre-hardning

The procedure of hardening tissue culture-grown bamboo cultures in a lab for 20–30 days prior to moving them into a greenhouse is called pre-hardening. Rooted bamboo cultures that were 3–4 weeks old were moved to full strength MS media with and without BAP (3.5–4.5 mg/L). Another group of samples was treated with half-strength MS media that contained and did not contain BAP (3.5–4.5 mg/L). Every experiment was carried out in triplicate, with 100 plants each set.

9. Primary hardening

Following pre-hardening, the in vitro plantlets were taken out of the culture jars and thoroughly cleaned with RO water to get rid of any remaining medium from the roots.

10. Secondary hardening

The well-developed root balls of the bamboo plants were then moved to the shade net house in two sets of polythene bags (6 cm × 6 cm) with a 1:1:1 potting mixer of vermicompost, soil, and sand. The second set was made up of vermicompost, soil, sand, and vesicular arbuscular mycorrhiza (VAM) in the following ratios: 1:1:1:0.5. The VAM culture was established at the Abellon R&D center in Ahmedabad, Gujarat, India, and mass production took place at the Abellon hardening center in Modasa, Gujarat, India. It was purchased from the ICAR, New Delhi. The shade net house was maintained at 35°C to 38°C with a 50%–60% humidity level. The mortality rate was computed by dividing the total number of dry cultures by the total number of transferred bamboo cultures. Every experiment was run in triplicate, using 150 plants in each set[8].

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The Bamboo Forest Growth Optimization Algorithm

1.Inspiration

Bamboo is a grass plant of the Poaceae and Bamboo genus, yet it can have the height of a tree. Young bamboo shoots can grow up to a meter each day. This quick development, according to Guihua Jin [36], is a crucial characteristic of woody bamboo that gives it an advantage over other trees in the forest setting by allowing it to compete with them.When bamboo is at the shooting stage, it grows in the rain; nevertheless, it takes three to five years for it to mature into bamboo. After then, the bamboo will grow at an incredible rate and suddenly exert force. When the bamboo does not develop for three or five years, its roots spread far and deeply beneath the surface. The term "deep" describes the depth of the earth. Bamboo roots have the ability to pierce extremely hard stone structures like steel. "Wide" refers to the bamboo's ability to extend its root system over several kilometers. Bamboo can readily acquire the nutrients and rainfall it requires on a plot of land that is several square kilometers in size.Bamboo is distinctive in its physiological characteristics, as seen by its reclining underground stem, sometimes known as a bamboo whip. It has numerous nodes and grows densely, with numerous fibrous roots and buds sprouting from the nodes. As Figure 2 illustrates. Bamboo whips are the main factor responsible for bamboo forests' rapid territorial expansion in addition to storing and supplying an abundance of nutrients for these woods. They are able to spread out and expand in any direction at random. These bamboos exchange nutrients through a network of interconnected rhizomes. They will share the pressure from the surroundings and impart nutrients to one another[7].

2 . Mathematical Model

Bamboo grows in stages, which can be summed up as budding, shoot growth, rapid growth, adulthood, flowering, and death. In this section, the stages of bamboo growth are mapped onto the algorithm optimization process, a mathematical model based on the stages of bamboo growth—bamboo root extension, bamboo forest expansion, and bamboo flowering—is constructed, and the BFGO method is suggested[7].

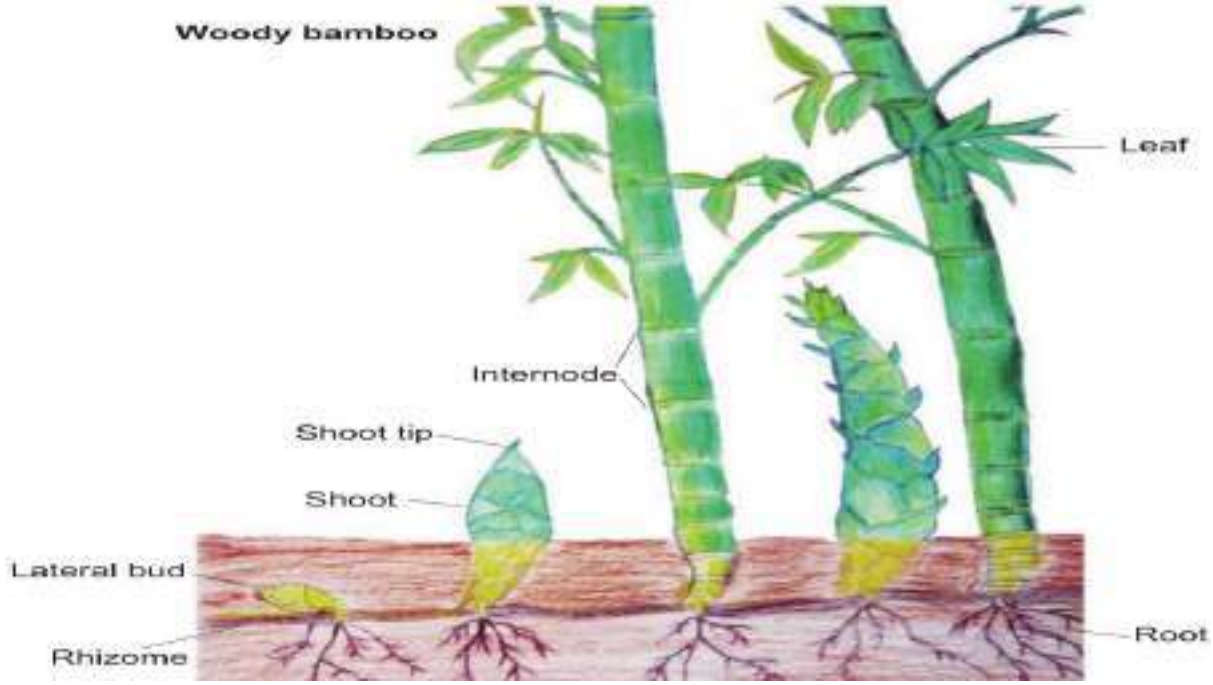

Fig.2 Structure of Bamboo [10]

RESULT

1.Aseptic Initiation

Ex-plants of bamboo that were harvested between October and January were first subjected to aseptic treatment. The liquid and solid media were supplemented with gentamicin (0–8 mg/L) in order to determine the optimal procedure for managing contamination. In both liquid and solid media, three to five sprouted axillary shoots were seen after ten to fifteen days after initiation. With 3 mg/L, 5 mg/L, and 7 mg/L of gentamicin, axillary shoots sprouted 3-5 days quicker in liquid media than in solid media (Table 3). When compared to the same concentration in solid media, sprouting was seen two days later in liquid media treated with 8 mg/L gentamicin . When

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compared to solid media with yellow leaves and shoots (Figure 1b) at a gentamicin dosage of 7 mg/L, we saw the highest results in liquid media with darker green shoots and leaves .

2.Shoot Multiplication

For shoot multiplication, various BAP and NAA combinations were investigated. After three weeks of good culture circumstances and clusters of 12-15 shoots (Figure 2 shooting), with an average multiplication rate of 3.5 times, NAA 0.5 mg/L and BAP 3 mg/L were the most successful.

3 . Rooting

Our goal was to determine the qualitative and quantitative effects of each auxin alone, in conjunction with BAP, and both with and without the addition of BAP.

4. One Step Processing

In comparison to NAA (1-4 mg/L) with addition of BAP (3 mg/L) (Figure 3b) (Table 1), the best rooting were found within 15 days in NAA 4 mg/L without addition of BAP (Figure 3a), displaying an average of 9.6 root numbers, root length 8 cm, and 83% rooted. 21% rooting was seen in the cases of BAP (3 mg/L) and IAA (2 mg/L). In contrast, Table 1 indicates that 3 mg/L IAA without BAP added resulted in 14% rootingIBA (1-4 mg/L) showed no rooting with or without BAP (3 mg/L) . For three weeks, the plants were kept at the roots stage.

5 . Two Step Processing

In the second set of rooting experiments, three weeks of liquid medium containing a combination of different doses of each of the three auxins was added to a BAP concentration of 3 mg/L. Afterwards, the plants were placed in solid growth media for three weeks, including 0.5 mg/L NAA and 3 mg/L BAP. The IAA + IBA + NAA combination at 1:2:2 mg/L concentrations showed 62% rooting, 10.2 average number of roots, and 9.1 cm average root length, respectively (Table 2, Figure 3b liquid medium, and Figure 3c solid media).

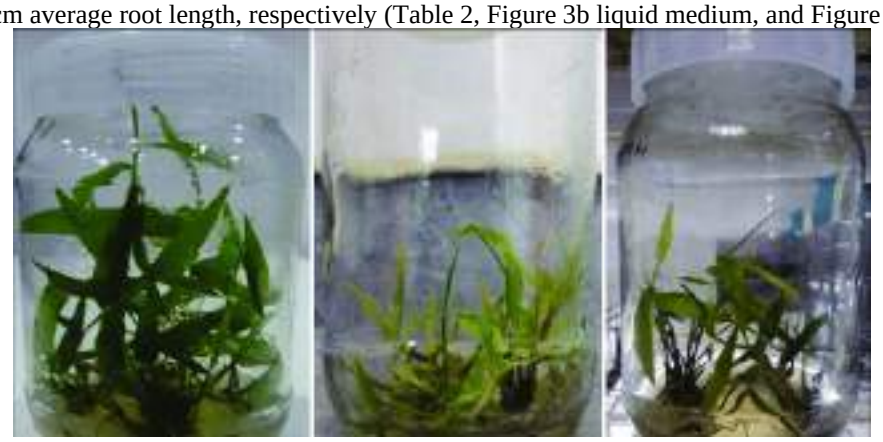

Fig . 3 [11]

6. Pre-Hardning

With 3 mg/L BAP, the bamboo shoot elongation reached its maximum at half strength of MS medium, measuring 6.8 ± 2.2 cm for the shoot and 12.4 ± 2.1 cm for the root (Figure 4). The quality of the leaves and green shoots was superior than the MS medium at its maximum strength. Plant survival rates in half strength MS media were 68%, whereas those in full strength MS medium were 37%.

7. Primary Hardening

The bamboo plants underwent primary hardening in two distinct potting formulations. One set had only coco peat, while the other contained a 3:1 ratio of coco peat to vermicompost. The combination of coco peat and vermicompost produced the best results, with shoot lengths of 6.85 ± 0.04 cm and root lengths of 14.70 ± 0.1 cm. Bamboo plants grown in coco peat alone exhibited 5.45 ± 0.09 cm shoot length and 11.55 ± 0.08 cm root length (Figure 5). The growth of coco peat alone (Figure 6a) and coco peat + vermicompost mixture (Figure 6b) is compared in Figure 6. Compared to plants grown only with coco peat (61%), plants treated with vermicompost had a survival percentage of 72%.

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8 . Secondary Hardening

To optimize the hardening process, 150 plantlets were transferred in triplicate to two potting mixes containing varying ratios of vermicompost:soil:sand:VAM and another mixture of vermicompost:soil:sand, as specified in the materials and methods section. VAM cultivation with vermicompost, soil, and sand produced the longest shoot and root lengths (8.25 ± 0.4 cm and 18.60 ± 0.1 cm, respectively).

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THE PRACTICAL LOGIC OF DIGITAL LABOR'S AUTONOMOUS IDENTITY UNDER TECHNOLOGICAL CONTROL

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ABSTRACT

Productive labor fundamentally aims to obtain the basic means of human survival. At its core, labor is a free and conscious practice activity aligned with human nature. However, modern platform systems, driven by technological advancements, implement mechanisms to monitor labor processes through strategies such as separating conception and execution, engaging in "algorithmic" games, and establishing customer evaluation systems. These mechanisms ultimately shape labor into an ideology of personal autonomy, concealing its true purpose of serving capital's pursuit of value enhancement and economic profit. In the era of the digital economy, overcoming the logic of capital and reconstructing individual ownership remains central to critiquing and transcending alienated labor. Achieving collective ownership of production resources such as digital technology and big data—shifting from private capital control to shared access—is the optimal choice for rebuilding individual ownership in the digital capital era. This transition not only helps to eliminate the alienation of digital labor and balance labor and capital justice but also enables human freedom, affirms human subjectivity, and offers a rational mode of existence for contemporary individuals.

KEYWORDS: *Digital Labor; Technological Control; Platform Systems; Autonomy; Logic of Capital*

1. INTRODUCTION

Production has been a central theme in classical social theory. In *Capital*, Marx elaborated on the "hidden abode of production", striving to uncover the oppressive and exploitative relations obscured within capitalist production processes, thereby revealing the actual conditions of production in capitalist societies. However, since the 1960s, with the rise of mass consumption in Western societies, theories centered on consumption have gradually replaced classical political economy's focus on production. In this historical context, consumption, as the natural derivative of production, has overstepped production to become the main historical theme, while production has been reduced to a necessary condition for achieving consumption. If this theoretical shift from production to consumption reflects the deindustrialization practices and societal transformations in Western societies—where the middle class ascended as the dominant social force—then the digital economy era presents a different landscape. The world is witnessing the emergence of a vast "super-net" of the Internet, accompanied by the rise of what might be the largest labor force of digital workers globally. Against this historical backdrop, Marx's theories on the working class and productive labor require refinement and development in alignment with contemporary themes. Exploring and examining the nature of productive labor in the digital economy era, as well as reconsidering and revealing the "hidden abode of production" within production settings and labor processes, are essential aspects of digital labor research. With continuous innovation in Internet and information technologies, the platform economy has experienced rapid growth both domestically and internationally in recent years. Due to relatively flexible and autonomous work schedules, coupled with the lack of restrictions based on education, gender, or class, ride-hailing and food delivery platforms have attracted a large number of workers. Ride-hailing platforms provide numerous employment opportunities and help address mobility issues for the public, while food delivery platforms similarly solve employment problems and save consumers significant time in dining. As key components of the sharing economy, these platforms enhance the efficient use of social resources, facilitate daily life for many, and foster new drivers of economic growth. However, the employment and organizational relationships between platform economies and their labor force differ significantly from those in traditional industries, driven by innovations in network technologies and socio-economic transformations. In the digital economy, the relationship between capital and labor has undergone profound changes compared to the industrial era, yet the fundamental dominance of capital over labor remains unchanged. Within new platform economic models, exemplified by ride-hailing and food delivery, capital utilizes data as a resource, the Internet platform as a carrier, and "digital labor" as a productive force. By influencing labor structures in the information society and reshaping value creation methods, capital exerts control over labor processes to ensure

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the orderly functioning of platform economies and secure the surplus value extraction that fuels capital accumulation. This paper examines the labor processes of ride-hailing drivers and food delivery couriers, as well as the operational procedures of platform systems, to elucidate the practical logic of autonomous identity in digital labor under technological control. By uncovering the control mechanisms within digital labor processes and the ideology of labor autonomy shaped by capital, this study aims to provide theoretical insights into labor governance in the digital economy.

2. SEPARATION OF CONCEPTION AND EXECUTION: DEPRIVATION OF CONTROL OVER THE LABOR PROCESS

According to the regulations of platform companies, ride-hailing drivers and food delivery couriers who meet certain conditions, such as age and driving experience, can join the platform system, after which the respective ride-hailing or food delivery applications are activated. Regardless of whether they are drivers or couriers, their labor processes—spanning from registration to their eventual exit—are broadly similar, as their work revolves around the internet platform system. The operational process appears simple, but the platform system not only monitors drivers' and couriers' labor processes in terms of time and space but also provides guidance on specific segments and routes of the delivery process. For instance, during the order acceptance phase, food couriers can use the platform's heat map of orders to determine specific areas for picking or waiting for orders based on regional demand. Crowdsourced couriers can flexibly decide whether to take orders based on the "cost-performance ratio" (e.g., distance and price), while team couriers passively accept orders assigned by the platform system. Ride-hailing drivers operate under two models: the "grab-order system" or the "dispatch-order system". In the former, the platform sends travel information to drivers within a certain radius, allowing them to grab the order autonomously; in the latter, the platform assigns an order to a specific nearby driver after complex calculations based on passenger information. While differences exist between the order acceptance processes of couriers and drivers, their subsequent workflows are largely uniform. During the food pickup phase, couriers can optimize their sequence of pickups based on the platform-provided estimated preparation times for orders. For delivery, the platform's routing and sequence suggestions help couriers save time and ensure accuracy and efficiency. Ride-hailing drivers, upon receiving an order, pick up passengers at designated locations and deliver them to their destinations via the platform's predetermined route. Throughout the service, drivers and couriers strictly adhere to platform guidelines regarding routes and behaviors, all while being monitored. An analysis of the platform system's operations and the labor processes of drivers and couriers reveals that digital labor under platform systems exhibits characteristics akin to labor control during monopoly capitalism, with strict technological control.

"The historical development of technology within capitalism has consistently functioned as a means of reproducing biopower, systematically regulating labor through social technological norms, procedures, and culture" (Fuchs & Mosco, 2017). In Marx's theory of technology, he delineates two types of technology: one as material artifacts concerning the relationship between humans and nature, and the other as social forms concerning relationships among humans (Grundmann, 1991; Chen, 2020). These two types correspond to two forms of technology applied in the labor process: first, the application of scientific technology in production, encompassing innovations in production or equipment technology; and second, the reorganization of the labor process, involving advancements in management technologies for workers. Marx's labor process theory reveals the dialectical relationship between reified technology and labor politics, emphasizing how technology becomes a tool for capital to control, exploit, and oppress laborers. The primary contribution of technology to the capitalist mode of production lies in improving labor productivity and advancing labor process management. Marx expounded on the transformation of capitalist production modes by examining changes in technological control. As Marx noted, "The revolution in the mode of production begins with labor power in manufacturing and with labor in large-scale industry" (Marx & Engels, 1995, p. 207). In the manufacturing era, craftsmanship dominated the labor process, with skilled workers independently completing tasks. Although capitalists implemented integrated production organizations and directly supervised labor, workers maintained control over production through the barriers formed by their private skills. Manufacturing labor exhibited vague technical divisions, granting workers relative autonomy over work pace and hours, enabling them to resist capitalists to some degree. Conversely, in large-scale industrial labor, automation accelerated worker specialization and refined technical divisions. "The principle of large-scale industry involves first breaking down each production process into its constituent elements, regardless of human hands" (Marx & Engels, 1995, p. 212). Machines replaced workers, seizing control of production tools, while natural forces supplanted human effort. Mechanized mass production dismantled the integrated organization of manufacturing labor, gradually stripping workers of control over the labor process. "The capitalist utilization of machinery fundamentally transforms the nature of labor and social labor itself. On one hand, it overcomes resistance to such trends; on the other, by subjugating previously inaccessible labor groups and displacing workers through machinery, it creates a surplus labor population, compelling them to conform to the rules imposed by capital" (Marx & Engels, 1995, p. 210). According to Marx, large-scale industry disrupts the fixation of labor and functions, generating worker mobility. The substitution of worker craftsmanship with machines eliminates distinctions based on age, gender, and other factors, thereby incorporating a vast number

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of children and women into the workforce under capital's direct domination. Technological innovation facilitates the acquisition of a controllable labor force for capital, exacerbating chaotic competition in the labor market under the pressures of unemployment crises, undermining workers' resistance, and worsening their living conditions.

As humanity transitions from the industrial era to the network era, societal and economic structures have shifted from tangible to virtual, embracing the digital economy. Correspondingly, labor forms and processes have undergone significant changes. Compared to the industrial production era, labor in the digital age exhibits new characteristics. Workers on various virtual platforms can choose flexible work schedules, appearing to enjoy greater "freedom" and "autonomy". For instance, platforms such as short-term rental services (*Airbnb*), food delivery platforms, and crowdworking systems (e.g., Amazon Mechanical Turk) attract numerous workers due to their flexible and elastic work modes. In recent years, the scale of workers participating in these platforms has grown annually (Katz & Krueger, 2019). However, the work state of virtual economy platform laborers is far from being genuinely free and autonomous. The capitalist profit motive remains unaltered within platform economies, instead manifesting through novel forms of infiltration and expansion. Capital's influence extends beyond controlling production labor processes, permeating circulation sectors such as ride-hailing drivers, food couriers, and delivery workers. According to Braverman, human labor possesses rationality and intentionality, granting it unparalleled adaptability. This adaptability not only enhances productivity but also increases surplus products. The multifaceted potential of human labor forms the basis for capital's expansion. Yet this inherent potential and uncertainty challenge capitalists: how can they maximize the quality and quantity of the purchased labor power? Thus, transferring control over the labor process from workers to capitalists becomes essential (Braverman, 1979, p. 54). Much like traditional industrial labor processes, the relationship between labor and capital in the platform economy remains relatively adversarial. From the laborer's perspective, they engage in the labor process; for capitalists, this process serves their profit-driven goals. In this antagonistic production relationship, the pressing question is how capital can realize the "full utility" of the labor power it purchases while simultaneously suppressing workers' resistance. Resolving these conflicts—balancing capitalist oversight with workers' autonomy—while maintaining stable labor relations and order is a critical and complex challenge in digital labor process theory. Drawing from Marx's analyses of the production process and structural changes within industrial capitalism, American economist Harry Braverman systematically explored the impacts of technology on job nature, worker psychology, class composition, and organizational forms during the era of monopoly capital in *Labor and Monopoly Capital*. Braverman expanded Marx's concept of reified technology, asserting that technological control not only applies to innovations in production machinery but also to the reorganization of production processes and labor management. Applying Braverman's theoretical framework to the labor processes of food couriers and ride-hailing drivers reveals significant insights. Braverman argued that early systems like household labor and subcontracting were transitional phases in which capitalists did not yet assume direct managerial roles or control over the labor process, contradicting the capitalist ethos of full exploitation. He identified the "free labor contract" as a prerequisite for capitalist relations. For capitalists, every moment of non-productive time among wage laborers represents a loss. Thus, labor processes under such contracts must maximize productivity while imposing the capitalist will on workers (Braverman, 1979, p. 63). Consequently, refining managerial methods to organize and control labor processes with greater precision becomes critical.

Today's ride-hailing and food delivery platforms exemplify capital's understanding of these dynamics. To maximize value extraction, platforms meticulously regulate the labor processes of vast driver and courier networks, ensuring compliant and orderly labor aligned with capital's objectives. Examination of their organizational strategies reveals adherence to Braverman's principles of Taylorism: (1) Separation of Labor Process and Worker Skill. Labor processes are decoupled from workers' crafts, traditions, and knowledge (Braverman, 1979, p. 104). In the labor processes of drivers and couriers, platforms collect and process data on delivery times, rider speeds, customer tolerance for delays, complaints, and ratings. Using algorithms, platforms aggregate these data points to calculate optimal routes and schedules, presenting drivers and couriers with precise instructions. This delegation of brainwork from workers to centralized "managerial" platforms ensures that labor relies entirely on the platform system's planning, not the worker's expertise. By deskilling drivers and couriers, platforms strengthen control over labor. Humans differ fundamentally from animals in their ability to separate the conceptualization and execution of tasks. However, as human labor becomes a social phenomenon, concept and execution can be divided, unlike animalistic instinct-driven action. Capitalists exploit this trait, reducing labor processes to mechanical, purpose-devoid actions. Workers detached from task conceptualization cannot optimize efficiency or work at a pace dictated by capital's profit motives. (2) Principle of Conceptual and Executive Separation. In capitalist wage relations, laborers sell their time to secure basic subsistence and relinquish autonomy over how their time is used. "Not only does capital belong to the capitalist, but labor itself becomes part of capital. Workers lose control over their tools and must surrender authority over their labor and its methods" (Braverman, 1979, p. 108). Similarly, platform systems dictate drivers' and couriers' working methods because equipping them with system knowledge would challenge capital's authority. Following Taylorist principles, platforms do not intend to enhance workers' knowledge or societal status. Instead, platforms aim to minimize training needs and increase output, thus reducing costs. Platforms encode constraints through symbolic systems such as automated task allocation, customer reviews, delivery schedules, and route planning. Drivers and couriers

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who deviate from these standards face penalties such as reduced ratings, diminished rewards, or fewer future assignments. (3) Systematic Pre-Planning and Calculation. In traditional management, workers relied on their expertise to determine the best ways to accomplish tasks. In modern scientific management, managerial departments outline detailed plans and instructions for workers, dictating both tasks and tools (Braverman, 1979, p. 110). Platform systems similarly analyze and compute data, not only to provide optimized guidance but also to strictly regulate workers' time and spatial movements. For example, by using data on traffic congestion, traffic lights, and road conditions, platforms determine the most efficient delivery routes to enhance customer satisfaction.

"If the first principle is to gather and develop knowledge about each labor process, and the second principle is to make this knowledge exclusive to management, leaving workers without it, then the third principle is to use this monopoly on knowledge to control every step and execution of the labor process" (Braverman, 1979, p. 110). Guided by these principles, modern platform systems separate the mental and manual labor of drivers and couriers, stripping them of control over the knowledge and skills embedded in the platform systems. Workers thus cease to be artisans, becoming instead "living tools of the managerial system" (Braverman, 1979, p. 124). The platform system functions as a tool for capital accumulation, not only improving productivity but also depriving drivers and couriers of control over their work. Through numerical control under technological oversight, drivers and couriers complete delivery tasks step-by-step, adhering to algorithmic procedures. This automated process demands minimal skill from workers, and the post-industrial gap between laborers and digital platforms fosters compliance with platform control, unlike the stronger resistance found in handcraft laborers of earlier industrial settings.

In summary, the technological control in platform systems bears striking similarities to labor organization and management in industrial automation. Platform systems uphold the principle of separating conception from execution, with the system itself functioning as the managerial entity and drivers and couriers acting as workers. Throughout the labor process, the platform system handles task assignments, route planning, time calculations, spatiotemporal monitoring, and performance quantification, reducing drivers and couriers to mere tools that sustain platform operations and fulfill capital's pursuit of value appreciation.

3. IMPLEMENTING "ALGORITHMIC" GAMES TO ENHANCE WORKER AUTONOMY AND SHAPE MECHANISMS OF CONSENT

While Marx and Braverman highlighted the technological despotism inherent in capitalist labor processes through their analyses of technology types, Burawoy, through his examination of worker autonomy, shed light on the scientific and technological hegemony in capitalist labor processes. Following Marx's method of political economy, Burawoy conducted field studies at Chicago equipment companies, where he analyzed piecework and "making out" games, arguing that the coupling of surplus games with internal labor markets and the internal state under structured domination shaped a consent mechanism within the working class.

Surplus games altered work organization to emphasize individualism, loosening certain managerial controls, such as part inspection and wage rate challenges, and increasing opportunities for shop floor bargaining and variation in piece-rate systems, thereby enhancing individual performance, effort, flexibility, and personal agency (Burawoy, 2008, p. 84). These games provide workers with opportunities for skill-building and personal expression. Surplus pay is not the primary motivation for participating in these games; rather, "the exercise of knowledge, skill, ingenuity, speed, and perseverance contributes to the excitement of the game and the pleasure of a 'successful completion'" (Burawoy, 2008, p. 92). As an identity mechanism, surplus games foster worker autonomy, unleash labor potential, and create a sense of "consent" to exploitation, masking the reality of workers being controlled by machinery and subjected to exploitation.

However, in the digital economy, the locus of control over labor processes has shifted from traditional factories and machinery to digital platforms. A significant characteristic of platform systems in managing human resources and evaluating performance is their use of software algorithms in place of human managers. The success of this substitution lies in the platform system's ability to establish a systematic evaluation and rating system for couriers' work practices. Based on factors like delivery volume, timeliness, and customer feedback, the platform constructs a "differentiated hierarchy" evaluation framework, upgrading it into a gamified system. Couriers of varying performance levels are rated differently, and to maintain a higher rating, couriers work tirelessly through the city streets, unable to disengage. "The game arises from workers' own initiatives to find ways of enduring subordination in the labor process, but it remains controlled, and when necessary, enforced by capital" (Burawoy, 2008, p. 93). As couriers' experience accumulates, the higher their rating, the greater the pressure they face in the following work cycle to maintain that rating. Through gamification, the courier is embedded within the platform's organizational framework, seamlessly merging the company's capital management with the courier's self-fulfillment. Ultimately, algorithmic exploitation by the platform gains legitimacy through the guise of gamification. Couriers become absorbed in the platform's operational mechanisms, and labor quotas are continuously met within this incentive structure.

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Platform incentive rules significantly boost drivers' and couriers' motivation, extend online labor time, and increase order acceptance. Driven by the incentive to "meet the order quota and earn bonuses", couriers unconsciously exert more effort, and the gamified environment adds enjoyment to their labor. "The difference between 'making out' and not is measured not in the few cents we earn in bonuses but in our sense of prestige, accomplishment, and pride" (Burawoy, 2008, p. 96). The transparency and openness of platform transaction rules and compensation systems stimulate driver and courier participation, fostering the positivity and fairness of "earning more by working more", which reinforces acceptance of platform operational norms. "We did not jointly decide what the rules of making out should be; instead, we are compelled to play this game and then go on to uphold its rules" (Burawoy, 2008, p. 99). The hierarchical management model for workers, or "calculated workers", as Gillespie terms it (Gillespie, Boczkowski, & Foot, 2014, pp. 167-194), is strengthened through platform algorithms, making organizational management more granular and turning digital labor into a calculable operational process. "Gamified and differentiated management mechanisms also shape an ideology of the 'worker entrepreneur'" (Sun, 2019). The hierarchical elevation in the platform system becomes a primary basis for drivers and couriers to assess the significance of their labor and the realization of self-worth. In digital capitalist labor processes, the gamified incentives and the platform's organizational management mechanisms complement each other. On one hand, capitalists use gamified incentives to grant digital laborers relative autonomy, thus motivating labor and enhancing individual agency. On the other hand, the platform's systematic regulatory mechanisms and normative recognition construct an ideology of "community of interests" that builds worker consent, mitigating class consciousness and resistance. As Upadhya suggests, "the spread of entrepreneurialism and individualism is one of the significant manifestations of postmodernization in technological capitalism" (Upadhya & Vasavi, 2006). Platform companies replace authoritarian control with structured designs and incentive plans, cultivating individualism and shaping a consent mechanism among workers. This fosters organizational control over digital labor, masking capital's exploitation and its pursuit of surplus value.

4. ESTABLISHING CUSTOMER EVALUATION SYSTEMS TO CONSTRUCT LABOR PROCESS MONITORING MECHANISMS

From setting wage levels and standards for rewards and penalties to methods of labor supervision, platform systems exert significant control over labor processes. A key means of monitoring labor quality within platform systems is by directly linking customer ratings to the earnings of digital laborers. Unlike traditional employment relationships, which rely on command-and-control systems, platform systems utilize a "digital reputation" mechanism to guide drivers' and couriers' work processes, ensuring efficient performance management. "Quality control can itself be crowdsourced to customers or other crowd workers, leveraging collective wisdom to determine each worker's performance level" (Prassl & Risak, 2015).

While platform models may differ, the basic approach is consistent. On both ride-hailing and food delivery platforms, after each completed transaction, the platform encourages customers to provide a star rating for the service, ranked from 1 to 5 stars. Higher star ratings indicate higher customer satisfaction and correspond with higher order rates for drivers and couriers. Customer ratings impact drivers' and couriers' reward performances and future order rates. High ratings, particularly in terms of order completion rate, are favored by customers and platform systems alike, making it easier for workers to secure future orders and receive more dispatches from the platform. The strong pursuit of high star ratings drives drivers and couriers to refine their service and invest in emotional labor, defined as "managing one's emotions to create positive verbal, facial, and bodily expressions" (Sun, 2019). For instance, couriers seeking high ratings may use polite, courteous, and friendly language when interacting with customers and express gratitude after completing orders. Ride-hailing drivers may improve their working environment by adjusting air conditioning, music, and providing amenities like tissues, chargers, and bottled water, responding positively to customer questions. Platform algorithms continue to refine labor discipline, emphasizing standardized and formalized service differences. Throughout the labor process, drivers and couriers transcend anonymous relationships by performing emotional labor. With algorithmic precision, platform systems increasingly normalize and rationalize emotional labor, further implementing labor discipline among platform workers.

The rating mechanism of platform systems is not only a critical tool for disciplining digital laborers but also an effective means of redirecting conflict between capital and labor. Whether a driver receives high star ratings from customers directly influences the intensity of their future workload. A one-star rating might require numerous five-star ratings to counterbalance its effect. If drivers fail to work diligently to offset poor ratings, their next phase of rewards and dispatch metrics will be seriously impacted. Failure to address low ratings may lead to deductions in rewards or even a portion of base pay. If ratings fall below a certain threshold, the driver's platform account may be deactivated, ultimately leading to a negative cycle in work conditions. "Platform systems use star ratings as a tool for enforcing specific rules, much like employers exert control over termination decisions" (Aloisi, 2016). This strict rating mechanism places drivers under constant evaluation. Under the "incentive" of continuous rating, drivers exhaust themselves to maintain high performance. While star ratings may seem based on customer assessment of service quality, this evaluation mechanism effectively

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redistributes managerial authority and redirects conflicts between capital and labor. Platform companies rely on customers' natural awareness of service quality to supervise and monitor drivers' and couriers' performance, thus shifting attention away from the company's control. In this monitoring mechanism, drivers and couriers bear the consequences of low ratings caused by external factors, such as system errors causing delays or passengers' personal moods, which can lead to conflicts between the worker and the customer. In this way, platform companies achieve comprehensive oversight of labor processes with minimal management costs, subtly transferring the burden of conflict onto digital laborers and customers, effectively masking the capital-driven exploitation and pursuit of surplus value.

5. CONCLUSION

In the context of the digital economy, technology has formed new alliances with capital, placing digital laborers in a modern work environment where they unknowingly relive the conditions faced by industrial-age workers. Technologically driven labor obscures the fundamental nature of digital laborers' existence, masking the call for labor justice within digital labor processes and, in doing so, reveals the inherent limitations of technological advancement itself. Under the dominance of capital logic, technology intensifies labor, leads to subjugation, and exacerbates the impoverishment of producers. In this regard, the development of science and technology should be rooted in the fundamental values of supporting human survival, growth, and prosperity. Achieving universal access to scientific knowledge, big data, and other means of production is a prerequisite for realizing the human-centered value of technology. In the digital economy era, the collective ownership of technological resources is essential to securing human freedom, affirming individual agency, and offering contemporary individuals a rational way of life.

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A REVIEW ON RECENT STRATEGIES IN AQbD APPROACH

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ABSTRACT

Recent strategies in the Analytical Quality by Design (AQbD) approach have transformed the way analytical methods are developed, optimized, and controlled in pharmaceutical and regulatory environments. AQbD integrates scientific knowledge and risk-based strategies to ensure the consistent performance and quality of analytical methods throughout their lifecycle. This article explores the latest advancements in AQbD, focusing on key strategies such as method understanding, risk assessment, and the application of experimental designs like Design of Experiments (DoE) to optimize method parameters. Emphasizing the importance of system suitability criteria, monitoring, and trending of method outputs, the article highlights how these strategies can enhance method robustness, reduce variability, and ensure product quality. Case studies from regulatory agencies, including the MHRA and British Pharmacopoeia, illustrate the practical application of AQbD concepts in the development of compendial methods, such as the Atorvastatin Assay method. By leveraging these innovative approaches, pharmaceutical industries can improve method performance, ensure compliance, and meet evolving quality standards.

KEYWORDS: *Analytical Quality by Design (AQbD), Quality by Design (QbD), Critical Quality Attributes (CQAs)*

1. INTRODUCTION

The pharmaceutical industry is increasingly embracing innovative approaches to ensure consistent product quality, with Analytical Quality by Design (AQbD) emerging as a key strategy in this evolution. AQbD, which builds on the principles of Quality by Design (QbD), applies a science- and risk-based approach to the development, validation, and lifecycle management of analytical methods. Unlike traditional methods that rely on fixed procedures, AQbD introduces a more dynamic and flexible framework that incorporates quality into the analytical process from the start. This allows for ongoing improvement and adaptation over time, ensuring more robust and efficient methods. The need for an Analytical Quality by Design (AQbD) approach arises from the increasing complexity of pharmaceutical processes, regulatory demands, and the emphasis on maintaining high levels of product quality and patient safety. Regulatory bodies like the FDA and EMA are placing greater importance on lifecycle management, making AQbD essential for ensuring that analytical methods remain robust, reproducible, and capable of delivering accurate results under varying conditions. By emphasizing an understanding of method variability, identifying critical method parameters (CMPs), and establishing a method operable design region (MODR), AQbD helps develop methods that are both compliant with regulatory standards and resilient to variations.

2. HISTORY OF AQbD[16]

1990- Dr. JOSEPH M. JURAN

Dr. Joseph M. Juran laid the foundation for the Quality by Design (QbD) approach with the concept that "quality should be designed into a product, and most quality problems stem from how a product was designed in the first place." He emphasized that quality should be incorporated into the product during the early stages of development, ensuring that potential issues are addressed proactively rather than reactively.

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2004-2012: ICH Published Guidelines That Outlined Qbd Approach
2004 ICH Q8: Pharmaceutical product development
2005 ICH Q9: Quality Risk Management
2007 ICH Q10: Pharmaceutical Quality System
2012 ICH Q11: Development & manufacturing of drug substance
2017: International Consortium For Innovation And Quality By Aqbd-Working Group:
In 2017, the International Consortium for Innovation and Quality (IQ) AQbD working group conducted a survey of pharmaceutical companies and identified those that were not only interested in applying the QbD concept in manufacturing but also in developing analytical methods using the QbD approach.
2018: ICH New Guideline
In 2018 ICH proposed a new guideline on the QbD approach i.e., ICH Q14
Q14 - Procedure Development
2020: USP General Chapter Analytical Procedure Life Cycle Management:
In 2020 the UNITED STATE PHARMACOPOIA (USP) published a general chapter on Analytical procedure life cycle management (1220) which explains about the application of AQbD approach.
2021: British Pharmacopeia:
In 2021 British Pharmacopoia published a supplementary chapter about AQbD which cantain **The Application of AQbD to Pharmacopoial Methods**
2022: ICH Guideline:
In 2022 ICH published a draft version of the ICH Q14 Analytical procedure development.
2022 R2) – Procedure Validation

3. BASIC TERMINOLOGY OF AQbD[16]

3.1 Analytical Target Profile(ATP):

The Analytical target profile is crucial concept in the ICH Q14 Guideline the specifies the conditions the pn analytical method must achieve in order to property quality a product quality attributes.

3.2 Critical Method Parameters (CMP) / Critical Method Variables (CMV)

A critical method/Process parameters (CMP) refers to a process variables in pharmaceutical products that influence a critical Quality attribute (CQA), As a result CMP must be monitored or controlled to ensure the drug product achieve the desired quality

3.3 Analytical Design Space

ICH Q8 (R2) defines the space design as the multidimensional combination and interaction of input variables (such as material attributes) and process parameters that have been shown to ensure quality operating within the design space is not considered a change.

3.4 Method Operable Design Region:

The Method Operable Design Region (MODR), or design space, refers to the combination of method parameter ranges (at a minimum including all critical parameters, but not limited to them) that have been evaluated and verified to meet both the Analytical Target Profile (ATP) criteria and the specific method performance criteria.

3.5 Critical Analytical Attribute (CAA)

The CAA is a characteristics or property whether physical, chemical, biological or microbiological that must fall within a specific limit range , or distribution to ensure the desired quality of the product .

3.6 Experimental Trials or Runs

Trials done on the new product to evaluation the effectiveness and safety of the product, services and the effect of the product is checked Ex. Clinical and preclinical trials done on new drug for people getting better way of treatment with new drug .

3.7 Control Stratergy

The product control strategy should be define the analytical method to be used in AQbD studies and specify the stage at which they should be applied. In other words developing ghe control strategy for the entire process from the methods initiation .

A robust control strategy is obtained during the data obtained during the method development and confirmation stages of while considering ATP criteria.

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4. RECENT STRATEGIES IN AQbD APPROACH:

4.1 GROUP 2017: INTERNATIONAL CONSORTIUM FOR INNOVATION AND QUALITY BY AQBD-WORKING

4.2 2020: USP GENERAL CHAPTER ANALYTICAL PROCEDURE LIFE CYCLE MANAGEMENT

4.3 2021: BRITISH PHARMACOPEIA - THE APPLICATION OF AQBD TO PHARMACOPOIAL METHODS

4.1 GROUP 2017: INTERNATIONAL CONSORTIUM FOR INNOVATION AND QUALITY BY AQBD-WORKING[7]:

Published on: April 2, 2017

Elizabeth Hewitt, Andy Rignall, Mark D. Trone, Patrick Jackson, Marion Chatfield, Mark Argentine, Qinggang Wang, Shreekant Karmarkar, Andrea M. Pless, Zeena Williams, Kimber Barnett, David Semin, Yanqun Zhao, Ariane Marolewski.

The Analytical Quality by Design Working Group (AQbD WG) of the IQ Consortium has published the results of a survey in Pharmaceutical Technology, focusing on the implementation of Analytical Quality by Design concepts by both small- and large-molecule pharmaceutical companies. The survey was distributed to IQ Consortium member companies and completed by 16 of them, including 12 large companies (with over 10,000 employees) and four smaller ones. It revealed that more than two-thirds of the companies had implemented AQbD to some extent, with larger companies being more likely to adopt AQbD concepts. The survey also explored the technical aspects of AQbD, challenges with implementation, business considerations, and regulatory experiences. Overall, the analysis of the survey responses concluded that AQbD implementation offers operational benefits, fostering continued interest and application.

More than two-thirds of the companies surveyed (69%, or 11 of the 16) had implemented AQbD in some form (Figure 1). As expected, large pharmaceutical companies had a higher implementation ratio (83%, or 10 of 12 companies) compared to smaller pharmaceutical companies (25%, or 1 of 4 companies). In other words, 91% (or 10 of the 11 companies) implementing AQbD concepts were from large companies, although these companies submitted significantly more survey responses. Among the varied responses, AQbD implementation occurred for both large and small molecules, with many companies indicating that their approaches were similar for both types.

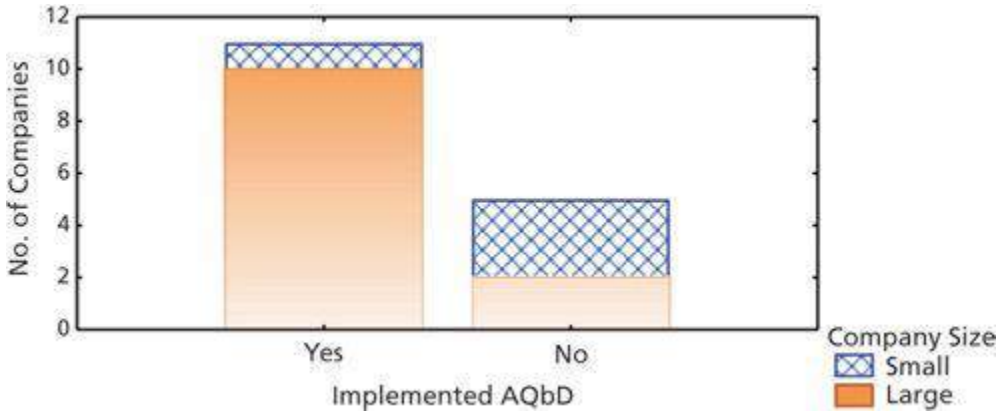

Fig: Breakdown of all responding companies by whether they have implemented analytical quality by design (AQbD) and their size. (All figures courtesy of authors

Companies that implemented AQbD concepts identified improved method performance as the primary business driver. Conversely, the five companies that did not integrate AQbD into their development programs cited concerns about increased costs and resource investments with minimal benefit as their main reasons.

4.1.1.Technical Details And Challenges With Implementation

Among the 11 companies that have implemented AQbD concepts, respondents were nearly evenly divided between those who recently started implementation and those who have been practicing AQbD for an extended period. Of the five companies that have not implemented AQbD, three indicated they are just beginning. Notably, most companies tend to practice AQbD concepts during late-stage

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development (over 80% in Phase III) and commercialization, rather than in earlier development stages, to maximize the value of their investment efforts.

4.1.2.AQbD Concept In Drug Development[7]

Table I presents a breakdown of AQbD implementation during the drug development lifecycle for the 18 respondents. This outcome aligns with the key benefits expressed from AQbD implementation, including achieving robust methods, better validation packages, and significantly improved method knowledge during development. Although not shown in Table I, some comments regarding utilization indicate that certain companies apply subsets of AQbD tools (e.g., modeling) during earlier development stages (Phases I and II), albeit with less systematic rigor compared to later phases to enhance knowledge development.

Table I: Analytical quality-by-design (AQbD) concept implementation during drug development process by respondent.

Response	Phase I	Phase II	Phase III	Post-Approval
1			X	
2			X	
3		X	X	
4				
5				
6				
7		X	X	X
8	X	X	X	X
9	X	X		
10	X	X	X	
11			X	X
12			X	
13		X	X	X
14			X	
15		X	X	
16				
17			X	
18	X			
Total:	4	7	12	4

Table : Analytical quality-by-design (AQbD) concept implementation during drug development process by respondent.

4.1.3 AQbD Concept In Drug Product Method

The survey clearly indicated that the primary focus for implementing AQbD concepts is on drug substance and drug product methods, with much lower application to the testing of other materials (Table II). Interestingly, and perhaps not surprisingly, respondents have applied AQbD concepts almost equally to chromatographic and non-chromatographic methods, while clearly not applying these concepts to compendial methods.

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Table II: Method types to which analytical quality-by-design concepts have been applied.

Type of methods	Percentage of respondents
Drug product methods	100
API methods	93
Non-chromatographic methods	57
Only chromatographic methods	47
Methods for API starting materials	33
Process intermediate methods	30
In process monitoring methods	22
Compendial methods	14

Table : Method Types To Which Analytical Quality-By-Design Concepts Have Been Applied.

Eight respondents reported that developing robust methods saved time, while six respondents disagreed. Although a multivariate AQbD-based approach was perceived to require more time and additional resources for lifecycle management of methods, it was believed that the resulting methods were more robust, leading to fewer issues encountered during routine use.

The majority of survey companies leveraged commonality among methods to enhance efficiencies in AQbD implementation. They utilized generic risk assessments based on method types, such as templates for reversed phase-high-performance liquid chromatography (RP-HPLC) assay methods, and standardized method development approaches, including standard chromatographic column screens. To address the increased resource demands of method development, 13 out of 15 respondents implemented various software packages like Fusion AE, DryLab, ChromSword, and ACD/AutoChrom. Respondents applied statistics (92%) and experimental design (100%) to improve AQbD efficiency, consistent with numerous literature examples promoting robust method development under AQbD. The simple design of experiments (DoE) approach was the most widely used tool for robustness testing, and 64% of companies employed modeling and simulation tools for AQbD applications. However, most respondents did not use any additional approaches beyond these tools to address the potential rise in resource demands for AQbD implementation.

Six of the 16 companies reported having departmental guidelines or standard operating procedures (SOPs) for implementing AQbD concepts, representing about half of those that have adopted AQbD. Comments indicated that some groups felt specific guidance on QbD implementation was unnecessary, with some responses noting that QbD aspects of analytical work were documented directly within work packages (e.g., method development or validation) rather than as separate entities.

4.1.4.Summary Of The Survey

In summary, results from a 34-question survey indicate that the majority of responding companies have adopted AQbD concepts over the past decade, with about half of the companies just beginning their implementation. A key driver for adopting AQbD principles has been the development of more robust analytical methods, alongside the use of various tools that enhance experimental design and modeling, demonstrating a commitment to this goal. Moreover, the greatest value from implementation is found during the late development stages and commercialization phases for optimal return on investment. These survey results align with an informal AQbD adoption survey conducted in November 2015, which involved representatives from approximately 25 biopharmaceutical companies, including small-molecule, large-molecule, and vaccine-related organizations. During that meeting, there was clear interest in advanced discussions of AQbD principles, with more robust analytical methods and enhanced regulatory flexibility (averaging 4.7 out of 5, with 5 being the highest rating) identified as drivers for developing AQbD case studies to further the conversation on the topic.

4.2. 2020: USP GENERAL CHAPTER (1220) ANALYTICAL PROCEDURE LIFE CYCLE MANAGEMENT[1]:

According to the USP GC (1220) AQbD called as A systematic approach to development of that begins with predefined objectives and emphasizes product and process understanding and process control,based on sound science and quality risk management. (USP) GC (1220).

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4.2.1. According To The Usp Gc The History Of AQbD Is
2004-2012 ICH guidelines outline AQbD concepts:
2004: Q8 Pharmaceutical development
2005: Q9 Quality risk managment
2007: Q10 Pharmaceutical quality system
2012: Q11 Development and Manufacture of Drug Substance

2013 Stimuli Article
PF 39(5) Lifecycle Management of Analytical Procedures

2016 Stimuli Article
PF 42(2) Fitness for Use PF 42(5) ATP PF 42(5) Analytical control strategy

2014-2017 ICH Q12
Pharmaceutical Product Lifecycle Management

2018 – Q14/Q2(R2) Working Group

2020 –BP/MHRA Consultation response application of AQbD concepts to pharmacopoeial standards
1ST SEP 2020 – USP GC published in PF46(5)

2021 – BP Supplementary chapter proposed
1ST DEC 2021 – USP GC became online in USP-NF
MARCH 2022 – Public Consultation **ICH Q14** draft guideline Procedure Development
ICH Q2(R2) draft guideline Procedure Validation
1ST MAY 2022 – USP GC become official

4.2.2.According To USP GC The Q14 Guideline Contains[9]:

Q14 – Procedure Development	Q2 (R2) – Procedure Validation
Minimal vs enhanced approaches	Selection of analytical procedure validation experiments and criteria
Analytical target profile	Considerations for multivariate procedures
Knowledge management	Specificity/selectivity
Risk management	Validation of the reportable range
Robustness	Validation of lower range limits
Analytical procedure control strategy	Accuracy and precision
Evaluation of change management	
Multivariate analytical procedures	
Real-time release testing	

4.2.3.Topics Covered In USP GC[1]

4.2.3.1.Analytical Target Profile (ATP)
ATP is a predefined objective that stimulates the performance requirments for the analytical procedure ,

It Include
Definition of analyte
Description of analytical matrix
Range

Used to measure the value and source of errors
1. **Bias -** How close the measurement is, on average, to the true value that is being measured (systematic error)
2. **Precision -** how much the measurement will vary randomly under routine use; (random error)

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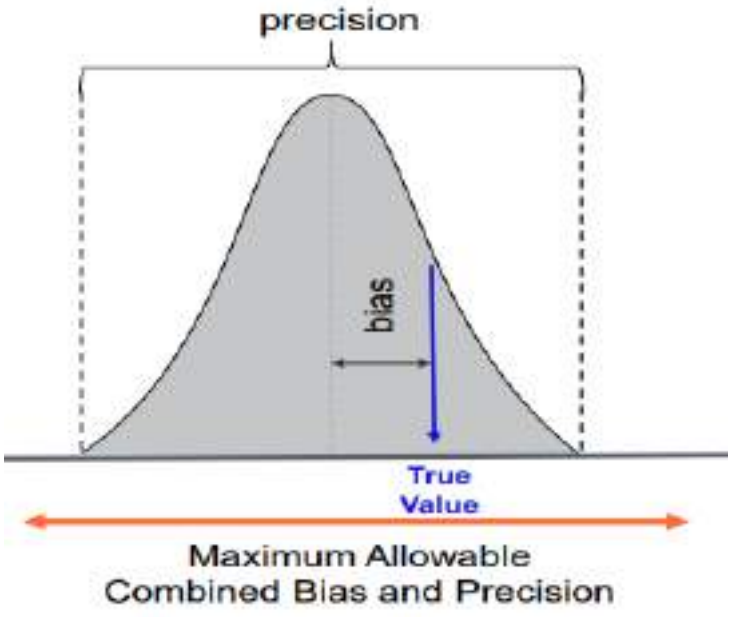

Fig. Analytical Target Profile (Atp)

4.2.3.2. Quality Risk Management (QRM)[22]

A systematic process for the assessment, control, communication, and review of risks to the quality of the reportable value throughout the lifecycle of the analytical procedure.

Quality risk management supports a practical and scientific approach to decision-making (ICH Q9).

Quality Risk Management Methodologies

Flowchart,
Process Mapping,
Cause And Effect Diagrams,
Failure Mode Effects Analysis (FMEA),
Failure Mode Effects And Criticality Analysis (FMECA) etc.

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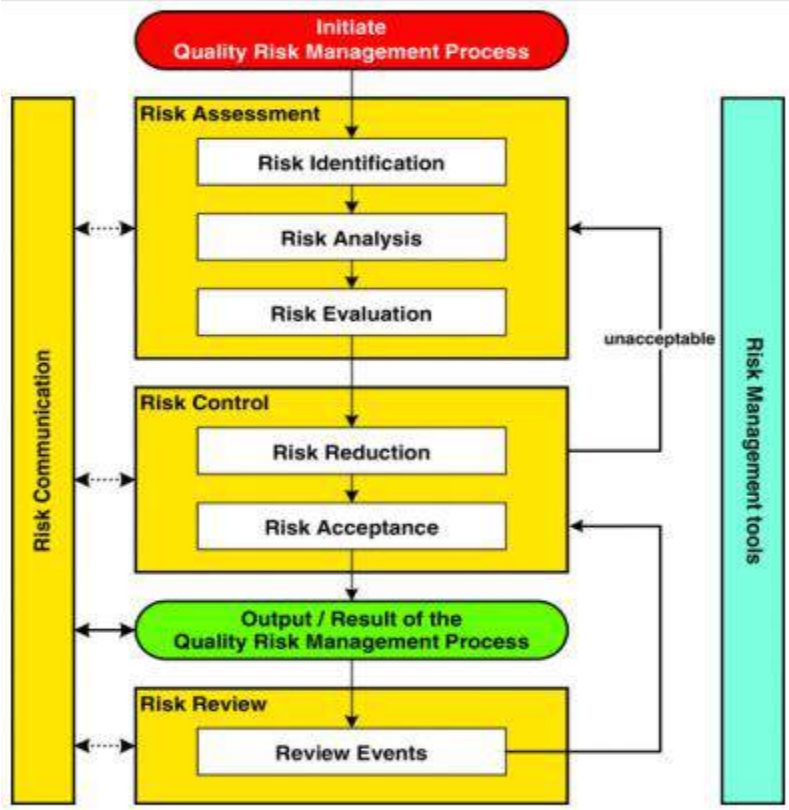

Fig. Overview of a typical QRM process (ICH Q9).

4.2.3.3. Method Operable Design Region (MODR):
MODR is a multidimensional combination and interaction of procedure parameters, where all combinations of study factors have been demonstrated to:
– Provide acceptable mean performance
– Provide acceptable robustness
– Ensure the ATP is fulfilled.

4.3 2021: BRITISH PHARMACOPEIA - THE APPLICATION OF AQBD TO PHARMACOPOIAL METHODS[25]:
This chapter is intended to serve as selective guidance for applying Analytical Quality by Design principles to pharmacopoeial procedures and throughout the entire Analytical Method Lifecycle, rather than as a mandatory requirement. The British Pharmacopoeia, along with its expert working party, will expand and revise this guidance as both internal and external knowledge advances and as further international standards are developed.

4.3.1. Application Of Analytical Quality By Design To Pharmacopoeial Methods:

4.3.1.1. Background

The development and control of an analytical method throughout the product lifecycle is a crucial part of the overall product control strategy. This control is founded on key concepts collectively known as 'Analytical Quality by Design (AQbD)'. The MHRA and British Pharmacopoeia have investigated the practical application of these concepts to a pharmacopoeial assay procedure, and they are using insights from this studyfootnote text{footnote}footnote to inform individual finished product monographs on a scientific and risk-based approach. This Supplementary Chapter outlines the principles and offers practical guidance for implementing AQbD principles in pharmacopoeial procedures. The chapter covers:

- A discussion of Quality Risk Management (QRM)
  - Risk identification tools: Ishikawa/Fishbone
  - Risk analysis tools: FMEA
  - Risk evaluation and control

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•Establishment of method understanding
  o Systematic method development and evaluation
  o Experimental design
  o Statistical approaches to support experimental design

Supplementary Chapter SC I, titled 'Basis of Pharmacopoeial Requirements,' provides an overview of the use, application, and necessity of pharmacopoeial procedures. The methods outlined in the Pharmacopoeia are designed to be robust, as they are used by analysts across a wide range of laboratories, sometimes only occasionally. The General Notices of the British Pharmacopoeia allow for alternative methods if they are known to yield results of equivalent accuracy. For instance, a manufacturer may opt to use their own optimized method. However, in cases of doubt or dispute, only the pharmacopoeial methods are deemed authoritative. The concepts presented in this supplementary chapter can support the development of both robust pharmacopoeial methods and alternative methods used by manufacturers, as well as their application throughout the product lifecycle to ensure the quality of a specific drug substance or its pharmaceutical preparation.

Analytical Quality by Design is an evolving field within analytical science, and this supplementary guidance chapter will be updated in future editions of the BP to include additional guidance on applying these concepts to pharmacopoeial methods and their role throughout the Analytical Method Lifecycle.

4.3.1.2.Application To The British Pharmacopoeia:
Analytical method performance—and thus the results produced by an analytical method—is generally subject to variability during routine use. It is therefore essential to understand how variability in method parameters (e.g., temperature, solvent composition, etc., for an HPLC method) can influence the results, as well as to consider the impact of typical changes in method conditions that may arise over time and across different laboratories (e.g., instrument type/design, reagent quality, sample shakers, analyst training, etc.).

Pharmacopoeial methods are designed to be applicable to a wide variety of available formulations, often requiring a review of data and laboratory evaluation of submitted, registered methods to confirm their suitability for pharmacopoeial use. This process involves applying quality risk management principles and tools to target the investigation on the method's most critical aspects, thereby maximizing the knowledge gained from laboratory work.

The case study conducted by the MHRA and the BP applied a stepwise process to explore how AQbD principles can be effectively implemented in pharmacopoeial procedures. The goal of this work was to demonstrate that AQbD can be used to develop robust, fit-for-purpose methods within the BP. The case study highlighted the value of applying these principles to an assay procedure, and the BP is continuing to apply and further investigate the insights gained across a range of pharmacopoeial procedures.

4.3.1.3.Quality Risk Management For Analytical Procedures[22]:
Building method understanding begins during method development and continues through formal validation (in line with conventional ICH Q2: Method Validation), as well as verification, method transfer exercises, and routine use, including for pharmacopoeial methods. Traditionally, the BP has applied risk management principles to guide the laboratory evaluation of analytical methods, and the outcomes of the AQbD case study have been used to enhance this process.

Pharmacopoeia users may not have prior knowledge of a given method beyond what is provided in the pharmacopoeia. This section summarizes the application of quality risk management tools, such as risk assessments, to analytical methods in the pharmacopoeia.

- **Quality Risk Management**

Before 2006, risk management principles were not as widely applied in the pharmaceutical industry as they were in other business areas. This changed with the publication of ICH Q9, which encouraged the industry to adopt risk assessment processes to support the manufacturing, development, and distribution of pharmaceutical products throughout the product lifecycle. One area where risk management approaches are now extensively applied is in developing robust control strategies for manufacturing processes. Similarly, risk management principles can be used to establish control strategies for analytical methods. By adopting a risk-based approach, controls for analytical methods can be focused on parameters most likely to affect the reliability of analytical results.

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- **Risk Analysis**

Risk analysis involves estimating the risk associated with each variable identified in the previous step. It considers both the likelihood of variation (probability) and the potential impact of that variation on the reportable result (severity). A variety of tools and approaches can be used to facilitate the risk analysis process (see ICH Q9 appendices for a range of examples).

- **Risk Evaluation And Control:**

Once the risk associated with each input variable is understood, an evaluation of the required controls is performed. These controls should focus on the variables most likely to impact the reportable result and, ideally, eliminate the probability of variation. This is the first step in building an analytical control strategy for a method (see section 5.1). When using an FMEA approach, this involves identifying steps to reduce the probability score, thereby lowering the overall risk. After implementing these steps, the risk score should be reassessed with the controls in place.

If the probability of variation cannot be significantly reduced, consideration should be given to detecting the variation before the reportable result is generated. For example, if batch-to-batch variation in chromatographic packing material cannot be eliminated, a resolution check may be introduced to detect any potential impact on the accuracy of the result (see section 5.2 for trending concepts). Ideally, "system suitability" tests should always be included to mitigate known risks, rather than merely satisfying a standard method template.

4.3.1.4. Establishing Method Understanding:

The effectiveness of a risk assessment, and ultimately the analytical control strategy for a given method, depends on the level of understanding of how method parameters relate to the method output, i.e., the result. Section 4 outlines approaches that can be adopted throughout the product lifecycle to ensure a thorough understanding of the method.

The MHRA and British Pharmacopoeia case study on Atorvastatin Tablets illustrates how the Pharmacopoeia may apply AQbD concepts when evaluating a method's suitability for compendial use. It is not expected that all of these concepts will be used in assessing the method's suitability.

- **Systematic Method Development And Evaluation:**

Experimental studies are conducted to support risk assessments by evaluating the impact of method parameters and environmental factors on method performance. These studies typically serve two main purposes:

- The Influences of deliberate variations in procedure-related method parameters (solvent strength, pH, sample concentration, etc.)
- The Influences of 'noise' factors (analyst, column batch etc.) which typically cannot be, or are preferred not to be controlled are evaluated.

When investigating deliberate variations in procedure-related method parameters, multifactor empirical modeling (e.g., Design of Experiments, or DoE) is generally preferred over one-factor-at-a-time (OFAT) experiments, although OFAT may be suitable in some cases. Mechanistic modeling, or a combination of mechanistic and empirical modeling, can also be used to reduce the experimental burden if shown to be appropriate. In addition to assessing the impact of method changes on the results, other key method attributes (such as resolution, sensitivity, accuracy, etc.) can be considered to understand method performance and optimize conditions.

The British Pharmacopoeia's case study employed several experimental designs, using multifactor approaches to assess the effects of various chromatographic, sample preparation, and stability factors with minimal injections (see Section 4.2). The case study also examined 'noise' factors; however, as this involved multiple product suppliers—which is primarily relevant for pharmacopeial applications—a more typical non-pharmacopeial example of studying 'noise' factors is provided in Section 4.2. By necessity, the case study explored these concepts in depth, though it would not be appropriate or effective to universally apply these concepts to all methods.

- **Utilising Method Development Tools And Statistical Analysis**

Analytical method parameters are factors related to the method's operation, specified either within a continuous range or at specific, controllable levels. The use of fractional factorial designs (or DoEs) for experimentation to develop general-purpose (linear) models, which describe the effects of changes in these parameters, is outlined below. These models are typically used to identify and/or confirm a setpoint and ranges for analytical method parameters to ensure robustness. While it is possible to define a broader operating region for method operation, this is not usually done.

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In the practical application of AQbD to the pharmacopoeial assay procedure, DoEs were conducted to investigate sample extraction, chromatography, and solution stability. Figure 3 illustrates a two-level fractional factorial design used to examine four mobile phase factors. A full two-level factorial design includes all combinations of chosen low and high levels for the parameters, represented by the cube's corners. A fractional factorial design, however, uses a subset (or fraction) of points, represented by the solid circles in this example. This half-fraction design uses 8 out of the 16 possible combinations (2^4) of low and high levels for the four factors. Additionally, center points—midpoints between low and high levels and often the planned setpoint for the method—are used to estimate variability under consistent conditions and to evaluate whether a linear model in the parameters is suitable. Fractional factorial designs are highly efficient due to hidden replication (each factorial point includes replication at a parameter level, unlike OFAT experiments, which use only one level). Running all factorial combinations is unnecessary, as an adequate model is typically obtained by considering the effects of single factors or interactions between two factors.

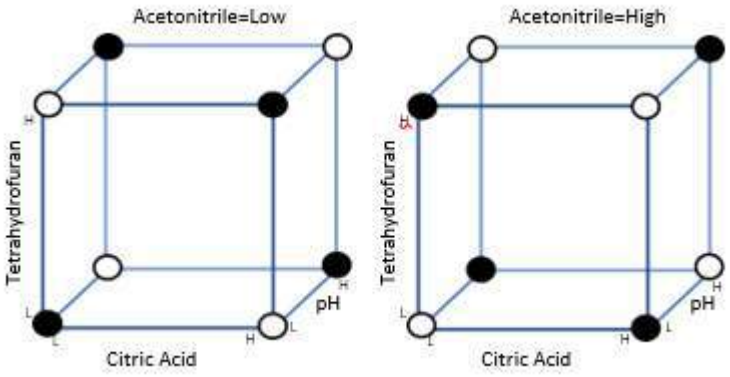

Fig. Utilising Method Development Tools And Statistical Analysis

- **Assessment Of Variation In Method Operating Conditions**

The variations in method operating conditions considered here are typical changes that can occur over time and across different laboratories, such as differences in instrument type, reagent quality, sample shakers, and analyst training. These variations, referred to as "noise factors," are not specified or controlled as method parameters. Studies are designed to challenge the method and assess the long-term effects of these noise factors on precision. Noise factors that significantly impact precision can be identified and further investigated to improve and control the method where feasible. Unlike designs that assess the effects of analytical method parameters, which mainly evaluate continuous factors, these studies focus on discrete, uncontrolled factors in the method description, such as the analyst. Conducting such a study during method transfer is often advantageous, as it combines both activities, conserves resources, and provides additional challenge by utilizing two laboratories.

Figure presents an example study in which the design should be selected based on the risk assessment and practical considerations. The factors and levels used are displayed at the bottom of the plot. In such a design, factors may be either "crossed" or "nested." In this example, the analyst, HPLC, and column (col) are nested within the lab, meaning each analyst is assigned to only one site. Prep is nested within each combination of analyst, HPLC, and column, with two injections performed for each prep. However, the analyst, HPLC, and column factors are crossed with one another, as each analyst uses more than one HPLC instrument. It is preferable to include a sufficient number of levels for all factors in the design (not only for preps and injections) to enable the effects or variations associated with each factor to emerge during the study, while recognizing practical constraints.

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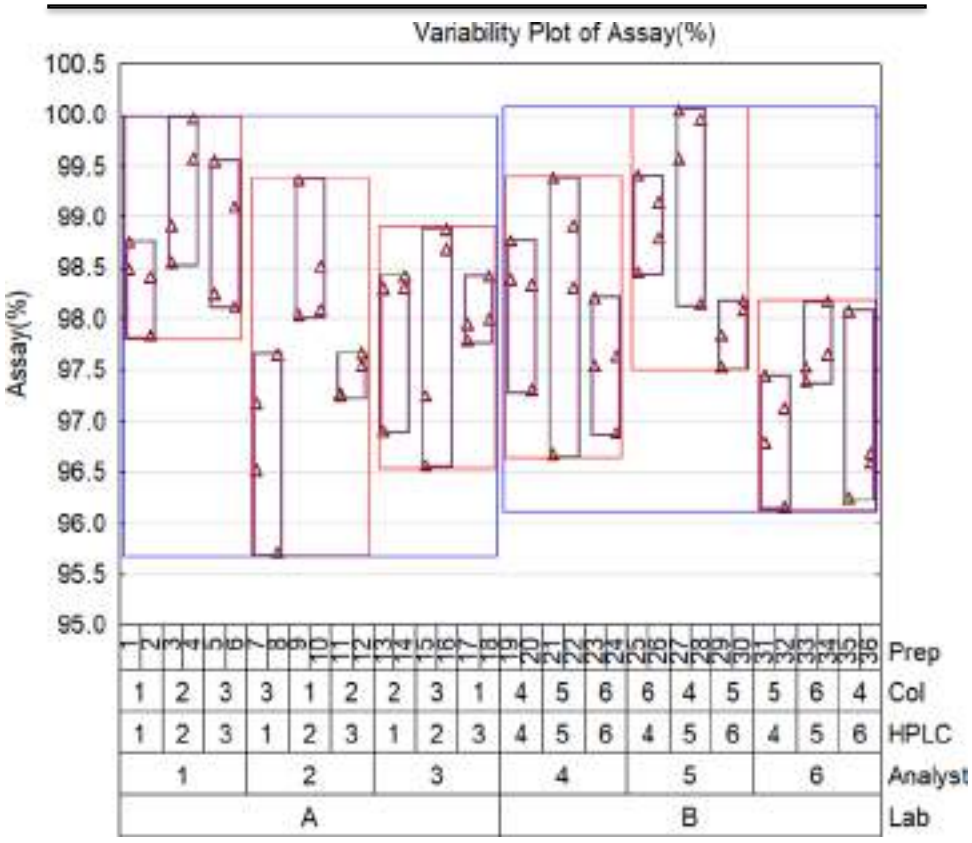

Fig. Assessment of Variation In Method Operating Conditions

4.3.1.5.The Analytical Control Strategy And Its Role In Ongoing Monitoring Of Method Performance[25]:

- **Analytical Control Strategy**

According to ICH Q10, a control strategy is a planned set of controls based on product and process understanding to ensure process performance and product quality. These controls may include parameters and attributes related to drug substance and drug product materials and components, facility and equipment operating conditions, in-process controls, finished product specifications, and the methods and frequency of monitoring and control associated with them.

Sections 3 and 4 outline the concepts that can be adopted to develop an analytical control strategy based on a deep understanding of the method and product. The MHRA case study confirmed that the appropriate control strategy for the atorvastatin tablets assay method was to follow system suitability criteria, specifically ensuring a minimum resolution between a critical pair (Atorvastatin and a closely eluting related substance)

The chromatographic conditions and permissible adjustments outlined in Appendix III, Chromatographic Separation Techniques, complement the analytical control strategy developed according to the processes described in this supplementary chapter for a pharmacopoeial method.

- **Ongoing Monitoring Of Methods**

Monitoring the results of analytical methods provides valuable insights into process capability. An additional strategy for identifying areas of risk and alerting users to potential issues before method failure is trending a range of different method outputs. Monitoring can alert users to trends and help take corrective action in advance. There are various ways to conduct monitoring, including trending results, control sample outcomes, and performance attributes such as the retention time of specific analytes, peak shape of principal peaks, and more. Additionally, monitoring measurements of reference or standard materials analyzed repeatedly over time can also be useful.

Figure presents a simple model of additional parameters that may need to be trended throughout the lifetime of a method, or in this case, for an individual column. The figure shows an inverse relationship between the resolution of a critical pair and the peak shape of

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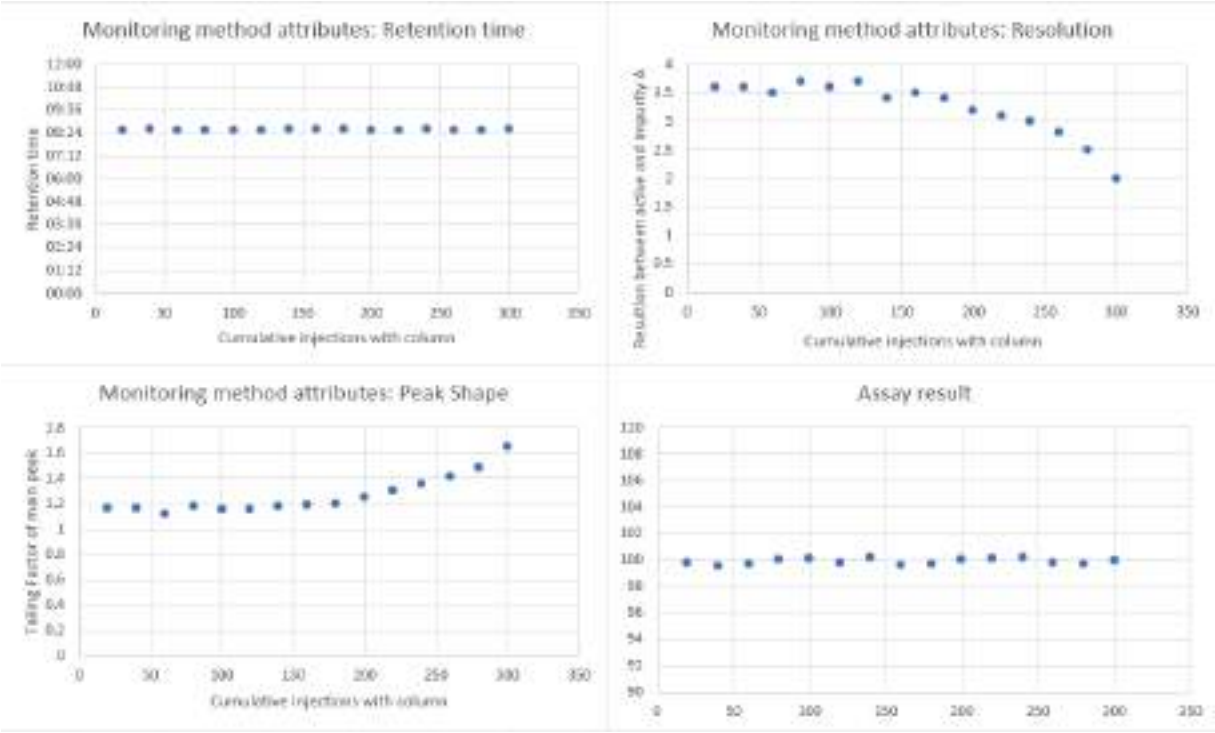
the active. In this example, an increase in peak tailing leads to a loss in separation between the drug substance and a major impurity. While the Assay value remains unaffected, the resolution is approaching a failure of the system suitability criteria, as is the peak shape.



5. CONCLUSION

In conclusion, recent strategies in the Analytical Quality by Design (AQbD) approach represent a significant evolution in the development and optimization of analytical methods. By integrating risk-based thinking, method understanding, and advanced experimental designs such as Design of Experiments (DoE), AQbD provides a structured framework to enhance the robustness, reliability, and performance of analytical methods. The implementation of system suitability criteria, the continuous monitoring and trending of method parameters, and the identification of potential risks contribute to maintaining high-quality standards throughout the product lifecycle. Regulatory case studies, such as those from the MHRA and British Pharmacopoeia, demonstrate the practical applications of AQbD in ensuring that methods not only meet but exceed compliance requirements. Moving forward, the adoption of AQbD principles will continue to drive improvements in analytical method development, reducing variability and enhancing product quality while supporting the evolving demands of the pharmaceutical industry.

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NOVEL METHOD OF LIPID DRUG MEMBRANE INTERACTION

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ABSTRACT
A better knowledge of the molecular processes behind drug-membrane interactions is essential for the development of novel medications. To far, a number of biochemical and biophysical methods have been developed to study biological membranes at the molecular level. This review centers on the accomplishments and new uses of contemporary analytical methods, such as spectrometry, calorimetry, acoustic sensing, and chromatography, in the investigation of drug interactions with lipid membranes. The benefits and drawbacks of these approaches were compared and carefully considered. Moreover, several biomimetic model membrane types, including lipid monolayers, liposomes, and supported lipid monolayers/bilayers, were described. Additionally, a brief overview of the general mechanics underlying the drug-membrane interaction process was given.
KEYWORDS: *bioanalysis; drug-membrane interactions; drugs; lipid membrane*

INTRODUCTION

The primary components of the cell membrane, which are a wide range of distinct lipids, proteins, and polysaccharides, make up this extremely complex and diverse structure. Amphipathic phospholipids make up the majority of the continuous lipid bilayer that makes up the cell membrane matrix. The cell membrane, which serves as a cell's border, is crucial to a drug's absorption, distribution, metabolism, and excretion (1).A medication molecule must first enter the bloodstream (the absorption process) and subsequently be delivered to its action locations (the distribution process) after being administered. The blood-brain barrier (BBB), the walls of the small capillaries lining the stomach, and the barrier membranes in the gastrointestinal tract are only a few examples of the biomembranes that can be involved in the drug's action. A growing body of research has demonstrated that drug molecules can interact with the lipid membrane either directly or indirectly. This interaction can result in modifications to the pharmacological activity, bioavailability, and physicochemical characteristics of the drug molecules, as well as a wide range of pharmaceutical effects and chemical structures (2). Adverse consequences, including medication resistance and severe side effects, can result from unfavorable drug interactions with lipid membranes.Due to inadequate medication specificity (Gashaw et (3). Examples include anaesthetics (4), anticancer medications (5), and nonsteroidal anti-inflammatory medicines (NSAIDs) (6). Therefore, it is crucial for biomedical researchers as well as the pharmaceutical industry to comprehend the inherent interactions between drugs and biomembranes.

• Analytical methods to study Drug-Membrane Interactions

Drug-membrane interactions can be investigated using a variety of analytical techniques, such as spectrometry, calorimetry, chromatography, and acoustic sensing technologies (7).

Ion-Association Mechanism High-Performance Liquid Chromatography

For more precise determination of the partitioning of ionic and zwitterionic chemicals in different phases, the HPLC IAM stationary phase was created. IAM stationary phases, which are sold commercially by Regis Technologies, are essentially made up of phospholipid monolayers, primarily phosphatidylcholine, covalently bound to porous silica spheres fig 1.Consequently, the use of IAMs could lead to improved understanding of biological partition and biological activity. Furthermore, IAM-HPLC measurement is more appropriate for medium- or high-throughput screening in early drug discovery because it is straightforward, quick, and repeatable when compared to the traditional method of determining drug partitioning in liposome/water systems (8). Numerous parallels have been drawn between the lipophilicity measured by IAM and the capacity factor, log...and the conventional logP and logD liposome/water and n-octanol/water partitioning systems (9). The outcomes demonstrated that IAM-HPLC is a more precise and efficient method for determining drug-membrane partition.

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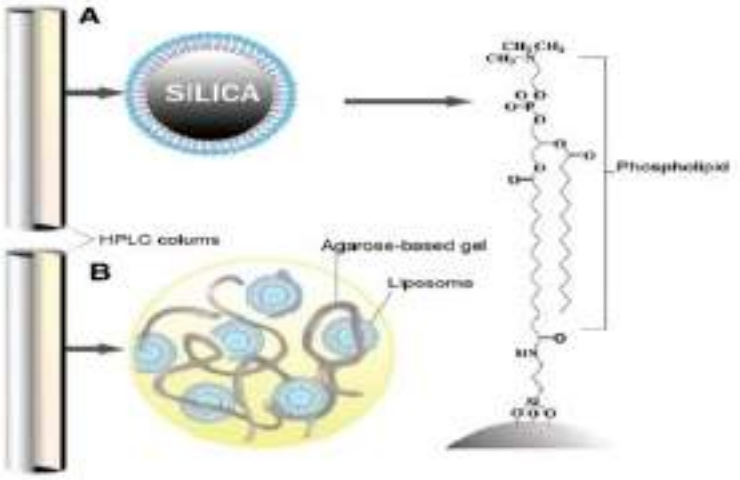

Fig 1: stationary phases of immobilized artificial membrane (IAM)

Immobilized Liposome Chromatography

In contrast to IAMs, variable membrane compositions may be used to change the biophysical characteristics of the lipid environment in ILC columns. The lipophilicity index calculated by ILC (logKs) and other techniques have different correlations. According to a comparative investigation, only for structurally related compounds were there substantial correlations discovered between logKs and the lipophilicity indices produced via IAM, n-octanol/water, and liposome/H2O systems (11).A comparative study revealed that significant correlations were only found between logKs and the lipophilicity indices obtained by IAM, n-octanol/water, and liposome/H2O systems for structurally related compounds. The lipophilicity index as determined by ILC (logKs) and other methods have different correlations. In contrast to IAMs, variable membrane compositions may be used to change the biophysical characteristics of the lipid environment in ILC columns.This suggested that the equilibrium between hydrophobic and In these systems, drug partitioning was controlled by electrostatic interactions. Three major issues with ILC include limited liposome stability, high sample demand, and challenges with column preparation.However, a recently published innovative approach demonstrated that liposomes on silica-based particle surfaces allowed for simpler column modification and a lower consumption of Liposome (12)

Electrokinetic Chromatography

Electrokinetic capillary chromatography, commonly known as electrokinetic chromatography (EKC), is a capillary electromigration method based on an amalgamation of HPLC and electrophoresis. EKC quantifies the analytes' electrophoretic mobility as well as their differential partitioning between a lipid dispersion (pseudo-stationary phase) and an encircling aqueous buffer solution (mobile phase) (13).

Capillary Electrochromatography

A kind of capillary liquid chromatography, capillary electrochromatography (CEC) is a newly discovered technique in which electroosmotic flow propels the mobile phase through a capillary. More stable lipid coatings are produced in CEC measurements because an IAM stationary phase is packed into a fused-silica capillary 14)). shown that there were linear correlations between CEC and HPLC results in a research including sixteen structurally distinct substances (15). Additionally, they noted that compared to IAM-HPLC, CEC required less analyte, eluent, and stationary phase even if its management was more sophisticated. A recent review examined the use of several capillary electromigration methods to investigate the interactions between lipid membranes and analytes (13).

Spectroscopic Techniques

This section will provide an overview of the spectroscopic methods that are frequently employed in the investigation of drug-membrane interactions. These methods include vibrational spectroscopy, mass spectroscopy (MS), electron paramagnetic resonance (EPR), fluorescence spectroscopy, X-ray diffraction (XRD), and small-angle neutron scattering (SANS). (33).

Fluorescence Spectroscopy

measures variations in fluorescence intensity to keep an eye on intermolecular interaction. When compared to alternative methods, fluorescence spectroscopy provides exceptional flexibility, great spatial resolution (down to the level of hundreds of nanometers), and

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sensitivity (down to the single-molecule level) (16). Fluorescent probes are frequently utilized since intrinsic fluorescence is uncommon in biological systems. presented an introduction to fluorescence probing of biological membranes (17).

NMR Spectroscopy

The magnetic characteristic of an atom's nucleus is known as NMR. According to the fundamental idea behind NMR spectroscopy is that some atoms' nuclei have a magnetic moment, which causes them to exhibit distinct energy levels and resonance frequencies when exposed to an external magnetic field (18),There are several of these nuclei in atoms found in lipid molecules, such as 1H, 13C, 31P, 17O, and 14N. According to lipids can also be chemically tagged with additional nuclei of interest, deuterium (2H), or fluorine (19F)(19).

EPR

Electron spin resonance spectroscopy, or EPR, is a technique that enables the direct identification of paramagnetic entities that have unpaired electrons (20).

Vibrational Spectroscopy

Vibrational spectroscopy examines an atom's nuclear vibration characteristics with little disturbance. It is mostly concerned with infrared absorption and Raman scattering. According to (21), it offers the most reliable way to distinguish between membrane behaviors, bilayer assemblies, and membrane structure and composition. Measuring the drug-induced vibrational shifts attributed to the particular chemical functional groups inside membrane systems allows for an analysis of drug-membrane interactions. The most used infrared spectroscopy technique for biophysical research is called Fourier transform infrared spectroscopy (FTIR). Analyte interactions with lipid membranes at the molecular level may be fully understood by using FTIR to monitor frequency fluctuation in the PO_2^- stretching, C=O stretching, and CH_2 stretching modes (22).

Diffraction of X-rays

When an entering X-ray beam has a wavelength that is comparable to the interatomic distances in the sample, some of the beam will be scattered, which is how XRD measurements work (23). X-ray diffraction (XRD) provides a direct and non-invasive method of determining the sample's structural characteristics, chemical makeup, and physical attributes by examining the angular distribution of the scattered intensity. Furthermore, X-ray diffraction (XRD) offers the benefit of estimating bilayer thickness of unsupported lipid membranes under near-native circumstances, down to Ångstrom length scales (24)

Neutron Scattering at small angles

Similar concepts underlie both SANS and SAXS, with the exception that in SANS, the neutron rather than the electron is the source of the scattering. Consequently, for a precise structural description of the biological membranes, SAXS and SANS may be applied as complementing approaches (25).

Calorimetric Techniques

The assessment of heat effects related to drug-membrane interaction forms the basis of calorimetric approaches (26). The quantity of material involved in the reaction and the pace of heat production are, in general, related to the amount of heat produced or consumed in a chemical reaction. Thus, calorimetric techniques may be used as thermodynamic and quantitative analytical tools. Pharmacology science has employed a number of sophisticated calorimetric methods (27). The most common methods for characterizing the drug interaction with membrane process are pressure perturbation calorimetry (PPC), isothermal titration calorimetry (ITC), and DSC. In Figure 2 typical instances of all three approaches are compiled.

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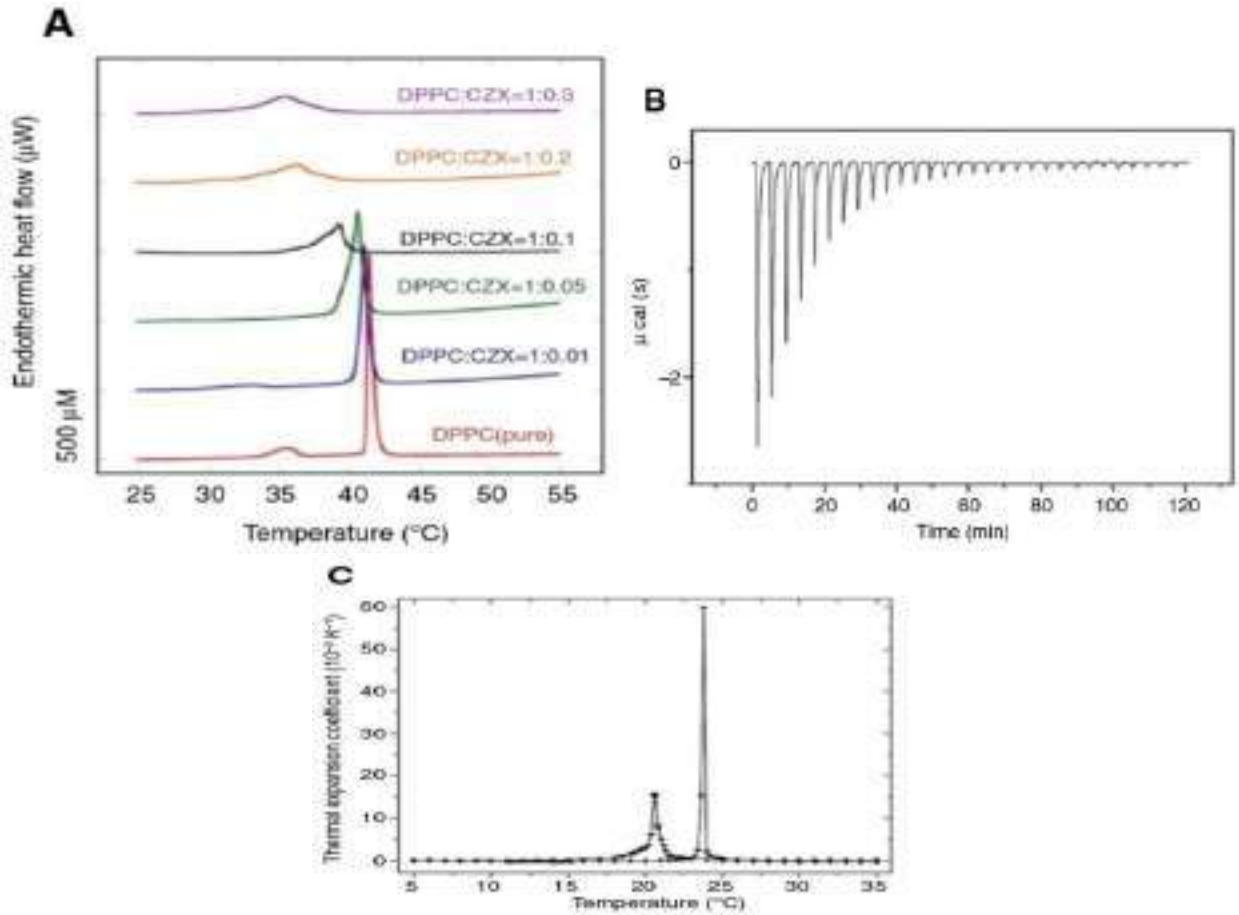

Fig 2 Calorimetry Technique

Differential Scanning Calorimetry

Heat capacity (Cp) of a material is measured using DSC, a non-perturbing method, as a function of temperature and time. It was created in 1962 by E. S. Watson and M. J. O'Neill, and Chapman utilized it for the first time in the 1960s to study the thermotropic behavior of biomembranes (28). The calorimetry of isothermal titration With the exception of operating at a constant temperature and including a titration module, the fundamental idea of ITC and DSC are identical (29). Every injection produces a record of the heat flow until the binding reaches saturation. The criteria for binding the generated isotherm may be used to determine thermodynamic values for the drug-lipid binding (30).

Pressure Perturbation Calorimetry

A relatively recent thermodynamic method called pressure perturbation calorimetry (PPC) analyzes the change in heat (ΔQ) that occurs when the pressure (ΔP) above a solution containing proteins or other biomolecules c4hanges (31).

Chromatographic Methods

Chromatography comprises a set of analytical methods that are employed to isolate, recognise, and measure distinct constituents within a blend.A stationary phase and a mobile phase interact and partition distinct substances differently, which is the foundation of chromatographic processes. To improve the identification of separated components, technologies such as electrochemical techniques and spectroscopy are frequently applied. There are several ways to classify chromatography, including gas chromatography, capillary liquid chromatography, supercritical fluid chromatography, liquid chromatography (LC), TLC, and others. based on the choice of stationary phase and mobile phase. Here, we'll focus on HPLC-based techniques, which are frequently used in studies of drug-membrane interactions.(32)

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CONCLUSION

comprising the drug's orientation, conformation, and localisation inside the membrane; the drug-inserted membrane's structural stability and phase behaviour; the drug's dynamics of interaction with the lipid membrane; and the effects of the drug-membrane interaction on the drug's ADME characteristics. Drug-membrane interactions can, in fact, be influenced by a number of variables, including the van der Waals force, hydrogen bonds, and hydrophobic and electrostatic interactions between certain lipid moieties, drug molecules, and membrane proteins. Therefore, additional analytical techniques are strongly advised to obtain a thorough knowledge of drug-membrane interaction events. Furthermore, the efficiency of on-site screening in the early stages of drug development will be significantly increased by the development of potent innovative combinations of methods, such as lab-on-a-chip hyphenation with MS methodologies.

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A REVIEW ON OF HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

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ABSTRACT

Nowadays HPLC is widely used instrumentation technique for separation and purification in various areas such as Biotechnology, Pharmaceuticals, Environmental food and polymer Industries.In this Review of High- Performance liquid chromatography contain Introduction, Chromatographic terms, Types and different classes of HPLC . As well as contain brief introduction to HPLC principle and Instrumentation, pumps, Included in detail with their efficiency.

This article is Written with the intension of reviewing several HPLC related topics including instrumentation , principles , manner of separation, characteristics, key parameter and Numerous application in various fields.

KEYWORDS: *HPLC , Instrumentation , pharmaceutical aid , Techniques , Application, Detector, columns , pumps.*

INTRODUCTION

In the late 1960s and early 1970s, liquid chromatography (HPLC) was developed. The amount that a unit remains in the column is determined by its separation between the liquid mobile phase and the stationary phase. In HPLC, this separation is affected by the interface phase interaction between the solute/residual phase and the solute/stimulus. So, unlike GC, changes in mobile phase composition can have a significant impact on your split , since the compounds have different mobilities , they leave the column at different times. In other words, the retention periods are different [1].Additionally taken into account is how these compounds interact with the column's stationary phase. The apparatus needed to execute high performance liquid chromatography consists of a detector, a stationary phase, and a pump that moves the analyte and mobile phase across the column. The detector also provides the retention time for the analyte. Retention period fluctuates according to the strength of interactions between the analyte and the stationary phase.[2,3

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 # DIFFERENT TECHNIQUES OF CHROMATOGRAPHY

1) **Normal phase chromatography :-** This is basic column chromatography. HPLC is relatively simple. The column is filled with silica molecules and the solvent used is non-polar.The polar components of the mixture passing through the column adhere to the polar silica particles more than the non-polar components. Therefore, the non-polar compounds in the column move faster [4,5].
2) **Reverse phase chromatography :-**Reverse phase HPLC is the most commonly used type of HPLC. In this mode silica is reduced by attaching long hydrocarbon chains to the surface. The polar mobile phase is used [6] Therefore, the bond between the polar metal and the polar molecules in the mixture is stronger than the hydrocarbon chains attached to the silica and the polar molecules in the solution [7]. Non-polar compounds attract hydrocarbon groups due to van der Waals dispersion forces. It Is less soluble in metals [8,9].
3) **Size exclusion chromatography:-** also known as gel permeation chromatography. It is also useful for finding the semi- and tertiary structures of proteins and amino acids. This method is used to determine the molecular weight of polysaccharides.
4) **Ion exchange chromatography: -**The attraction between the dissolved ions and the ion sites associated with the stationary phase is maintained in ion exchange chromatography. This type of chromatography is often used in water purification, ligand exchange chromatography, protein ion exchange chromatography, high pH anion exchange chromatography of carbohydrates and oligosaccharides and other applications [10,11].
5) **Bioaffinity:-** Separation is based on specific reversible interaction of proteins with ligands.It protects the proteins bound to the ligand attached to the column. The formation of these complexes involves the participation of common molecular forces such as van der Waals interaction, electrostatic interaction, dipole-dipole interaction, hydrophobic interaction and hydrogen bonding.

6) Separation Mode:- There are two types of separation in HPLC, based on the composition of the eluent:

I) Isocratic: In the isocratic separation mode there is a constant composition of eluent. This means that the equilibrium conditions in the column and the velocity of the compounds moving through are the same.

II) Gradient: The gradient separation mode contains different combinations of detergents. This method greatly increases the resolution power of the system due to the higher intensity. The width of the peak depends on the speed of mixing of the detergent.

PRINCIPLE OF HPLC

The principle of HPLC is that the sample solution is injected into a column of porous materials(mobile phase) and the liquid phase (mobile phase) is pumped into higher pressure. The principle of phase separation is the introduction of solutes into the stationary phase based on its affinity for the stationary phase [12].

INSTRUMENTATION:

1. Solvent reservoir
2. Pump
3. Sample injector
4. Column
5. Detector
6. Data collection device or integrator

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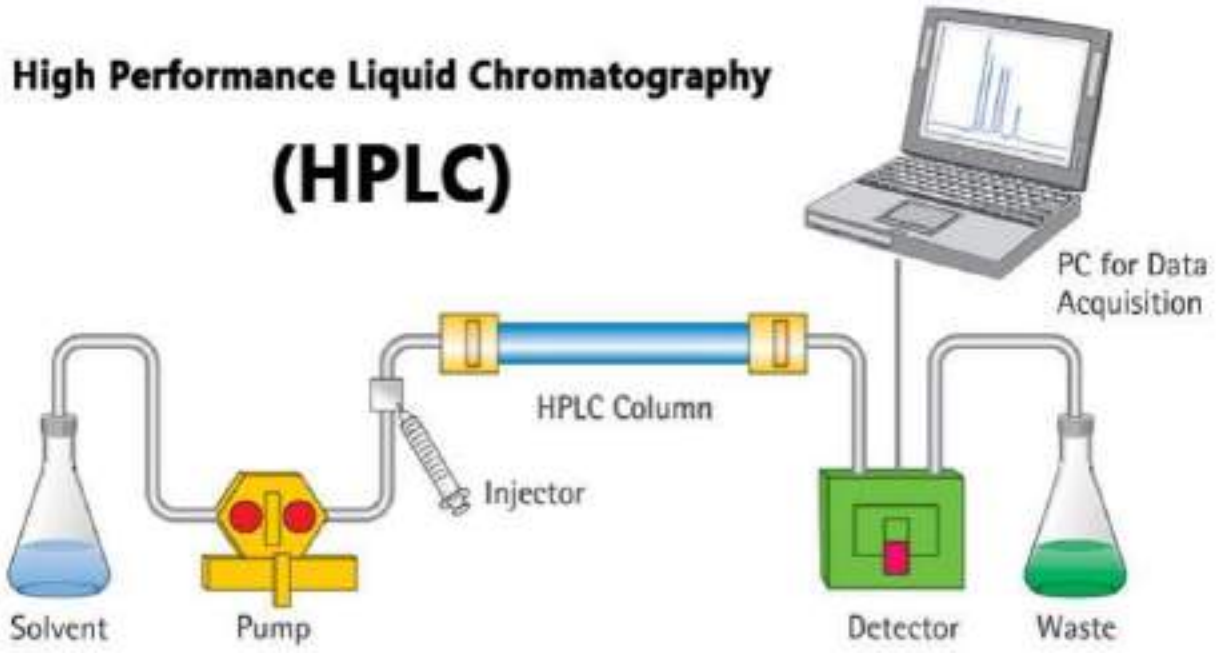

1)Solvent Reservoir:- The solvent is stored in the solvent reservoir (mobile phase). Here are containers crafted from glass or stainless steel that stay free from discoloration. Glass bottles are considered the most common type of solvent reservoir. In addition to handling the mobile phase, the pump must meticulously and precisely blend solvents together. Low pressure mixing and high pressure mixing are the two types of mixing units. The degassing mechanism eliminates any air bubbles that may have been trapped in the solution. [13].

2) PUMPS

The pump is an important part in liquid chromatography. The mobile phase is drawn from the metal tank to the column using a pump at high pressure. The pump pressure range is 4000 - 6000 psi. Mobile phase composition, particle size, mobile phase flow and column size are factors that depend on the proper operation of the pumps. The best features of pumps are metal [14,15].

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3) Sample Injector :- Septum machines are available for injection of sample fluid. The ability to introduce [objective] the sample into a continuous flow mobile phase stream which transports the sample to the HPLC column is delivered by an injector (sampler or autosampler). The combination of the ring injector and the new rotary valve can produce repeatable results. Sample volumes range from 5 to 20 microliters (liters).Septum injections are available to inject sample fluid. Sample injection can be done when the mobile phase is running or stopped. The combination of the ring injector and the new rotary valve can produce repeatable results [16, 17].

4) Columns:- Columns are typically manufactured from clean stainless steel, measuring approximately 50 to 300 millimeters in length, with an inner diameter ranging from 2 to 5 millimeters. They are typically filled with a stationary component having a molecular size ranging from 3 to10 millimeter [18-25].

5) Detector :-Detectors in HPLC are placed at the end of the analytical column. The function of the converter (Detector) is to check the solution that came from column. The electrical signal is proportional to the concentration of the individual units in the filter.

a) UV- visible Detector:- This detector is the most commonly used in HPLC. Most organic compounds absorb light in the UV range (190-400 nm) and the visible range (400-750 nm). This is based on the Beer-Lambert law. Deuterium and high pressure xenon lamps are sources of UV radiation. It has many advantages and disadvantages [26].

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b) Refractive index Detector :- Refractive index is an important property of column eluent. In this detector, the detection of the solute change depends on the total refractive index of the mobile phase. Mass spectrometers have a low sensitivity. Refractive index is very useful for detecting non-ionic compounds, and non-ions do not absorb ultraviolet range and fluorescence [27].

The different types of RI players are as follows [28].
i. Christiansen effect detector
ii. Interferometer detector
iii. Thermal lens detector
iv. Dielectric constant detector
• Advantages:
1.Reacts with all solvent
2. Does not affect flow rate
• Disadvantages:
1. Not as sensitive as most other types of detectors
2. Cannot be used with gradient washes.

c) Photodiode detector (PAD), diode array detector :-Photodiode array (radioactive devices) are used in the detection module. DAD detects absorption in the UV to VIS region. Although there is only one light-receiving unit on the sampling side, DAD has multiple photodiode arrays (1024 for L-2455/2455U) to acquire information over a wide range of wavelengths simultaneously. is one of the benefits of DAD [29].

d) Fluorescence Detector:- This detector stands as the most sensitive and specific among all the existing High-Performance Liquid Chromatography (HPLC) detectors. It is capable of identifying the presence of a single analyte molecule within the flow cell. The sensitivity of this detector is measured to be 10 - 1000 times greater than that of a UV detector [30].
• There are several types of fluorescence detectors available,
including:
1. Single Wavelength Excitation Fluorescence Detector
2. Multi-Wavelength Fluorescence Detector
3. Laser-Induced Fluorescence Detector

e) Electrical Conductivity Detector: - This device offers a universal, reproducible, and highly sensitive method for the detection of various charged species, including anions, cations, metals, and organic acids. It measures the conductivity of the total mobile phase, thereby classifying it as a bulk density detector. The electrodes of this detector are typically composed of platinum, stainless steel, or other noble metals [31].

Features of Detectors used in HPLC :-
1) It must generate a reliable and reproducible signal
2) It should be non destructive
3) The peaks should not be expanded
4) It must to be unaffected by the gradient or eluent composition
5) The response must not be impacted by temperature changes [32].

6) Data Collection Device:-The data collection device gracefully captures signals from the detector, which are then recorded on graph recorders or electronic integrators. These devices vary in their multifaceted capabilities, including processing, storing, and reprocessing chromatographic information. The interconnected PC monitors the health of the components, coordinating their responses and transferring data to a readable chromatograph. The output is typically captured as a sequence of peaks, with each peak corresponding to a specific compound within the mixture as it flows through the detector and absorbs UV light.

• **Components of Method Validation:** The following are typical analytical
performance characteristics which may be tested during methods validation:
1. Accuracy
2. Precision

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3. Linearity
4. Detection limit
5. Quantitation limit
6. Specificity
7. Range
8. Robustness

1. Accuracy:- Accuracy is defined as the degree to which a measured value approaches the true or accepted value. Accuracy refers to the difference between the observed mean value and the actual value. To determine lt , apply the procedure to samples with known amounts of analyte added. Analyze these against standard and blank solutions to guarantee no interference. The accuracy of the test results is calculated as a percentage of the analyte recovered by the assay. Recovery can be represented as the assay of known levels of analyte [33].

2.Precision :- The degree of agreement (scatter) between measurements acquired from multiple samplings of a homogenous sample under specified conditions. Precision measures the reproducibility of the entire analytical technique [34].It has two components: repeatability and intermediate precision.

Repeatability refers to the variation encountered by a single analyst on the same instrument. The method does not distinguish between variations caused by the instrument or system and those caused by sample processing. Validation involves testing numerous replicates of an assay composite sample using a specific analytical procedure. The recovery value is calculated. Intermediate precision refers to variations within a laboratory, including between days, instruments, and analysts [35,36].

3. Linearity :- Linearity refers to an analytical process producing a result proportional to the analyte concentration in the sample. If the procedure is linear, the test findings are proportional to the concentration of analyte in samples within a specific range. Linearity is typically defined as the confidence limit around the slope of a regression line [37].

4.Limits of detection and quantitation: - The limit of detection (LOD) is the smallest concentration of an analyte in a sample that can be detected but not quantified. LOD is defined as a concentration at a specific signal-to-noise ratio, typically 3:1. The limit of quantitation (LOQ) is defined as the lowest concentration of an analyte in a sample that can be determined with acceptable precision and accuracy using the method's stated operational parameters [38,39].

5.Specificity:- Specificity refers to the capacity to accurately assess an analyte in the presence of predicted components. Impurities, degradants, matrix, and other components are typical examples. Analytical procedures with limited specificity can be supplemented by additional procedures. This term carries the following implications: Identification ensures the identity of an analyte. Purity tests verify the accuracy of an analyte's impurities, including related compounds, heavy metals, residual solvents, and more. An assay measures the content or potency of an analyte in a sample, providing precise results [40].

6.Range:- The method's range refers to the top and lower levels of an analyte determined with acceptable precision, accuracy, and linearity. It is typically expressed in the same units as the test findings and can be based on a linear or nonlinear response curve [41].

7.Robustness :-The robustness of an analytical procedure refers to its ability to withstand tiny but deliberate alterations in method parameters, indicating its reliability throughout routine usage [42].

 # Future Trends

Emerging Technologies

Further advancements in HPLC technology:

- **Nano-HPLC :** offers improved sensitivity with reduced sample consumption.
- **Microfabricated Columns:** Miniaturization leads to faster and more efficient separation.
- **Advanced Detection Methods:** Improved sensitivity and selectivity through detector advancements. Integration with Other Techniques. HPLC and other analytical techniques are increasingly being combined for better results.
- **HPLC-MS :** combines HPLC and mass spectrometry to provide molecular information
- **HPLC-NMR:** Combines high-performance liquid chromatography with nuclear magnetic resonance for structural elucidation.
- **HPLC-FTIR:** Combines HPLC with Fourier-transform infrared spectroscopy for comprehensive compound identification.

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• Advantages

1) It has made significant contribution to the growth of analytical science and its diverse application in pharmaceuticals, environmental, forensics, foods, polymers and plastics, clinical fields etc.
2) HPLC provides a highly specific, reasonably precise, and fairly rapid analytical method for a plethora of complicated samples.
3) HPLC is capable of tackling macromolecules.
4) It is profoundly suitable for most 'pharmaceutical drug substances'.
5) It offers an efficient means of analysis pertaining to 'labile natural products'.
6) Preparation and introduction of sample is easy and simple in HPLC.
7) Resolution of compounds and speed of separation is high.
8) HPLC software is capable of reporting precise and accurate results.
9) Sensitivity of detectors used is high.

• Disadvantages

1) HPLC is considered one of the most important techniques of the last decade of the 20th century. Despite of the several advantages there are certain limitations also. Limitations include price of columns, solvents and a lack of long term reproducibility due to proprietary nature of column packing. Others include:
2) Complexity of separation of certain antibodies specific to the protein.
3) The cost of developing an HPLC apparatus for assay or method of separation of individual components is tremendous.
4) Low sensitivity of some compounds towards the stationary phase in the columns is difficult.
5) Certain compounds get absorbed or react with the chemicals present in the packing materials of the column.
6) Sometimes the pressure may get too high or low that the column cannot withstand or separation may not takes place.
7) Qualitative analysis may be limited unless HPLC is interfaced with mass spectrometry.
8) Resolution is limited with very complex samples.
9) Newer trends with better efficacy have been established.

APPLICATION

- HPLC is used in the food business as well as in the pharmacy, environmental, clinical, and forensic domains. Resolution, identification, and quantification of a molecule are among the data that HPLC may provide. It also helps with purification of mixtures of substances, molecular weight measurement, and chemical separation.

Other applications includes:-

• Pharmaceutical application:- 1) Research on the dissolution of tablets used to administer medicinal dosages.stability research and shelf-life calculations. 2) Determining the pharmacological active components in dose formulations. 3) Pharmaceutical formulation assay and impurity analysis. 4) Quality assurance. 5) Development and research.

• Environmental application:- include the identification of phenolic chemicals in potable water. Diphenhydramine detection in sedimented samples. Pollutant biomonitoring .

• Forensic:- Drug quantification in biological samples is part of forensics. Anabolic steroid detection in sweat, hair, urine, and serum. identifying whether cocaine and its metabolites are present in the blood. textile industry forensic analysis .

• Clinical:- Quantification of ions in human urine. Antibiotic analysis in blood plasma. Estimation of bilirubin and bilivirdin in blood plasma in the presence of hepatic diseases. Endogenous neuropeptides can be detected in extracellular fluids .

• Food and Flavor:- Maintaining the standard of drinking water and soft drinks. evaluation of alcohol and its byproducts.analysis of fruit liquids for sugar. Polycyclic chemicals in vegetables are analyzed. trace examination of agricultural produce containing military high explosives. checking fruits for pesticides and insecticides .

USES OF HPLC: 1) This method is employed in chemistry and biochemistry research to analyze complex mixtures, purify chemical compounds, create synthesis processes for chemical compounds, isolate natural products, or forecast physical characteristics.
2) It is also employed in quality control to monitor degradation, quantify tests of finished products, manage and enhance process yields, and guarantee the purity of raw materials.
3) It is also employed for the analysis of water and air contaminants.
4) Food and pharmaceuticals goods are surveyed by federal and state regulatory bodies using HPLC.

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CONCLUSION

The HPLC has mostly used an analytical technique. It can be used in both laboratory and clinical science. Reverse phase elution is advantageous over the normal phase. Since isocratic elution decreases the loading capacity, gradient elution is more useful. C8 and C18 columns are generally used. UV detectors are widely used. The typical average pH of reversed-phase on silica-based packing is 5.0. Adequate buffer concentration is 10-50 mM. Different applications are in the field of pharmaceutical analysis,environment, forensic, food, and clinical. Other applications include preparation, chemical separation, purification, and identification. The only disadvantage of HPLC is the high cost.

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RECENT UPDATE IN ANALYTICAL METHOD VALIDATION

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ABSTRACT

Analytical method validation is a critical step in ensuring the accuracy, precision, and reliability of analytical results. This review article provides an overview of the Current practices and regulatory requirements for analytical method validation. The Article discusses the importance of method validation, the different types of Validation (full, partial, and cross-validation), and the performance characteristics That need to be evaluated (accuracy, precision, specificity, sensitivity, linearity, Range, robustness, and ruggedness). The regulatory requirements for method Validation from various agencies such as the US FDA, ICH, and ISO are also Discussed. The article highlights the challenges and limitations of method validation And provides guidance on best practices for validating analytical methods. Additionally, the article reviews the different statistical tools and techniques used in Method validation, including regression analysis, analysis of variance, and Measurement uncertainty. The review concludes by emphasizing the importance of Method validation in ensuring the quality and reliability of analytical results.

KEYWORDS: *Validation, precision, specificity, accuracy, ICH guidelines*

1.INTRODUCTION

The chemistry of analytical process is the branch of chemical science that investigates and Disseminates information regarding the separation of chemical substances that are subsequently Recognised. In chemical analysis, quantification and qualification are looked at. First, the various chemical Ingredient or sample mixes are separated. The process of identifying these is referred to as Qualitative. The analytical procedure, also referred to as the quantification process, establishes the Quantity of a particular chemical component. factors influence the choice of analysis methodology, including the sample matrix, Analyte concentration, physical and chemical characteristics, analysis costs and rate, sample quantity, and quantitative or qualitative assessments of the sample. If the information pertains to the identification of chemicals

2. DEFINATION

According to FDA (FOOD AND DRUG ADMINISTRATION) VALIDATION is a procedure for Production and process control designed to assure that the drug products have their identity, Strength, quality and purity. According to FDA guidelines in May 1987, the validation packages Must provide the necessary information and test procedures required to prove that the system and process meet the specified requirements.

2.1) Importance of Validation

- Assurance of quality
- Time bound
- Process optimization
- Reduction of quality cost.
- Nominal mix-ups, and bottle necks
- Minimal batch failures,

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• improved efficiently and productivity
• Reduction in rejections.
• Avoidance of capital expenditures
• Fewer complaints about process related failures.
• Reduced testing in process and in finished goods.
• More rapid and reliable start-up of new equipment's
• Easier scale-up form development work.
• Easier maintenance of equipment.
• Improved employee awareness of processes.

2.2) When does Validation Begin?
Validation should ideally commence in the lab at the very beginning. In the laboratory, researchers Find out precisely how the product reacts and what conditions are needed to make it. They discover When the product breaks down or becomes unstable, useless, and when its quality starts to decline. Following the laboratory's establishment of the boundary processing criteria, the data can be Utilised to create validation requirements.

2.3) When does Validation Ends?
Validation of a system never truly ends. Once a new system and process have been validated the system still requires Maintenance, periodic calibrations and adjustment. Therefore, the process is always under scrutiny and constant evolution

2.4) Departments responsible
- ❖ Site validation committee (SVC) :- Develop site master validation plan, Prepare/execute/approve validation Studies.
- ❖ Manufacturing Department :- Prepares the batches as a routine production batch.
- ❖ Quality Assurance :- Ensure compliance, see that documentations/procedures are in place, approves protocols And reports.
- ❖ Quality Control :- Perform testing and reviews protocol and report as needed.

3) TYPES OF VALIDATION
Validations are of different types which are given below:
1. Process Validation
2. Analytical Method Validation
3. Cleaning Validation
4. Computerized System validation

3.1) Process Validation
The manufacturing process should be Flexible with some restrictions during the Process of Manufacture of the product. The Achievement of the alluring qualities should be ensured with the Prevention of Essential properties. For achieving these, Process validation is performed

3.1.1) Goals of the process validation
1) It provides the guarantee for the Assurance of the good quality which is Required for the Industry.
2) For diminishing different batches Variation.
3) For saving the time and money from Retesting and reprocessing.
4) For the process with fulfillment of the Criteria of robust.
5) For the consistence manufacture of the Product and the process Reproducibility.
6) Declination of expenses due to product Defect.
7) For the regulatory compliance.
8) For the higher quality confirmation

3.2) Analytical method validation
Analytical method validation is the process of verifying that an analytical method is suitable for it's Intended use. It involves evaluating the performance characteristics of the method to ensure that it can accurately and reliably measure the analyte of interest.

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3.2.1) Purpose of Analytical Method Validation :
To ensure the accuracy, precision, and reliability of analytical results.
To demonstrate that the method is fit for its intended purpose.
To comply with regulatory requirements.

3.2.2) Stages of Analytical Method Validation:
1. Method Development : Developing a new analytical method or modifying an existing one.
2. Method Optimization : Optimizing the method parameters to achieve the desired performance.
3. Method Validation : Evaluating the performance characteristics of the method.
4. Method Verification : Verifying the performance of the method in routine use.

Method validation is a reported program that offers with that the Processing system will give a high level of affirmation to meet its Predicated acceptance basis
The performance characteristics required to validate various methods by using various guidelines Such as USP, ICH, FDA, European guidelines etc.

3.3) Cleaning validation
Cleaning validation is the methodology used to assure that a cleaning process removes chemical And microbial residues of the active, inactive or detergent ingredients of the product manufactured In a piece of equipment, the cleaning aids utilized in the cleaning process and the microbial Attributes. All residues are removed to predetermined levels to ensure the quality of the next Product manufactured is not compromised by residues from the previous product and the quality of Future products using the equipment, to prevent cross-contamination and as a good manufacturing practice requirement.

The U.S. Food and Drug Administration (FDA) has strict regulations about cleaning validation. For example, FDA requires firms to have written general procedures on how cleaning processes will be validated. Also, FDA expects the general validation procedures to address who is Responsible for performing and approving the validation study, the acceptance criteria, and when Revalidation will be required. FDA also require firms to conduct the validation studies in Accordance with the protocols and to document the results of studies. The valuation of cleaning Validation is also regulated strictly, which usually mainly covers the aspects of equipment design , cleaning process written, analytical methods and sampling

Fig.1 Visual Inspection of cleaning validation

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3.4) Computerized system validation

This is widely used in the Pharmaceutical, Life Sciences and BioTech industries and is a cousin of software Testing but with a more formal and documented approach. The validation process begins With validation planning, system requirements definition, testing and verification activities, and validation reporting. The system lifecycle then enters the operational phase and continues until System retirement and retention of system data based on regulatory rules. Similarly, The Rules Governing Medicinal Products in the European Union, Volume 4, Annex 11: Computerised Systems applies to all forms of computerized systems used as part of a GMP Regulated activities and defines Computer System Validation Elements.

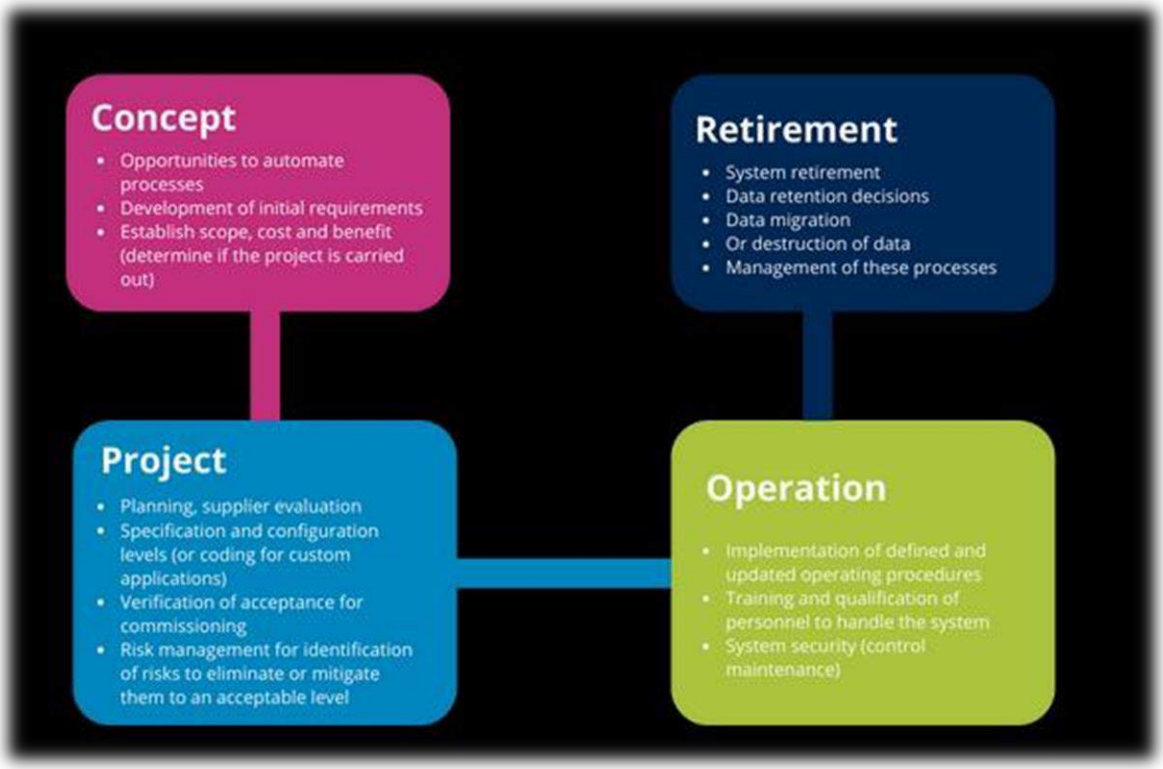

Fig .2 Complete guide to computerized system validation

Validation of analytical procedure is the Legal requirement and is Mandatory to Perform.
ICH guidelines [Q2 (R1)] have Set the guidelines for the validation of Analytical method.

4) TYPES OF ANALYTICAL METHODS TO BE VALIDATED

The validation of the analytical methods must be performed for
The following test:

1) Identification tests
2) Analysis of the impurities for its Quantification and its limit test
3) Analysis of active pharmaceutical Ingredient for is Quantification

4.1) Identification Tests

For the identity Of chemical or ingredient, Identification test is planned. It can be done by Various type of analytical Method. Examination of various Properties such as reaction with other Substances, spectral Evaluation, Properties of chromatogram and so on. In this Test, comparison of sample is done with the reference Standard.

4.2) Analysis of the impurities for its Quantification and its Limit test: Impurities can be quantified and identified. almost all raw materials Contain the impurities. Total removal of the impurities is very difficult task. So regulatory body has set certain Criteria for

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the limit in the presence of the impurities. Percentage purity of the Chemicals is reflected by this test. Following the various parameters of the validation in limit test is less essential whereas it is almost criteria For quantification analysis..

4.3) Analysis of API for its Quantification: Quantification of API or other chemical is the most essential Part of the analytical test. It reflects the accurate presence and proper action of The API in the drug product. With Regard to such archive, assay can be defined as estimation of active Pharmaceutical ingredient in the Product quantitatively. The quantification of API should follow certain procedure which has same Parameters of validation. In the same Way, Dissolution which also deals with the release of API should follow the Same guidelines of the validation.

5) ANALYTICAL METHOD VALIDATION CHARACTERISTICS

An ICH guideline has set certain criteria for the validation of Analytical method.

The parameters are listed below:

- Specificity
- Accuracy
- Precision
- Repeatability
- Intermediate Precision
- Reproducibility
- Limit of Detection
- Limit of Quantification
- Linearity
- Range
- Robustness

5.1) ACCURACY

Accuracy of an analytical method may be defined as, "Closeness of test results obtained by the method to true value".
i.e. measure the exactness of analytical method. It is expressed as percent recovery by the assay of known amount of analyte in the linearity range.

5.1.1) Determination methods

Application of analytical method to an analyte of known Concentration The accuracy may be determined by application of the analytical method to an analyte of known purity (example: Reference standard) and also by comparing the results of the method with those obtained using an alternate procedure that has been already validated..

5.1.2) Spiked – placebo recovery method

In this method, a known amount of pure active constituents Is added to formulation blank (sample that contains all Other ingredients except the active) and then perform the assay of resulting mixture and compare the obtained results With predictable results.

5.1.3) Standard addition method

In this method, perform the assay of given sample, then add a known amount of active constituent to that assayed Sample. After that this sample is again assayed. The Difference between the results of the two assays is compared With the expected results.

5.1.4) Acceptance criteria

The mean value should be within 15% of the supposed value Except at LLOQ, where it should not deviate by more than 20%. the deviation of the mean from the nominal value serves as the measure of accuracy

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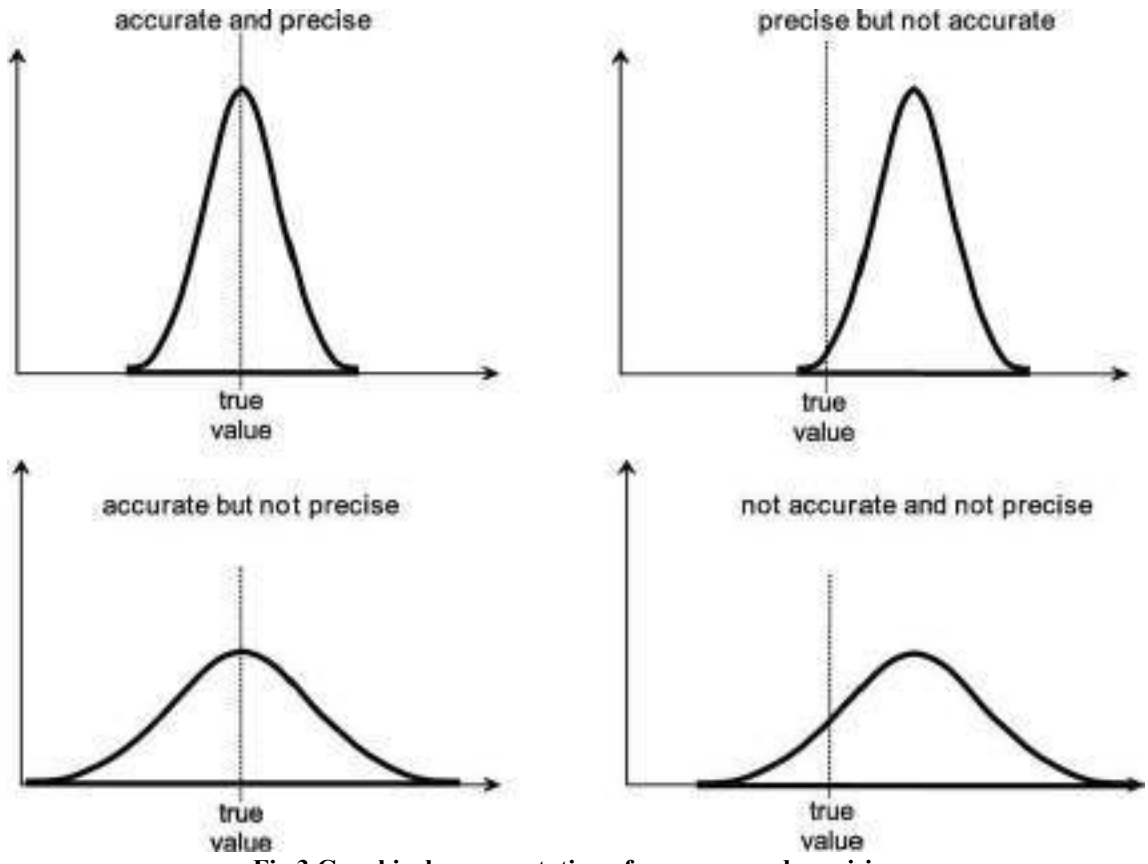

Fig.3 Graphical representation of accuracy and precision

5.2) PRECISION

The precision of an analytical method may be defined as, "Closeness of agreement between a series of measurements Obtained from multiple sampling of the same standardized Sample under the prescribed conditions. Should be investigated using homogeneous, authentic samples.

Expressed as SD/ % RSD = Standard Deviation ×100÷ Mean

Precision……. Considered at 3 levels,

5.2.1) Types of Precision

Repeatability Precision : The ability of an instrument or Method to produce consistent results when measuring the Same sample under the same conditions.

Reproducibility Precision*: The ability of an instrument Or method to produce consistent results when measuring the Same sample under different conditions, such as different Operators, instruments, or locations.

Intermediate Precision: The ability of an instrument or Method to produce consistent results when measuring the same Sample under different conditions, such as different days or Analysis

5.3) SPECIFICITY

Specificity refers to the ability of an analytical method to detect And measure a specific analyte or component in the presence of Other substances or impurities

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5.3.1) Identification test : It assures the identification Of the ingredient.

5.3.2) Purity Tests: The total removal of the Impurities is almost impossible. So certain Limits are set for impurities. Impurities can be present in the form of content of Residual solvent, heavy metals, related Substances etc. The test of such substances can be done by purity test.

5.3.3) Assay (Content or Potency): It refers to The quantitative determination of the API.API shows the potency of the drug. (ICH Harmonized tripartite guideline, 2005)

5.4) LINEARITY
Linearity refers to the ability of an analytical method to provide results that are directly proportional to the concentration of the Analyte.

5.4.1) Methods to Evaluate Linearity:
1. Calibration Curve: Plotting the analytical response against the concentration of the analyte.
2. Regression Analysis: Calculating the correlation coefficient (r) and coefficient of determination (r^2).
3. Residual Plot: Plotting the residuals against the concentration of the analyte.

5.4.2) Acceptance Criteria:
1. Correlation Coefficient (r) : ≥ 0.99
2. Coefficient of Determination (r^2) : ≥ 0.99
3. Residual Plot : Randomly distributed residuals

5.4.3) Identification tests : To ensure the identity of an analyte.

5.4.4) Purity tests
To ensure that all analytical procedures performed allow an accurate statement of the content of impurities of an Analyte, i.e. related substances test, heavy metals etc.

5.4.5) Assay
To provide an exact result which allows an accurate statement on the content or potency of an analyte in a sample?

5.5) LIMIT OF DETECTION
The limit of detection of an analytical procedure is the lowest amount of an analyte in a sample that can be detected, but Not necessarily quantify under stated experimental conditions. Simply indicates that the sample is below or above Certain level. The LOD will not only depend on the procedure of analysis but also on type of instrument.

5.5.1) Measurement is based on
• Visual evaluation.
• Signal to noise ratio.
• The standard deviation of the response and the slope.

Visual Evaluation
LOD is determined by the analysis of samples with known concentration of analyte and by establish the minimum level At which the analyte can be detected. It can be used for instrumental and non-instrumental procedure.

Signal to Noise Ratio
This approach can only be applied to analytical procedure which shows baseline noise. It is performed by comparing Measured signals from samples with known low concentration of analyte with those of blank samples and establishes The minimum concentration at which the analyte can be detected.
Signal to noise ratio 2:1 or 3:1 is generally accepted.the standard deviation of the response and the slope

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LOD =3.3σ / s
Σ= Standard deviation of the response.
S = Slope of the calibration curve of the analyte from regression line.

5.6) LIMIT OF QUANTITATION

The LOQ is the lowest amount of analyte in a sample which can quantitatively determine that may be measured with an acceptable level of accuracy and precision under the stated operational conditions of the method. LOQ can vary with the type of method employed and the nature of the sample.

5.6.1) Measurement is based on

- Visual evaluation.
- Signal to noise ratio.
- The standard deviation of the response and the slope.

Visual Evaluation

LOQ is determined by the analysis of samples with known concentration of analyte and by establish the minimum level at which the analyte can be detected. It can be used for instrumental and non-instrumental procedure.

Signal to Noise Ratio

This approach can only be applied to analytical procedure which shows baseline noise. It is performed by comparing Measured signals from samples with known low concentration of analyte with those of blank samples and establishes The minimum concentration at which the analyte can be detected. Signal to noise ratio 10:1 is generally accepted.
The standard deviation of the response and the slope,

LOD = 10σ / S
Σ = Standard deviation of the response.
S = Slope of the calibration curve of the analyte from regression line.

5.7) RANGE

Range of analytical procedure is the interval between the upper and lower concentration of analyte in the sample for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy, and linearity. normally derived from linearity studies and specific range is dependent upon proposed application of the procedure.
The following minimum specified ranges should be considered:

❖Assay of a drug substance or a finished (drug) product: 80 to 120 % of the test concentration.
❖Content uniformity: 70 to 130 % of the test concentration.
❖Dissolution testing: +/-20 % over the specified range;

5.8) ROBUSTNESS

Ruggedness is the ability of an analytical method to resist changes in its performance due to variations in experimental conditions, instrument, or analyst.
Examples of typical variations are
❖Stability of analytical solutions;
❖Extraction time :- In the case of liquid chromatography, examples of typical variations are:
❖ Influence of variations of pH in a mobile phase;
❖ Influence of variations in mobile phase composition;
❖ Different columns;
❖ Temperature;
❖ Flow rate.
In the case of gas-chromatography, examples of typical variations are:
❖ Different columns;
❖ Temperature;

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❖ Flow rate.

5.9) RUGGEDNESS

Degree of reproducibility of test results obtained by analyzing the same sample under variety of normal test conditions such as different.

- Analysts
- Instruments
- Days
- Reagents
- Columns and TLC plates.

i.e. lack of influence of environmental variables on the method. Comparison of reproducibility of test results to the precision of assay is the direct measure of ruggedness of the method.

6) CONCLUSION

The conclusion of an analytical method validation review emphasizes the industries role of method validation in ensuring accurate, reliable, and regulatory-compliant results. It highlights key validation parameters such as accuracy, precision, and specificity, and stresses the need for ongoing development of validation techniques to meet emerging challenges in various industries.

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A REVIEW ON HERBAL COSMETICS

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ABSTRACT

The growing demand for herbal cosmetics is a testament to a significant shift in consumer preferences toward natural, safer alternatives to traditional, chemical-laden beauty products. Many women today seek eco-friendly options that not only nourish and protect their skin but also align with their values of sustainability and wellness. The growing demand for herbal cosmetics is a testament to a significant shift in consumer preferences toward natural, safer alternatives to traditional, chemical-la of cosmetics, however, stretches back millennia and reflects the diverse uses humans have made of natural substances. In Prehistoric times, around 3000 BC, early humans used colours for practical and ritualistic purposes—either to attract animals for hunting or to protect themselves from enemies by invoking fear through body art. Over time, the uses of cosmetic expanded, incorporating medicinal and aesthetic purposes. Offered by plants. Many plants, like the onion Dayak bulb, kemuning leaf, pegagan, red betel, pecan, and sweet root, have been traditionally used in various cultures for their healing and beautifying properties. These plants serve as the foundation for modern herbal cosmetics, offering alternatives that are both effective and natural for enhancing beauty and well-being. Herbal cosmetics, which draw from these ancient traditions, have flourished due to the myriad benefits .

KEYWORD: *herbal cosmetic ,cosmetic, natural products, skin care*

INTRODUCTION

Cosmetics are designed to be applied to the body to cleanse, beautify, or alter appearance, enhancing attractive features. They encompass a wide range of products, including makeup, skincare, haircare, and fragrances.[1] the word cosmetic come from the Greek word “cosmikos “which means the skill of strength, arrangement, decorating. [2] herbal cosmetic referred to as product here, are made using various permitted cosmetic components to create a base to use one or more herbal ingredient provide only defined cosmetic benefits will be called “herbal cosmetic” .[3]

The definition of cosmetics under the Drugs and Cosmetics Act highlights that these products are intended for various applications on the human body for purposes like cleansing, beautifying, and altering appearance. Importantly, cosmetics do not require a drug license, distinguishing them from pharmaceuticals that are meant to treat or prevent diseases. This regulatory difference affects how cosmetics are marketed and monitored for safety and efficacy.[4]

The rising demand for herbal medicines is largely attributed to their compatibility with skin and minimal side effects. Herbal cosmetics, made from natural herbs and shrubs, are often considered safer alternatives to synthetic products. These natural ingredients not only avoid adverse reactions but also provide essential nutrients and minerals that can benefit the skin and overall health. This trend reflects a growing preference for products that align with natural and holistic wellness principles.[5]

Factors such as health, daily habits, work routines, climate, and maintenance practices significantly influence an individual’s skin and hair health. During summer, excessive heat can lead to dehydration, resulting in wrinkles, freckles, blemishes, pigmentation, and sunburn. Conversely, extreme winter conditions can cause skin and hair damage, manifesting as cracks, cuts, infections, and hair loss. Proper care and protection against these environmental factors are essential for maintaining skin and hair beauty.[6, 7]
Herbs are made from original ingredients in plant, leave, roots, fruits and flowers which have properties for healthy and beauty.[8]
Herbs are derived from various parts of plants, including leaves, roots, fruits, and flowers, and possess beneficial properties for health and beauty. Active chemical compounds found in these plants—such as alkaloids, flavonoids, terpenoids, steroids, tannins, and saponins—play crucial roles in their therapeutic effects. Phytochemical screening can identify and quantify these compounds, helping to understand their potential benefits in herbal formulations.[9]
Herbal cosmeceuticals.

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Cosmetics containing an active ingredient obtained from plant origin are generally known as herbal cosmetics

Cosmetic Preparation Divided 3 categories-

1) **Solid** : face powder, talcum powder, compact powder.
2) **Semisolid** : cream, ointment, liniment.
3) **Liquid** : lotion, hair oil, shampoo, mouthwashes, spray etc. [10]

Classification of Cosmetic

1) **Skin cosmetics**
   -cream
   -scrub
   -lip balm
   -powder
   -lotion/liniment
   -face pack
   -deodorant and antiperspirant
   -bath preparation
2) **Hair Cosmetics**
   -shampoo
   -hair dressings
   -hair colorant
   -fixative
   - bleaching
3) **Tooth Cosmetics**
   -tooth powder
   -tooth paste
   -mouth wash
4) **Nail Preparation**
5) **Shaving Preparation**
6) **Foot Preparation**. [11]

Advantage of herbal cosmetic on traditional cosmetic

1. They do not provoke allergic reactions and do not have any negative side effects.
2 . They are easily incorporated with skin and hair.
3. These are very effective than other cosmetics with small quantity.
4. Easy to available and found in large of variety of plants.
5. They have more stability, purity, efficacy, with their herbal constituents.
6. Easy to manufacture.
7. The storage and handling of herbal cosmetics is easier and for prolong period.
8. Cheap in cost.[12]

Applications of Herbal Products in Cosmetics.

1. **Herbal Skin Care Products**: Lavender Silk , Lotions creams, Body powder, Lavender Herbal body powder, 7 Skin Care Creams.
2. **Herbal Hair Care Cosmetics** : Henna (LawsoniaInermis), Amla (EmblicaOfficinalis), Shikakai (Acacia Concinna), Brahmi (BacopaMonnieri), Bhringraj (Eclipta Alba), Guar Gum (Cyamopsistetragonolobus.
3. **Herbal Lip Care Cosmetics** : Herbal Lipsticks, Herbal Lip Gloss, Herbal Lip Balm,Herbal Lip plumper.
4. **Herbal Eye Care Cosmetics**: Eye Make Up, EyeShadows, Eye Gloss, Liquid Eye Liners .
5. **Creams**: Aloe Moisturizing Hand Cream, Rich Face and Hand Cream, Herbal Moisturizers
6. **herbal Oils** : Herbal oils are Effective for Baldness, Falling of Hair, Thinning of Hair, Dandruff, and Irritation & Itching of Scalp, Patchy Baldness, and Maintenance of fine Head of Hair.
7. **Herbal Perfumes and fragrances** : Citrus Fragrance: The light, fresh character of citrus Notes (bergamot, orange, lemon, petitgrain, mandarin etc.) is often combined with more Feminine scents (flowers, fruits and chypre). [13-14]

Benefits of Herbal Cosmetic

1) **Use of herb cosmetics: Aloe Vera Benefits**

• Smooth and Supple Skin: Aloe vera helps maintain skin and hydration.
• Anti-Aging Properties: It can delay the appearance of fine lines and other signs of aging.

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• Healing Cracked Heels: Aloe vera promotes healing and soothes cracked skin on the heels.
• Moisturization

2) Use of Herb Cosmetics: Sandalwood Benefits

• Tightens Skin: It has firming properties that tighten drooping skin tissues.
• Youthful Appearance: Regular use can contribute to a more youthful look.
• Antimicrobial Properties: Sandalwood is effective in combating bacteria and fungi, promoting overall skin health.

3) Use of herb cosmetic: Turmeric Benefit

• Lightens Stretch Marks: Turmeric can help reduce the visibility of stretch marks.
• Reduces Fine Lines and Wrinkles: It effectively diminishes the appearance of aging signs.
• Relief from Burns: Provides quick relief for minor burns and promotes healing.
• Antiseptic and Anti-Inflammatory: Its properties help protect against infections and reduce inflammation, making it beneficial for skin health

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4) Use of Herbal Cosmetics: Rose Benefits

• Natural Toner: Rose water acts as an effective toner, refreshing and balancing the skin.
• Prevents Dark Circles: It can help reduce the appearance of dark circles under the eyes.
• Moisture Lock: Rose water aids in retaining moisture in the skin, keeping it hydrated and supple.

5) Use of Herbal Cosmetics: Papaya Benefit

• Exfoliates Dead Skin Cells: Papaya contains enzymes that help remove dead skin, promoting a brighter complexion.
• Prevents Balding: It may strengthen hair follicles, potentially reducing hair loss.
• Treats Sore and Cracked Heels: Papaya can soothe and heal cracked skin on the feet.
• Skin Whitening

6) Use of Herbal Cosmetics: Cucumber Benefits

• Lightens Complexion: Cucumber can help reduce dark patches, promoting a brighter skin tone.
• Reduces Freckles: It may assist in diminishing the appearance of freckles.
• Eases Dark Circles: Cucumber is effective in alleviating dark circles under the eyes.
• Soothes and Softens Skin: Its hydrating properties help soothe and soften the skin, making it feel refreshed

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7) Use of Herbal Cosmetics: Tea Benefits

• Adds Shine to Dull Hair: Certain teas, especially green tea and black tea, contain antioxidants polyphenols that help improve scalp health and promote hair shine.

• Eliminates Darkness Around the Eye Area: The caffeine and antioxidants in tea can help reduce puffiness and dark circles.

• increases Resistance Against Infections: Tea, especially green tea, is rich in catechins and polyphenols, compounds that have immune-boosting properties.

8) Use of Herbal Cosmetics: Coffee Benefits

• Regulates Cell Regrowth: Coffee stimulates cell turnover, promoting health skin regenerating
• Reduces Hair Fall: It can strengthen hair follicles, helping to minimize hair loss.
• Increases Skin Elasticity: Coffee enhances skin firmness and elasticity, contributing to a youthful appearance.
• UV Protection: Its antioxidant properties help protect the skin from harmful UV [4]

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Herbal Medicines for Treatment of Various ailments

Hair care :

1. Amla oil

Source: Emblica officinalis
Family:(Euphorbiaceae)
Benefits: Rich in Vitamin C, tannins, and minerals; nourishes hair, promotes darkening, and stimulates growth.[15]

2. Coconut Oil

Source: Cocos nnucifera
Family: (Palmea)
Benefits: Moisturizes and conditions hair; helps reduce protein loss and adds shine.

3. Almond oil

Source: Prunus dulcis
Benefits: Nourishes, softens, and strengthens hair; acts as a cleansing agent.

4. Arachis Oil

Source: Arachis hypogea
Family :(Leguminosae)
Benefits: Pale yellow oil with a nutty scent; used in hair oils and conditioners.

5. Castor Oil

Source: Ricinus communis
Family:(Euphorbiaceae)
Benefits: Acts as an emollient; promotes hair growth and moisture retention.

6. Eucalyptus Oil

Source: Eucalyptus species
Family: (Myrtaceae)
Benefits: Helps eliminate dandruff, promoting healthy hair growth.

7. Rose Oil

Source: Rosa damascena and Rosa centifolia
Family:(Rosaceae)
Benefits: Primarily used in perfumery; has a calming scent that can enhance overall hair care routines.

8. Citronella Oil

Source: Cymbopogon species
Family:(Cardiopteridaceae)

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Benefits: Provides a fresh scent; used in deodorants but can cause skin irritation in large amounts.

9. Olive Oil

Source: Olea europaea
Family: (Oleaceae)
Benefits: Acts as a potent hair and skin conditioner; rich in fatty acids like triolein and squalene, enhancing moisture retention and penetration.

10.Sunflower Oil

Source: Helianthus annuus
Family:(Asteraceae)
Benefits: Contains lecithin and tocopherols; smoothing properties and non-comedogenic, making it suitable for various skincare products.[16]

11.Light Liquid Paraffin

Composition: Mixture of hydrocarbons.
Benefits: Odorless and colorless, used for its spreadability in bath oils, lotions, and hair oils.

12.Heavy Liquid Paraffin

Composition: Similar to light liquid paraffin.
Benefits: Soothing effect on skin, commonly found in creams and hair oils.

13.Waxes

Composition: Esters of fatty acids and high molecular weight alcohols.
Uses: Serves as a base in cosmetics, such as lipsticks.

14.Beeswax

Source: Produced by Apis mellifera (bees).
Benefits: Comprises myricyl palmitate; helps form emulsions by incorporating water.[17]

15.Antioxidants

Role: Combat free radicals and promote skin health.
Sources: Both synthetic and natural options are effective, with growing interest in herbal antioxidants. [17-18].

16.Tamarind

Source: Tamarindus indica
Family:(Fabaceae)
Benefits: Rich in amino acids, vitamins, and antioxidants; high phenolic content supports overall skin health.[19]

17.Vitamin c

Role: Essential for collagen production and repairing photo-damaged skin; helps counteract aging effects.

18.itamin E

Role: Major antioxidant in tissues; protects cell membranes from lipid peroxidation and supports skin health.[20]

Skin Protection

1. Green Tea

Source: Camellia sinensis
Family:(Theaceae)
Benefits: Rich in polyphenolic catechins, especially EGCG, which offer strong antioxidant properties—20 times more potent than Vitamin E. Green tea protects against chemical and UV-induced carcinogenesis, reduces inflammation, and guards against cellular damage.[21-22]

2.Calendula

Source: **Calendula officinalis**
Benefits: Known for its antioxidant, anti-inflammatory, and wound-healing properties. Calendula is effective in treating acne, soothing irritated skin, and has shown some efficacy in managing radiation dermatitis.[21, 23,24]

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3.Turmeric

Source: Curcuma longa

Benefits: Traditionally used in Hindu culture for its brightening effects, turmeric has anti-inflammatory properties. Studies indicate it can reduce UVB-induced skin damage and promote a natural glow.[15,25]

Anti-Aging Treatments

1. Carrot

Source: Daucus carota
Family: (Apiaceae)
Benefits: Rich in Vitamin A and carotenoids (especially β-carotene), which are essential for skin health. Carrot seed oil is known for its anti-aging, revitalizing, and rejuvenating properties.[26]

2. Ginkgo

Source: Ginkgo biloba
Family: (Ginkgoaceae)
Benefits: Known as a circulatory tonic, it enhances blood flow, particularly to the brain and eyes, helping to protect against degenerative diseases. Ginkgo extract contains flavone glycosides and terpenes, providing antioxidant and anti-inflammatory benefits.[21, 27]

3. Rhodiola Rosea

Common Names: Golden root, arctic root
Benefits: This adaptogen is known for its ability to combat fatigue and stress, potentially improving skin resilience. It supports overall skin health and vitality.[28]

Dandruff Treatment

1.Henna

Source: Lawsonia inermis
Family: (Lythraceae)
Benefits: Contains lawsone, which has dye properties, and other beneficial compounds like gallic acid and tannins. Henna is praised for its high Vitamin C content and can treat hair and scalp issues, promoting overall hair health. [29]

2.**Neem**

Source: Azadirachta indica
Family:(Meliaceae)
Benefits: Known for its blood-purifying, antifungal, and antibacterial properties, neem effectively treats dandruff and scalp infections, providing relief from itching and irritation.[30]

3.Shikakai

Source: Acacia concinna
Family:(Leguminosae)
Benefits: Traditionally used for washing hair, shikakai promotes hair growth and scalp health. It contains saponins and other compounds that help cleanse the scalp, improve hair texture, and combat dandruff.[31]

Dry Skin Treatments

1.Aloe Vera

Source: Native to southern Africa
Benefits: Known for its soothing gel, aloe vera moisturizes and heals the skin. It contains amino acids, vitamins (A, C, E, B), and antioxidant compounds that promote skin health.[32]

2.Coconut Oil

Source: Extracted from Cocos nucifera
Family: (Arecaceae)
Benefits: Rich in lower chain fatty acid glycerides, coconut oil serves as an excellent moisturizer and skin softener. It remains effective in both liquid and solid forms.[21]

3.Jojoba Oil

Source: Extracted from Simmondsia chinensis

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Family: (Simmondsiaceae)
Benefits: Composed of liquid wax esters, jojoba oil mimics human sebum, replenishing lost moisture and restoring the skin's natural pH balance. It is stable and widely used in cosmetics.[33]

4.Olive Oil
Source: Extracted from Olea europaea
Family: (Oleaceae)
Benefits: Contains beneficial fatty acids such as triolein and squalene. Olive oil acts as a skin and hair conditioner, enhancing moisture retention in cosmetic formulations.[33]

5.Sunflower Oil
Source: Extracted from Helianthus annuus
Benefits: Non-volatile oil known for its moisturizing properties, sunflower oil is rich in vitamins and fatty acids, making it effective in lotions and creams for hydra. [21-22]

Herbal Cosmetic Use In Daily life

1) **Aloe vera**: Aloe vera is a versatile herb widely valued in the cosmetic industry for its moisturizing properties, which help soften the skin and promote a youthful appearance. Its healing abilities make it effective for treating various skin issues, including rashes, bruises, and sunburn.

2) **Avocado**
Avocado oil is rich in vitamin D, often referred to as the "sun-ray vitamin," which nourishes the skin. Its unique ability to penetrate both the dermis and epidermis makes it effective for rejuvenating skin from within. This property is especially beneficial for individuals who may have limited sun exposure due to health issues.

3) **Almond**:
Almond oil is known for its gentle nature, making it one of the safest oils for cosmetic use due to its lower acidity compared to other oils. Additionally, almond oil has properties that can promote skin brightening, which is often harnessed in fairness creams.

4) **Henna**
Henna has a long history of use for dyeing hair and decorating skin, particularly for women. It is considered a safe dye that not only enhances appearance but also imparts shine and health to the hair. Additionally, henna tattoos are known for being gentle on the skin, with minimal risk of side effects.

5) **Sandalwood**
Sandalwood is valued in cosmetics for its ability to freshen and revitalize dull skin. Sandalwood paste is renowned for its healing properties, effectively addressing various skin issues while imparting a unique glow. It's commonly used in face packs and scrubs, making it a popular ingredient for enhancing skin radiance.

6) **Saffron**
Saffron has long been regarded as a powerful herb for treating skin ailments and promoting skin cleansing, as noted by the ancient Indian physician Charaka. It is commonly used in cosmetics, particularly in fairness creams, cleansers, and anti-blemish lotions, due to its skin-brightening and rejuvenating properties.

7) **Elder tree**
Every part of the elder tree is utilized in cosmetic products, including soothing lotions, beautifying creams, healing ointments, and skin-softening balms. Known for its pleasant scent, elder has remarkable healing properties for sunburn and effectively helps reduce blemishes, spots, and freckles caused by sun exposure.

8) **Neem**:
Neem is renowned for its antifungal, antibacterial, and detoxifying properties, making it a key ingredient in various cosmetic products such as lotions, creams, toothpastes, soaps, and shampoos. Its efficacy in treating itchy skin, eczema, and psoriasis has led to its inclusion in many medicinal dermatology products. Additionally, neem is often found in anti-aging formulations due to its skin-rejuvenating effects.

9) **Lavender**:

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Lavender is widely used in cosmetics for its exotic scent, appearing in perfumes,oils, talcum powders, bath gels, soaps, and shampoos. Beyond its fragrance, lavender possesses excellent antiseptic and antifungal properties, making it effective in providing relief from acne and psoriasis.

10) Amla

Amla, or Emblica officinalis, is highly valued in the cosmetic industry for its rich vitamin C content, making it an excellent ingredient for skincare. Additionally, the oil extracted from amla is effective in addressing various hair and scalp issues, promoting overall hair health and vitality. [34]

For basic skin care, there are three key components essential for maintaining healthy skin:

1. **Cleansing Agent**: Cleansing helps to remove dust, dead skin cells, dirt, and other impurities that clog pores. Some common natural cleansers include vegetable oils such as coconut, sesame, and palm oil, which effectively cleanse the skin without stripping it of its natural oils.
2. **Toners**: Toners help to tighten and balance the skin, ensuring it is protected from environmental pollutants and toxins. Natural toners often include ingredients like witch hazel, geranium, sage, lemon, ivy burdock, and various essential oils, which work to refresh and invigorate the skin.
3. **Moisturizing**: Moisturizers are crucial for keeping the skin soft, hydrated, and supple. They help to lock in moisture and prevent dryness, ensuring the skin remains smooth and well-nourished.

Table 1: Hair Cosmetics

Latin Name	Common Name	Part Used	Uses
Aloe Vera	Aloe	Leaf	Moisturizer, shampoos
Azadirachtaindica	Neem	Leaf	Antif-atigue graying of hair, Alopecia
Bacopamonnei	Brahmi	Entire herb	Hair growth, Good for sleep, shampoos
Cerdus deodar	Deodar	Wood	Soap, shampoos
Centellaasiatica	Gotu Kola	Plant	Hair care, Darkeningofhair, hair oil
Citrus lemon	Lemon	peel	Prevent hair loss
Eclipta alba	Bhringraj	Plant	Promoting hair growth, Shampoos, Hair oil
Emblicaofficinalis	Amla	Fruits	Hair care, preventsgrayness, Anti stress
Hibiscus rosasinesis	China rose	Flower	Improves hair, prevents premature greyness
Lawsonia alba	Henna	Leaf	Hair growth, Naturalconditiour
Marticariachamomilla	Chamomile	Flower	Hair tonic
Moringaoleifera	Benjamin	seed	Hair oils
Sapindustrifoliatus	Soap wort	Fruit	Natural detergent, shampoos
Triticumsativum	Wheat germ	Germ	Natural source of Vit.E, shampoos
Wedeliacalendulaceae	Bhangra	Entire herb	Hair care, shampoos
Rosa centifolia	Gulab	Rose	Coolant, Antifatigue
Acacia concina	Shikakai	Pod	Natural cleansing agent, Detergent

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Latin Name	Common Name	Part Used	Uses
Acacia Arabica	Babul	Bark	Teeth disorders
Azadirachitaindica	Neem	Leaf	Toothache, Antibacterial, Dental carries
BarleriaPrionitis	Vajradanti	Entire herb	Strengthens teeth, Tooth ache
Syzygiumaromaticum	Clove	Bud	Toothache, Antiseptic
SalvadoraPersica	PIlu	Twigs	Antimicrobial

Table 2: Skin Cosmetics

Latin Name	Common Name	Part Used	Uses
Acoruscalamus	Sweet flag	Rhizome	Aromatic, Dusting Powder, skin Lotions
Allium sativum	Garlic	Bulb	Promote Skin healing, Antibacterial
Aloe vera	Aloe	Leaf	Moisturizer, sun screen Emollient
Alpinia galangal	Galangal	Rhizome	Aromatic, Dusting powder
Avena sativa	Oat	Fruit	Moisturizer, skin tonic
Azadirachtaindica	Neem	Leaf	Antiseptic, reduce dark spots, antibacterial
Calendula officinalis	Marigold	Flower	Skin care, anti-inflammatory, antiseptic
Centellaasiatica	Gotu cola	Plant	Bound healing, reduce stretch marks creams
Cichoriumintybus	Chicory	Seed	Clear skin of blemishes
Citrus aurantium	Orange	Peel	Skin creams, anti-acne, antibacterial
Curcuma longa	Turmeric	Rhizome	Antibacterial, antimicrobial skin creams
Cyperusrotundus	Nagarmotha	Roots	Suntan, astringent, anti-inflammatory
Daucuscarota	Carrot	Seed	Natural source of Vit. A, creams
Euphorbia hirta	Spurge herbs	Entire	Skin diseases, cracked lips
Rubiacordifolia	Manjistha	root	Wound healing, Lighten pigmentation marks

Table 3: Tooth Preparation

CONCLUSION

Herbal cosmetics are crafted using safe, permissible cosmetic ingredients combined with herbal components aimed at treating and enhancing the skin.In conclusion, effective hair care involves a holistic approach that combines proper hygiene, suitable products, and healthy lifestyle choices. Natural ingredients can enhance hair health by providing nourishment, hydration, and protection. Regular trimming, scalp care, and protection from environmental damage also play vital roles. Ultimately, personalized hair care routines tailored to individual hair types and concerns can lead to healthier, more vibrant hair. Emphasizing quality ingredients and consistent practices is key to achieving and maintaining optimal hair health.

This movement is based on the belief that the plants have a vast potential for their use As a curative medicines. Some of plants were found to have dual use, Both as curative and cosmetic. Quality control test must be safe for longer period of time.

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A REVIEW ON APPLICATION OF PROCESS ANALYTICAL TECHNOLOGY (PAT)

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ABSTRACT

The initiative titled "Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century—A Risk-Based Approach," launched by the FDA in August 2002, aimed to modernize and improve pharmaceutical manufacturing processes, encouraging the adoption of Process Analytical Technology (PAT) within the industry. PAT offers significant potential for enhanced operational control and regulatory compliance through continuous real-time quality assurance. Over the past decade, extensive research and development have been conducted by both academic and industrial contributors on this subject. This paper begins with a concise overview of the evolution of PAT concepts and explores their broader application within the pharmaceutical industry. The focus then shifts to PAT applications in biotech processes, with particular attention to developments over the last five years. While there has been substantial progress in the ability to analyze and monitor critical process and quality attributes in the biotech industry, further advancements are needed in utilizing this data for process control, optimizing yield, and ensuring product quality. Achieving these outcomes is essential to fully realize the benefits of PAT implementation.

KEYWORDS: *Process Analytical Technology (PAT), PAT Goals, PAT Framework, What is PAT, PAT Application In Chemical Industries, PAT Application In The Pharmaceutical Industry, PAT Appllication In The Biotechnology Industry.*

INTRODUCTION

Process Analytical Technology (PAT) encourages the voluntary development and implementation of innovative approaches to pharmaceutical development, manufacturing, and quality assurance. The scientific, risk-bas*-d framework of PAT is designed to promote innovation and enhance efficiency in these areas. This framework is built on a thorough understanding of the manufacturing process, which facilitates innovation and allows for risk-based regulatory decisions by both the industry and regulatory agencies. It comprises two key components: (a) a set of scientific principles and tools that support innovation, and (b) a regulatory strategy designed to accommodate and encourage such innovation.

The regulatory strategy includes a PAT team approach for Chemistry, Manufacturing, and Control (CMC) review, as well as for current good manufacturing practice (CGMP) inspections. It also involves joint training and certification for PAT review and inspection staff, ensuring a consistent and knowledgeable approach to regulatory oversight.

Traditionally, pharmaceutical manufacturing has relied on batch processing, where laboratory testing is conducted on collected samples to assess quality. While this approach has been effective in delivering safe and reliable pharmaceuticals, there are now significant opportunities for improvement through innovation in product development, process analysis, and control.

Despite these opportunities, the pharmaceutical industry has often been reluctant to adopt innovative manufacturing systems. One frequently cited reason is regulatory uncertainty, which arises from the perception that the current regulatory framework is rigid and not conducive to innovation. For instance, many manufacturing processes are seen as static, with any changes requiring regulatory submissions. Additionally, other scientific and technical challenges have contributed to this hesitancy.

As pharmaceuticals play an increasingly vital role in healthcare, the manufacturing sector must evolve by integrating innovation, cutting-edge scientific and engineering knowledge, and advanced quality management practices. This will enable the industry to meet the challenges posed by new discoveries, such as novel drugs and nanotechnology, as well as emerging trends like personalized medicine and genetically tailored treatments.

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PAT Goals

The US FDA introduced an initiative titled "Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach." This initiative aims to enhance the American public's access to high-quality healthcare services by modernizing pharmaceutical manufacturing practices. Its goals are designed to achieve the following:

Ensure that the most up-to-date risk management and quality systems approaches are integrated into pharmaceutical manufacturing, while maintaining product quality.

Encourage manufacturers to adopt the latest scientific advancements in pharmaceutical manufacturing and technology.

Facilitate a coordinated and synergistic operation between the agency's submission review and inspection programs.

Promote consistent application of regulations and manufacturing standards by both the agency and manufacturers.

Support innovation in pharmaceutical manufacturing through the agency's risk-based management approach.

Optimize the use of agency resources to efficiently address the most significant health risks.

This approach is grounded in science and engineering principles for assessing and mitigating risks related to poor product and process quality. The desired state of pharmaceutical manufacturing and regulation is characterized by the following:

Product quality and performance are ensured through the design of effective and efficient manufacturing processes.

Product and process specifications are developed based on a mechanistic understanding of how formulation and process factors influence product performance.

Continuous, real-time quality assurance is implemented.

Regulatory policies and procedures are adapted to reflect the most current scientific knowledge.

Risk-based regulatory approaches take into account:

1. The level of scientific understanding regarding how formulation and manufacturing process factors affect product quality and performance.
2. The capability of process control strategies to prevent or reduce the risk of producing poor-quality products.

PAT Framework

Quality is built into pharmaceutical products through a thorough understanding of several critical factors, including:

The intended therapeutic goals, the patient population, the route of administration, and the drug's pharmacological, toxicological, and pharmacokinetic profiles

The chemical, physical, and biopharmaceutical properties of the drug.

Product design and the selection of components and packaging based on the drug's attributes.

The design of manufacturing processes using principles from engineering, material science, and quality assurance to ensure consistent and reproducible product quality and performance throughout the product's shelf life.

Effective innovation in drug development, manufacturing, and quality assurance should address key questions, such as:

What are the mechanisms of drug degradation, release, and absorption?

How do product components influence quality?

Which sources of variability are critical to control?

How does the manufacturing process handle variability?

A key objective of the PAT framework is to design and develop well-understood processes that consistently deliver a predefined level of quality at the end of production. Improvements in quality, safety, and efficiency will vary based on the specific process and product, and may include:

Reducing production cycle times through on-line, in-line, and at-line measurements and controls.

Preventing rejects, waste, and reprocessing.

Enabling real-time product release.

Increasing automation to enhance operator safety and reduce human error.

Optimizing the use of energy and materials while increasing production capacity.

Supporting continuous processing to improve efficiency and control variability.

What is PAT

Process Analytical Technology (PAT) is defined as "a system for designing, analyzing, and controlling manufacturing processes through timely measurements (i.e., during processing) of critical quality and performance attributes of raw materials, in-process materials, and final products, with the goal of ensuring product quality." The main objective of PAT is to develop well-understood processes that consistently deliver a predefined level of quality at the end of manufacturing. A process is considered well understood when:

1. All critical sources of variability are identified and explained.
2. Variability is controlled by the process itself.
3. Product quality attributes can be accurately predicted under defined conditions, including materials, process parameters, and environmental factors.

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PAT implementation aims to achieve one or more of the following
Enhanced process understanding.
Improved yields by preventing scrap, rejects, and reprocessing.
Reduced production cycle times through in-line, on-line, or at-line measurements and control.
Lower energy consumption and increased efficiency through the transition from batch to continuous processes.
Cost reduction through minimized waste and energy usage.
Real-time release of product batches.
From an implementation perspective, PAT can be seen as a three-step process:
1. Design Phase: This phase begins during process development, when unit operations are being designed, optimized, and characterized. Critical Quality Attributes (CQA) and Critical Process Parameters (CPP) are identified, which influence the CQAs. Understanding these is key for the next phases of PAT.
2. Analyze Phase: In this phase, suitable analyzers are identified to monitor CQAs and CPPs. PAT applications can occur in various modes:
At-line: Samples are removed and analyzed close to the process stream.
On-line: Samples are removed for analysis and then returned to the process.
In-line: Samples are analyzed without removal.
Off-line: Samples are removed and analyzed away from the process stream.
For effective PAT, analytical results must be available quickly enough to support real-time decision-making.
3. Control Phase: This phase involves designing control strategies based on process understanding, allowing data from the analyzers to be used for real-time process adjustments, ensuring consistent performance and product quality.

PAT goes beyond just analysis. For example, in biotech processes, UV absorbance at 280 nm is often used to monitor chromatography columns separating products from impurities such as host-cell proteins (HCP). If the product and HCP are well-separated, UV absorbance can effectively guide consistent product pooling, as shown in Fig. 1 However, if the separation is poor (as in Fig. 1), UV absorbance alone may not be suitable for PAT, as it could lead to inconsistent product quality due to variable HCP levels.
In essence, PAT ensures that the manufacturing process is continuously monitored and controlled to maintain high product quality, leveraging advanced analytical tools and real-time data to drive informed process decisions.

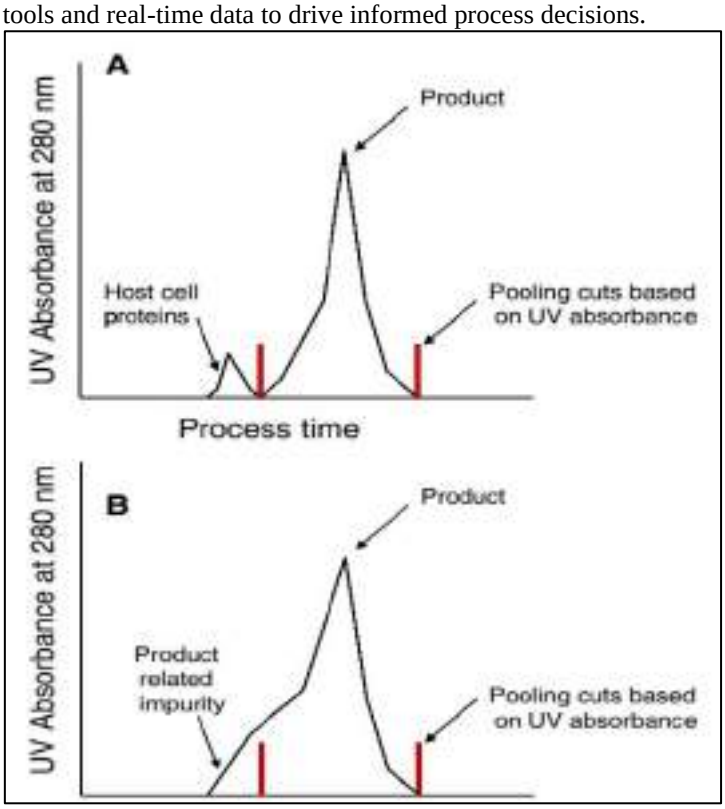

Fig. 1 Use of UV absorbance at 280 nm for pooling of fractions from a process chromatography column separating a protein product from other host cell proteins. A. Baseline separation of product from HCP. B. Incomplete separation of product from HCP

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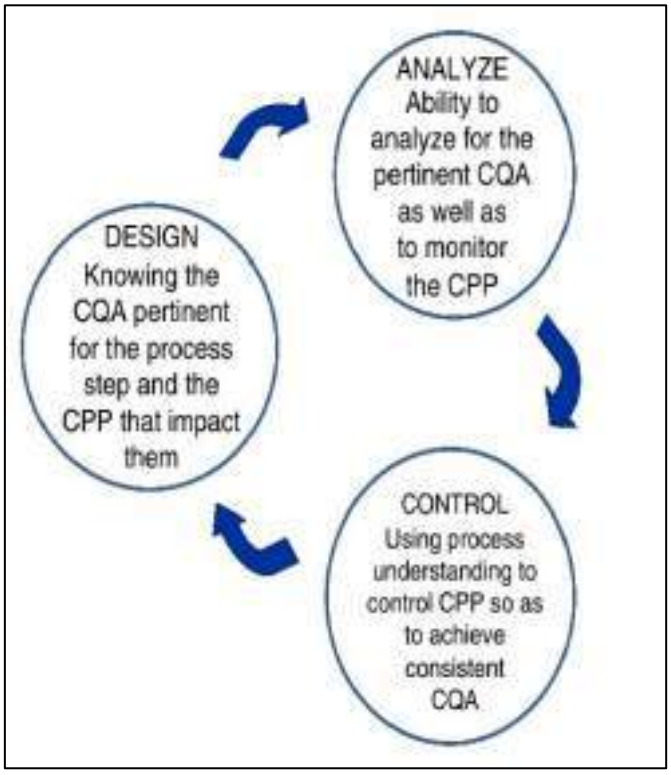

Fig. 1.1 The three steps that must be taken for PAT implementation, and the objective of each step

PAT Application In Chemical Industries

The The concept of Process Analytical Technology (PAT) has been applied in the chemical industry for several decades and has been extensively reviewed in various publications. Over time, the industry has adopted process analyzers and modeling techniques that not only optimize productivity and product quality but also provide real-time assurance of process control. In the event of deviations, these tools suggest corrective measures to bring the process back under control. Table 1 summarizes some recent applications of PAT in the chemical industry.

Common process analyzers used in these applications include Near Infrared (NIR) spectroscopy, acoustic sensors, nuclear magnetic resonance (NMR), Raman spectroscopy, attenuated total reflectance (ATR), and Fourier transform infrared spectroscopy (FTIR). To analyze and model the large amounts of data generated by these analyzers, statistical methods such as Process Component Analysis (PCA), Partial Least Squares (PLS), and Soft Independent Modeling of Class Analogy (SIMCA) are employed.

NIR and Mid Infrared (MIR) spectroscopy, for instance, have been proposed as tools for predicting the quality of diesel/biodiesel blends by evaluating parameters such as density, sulfur content, and distillation temperatures. These methods have demonstrated performance comparable to traditional, more labor-intensive techniques. NIR has also been utilized as an analyzer to assess the effects of various operating conditions on the recovery, selectivity, and productivity in the production of methyl isobutyl ketone (MIBK). This PAT approach allowed for more time-efficient experimentation, resulting in a 30% increase in MIBK productivity.Additionally, NIR, combined with appropriate statistical tools, has been applied in raw material analysis, product quality measurement, and process monitoring.

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Table 1 Example Of PAT Application In The Chemical Industry

Application	Process Analyzer	Statistical Tool	Obervation
Rapid and accurate tablet identification	Acoustic resonance Spectroscopy	Partial least-squares (PLS) calibration	NIR and MIR spectra have been shown to help in predicting distillation temperature and sulfur content of diesel or biodiesel
On-line determination and control of the water content of a continuous conversion Reactor	NIR	PLS with distributed control system	On-line process control led to significant improvement in yield
Simultaneous determination of methanol and ethanol in gasoline	NIR	PSL	Non-destructive and non-polluting method of analysis enables faster detection of methanol adulteration of the gasoline
Simultaneous monitoring of solute concentration and polymorphic state of the crystal	Raman spectroscopy and attenuated total reflectance (ATR) Fourier transform infrared (FTIR) spectroscopy	PLS	PAT approach was utilized to understand how the feeding strategy for the reactant affects the polymorph composition of L-glutamic acid
Analysis of the organic content of waste water	Nuclear magnetic resonance (NMR) spectroscopy	PLS	Less time-consuming and the cost-effective method for analysis of organic content
Catalysis reaction involving conversion of acetone to methyl isobutyl ketone (MIBK)	In-line NIR	Design of experiments (DOE), Principle components analysis (PCA), PLS, and cluster analysis	PAT application helped in determination of the factors affecting the productivity, selectivity, and yield of the MIBK and thereby leading to improved productivity for MIBK
Industrial process for granulation of urea during fertilizer production	Acoustic sensor with high temperature microphone probe	PCA and PLS PAT	PAT approach used to predict fluidization airflow, reflux of fines to the reactor, granule moisture content, and granule size
Raw material identification and quality control	NIR	K nearest neighbor (KNN) and soft independent modeling of the class analogy (SIMCA)	Fast and cost-effective method for raw material analysis

PAT Application In The Pharmaceutical Industry

The nnovations in process analytical chemistry and advancements in data capture and analysis have been key drivers in the adoption of Process Analytical Technology (PAT) within the pharmaceutical industry. The main feature of PAT is that it integrates quality

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into the product during the manufacturing process, rather than testing for quality after production. The PAT framework combines risk management with at-line and on-line sensors to monitor, control, and design processes while predicting process performance. Various analytical techniques are used in the pharmaceutical industry, such as Fourier transform infrared spectroscopy (FTIR), UV-spectroscopy, gas chromatography, high-performance liquid chromatography (HPLC), X-ray diffraction spectroscopy, and near-infrared (NIR) spectroscopy.

In a typical tablet manufacturing process, PAT approaches can be applied to different stages of production, including dispensing, blending, milling, compression, and tablet coating. For instance:
NIR spectroscopy is used to quickly and reliably test raw material quality, ensuring that only raw materials that meet specifications are used in the process.
In-line temperature monitoring during extrusion can be controlled through feedback loops connected to the heating/cooling system.
Particle-size distribution can be continuously monitored during milling to ensure process consistency, with control provided via feedback or feed-forward mechanisms
At-line testing of weight, thickness, potency, and hardness can be conducted at the tablet press, allowing for continuous quality verification and feedback control during compression.
This approach not only enhances process understanding but also improves process control.
Recent PAT applications in the pharmaceutical industry have focused on a range of technologies. NIR is widely used for applications like determining active ingredient content, characterizing powder flow, analyzing raw materials, and measuring dissolution rates. Other analytical tools include acoustic resonance spectroscopy, terahertz pulsed spectroscopy, and laser-induced breakdown spectroscopy. These tools demonstrate the increasing capability to design processes where each step is continuously monitored and controlled to ensure it performs as expected.
While significant progress has been made, using analyzer data to adjust operating conditions and maintain process control remains relatively rare. Developing such control schemes is expected to be a key focus of the pharmaceutical industry in the future.

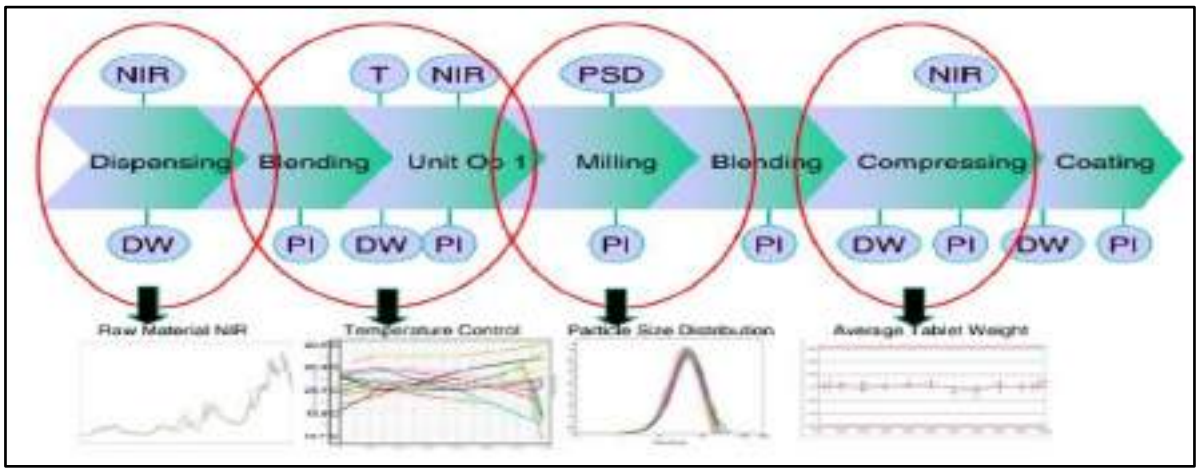

Fig:-2 The different unit operations that comprise a typical pharmaceutical process.

Table 2: Examples of PAT applications in the pharmaceutical industry

Application	Process Analyzer	Statistical Tool	Obervation
Rapid and accurate tablet identification	Acoustic resonance spectroscopy	Principle-components analysis (PCA)	A fast and non-destructive method for on-line analysis and label comparison before shipping, to avoid mislabeling of drug
Quantification of the active ingredient in pharmaceutical injectable formulations	NIR and UV–visible Spectroscopy	PLS	More ecoomical and less time-consuming method for quantification of the lysine clonixinate
Powder flow characterization	NIR	PLS	Real time information on the flowing cohesive powder mixture was used to avoid powder segregation or agglomeration and thus to maintain product quality

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Monitoring capsule manufacturing at small-scale level	NIR	PLS	PAT was utilized for testing of identity and quality of raw materials, for blend uniformity analysis, and for final content analysis of busulfan pediatric capsules
Active determination of content of uncoated pharmaceutical Pellets	NIR	Partial least-squares (PLS) analysis	NIR method was developed and validated for determination of active content ranging from 80-120% of the usual active content of the Uncoated pharmaceutical pellets.

PAT Appllication In The Biotechnology Industry

The /Figure 3 illustrates a typical process for producing a biotech product, highlighting some of the major unit operations involved. While the earlier discussion on implementing PAT in the chemical and pharmaceutical industries is also relevant to biotechnology, there are unique considerations that arise with biotech processes and products These include:

1. Proteins, the primary products in biotechnology, are large, complex, and heterogeneous molecules.
2. Biotech processes are significantly more complex than typical chemical or small-molecule drug manufacturing processes in terms of the number of batch records, product quality tests, critical process steps, and the quantity and complexity of generated process data .
3. Protein products are highly sensitive to the manufacturing process used in their production. Lot-to-lot variability in product quality is common, even when the same process is followed. Additionally, variability in raw materials can also impact product quality .
4. The raw materials used in biotech manufacturing are complex and prone to lot-to-lot variability .
5. Our understanding of the relationship between each product's quality attributes and the clinical safety and efficacy of the drug is generally limited

Due to these factors, implementing PAT for biotech processes is more challenging Table 3 and Figure 5 help illustrate these challenges. Table 3 presents key biotech unit operations, their typical process times, important quality or process attributes, analytical methods for measuring these attributes, analysis times, and the ratio of available decision-making time to analysis time. Figure 5 visualizes how this ratio changes across different unit operations.

The ease of implementing PAT in a given operation can often be gauged by this ratio. For example, processes like mammalian cell culture, where decision-making time is ample and sample analysis can be done without rushing, allow relatively straightforward PAT implementation. On the other hand, for operations like process chromatography, where the available decision-making time is shorter than the analysis time, successful PAT implementation may require adjustments in process design, equipment, or analytical methods

In this review, we will categorize the process into four main parts: upstream, harvest, downstream, and formulation. In the following sections, we will examine PAT applications in each of these areas. We will also discuss the role of PAT in chemometrics.

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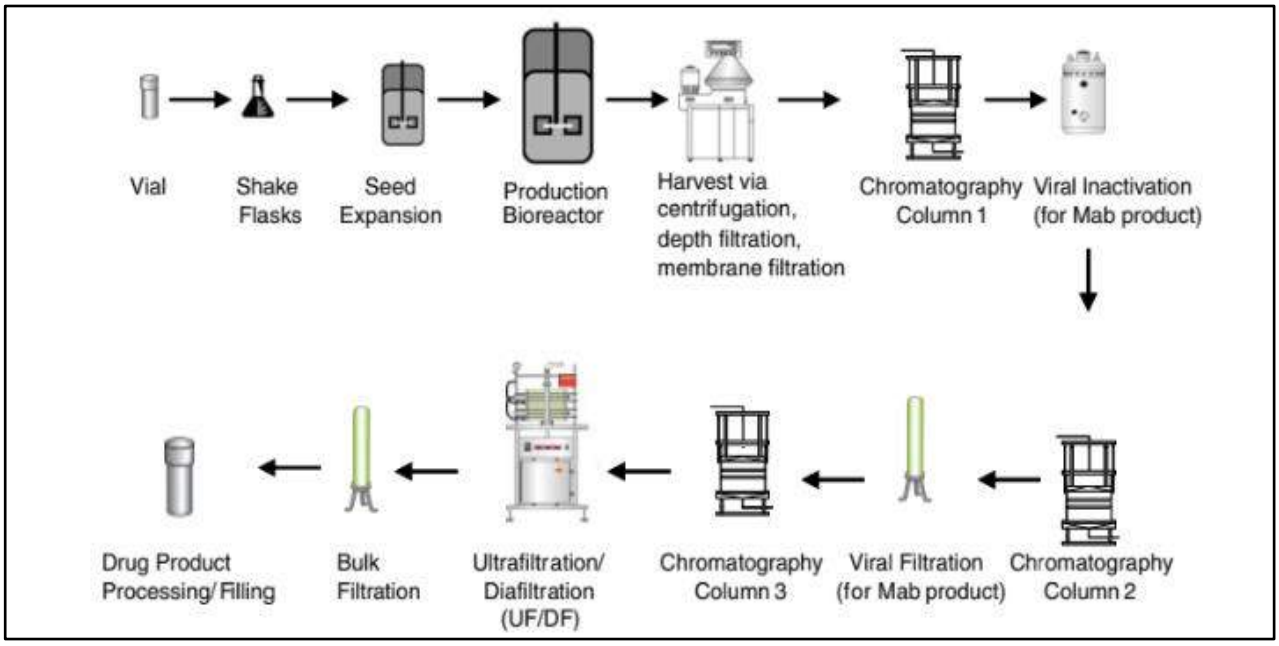

Fig. 3 A typical production process for a biotech product

Table 3 : Illustration of the challenges of executing PAT for biotech processesIllustration of the challenges of executing PAT for biotech processes.

Process Segment	Major process steps	Typical process time, tp (hrs)	Typical decision time, td (hrs)	Quality Attribute (QA) or Process Attribute (PA)	Analytical Method	Typical analysis, ta (hrs)	Ratio (td/ta)
Upstream	Microbial fermentation (production)	24	2	Misncorporation	HPLC	1	2
	Mammalian cell culture (production)	240	10	Glycosylation	Oligosaccharide profile	1	10
Downstream	Refolding	20	2	Misfolds	HPLC	0.5	4
	Chromatography	8	0.5	Aggregation	HPLC	1	0.5
Harvest	Certrifugation	8	1	Recovery	HPLC	1	1

CONCLUSIONS

1. Enhanced Process Understanding and Control: PAT technologies have demonstrated their capacity to significantly improve process understanding by providing real-time insights into critical quality attributes (CQAs) and critical process parameters (CPPs). This enables industries to achieve consistent product quality through improved process control.
2. Reduction in Production Costs and Time: With the application of PAT, companies can achieve faster production cycles, reduce waste, and minimize the need for post-process testing. The reduction in rework and scrap due to real-time adjustments based on PAT data leads to lower costs and a more efficient workflow.
3. Regulatory Compliance and Quality Assurance: PAT aligns closely with regulatory guidelines (e.g., from the FDA) that promote quality-by-design (QbD) principles. By integrating PAT, companies can meet compliance requirements more effectively while enhancing quality assurance throughout the production cycle.
4. Applications Across Industries: While PAT originated in the pharmaceutical industry, its applications have expanded into sectors like biotechnology, food processing, and chemicals. This versatility underscores PAT's adaptability in different manufacturing contexts, which is driving broader industry adoption.
5. Challenges and Future Directions: Despite its benefits, the adoption of PAT is challenged by high implementation costs, the need for skilled personnel, and data integration issues. Future directions may focus on developing cost-effective PAT tools, better data management systems, and advanced modeling techniques to support real-time decision-making.

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6. Overall Impact and Future Prospects: The integration of PAT represents a shift towards smarter, more sustainable manufacturing practices. As technology advances and industry experience grows, PAT is expected to play an increasingly central role in optimizing manufacturing, ensuring quality, and meeting industry demands for efficiency and regulatory adherence.

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A REVIEW ON DISORDERS OF WHITE BLOOD CELLS

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ABSTRACT

White blood cells (WBCs), or leukocytes, play a crucial role in the body's immune. System by defending against infections, foreign invaders, and abnormal cells. Disorders of white blood cells can arise from either excessive proliferation or deficiency of these cells, leading to a broad spectrum of diseases, including leukemias, lymphomas, and immune disorders. This review provides an overview of the most common disorders affecting white blood cells, focusing on the pathophysiology, clinical manifestations, diagnosis, and treatment options.Disorders Of White Blood Cells (WBCs) Disorders of white blood cells (WBCs), or leukocyte disorders, affect the production, function, or quantity of these immune cells, leading to significant health complications..

INTRODUCTION

White blood cells (WBCs) are a critical component of the immune system, involved in protecting the body from infections and ensuring proper immune responses. WBC disorders are characterized by abnormalities in the production, function, or life cycle of these cells. These disorders can be classified into two broad categories: proliferative disorders (e.g., leukemias) and deficiency or dysfunction disorders., leukopenia or immune deficiencies white blood cell (WBC) disorders encompass a range of medical conditions that affect the production, function, or survival of white blood cells, which are critical for immune defense and maintaining overall health. White blood cells, also known as leukocytes, play an essential role in the body's defense against infections toxins, and other foreign invaders. A review article on this topic can provide a comprehensive understanding of the pathophysiology, clinical manifestations diagnostic approaches, and management strategies associated with these disorders.. A review article on disorders of white blood cells (WBCs) would typically summarize and analyze current research and knowledge on the various types, causes, mechanisms, diagnosis, and treatment of these conditions. It would include an overview of:Types of WBC Disorders: The article would cover leukopenia (low WBC count), leukocytosis (high WBC count), and specific disorders like neutropenia, lymphocytopenia, leukemias, lymphomas, and myelodysplastic syndromes. Pathophysiology and Mechanisms: A review would explain how each disorder affects WBC production, function, or lifespan, detailing the underlying molecular or genetic factors where known.Diagnosis: Key diagnostic tools, including blood tests, bone marrow biopsy, fluro cytometry, and molecular assays, would be discussed to help in identifying and categorizing WBC disorders.Treatment Approaches:

Types of Disorders of White Blood Cells

Proliferative Disorders

- **Lymphoma**
- **Leukemia**
- **Leukopenia**
- **Leukocytosis**
- **Neutropenia**
- **Cuclic Neutropenia**

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Immune Deficiencies
Autoimmune Deficiencies
Proliferative Disorders of White Blood Cells
Lymphoma
Lymphomas are malignancies that originate in the lymphatic system. The two main types are
1.odgkin Lymphoma (HL): Characterized by the presence of Reed-Sternberg cells.
2.Non-Hodgkin Lymphoma (NHL): Includes a diverse group of lymphoid malignancies.
Pathophysiology: Lymphomas involve the uncontrolled proliferation of lymphocytes, which accumulate in lymph nodes and other tissues.
Clinical Manifestations: Enlarged, painless lymph nodes, fever, night sweats, and weight loss.
Diagnosis: Biopsy of lymph nodes, imaging studies, and blood tests.
Treatment: Chemotherapy, radiation therapy, immunotherapy, and bone marrow transplantation.

Leukemia
Leukemia is a cancer of blood-forming tissues, including the bone marrow, which results in the uncontrolled proliferation of abnormal white blood cells.

There are four major types
1.Acute Lymphomytic Leukemia(All) : Characterized by the rapid increase immature lymphocytes. Common in childrens
2.Acute Myeloid Leukemia(AML): Involves myeloid precursor cells and is seen primarily in adults.
3.Chronic Lymphomytic Leukemia (CLL): Affects mature lymphocytes and progresses slowly. Common in older adults
4.Chronic Myeloid Leukemia(CML): Involves myeloid cells, marked by the presence of the Philadelphia chromosome.

Pathophysiology: The rapid or uncontrolled production of immature WBCs interferesinfections norrmal hematopoiesis, leading to anemia, thrombocytopenia, and increased sussusceptibility to infections

Clinical Manifestations: Symptoms include fatigue, recurrent infections, eassusceptibilit, fever, and unexplained weight loss**.**

Diagnosis: Diagnosed through blood tests (complete blood count with differential), bone marrow biopsy, and genetic testing.

Treatment: Chemotherapy, targeted therapy, bone marrow transplant, and immunotherapy are common treatment options depending on the leukemia subtype.

Leukopenia
Leukopenia refers to a reduced number of white blood cells, particularly neutrophils, which increases susceptibility to infections.

1.Neutropenia: A subtype of leukopenia that specifically affects neutrophils. It can be congenital or acquired, often resulting from chemotherapy, radiation therapy, or autoimmune diseases.

Pathophysiology: Bone marrow suppression or destruction leads to inadequate production of neutrophils.

Clinical Manifestation: Recurrent infections, fever, and mouth sores are common.

Diagnosis: Confirmed through a complete blood count (CBC) and bone marrow biopsy.

Treatment: Treatment involves addressing the underlying cause, such as discontinuing an offending medication or administering granulocyte colony-Stimulating factor (G-CSF).

Leukocytosis
Leukocytosis is a condition characterized by an abnormally high white blood cell (WBC) count, usually above 11,000 WBCs per microliter in adults, although this can vary by age and other factors. White blood cells are essential components of the immune system, helping the body fight infections and inflammation. While leukocytosis itself is not a disease, it is often an indicator of an underlying condition that is causing the immune system to activate.

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Types of Leukocytosis

Leukocytosis is generally categorized based on the specific type of WBC that is elevated:

1.Neutrophilia: An increase in neutrophils, which are the primary WBCs involved in combating bacterial infections. Neutrophilia is often seen in infections, inflammation, stress, or after certain types of surgery or injury.

2.Lymphocytosis: An increase in lymphocytes, typically associated with viral infections such as mononucleosis, hepatitis, and certain types of leukemia.

3.Monocytosis: An elevated monocyte count, often seen in chronic infections (e.g., tuberculosis), autoimmune diseases, and certain types of cancer.

4.Eosinophilia: An increase in eosinophils, commonly associated with allergic reactions, parasitic infections, and some types of autoimmune diseases.

5.Basophilia: A rise in basophils, which is rare and usually associated with chronic myeloid leukemia (CML) and other specific inflammatory or allergic conditions.

Diagnosis: Diagnosing Leukocytosis Typically Involves

Complete Blood Count (CBC): The primary test for identifying leukocytosis, which reveals the overall WBC count and differentials (breakdown of WBC types).Peripheral Blood Smear: Allows microscopic examination of WBCs to identify abnormal shapes or structures that may indicate leukemia or other blood disorders.

Bone Marrow Biopsy: Used when malignancy is suspected, providing information about WBC production in the bone marrow.

Treatment: Treatment of leukocytosis depends on the underlying cause:

Infection Control: Antibiotics, antivirals, or antifungals are prescribed for infections that may be causing the elevated WBC count.

Anti-inflammatory Medications: In cases where inflammation is the cause, corticosteroids or other anti-inflammatory drugs can help manage WBC production.

Addressing Allergies: Antihistamines or corticosteroids are used to manage leukocytosis associated with allergic reactions.

Management of Blood Cancers: In leukemias or myeloproliferative disorders, chemotherapy, radiation, targeted therapies, or stem cell transplants may be used to control abnormal WBC proliferation.

Lifestyle Changes: For stress-related leukocytosis, lifestyle adjustments, including smoking cessation, stress management, and diet, can help.

Neutropenia

Neutropenia is a condition characterized by an abnormally low count of neutrophils, which are a type of white blood cell essential for fighting off bacterial and fungal infections. Neutrophils are the most abundant type of white blood cell, and their role is to quickly respond to infection by engulfing and destroying pathogens. When neutrophil levels drop, the body becomes more susceptible to infections, especially bacterial infections.Neutrophil Counts and Severity of Neutropenia

Neutropenia is often classified by the level of neutrophils in the blood, measured in cells per microliter (µL)

Mild Neutropenia: 1000-1500 cells/µL

Moderate Neutropenia: 500-1000 cells/µL

Severe Neutropenia: Below 500 cells/µL

People with severe neutropenia are at the highest risk of developing life-threatening infections, as their immune response is significantly compromised.

Symptoms of Neutropenia

Neutropenia itself may not cause specific symptoms, but because it makes individuals more vulnerable to infections, symptoms are often related to infections and may include:

Fever, particularly recurrent or persistent fevers

Chills and sweating

Mouth sores or gum infections

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Skin infections
Sinus infections
Respiratory infections, like pneumonia
Frequent urinary tract infections (UTIs)
In severe cases, infections can become life-threatening and may quickly spread through the bloodstream, leading to a condition known as sepsis.

Diagnosis of Neutropenia
Diagnosis of neutropenia typically involves:
Complete Blood Count (CBC): The primary test for diagnosing neutropenia, which reveals low neutrophil levels. This test may be repeated to confirm persistent neutropenia.

Peripheral Blood Smear: Used to examine the appearance and characteristics of blood cells under a microscope, which can provide additional information about the health of neutrophils.

Bone Marrow Aspiration and Biopsy: If bone marrow suppression or a bone marrow disorder is suspected, a biopsy may be performed to examine neutrophil production at the source.

Additional Tests: Additional blood tests or imaging studies may be performed to check for underlying infections, nutritional deficiencies, autoimmune markers, or other conditions contributing to neutropenia.

Genetic Testing: In cases of suspected congenital neutropenia, genetic tests may be conducted to identify specific gene mutations responsible for low neutrophil counts.

Treatment of Neutropenia
Treatment for neutropenia depends on its severity, cause, and the presence of any underlying conditions:

Treating Underlying Conditions: If an underlying infection, autoimmune disease, or nutritional deficiency is identified, treating it may help improve neutrophil levels.

Growth Factors: Granulocyte colony-stimulating factor (G-CSF) or granulocyte-macrophage colony-stimulating factor (GM-CSF) are medications that stimulate neutrophil production in the bone marrow. These growth factors are often used in cancer patients undergoing chemotherapy to reduce the risk of infection.

Antibiotics and Antifungals: For patients with infections or a high risk of infection, prophylactic (preventative) antibiotics or antifungals may be prescribed to protect against bacterial and fungal infections.

Medications: In cases of autoimmune neutropenia, immunosuppressive drugs or corticosteroids may be used to prevent the immune system from attacking neutrophils.

Bone Marrow or Stem Cell Transplant: In severe or congenital cases of neutropenia, particularly if other treatments are ineffective, a bone marrow or stem cell transplant may be considered.

Nutritional Support: Addressing deficiencies in vitamin B12, folate, or copper can help increase neutrophil production if these deficiencies are causing neutropenia.
Management and Prevention of Infection in Neutropenic Patients
For those with neutropenia, managing and preventing infection is critical:

Good Hygiene: Frequent handwashing and personal hygiene are essential to prevent infections.

Avoiding Crowds and Sick People: People with severe neutropenia are often advised to avoid large crowds or close contact with anyone who is sick.

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Safe Food Practices: Avoiding raw or undercooked foods and practicing food safety can reduce exposure to pathogens.

Vaccination: Staying up-to-date with vaccinations may reduce the risk of infections, though live vaccines are usually avoided in immunocompromised individuals.

Prompt Medical Attention: Patients with neutropenia are encouraged to seek prompt medical care if they develop fever or other signs of infection, as infections can progress rapidly.

Cyclic Neutropenia
Cyclic neutropenia is a rare, inherited blood disorder characterized by regular, recurring periods of low neutrophil levels (neutropenia) that typically occur every 21 days. During these cycles, neutrophil counts drop significantly for a few days before gradually returning to normal levels. This cyclical drop in neutrophils makes individuals more susceptible to infections during these low periods.

Pathophysiology of Cyclic Neutropenia
In individuals with cyclic neutropenia, neutrophil production follows a cyclical pattern, with regular fluctuations in neutrophil levels. The cycle is generally around 21 days, although it can vary between individuals. The condition affects the bone marrow's ability to consistently produce neutrophils, leading to alternating periods of neutropenia and normal neutrophil levels.

The recurring cycle Is thought to result from the body's attempt to compensate for abnormal neutrophil production. When neutrophil counts drop, the body increases production temporarily, but this stimulation is not sustained, leading to periodic low counts.

Symptoms of Cyclic Neutropenia
Symptoms of cyclic neutropenia tend to appear during the neutropenic phase, when neutrophil counts are low and the immune system is less effective at fighting off infections. Common symptoms include:
Recurrent Infections: These may be bacterial or fungal, and commonly affect the respiratory tract, skin, and mouth.

Mouth Ulcers: Painful sores or ulcers in the mouth are common during neutropenic episodes.

Gingivitis and Periodontal Disease: Inflammation of the gums and other oral tissues can occur, leading to pain, swelling, and bleeding.

Fever: Fever often accompanies infections during neutropenic periods.

Fatigue and Malaise: Generalized feelings of weakness or unwellness may occur, especially if infections are present.
Infections may vary in severity, with the most serious cases leading to systemic infections or sepsis, which can be life-threatening if untreated.

Diagnosis of Cyclic Neutropenia
Diagnosing cyclic neutropenia typically involves several steps and laboratory tests, including:

Complete Blood Count (CBC): Repeated blood counts are necessary to observe fluctuations in neutrophil levels over several weeks, confirming the cyclical pattern of neutropenia.

Serial Neutrophil Counts: Blood samples are taken every few days over a period of 6-8 weeks to monitor changes in neutrophil counts and establish a cyclical pattern.

Genetic Testing: Genetic testing can identify mutations in the ELANE gene, confirming the diagnosis. This test can also be helpful in distinguishing cyclic neutropenia from other forms of neutropenia.

Bone Marrow Biopsy: In some cases, a bone marrow biopsy may be performed to examine neutrophil production in the bone marrow and to rule out other bone marrow disorders.

Family History: Since cyclic neutropenia is inherited, a family history of similar symptoms may help in making the diagnosis.

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Treatment of Cyclic Neutropenia

While there is no cure for cyclic neutropenia, treatment focuses on managing symptoms, reducing the frequency of infections, and improving quality of life. Treatment options include:

Granulocyte Colony-Stimulating Factor (G-CSF): G-CSF, particularly filgrastim, is commonly used to stimulate the production of neutrophils and reduce the duration and severity of neutropenic episodes. Regular G-CSF injections can help maintain neutrophil counts above critical levels and reduce infection risk. However, G-CSF therapy may not completely eliminate the cycles, though it can make them less severe.

Antibiotics and Antifungals: Preventative (prophylactic) antibiotics or antifungals may be prescribed to reduce the risk of infections during periods of neutropenia. They are also used to treat any active infections promptly.

Good Oral Hygiene: Because of the high risk of mouth sores, good oral care practices, including regular dental check-ups, help reduce oral infections.

Avoiding Exposure to Infections: People with cyclic neutropenia are advised to avoid crowded places and close contact with sick individuals during neutropenic episodes to reduce infection risk.

Symptomatic Care: Pain management, hydration, and rest may be necessary during infection episodes to help alleviate symptoms.

Immune Deficiency Disorders in WBC

Immune deficiency disorders involving white blood cells (WBCs) are conditions in which part of the immune system is either absent or does not function properly, leading to an increased risk of infections, autoimmune diseases, and certain cancers. These disorders are often caused by defects in WBC production, function, or signaling pathways. WBCs play a key role in protecting the body from infections, so a deficiency can severely impact a person's ability to fight off pathogens.Immune deficiency disorders can be primary (inherited or congenital) or secondary (acquired due to external factors like infections, medications, or diseases).

Types of Immune Deficiency Disorders

Immune deficiency disorders related to WBCs can be broadly classified as follows:

Primary Immune Deficiency Disorders (PIDD): These are genetic or congenital disorders present from birth. They include:

Severe Combined Immunodeficiency (SCID): Known as "bubble boy disease," SCID is characterized by a severe lack of T cells and often B cells, resulting in extreme vulnerability to infections.

Common Variable Immunodeficiency (CVID): CVID involves low levels of antibodies (immunoglobulins) due to dysfunctional B cells. It often manifests later in life and leads to recurrent infections, especially of the respiratory and gastrointestinal tracts.

X-Linked Agammaglobulinemia (XLA): A genetic disorder affecting boys, in which B cells do not mature properly, leading to very low antibody levels.

Chronic Granulomatous Disease (CGD): Caused by defects in neutrophils, which makes it hard for the body to kill certain bacteria and fungi, leading to recurrent infections and granuloma formation.

Leukocyte Adhesion Deficiency (LAD): Characterized by a defect in the adhesion and movement of neutrophils, making it difficult for WBCs to reach sites of infection.

Wiskott-Aldrich Syndrome (WAS): An X-linked disorder characterized by abnormal T cells and platelets, leading to infections, eczema, and an increased risk of autoimmune diseases and cancers.

DiGeorge Syndrome: A chromosomal disorder leading to thymic aplasia, which causes a lack of T cells and affects overall immunity.

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Secondary (Acquired) Immune Deficiency Disorders: These occur due to external factors, such as infections or medical treatments, and include:
HIV/AIDS: HIV infects and destroys CD4+ T cells, leading to immune suppression. As HIV progresses to AIDS, patients are highly susceptible to opportunistic infections and cancers.
Chemotherapy-Induced Immune Suppression: Chemotherapy drugs often destroy rapidly dividing cells, including WBCs, leading to neutropenia (low neutrophil count) and increased infection risk.

Chronic Diseases: Conditions like diabetes, kidney disease, and liver disease can weaken immune function.

Organ Transplant Immunosuppression: Drugs used to prevent organ rejection suppress the immune system, increasing susceptibility to infections.

Malnutrition: Severe lack of protein, vitamins, and minerals can impair WBC function and lead to immunodeficiency.

Symptoms of Immune Deficiency Disorders
People with immune deficiency disorders commonly experience symptoms related to frequent and prolonged infections. These symptoms vary depending on the specific type of immune deficiency but may include:

Frequent Infections: Such as sinusitis, bronchitis, pneumonia, and skin infections. These infections may not respond well to standard treatments and may recur.

Unusual or Opportunistic Infections: Infections caused by organisms that typically do not affect healthy individuals, such as certain fungi, viruses (e.g., cytomegalovirus), and mycobacteria.

Delayed Wound Healing: Due to ineffective neutrophil or immune cell response.

Chronic Diarrhea: Often caused by gastrointestinal infections or a malfunctioning immune response in the gut.

Poor Growth and Development: Especially in children, due to chronic illness and malnutrition caused by persistent infections.

Autoimmune Symptoms: Some immune deficiencies increase the risk of autoimmune diseases, where the immune system attacks the body's own tissues.

Swollen Lymph Nodes and Enlarged Spleen: Often found in immune deficiencies due to chronic infection or immune cell dysfunction.

Diagnosis of Immune Deficiency Disorders
Diagnosing immune deficiency disorders involves a thorough medical history, physical examination, and laboratory testing to assess immune cell function and antibody levels. Key diagnostic steps include:

Complete Blood Count (CBC) with Differential: Measures the levels and proportions of various WBCs, providing clues to immune function.

Immunoglobulin Level Testing: Measures levels of IgG, IgA, IgM, and IgE to identify deficiencies in antibody production.

T and B Cell Counts: Flow cytometry can quantify T and B lymphocytes, which helps identify conditions like SCID and XLA.

Neutrophil Function Tests: Measures the ability of neutrophils to kill bacteria, which is crucial in diagnosing CGD.

Complement System Testing: Measures the activity of complement proteins, which help immune cells target pathogens. Complement deficiencies can increase susceptibility to infections.

Genetic Testing: Used for inherited disorders like SCID, XLA, and CGD, allowing for precise identification of mutations responsible for the disorder.

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Treatment of Immune Deficiency Disorders
Treatment depends on the type and severity of the immune deficiency, and may include:

Antibiotics and Antifungals: Used to treat and prevent infections. Prophylactic antibiotics may be given to prevent recurring infections.

Immunoglobulin Replacement Therapy: For conditions like CVID and XLA, where antibody production is impaired, intravenous or subcutaneous immunoglobulins (IVIG/SCIG) can help prevent infections.

Bone Marrow or Stem Cell Transplant: The only potential cure for severe immune deficiencies like SCID, CGD, and Wiskott-Aldrich syndrome, a transplant can replace defective immune cells with healthy ones.

Enzyme Replacement Therapy: Used for some forms of SCID, such as adenosine deaminase (ADA) deficiency SCID, where patients receive the missing enzyme.

Gene Therapy: An emerging treatment where defective genes are corrected using viral vectors. Gene therapy has shown promise for some types of SCID and CGD.

Antiviral Therapy: For conditions like HIV/AIDS, antiviral drugs can suppress the virus and improve immune function.

Vaccinations: Specially formulated vaccines may be used to protect against infections; however, live vaccines are usually avoided in patients with severe immune deficiencies.

Autoimmune Deficiency Disorders in WBC
Autoimmune deficiency disorders related to white blood cells (WBCs) occur when the immune system mistakenly targets the body's own cells and tissues, leading to inflammation, tissue damage, and organ dysfunction. In these conditions, WBCs play a direct role in attacking self-antigens due to a breakdown in immune tolerance, resulting in various autoimmune diseases. While these disorders are often classified under autoimmune diseases, they involve both immune deficiency (impaired immunity) and immune dysregulation (overactivity against self-tissues). In a healthy immune system, WBCs can distinguish between the body's own cells (self) and foreign invaders (non-self) through a process known as immune tolerance. In autoimmune disorders, however, WBCs fail to maintain this distinction and instead recognize self-antigens as threats. This abnormal response leads to the production of autoantibodies and self-reactive T cells, which attack the body's own tissues. These disorders vary widely in severity, with some targeting specific organs or tissues (organ-specific) and others affecting multiple body systems (systemic). They can involve various types of WBCs, such as T cells, B cells, and macrophages, with specific WBC types playing key roles depending on the disease.

Key Autoimmune Deficiency Disorders Involving WBCs
Some of the most notable autoimmune deficiency disorders that directly involve or affect WBC function include:

Systemic Lupus Erythematosus (SLE)
SLE is a systemic autoimmune disease where the immune system attacks multiple organs, including the skin, kidneys, joints, heart, and nervous system. B cells produce a wide array of autoantibodies that target components of the cell nucleus (e.g., anti-nuclear antibodies, or ANAs), leading to widespread inflammation. T cells and other WBCs become dysregulated, further promoting autoimmunity and tissue damage. Symptoms include a characteristic butterfly-shaped facial rash, joint pain, fatigue, and organ damage.

Rheumatoid Arthritis (RA)
RA is an autoimmune disorder that primarily targets the joints, leading to chronic inflammation, pain, and joint deformity. T cells, especially helper T cells, play a significant role by promoting inflammation and stimulating other immune cells (macrophages and B cells) to attack joint tissue. B cells produce autoantibodies, like rheumatoid factor (RF) and anti-citrullinated protein antibodies (ACPAs), which further drive inflammation and joint damage. Symptoms include swollen, painful joints, fatigue, and stiffness, particularly in the morning.

Multiple Sclerosis (MS)
MS is an autoimmune disease in which T cells attack the myelin sheath, a protective covering of nerve fibers in the central nervous system. The immune attack leads to demyelination, impairing nerve transmission and causing neurological symptoms such as muscle

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weakness, numbness, vision problems, and coordination issues. Both T cells and B cells are involved in this immune response, with activated T cells crossing the blood-brain barrier and initiating inflammation.

Type 1 Diabetes Mellitus
Type 1 diabetes is an autoimmune condition where T cells attack and destroy insulin-producing beta cells in the pancreas. This leads to insulin deficiency and hyperglycemia, requiring lifelong insulin therapy for management. Cytotoxic T cells (CD8+ T cells) are particularly active in targeting pancreatic cells, while helper T cells and B cells also contribute to the autoimmune respoloss Symptoms include excessive thirst, frequent urination, fatigue, and weight loss.

Autoimmune Hemolytic Anemia (AIHA)
In AIHA, the immune system targets and destroys red blood cells, leading to anemia and other complications. Autoantibodies produced by B cells bind to red blood cells, marking them for destruction by macrophages and other immune cells. Symptoms include fatigue, pallor, jaundice, and, in severe cases, heart problems and organ damage.

Immune Thrombocytopenic Purpura (ITP)
ITP is an autoimmune disorder where antibodies target platelets, leading to their destruction and resulting in low platelet counts (thrombocytopenia). T cells and B cells are involved in producing autoantibodies against platelets, leading to increased bleeding risk. Symptoms include easy bruising, frequent nosebleeds, bleeding gums, and petechiae (tiny red spots under the skin).

Graves' Disease
Graves' disease is an autoimmune disorder that causes overactivity of the thyroid gland (hyperthyroidism). B cells produce autoantibodies that mimic thyroid-stimulating hormone (TSH), causing the thyroid gland to overproduce thyroid hormones. Symptoms include rapid heartbeat, weight loss, tremors, sweating, and eye problems (Graves' ophthalmopathy).

Hashimoto's Thyroiditis
Hashimoto's thyroiditis is an autoimmune disease where the immune system attacks the thyroid gland, leading to hypothyroidism (low thyroid hormone levels). B cells produce autoantibodies against thyroid antigens, including thyroid peroxidase (TPO) and thyroglobulin, leading to inflammation and thyroid cell destruction. Symptoms include fatigue, weight gain, cold intolerance, and depression.

Mechanisms Behind Autoimmune Deficiency Disorders in WBCs
Autoimmune deficiency disorders involving WBCs arise due to a combination of genetic, environmental, and immunological factors. Here are some key mechanisms:

Genetic Predisposition: Certain genetic mutations increase the risk of autoimmunity by altering immune system regulation, T cell and B cell function, and self-tolerance.

Failure of Immune Tolerance: In a healthy immune system, regulatory T cells and other mechanisms suppress self-reactive immune cells to maintain tolerance. In autoimmune disorders, these regulatory functions fail, allowing self-reactive T cells and B cells to become activated**.**

Molecular Mimicry: This occurs when foreign antigens (from infections, for instance) resemble self-antigens, leading the immune system to mistakenly attack similar-looking body tissues. This is seen in disorders like MS and rheumatoid arthritis.

Autoantibody Production: B cells may become dysregulated and produce autoantibodies, which target the body's own cells. These autoantibodies play a key role in many autoimmune diseases, such as SLE, AIHA, and Hashimoto's thyroiditis.

T Cell Dysregulation: Dysfunctional T cells, particularly helper T cells and cytotoxic T cells, contribute to inflammation and tissue damage. In many autoimmune diseases, T cells lose their ability to distinguish self from non-self.

Symptoms of Autoimmune Deficiency Disorders
Symptoms vary based on the affected tissue or organ and may include:

Fatigue and Malaise: Common in systemic autoimmune diseases like SLE and rheumatoid arthritis.

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Inflammation and Pain: Swelling, redness, and pain in affected areas (e.g., joints in RA, thyroid in Hashimoto's).

Organ-Specific Symptoms: Neurological issues in MS, high blood sugar in type 1 diabetes, or thyroid dysfunction in Graves' disease and Hashimoto's. Autoantibody-Related Symptoms: Jaundice and anemia in AIHA, bruising in ITP.

Chronic and Recurrent Infections: Some autoimmune conditions also have immunodeficiency components that make individuals more prone to infections.

Diagnosis of Autoimmune Deficiency Disorders
Diagnosis typically involves blood tests, imaging, and other specialized tests:

Blood Tests
Autoantibodies: Testing for specific autoantibodies like ANA (SLE), RF and ACPAs (RA), TPO antibodies (Hashimoto's), and anti-thyroid antibodies (Graves' disease).

Complete Blood Count (CBC): To check for signs of anemia, low platelet counts, or leukopenia (low WBC count).

C-Reactive Protein (CRP) and Erythrocyte Sedimentation Rate (ESR): These markers indicate inflammation levels in the body.

Imaging Tests
MRI: Often used in diagnosing MS to detect brain lesions.

Ultrasound: Can assess organ damage in the thyroid (Graves', Hashimoto's) or joints (RA).

Other Specific Tests

Thyroid Function Tests: Assess levels of thyroid hormones and TSH in thyroid autoimmune diseases.

Blood Glucose Testing: To diagnose type 1 diabetes.

Treatment of Autoimmune Deficiency Disorders:
Treatment focuses on reducing immune system overactivity, managing symptoms, and preventing organ damage:

Immunosuppressive Medications: Drugs like corticosteroids, methotrexate, and azathioprine suppress the immune system to reduce inflammation and prevent tissue damage.

Biologic Therapies: Target specific immune pathways, such as TNF inhibitors (for RA), anti-CD20 antibodies (rituximab for B-cell depletion), and IL-6 inhibitors.

Plasmapheresis: A procedure that filters autoantibodies from the blood, used in severe cases like SLE.

Disease-Specific Medications:
Insulin for type 1 diabetes.
Thyroid hormone replacement for Hashimoto's.
Antithyroid drugs or radioactive iodine for Graves' disease.

Pain Management: Non-steroidal anti-inflammatory drugs (NSAIDs) and physical therapy for symptomatic relief.

CONCLUSION

Disorders of white blood cells encompass a wide range of conditions, from malignant proliferations like leukemias and lymphomas to immune deficiencies and neutropenias. Advances in genetic testing, targeted therapies, and bone marrow transplantation have improved

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outcomes for many patients. Ongoing research into the underlying genetic and molecular mechanisms of these disorders holds the promise for more effective and personalized treatments in the future.

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A REVIEW ON QUALIFICATION OF MANUFACTURING EQUIPMENT AUTOCLAVE, HOT AIR OVEN, TABLET COMPRESSION MACHINE

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ABSTRACT

Validation is one of the important steps in achieving and maintaining the quality of the final product batch after batch. Without equipment, we cannot manufacture a product. If equipment is validated, we can ensure that our product is of the best quality. Validation of the equipment is called the Qualification. This review focuses on the qualification of Autoclaves, Hot Air Ovens, and Tablet Compression Machines, essential equipment in pharmaceutical manufacturing. We discuss the systematic approach to qualification, including Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)

KEYWORDS: *Validation, Equipment Qualification, Autoclave, Hot air Oven & Tablet Compression Machine*

INTRODUCTION

In manufacturing facilities, validation test procedures are used to validate equipment and processes that may influence product quality. The tests for validation are used in accordance with approved written qualification procedures. All necessary activities and responsibilities for the qualification and validation are controlled and specified in this Validation Master Plan. Every step of the described validation program for facilities, equipment, processes, process controls, and cleaning is in accordance with the current European Community Guidelines for GMP and FDA, and the cGMP guideline for finished pharmaceutical manufacturers

DEFINITION

Validation may be defined as "Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes." It has been made mandatory by the regulatory bodies to prove the safety, efficacy, purity & effectiveness of the drug product, medical devices & biologics in the market place &health system.

IMPORTANCE OF VALIDATION

- Increased throughput
- Reduction in rejections and reworking
- Reduction in utility costs
- Avoidance of capital expenditures
- Fewer complaints about process-related failures
- Reduced testing in-process and in finished goods
- More rapid and reliable start-up of new equipment
- Easier scale-up from development work
- Easier maintenance of equipment
- Improved employee awareness of processes
- More rapid automation

EQUIPMENT QUALIFICATION

Qualification: Action of proving and documenting that equipment or ancillary systems are properly installed, work correctly, and actually lead to the expected results. Qualification is part of validation.

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The individual qualification steps alone do not constitute process validation.

1. Design Qualification(DQ)
2. Installation Qualification(IQ)
3. Operational Qualification(OQ)
4. Performance Qualification(PQ)
5. Maintenance Qualification(MQ)

Who should do Equipment Validation?

The vendor or the user has the ultimate responsibility for the accuracy of the analysis results and also for equipment qualification. DQ should always be done by the user. While IQ for a small and low cost instrument is usually done by the user, IQ for large, complex and high cost instruments should be done by the vendor. OQ can be done by either the user or the vendor. PQ should always be done by the user because it is very application specific, and the vendor may not be familiar with these. As PQ should be done on a daily basis, this practically limits this task to the user.

Design Qualification (DQ)

"Design qualification (DQ) defines the functional and operational specifications of the instrument and details for the conscious decisions in the selection of the supplier". The steps that should be considered for inclusion in a design qualification. Description of the analysis problem, Description of the intended use of the equipment, Description of the intended environment,Preliminary selection of the functional and performance specifications, Preliminary selection of the supplier, Final selection of the equipment, Final selection of the supplier, Development and documentation of final functional and operational specifications,

Installation Qualification (IQ)

“Installation qualification establishes that the instrument is received as designed and specified, that it is properly installed in the selected environment, and that this environment is suitable for the operation and use of the instrument.” The qualification involves the coordinated efforts of – The vendor. The operating department. The project team (which provide input into the purchase, installation, operation and maintenance of the equipment).

Operational Qualification (OQ)

"Operational qualification (OQ) is the process of demonstrating that an instrument will function according to its operational specification in the selected environment”. The proper operation of equipment is verified by performing the test functions specified in the protocol. A conclusion is drawn regarding the operation of equipment after the test functions are checked and all data has been analyzed. Following are the contents of equipment operation qualification:

1. Application S.O.P’s, 2.Utilization List, 3.Process Description,4. Test Instrument Utilized To Conduct Test, 5. Test Instrument Calibration, 6.Critical Parameters, 7. Test Function (List), 8. Test Function Summaries.

Performance Qualification (PQ)

"Performance Qualification (PQ) is the process of demonstrating that an instrument consistently performs according to a specification appropriate for its routine use ". PQ should always be performed under conditions that are similar to routine sample analysis. PQ should be performed on a daily basis or whenever the equipment is being used. In practice, PQ can mean system suitability testing, where critical key system performance characteristics are measured and compared with documented.

AUTOCLAVE

Autoclave is equipment that make use of pressurized steam in order to eliminate microorganisms. It is also used in sterilization of medical application .used in chemical industry for sterilization of vulcanizing rubber,curing composites and hydrothermal synthesis.

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STERILIZER	TEMPERATURE	PRESSURE	TIME
Steam Autoclave • Unwrapped Items • Lightly Wrapped Items • Totally Wrapped Items	121° C (250 ° F) 121° C (270 ° F) 132° C (270 ° F) 132° C (270 ° F)	15 psi 30 psi 30 psi 30 psi	15 min 3 min 8 min 10 min
Dry Heat Wrapped	170° C (340 ° F)		60 min
Chemical Vapor	132° C (270 ° F)	20-40 psi	20 min
Ethylene Oxide	Ambient		8-10 hr

Figure No. 1

Figure No. 2

- **Need and Importance**

1. Autoclave are known as steam sterilizers, it is used for healthcare and industrial applications.
2. It can also uses steam under pressure to kill harmful bacteria, virus, fungi and spores on items.
3. Autoclave used to sterilize surgical equipment, laboratory instruments, pharmaceutical item and other materials.
4. It also sterilize solid ,liquid ,hallows and instruments of various shape and sizes

- **Basic Qualification Approach**

User Requirement specification: The set of owner, user and engineering requirements necessary and sufficient to create a feasible design meeting the intended purpose of the system.

1 Design Qualification (DQ): The documented verification that the proposed design of facility, system and equipment is suitable for intended purpose.

2 Installation Qualification (IQ): The documented verification that the facility, system and equipment as installed or modified comply with approved design and the manufactures' recommendations.

3 Operational Qualification (OQ): The documented verification that the facility, system and equipment as installed or modified performance as intended throughout the anticipated operating ranges.

4 Performance Qualification (PQ): he documented verification that the facility, system and equipment as connected together, can perform effectively and reproducibly, based on approved process methods and products specifications.

Hot air Oven

Air oven are electrical devices used in sterilization. The oven uses dry heat to sterilize articles over several hours to destroy microorganisms and bacterial spores. Generally, they can be operated from 50°C to 200 °C. It is found in hospitals and laboratories where medical professionals and laboratory technicians use it. Examples of items that aren't sterilized in a hot air oven are surgical dressings, rubber items, or plastic material.

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Higher Temperatures and Longer exposure time required
Typical Cycles

- 160°C for 120minutes
- 170°C foe 60 minutes
- 180°C for 30 minutes

Figure No. 3

Used for

✓ Glassware and product container used in aseptic manufacture, non aqueous thermostable powders and liquids (oils)
✓ Also used for depyrogenation of glassware.

The hot air oven is the equipment which is utilized to provide the dry heat medium and it must be validated to ensure that the system is able to provides sterile and depyrogenated components, on a reproducible basis

Design Qualification

- The DQ outline the key features of the system designed to address the user requirement, regulatory compliance and selection rationale of a particular supplier.

- **The following are the key considerations for DQ**

➢ Physical dimensions of the equipment and accessories
➢ Suitable operating environment of the instrument
➢ Health and safety requirement

Installation Qualification

- It is carried out after or concurrently with the installation of the equipment at the user's premises.
- The purpose is to provide documentary evidence that the correct equipment has been received and installed as per plan and protocol.
- IQ documents should be reviewed and approved by designated responsible individuals.

It includes details of-

➢ **Structural-** Check dimensions, presence of seal
➢ **Filters-** Proper identification,type,size,air capacity, flow rate
➢ **Electrical -** Proper identification, safety cutoff
➢ **HVAC-** System provides the temperature and pressure differential required.
➢ **Air supply-** Identify source, duct size.
➢ **Air or natural gas-** Check that the source and type of supply are consistent with the manufacturer's recommendations.
➢ **Heaters-** Record the manufacturer's model no., the no. of heating elements.
➢ **Blowers-** Check for use of correct fan belt & that is in good condition.

Operational Qualification

- It is documented verification that the system or subsystem performs as intended throughout all specified operating range
- The OQ document should be reviewed and signed by the required department representatives.
- The components of system must satisfy the operating ranges as determined by the purchase order specifications.
- Each of the following process components must be identified & the operating performance & range determined.

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- **Temperature Monitors**
- **Cycle Timer**

The accuracy of timer must be determined, so that assurance is provided for cycle time.

- **Door Interlocks**

If a unit is equipped with double doors, the interlocks must operate such that the door leading to the aseptic area cannot be opened if the door to the non-aseptic area is opened.

- **Heaters**

All of the heating elements must be functional.

- **Blowers**

The air velocity consistent and motor speed of blowers should be noted in the OQ records.

- **Cooling Coils**

If coils are present, the type and size of the coils and temperature of the cooling medium at the inlet and outlet of the coils should be recorded.

- **Chamber Leaks**

The perimeter of the doors for batch sterilizers should be checked for air leakage while operating.

- **Particulates Counts**

Particulate count should be checked within the containers before and after sterilization to quantitate the particle load contributed to the product by sterilization process

Performance Qualification

Verifies that the equipment performs according to design specifications and user defined requirements in a reliable & reproducible manner under normal production conditions

Physical

- Heat penetration studies on empty chamber
- Heat distribution study on loaded chamber
- Heat penetration study on loaded chamber

Microbiological

- Bio-challenge/ Pyro-challenge studies

Tablet Compression Machine

The press is automatic, high speed rotary press. A motor drives the press at speeds that vary from 410 to 1630 tablets per minute (rpm). The material being tableted is fed from a hopper by gravity through the feed frame into dies. Regulating the weight adjusting cam controls the weight of material in each tablet can be adjusted.

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Figure No.4 Tablet Compression Machine

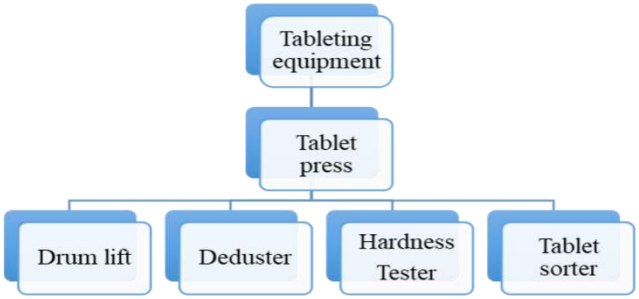

Figure No.5 Components of tableting Equipment

Installation Qualification

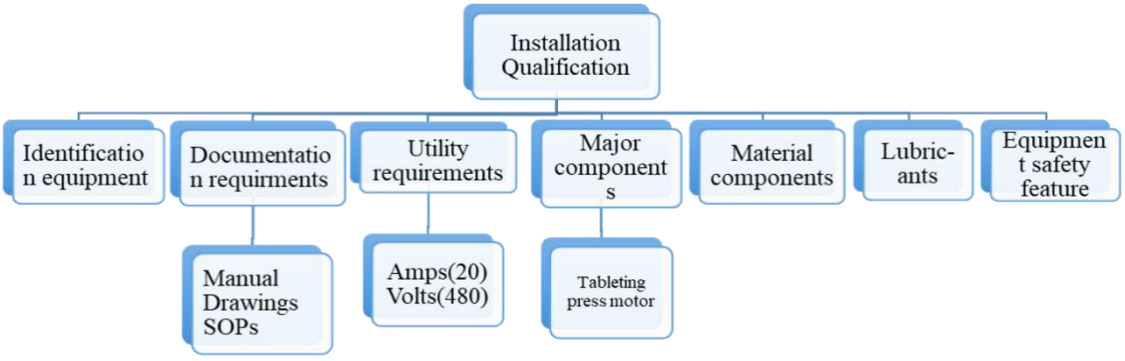

Figure No.6 IQ elements of a tablet press

The supporting electrical utilities must meet all electrical codes.
The information required for an IQ evaluation is equipment identification, required documentation, equipment utility requirements,majorcomponentspecifications, component material, lubricants and equipment safety features.

Equipment Identification
Record the equipment identification numbers,along with the following information:

- Model number

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- Serial number
- Company assigned equipment number and
- Location of the equipment

Required Documentation
Record the equipment manufacturer's operation and maintenance manual and drawings. Record the SOP that cover the setup, operation and cleaning of the tablet press.

Equipment Utility Requirements:
Compare the manufacturer's specified volts
(V) and amps (A) requirements to their as- found conditions at the time of qualification testing and record. Also record the location of the power supply source.

Major Component Specifications
The component specifications section ofthe protocol verifies that the tablet press components purchased were delivered and installed.

Component Material
Record the material of each component that contacts the product.

Lubricants
Record the lubricants used to operate the tablet press and indicate if they make contact with the product.

Equipment Safety Features
The objective of testing equipment safety features is to verify that the safety features on the tablet press functionaccording to the manufacturer'sspecifications. This test is performed with the tablet press empty. Verify that all of the guards are present and record the results.

Operational Qualification
An OQ evaluation should establish that the equipment can operate within specified tolerances and limits. The mechanical ranges of the tablet press are challenged, along with the basic tablet press operations. The tablet press will be validated for its operating ability, not how well it makes tablets. Information required for the OQ evaluation is: calibration of the instruments used to control the tablet press, equipment control functions (switches and push buttons) and equipment operation (cam tracks, upper punches, lower punches, feed frames, take off bars, rotor head direction, tablet press speed).

Calibration Requirements
Verify that all the critical instrumentson the equipment have been logged into the calibration system, have calibration procedures in place and are in calibrationat the time of qualification testing. Record all information for calibrated instruments used to control the tablet press.

Equipment Control Functions
The objective of testing equipment control functions is to verify that the switches and push buttons on the tablet press operate per the manufacturer's specifications. The tests will be performed with the tablet press empty. Operate each control and verify its proper position.

Equipment Operation

A) Cam Tracks Test
The objective of the cam track test is to verify that the upper and lower cam tracks make contact with the upper punches according to the manufacturer's specification. Use the following procedure and record the results.

- Install the punches and verify that the cams are contacting the punch head angles onthe both the sides of the double-sided cams.
- Verify that the punches are contacting one side of the single-sided came through a full cam track, upper and lower.

B) Upper Punch Test
The objective of the upper punch test is to verify that the upper punch penetration isaccording to the manufacturer's specification. A verniercaliper is required for this test, which is performed as follows:

- Attach a piece of tape to mark the depth of penetration of an upper punch when it isset to a standard depth.

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- Remove the upper punch and use a calibrated vernier caliper to measure the depth of penetration into the die. Record the results and instrument used to measure the depth.

C) Lower Punch Test

The objective of the lower punch test is to verify that the lower punch height is set according to the manufacturer's specification. A dial indicator test is required. Measure the height of the lower punch above the die with a dial indicator and record the results and the instrument used to measure the height.

D) Feed Frame Test

The objective of the feed frame test is to verify that the feed frame distance above the rotor head is according to the manufacturer's specification. Feeler gauge test: Measure the clearance between the feed frame and the motor head with a feeler gauge and record the results and the instrument used to measure the clearance.

E) Take Off Bar Test

The objective of the take-off bar test isto verify that the take-off bars do not makecontact with the lower punches. Turn the tablet press by hand and verify that the takeoff bars do not make contact with the lower punches. Record the results.

F)Tablet Press Rotation Direction

The objective of the rotation direction test is to verify that the rotor head rotates in the proper direction. The tests will be performed with the tablet press empty. Press the start switch and observe the direction of the rotation of the rotor head as viewed from front of the press and record the results.

G) Tablet Press Speed

The objective of the speed test is to verify that the measured speeds are within ± 10% of the manufacturer's specification of a minimum of 9 rpm and a maximum of 36 rpm. This test will be performed with the press empty. A stop watch is required for this test. Measure the speed of the rotor head with a calibrated stopwatch. Verify that the measured speeds are within ± 10 % of the manufacturer's specification and record the results and the instrument used to measure the speed

.

Performance Qualification

Once the equipment is properly installed and functioning within is properly installed and functioning within specified operating parameters, it must be shown that the tablet press can operate reliably under routine, minimum and maximum operating conditions.

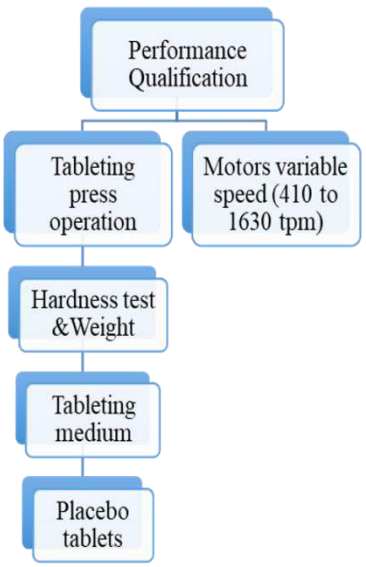

Figure No.7 PQ elements of a tablet press.

The objective of the weight and hardness test is to verify that tablet weight and hardness can be maintained consistently throughout the entire weight and hardness setting range.

The materials and instruments required for this test are a placebo and a weight, hardness, and thickness gauge.

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Compress tablets using placebogranulation. Record the placebo used. Obtainthe average weight and hardness of 5 tablets at start up, 10, 20 and 30 min and record the results and the instrument used to measure the weight and hardness.

Test Functions

1. Perform Installation Qualification.
2. Perform general operational controls verification testing.
3. Operate system throughout the range of operating design specifications or range of intended use.
4. Verify that all safety devices of the tablet press are operating as specified in the manual.
5. Verify that recommended lubricants are used during machine operation.
6. Perform controller security challenges to verify that specified parameters cannot be altered without appropriate supervisory control.
7. Perform capability and consistency studies to check the weight variation of each product as per SOP.

Acceptance Criteria

1. The system is installed in accordance with design specifications, manufacturer recommendations, and GMPs. Instruments are calibrated, identified, and entered into the calibration program.
2. General controls and alarms operate in accordance with design specifications.
3. The system operates in accordance with design specifications throughout theoperating range or range of intended use.
4. The safety devices must operate as specified in the manual
5. The recommended lubricants must be used as specified in the manual.
6. The storage location of the lubricants must be according to manufacturer recommendations.
7. Unauthorized changes to cycle parameters must not be allowed without supervisorycontrol or password.

The machine must be in statistical controlas per capability and consistency studies.

CONCLUSION

Allot extra time for validation. It always takes longer than we think, particularly with a new installation. All phases of validation successfully completed and final report signed off. Review overall validation process and deviations to determine how process could be handled better in the future. The important points are: Carefully write protocols and acceptance criteria, try to anticipate problems or issues in advance. Coordination with other ongoing activities to ensure required resources will be available when needed. Coordination with vendors. Unless equipment qualification has not already been legally mandated today, in the near future it will have overriding importance, primarily in the pharmaceutical industry and in the food and cosmetics sectors. The main goal in qualifying laboratory equipment is to ensure the validity of data. The current equipment qualification programs and procedures used within the pharmaceutical industry are based on regulatory requirements, voluntary standards,vendor practices, and industry practices. The result is considerable variation in the way pharmaceutical companies approach the qualification of laboratory equipment and the way they interpret the often vague requirements.

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AN STUDY ON PHARMACEUTICAL SALES AND MARKETING FOR THE REGION OF JALNA (MAHARASHTRA) IN GYNECOLOGICAL PREPARATIONS

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ABSTRACT

The pharmaceutical industry plays a critical role in improving healthcare, and regional studies focusing on specific medical specialties such as gynecology offer valuable insights into market trends, sales dynamics, and the effectiveness of marketing strategies. This review paper aims to explore the pharmaceutical sales and marketing landscape in the region of Jalna, Maharashtra, with a focus on gynecological preparations. Jalna, a rapidly developing district in Maharashtra, presents unique challenges and opportunities in the pharmaceutical market due to its socio-economic diversity, growing healthcare infrastructure, and specific regional health concerns.

The study examines key elements of pharmaceutical sales, including market demand for gynecological products, the influence of local healthcare professionals, and the role of pharmaceutical companies in shaping product adoption. Through in-depth analysis, the paper outlines the role of medical representatives, promotional strategies, and product training in influencing sales in the gynecology sector. The research also evaluates the regulatory environment and its impact on the marketing of pharmaceutical products in Jalna, specifically within the gynecological category. Additionally, the paper provides insights into the types of pharmaceutical products being marketed, the distribution channels, and the pricing strategies employed by pharmaceutical companies to meet the needs of gynecologists and their patients.

By examining the current market trends, customer preferences, and sales strategies, the paper highlights the challenges faced by pharmaceutical companies in targeting gynecologists in rural and semi-urban regions. It also explores how cultural factors, physician-patient relationships, and awareness levels among women about gynecological health influence pharmaceutical marketing strategies. The study identifies key marketing approaches, such as digital marketing, physician engagement, and continuing medical education (CME) programs, which are essential for boosting sales and product visibility in the gynecology segment.

KEYWORDS: *Pharmaceutical Sales, Pharmaceutical Marketing, Gynecological Preparation, sales Strategies, Gynecology Products, Medical Representatives, Pricing Strategies, Rural Pharmaceutical Marketing, Physician Engagement.*

INTRODUCTION

Pharmaceutical marketing and sales play a critical role in improving healthcare outcomes by ensuring that effective and necessary medications are accessible to healthcare professionals and patients. In India, the pharmaceutical market is one of the largest in the world, with significant regional variations due to differing healthcare needs, economic conditions, and social factors. Jalna, a growing district in Maharashtra, provides an interesting case study in understanding pharmaceutical marketing, especially in the niche of gynecology.

The region of Jalna has seen rapid advancements in healthcare infrastructure over the past decade, although it still faces challenges typical of semi-urban and rural regions, including limited access to specialized healthcare products and services. With the rising awareness about women's health and an increasing number of healthcare professionals focusing on gynecology, there is a noticeable demand for specialized pharmaceutical products. This shift has prompted pharmaceutical companies to tailor their marketing strategies to cater to the specific needs of gynecologists, hospitals, and clinics in Jalna.

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In this context, pharmaceutical sales and marketing strategies must adapt to local conditions, market dynamics, and regulatory factors that shape the healthcare landscape. The gynecological product market is characterized by a wide variety of medications, including hormonal therapies, contraceptives, and fertility treatments, which require specialized knowledge from both pharmaceutical companies and healthcare providers. Pharmaceutical marketing in this area involves complex strategies aimed at educating gynecologists, ensuring product availability, and establishing strong relationships with healthcare professionals.

This review paper explores the sales and marketing of pharmaceutical products in the gynecology sector, with a particular focus on the region of Jalna, Maharashtra. It delves into the role of medical representatives, the influence of promotional activities, and the impact of local healthcare trends on the sales of gynecological preparations. Moreover, it examines how pharmaceutical companies in Jalna use pricing strategies, product training, and distribution channels to improve market penetration.

Understanding the challenges and opportunities in this region is essential for companies aiming to expand their footprint in Maharashtra, particularly in the gynecology segment. The paper will also explore how various regional factors, such as socio-economic conditions, local culture, and the increasing importance of women's healthcare, shape pharmaceutical marketing strategies. By analyzing the pharmaceutical market in Jalna, this study provides valuable insights for pharmaceutical companies, healthcare professionals, and policymakers to improve healthcare access and delivery in emerging markets.

Additionally, this paper aims to highlight the evolving trends in pharmaceutical sales, including the shift towards digital marketing, the role of e-detailing, and the influence of continuing medical education (CME) programs in enhancing pharmaceutical sales performance. Ultimately, the paper provides a comprehensive understanding of how pharmaceutical companies can successfully navigate the challenges of marketing and sales in the gynecology sector in Jalna, Maharashtra, and the broader context of India's emerging pharmaceutical market.

Pharmaceutical Market Dynamics in Jalna

The pharmaceutical market in Jalna, Maharashtra, has seen significant growth in recent years, driven by the increasing demand for healthcare services and products. Jalna, a district in the Marathwada region, has a population that is progressively becoming more health-conscious, contributing to the expansion of the pharmaceutical market. The dynamics of this market are shaped by several factors, including healthcare infrastructure, population needs, local healthcare challenges, and regional economic conditions.

1. Healthcare Infrastructure and Demand

Jalna, while still considered a semi-rural area, has seen substantial improvements in its healthcare infrastructure. Over the years, the establishment of modern hospitals, private clinics, and diagnostic centers has played a pivotal role in meeting the growing demand for pharmaceutical products, especially in specialized fields such as gynecology. These healthcare institutions rely on pharmaceutical sales for medical supplies, including medications for women's health, fertility treatments, hormonal therapies, and contraceptives. The demand for gynecological products has increased significantly due to rising awareness about women's health, both in urban and rural areas. However, there is a disparity in access to healthcare services, with rural areas often lagging in terms of accessibility to the latest medicines and specialized treatments.

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2. Market Trends and Consumer Behavior

The pharmaceutical market in Jalna has been significantly influenced by the rising awareness of women's health issues. Traditional cultural barriers around discussing reproductive health are being gradually overcome, and there is growing acceptance of gynecological treatments such as contraceptives and fertility medications. Additionally, the younger population is becoming more open to discussing issues related to reproductive health, leading to increased demand for products like pregnancy supplements, hormonal therapies, and over-the-counter medications for infections.

The consumer base In Jalna is price-sensitive, with many individuals preferring generic medications or local brands over higher-priced branded products. As a result, pharmaceutical companies must focus on delivering affordable solutions while maintaining quality standards. Marketing strategies that emphasize cost-effectiveness and accessibility are often more successful in this market. Furthermore, the increasing penetration of internet services in Jalna has opened up new channels for pharmaceutical marketing, including digital platforms, e-commerce sites, and telemedicine services.

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3. Competitive Landscape

The pharmaceutical market in Jalna is competitive, with both national and regional players vying for market share. While multinational companies tend to focus on advanced, branded products, regional pharmaceutical manufacturers offer a wide range of affordable generics. Both types of companies must adjust their marketing and sales strategies to suit the local conditions. Multinationals typically focus on building relationships with healthcare professionals through continuing medical education (CME), conferences, and direct engagement. In contrast, regional players concentrate on product availability and accessibility in smaller clinics and medical stores.

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Gynecological Preparations Market in Jalna

The gynecological preparations market in Jalna, Maharashtra, is a significant segment of the broader pharmaceutical industry, driven by an increasing demand for products related to women's health. This market includes a wide range of medications used in treating various gynecological conditions, such as hormonal disorders, reproductive health issues, infections, and contraception. With the rise in awareness about women's health, there has been a notable increase in the adoption of these products, especially among women in both urban and rural areas.

1. Types of Products in the Gynecological Preparations Market

The gynecological preparations market in Jalna primarily consists of the following categories:

Contraceptives: Oral contraceptives, intrauterine devices (IUDs), and emergency contraceptives are among the most widely consumed products. Family planning awareness programs, combined with increasing education on reproductive health, have significantly boosted the demand for these products.

Hormonal Therapies: Products such as hormone replacement therapy (HRT), estrogen, and progesterone-based medications are used for treating conditions like menopause and polycystic ovary syndrome (PCOS). These medications are increasingly popular due to rising awareness of hormonal imbalances among women.

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Fertility Treatments: Infertility is a growing concern, and products like ovulation-inducing drugs, fertility supplements, and injectables are in demand. With increasing awareness about fertility challenges, gynecological clinics and private practitioners in Jalna are using these products to treat women seeking to conceive.

Antibiotics and Antifungals: These medications are used for treating infections commonly found in the gynecological domain, such as vaginal infections, sexually transmitted diseases (STDs), and other reproductive tract infections.

Pregnancy Supplements: Iron, calcium, folic acid, and multivitamins are crucial during pregnancy, and these products see high demand in both urban and rural settings in Jalna.

2. Market Drivers
Several factors contribute to the growing market for gynecological products in Jalna:
Health Awareness: Government initiatives, educational campaigns, and local NGOs have raised awareness about women's health, leading to increased demand for gynecological medications.

Improved Access to Healthcare: The expansion of healthcare facilities, including gynecological clinics, hospitals, and healthcare centers, has increased the accessibility of specialized treatments.

Cultural Shifts: Increasing acceptance of discussing women's health issues and addressing concerns like menstrual health, family planning, and fertility treatments have contributed to a positive market outlook for gynecological products.

3. Challenges
Despite growth, there are several challenges:
Affordability: The affordability of certain high-end gynecological products remains a barrier in rural areas of Jalna. Many women prefer generics or over-the-counter medications that are more affordable.

Limited Awareness of Specialized Treatments: While basic gynecological treatments have gained popularity, awareness about advanced treatments like fertility medications or hormonal therapies remains limited.

Sales and Marketing Strategies for Gynecological Products in Jalna
The sales and marketing strategies for gynecological products in Jalna, Maharashtra, need to be tailored to the region's demographic, economic conditions, and healthcare landscape. Effective strategies rely on addressing the unique needs of both healthcare professionals (HCPs) and consumers while ensuring accessibility, affordability, and awareness.

1. Targeting Healthcare Professionals

Pharmaceutical companies often focus on building relationships with gynecologists, family planning specialists, and general practitioners who prescribe gynecological products. In Jalna, the primary strategy for promoting these products involves educating healthcare providers about the latest advancements, treatments, and product benefits. This is typically done through:

Continuing Medical Education (CME) programs and workshops to keep professionals informed about new products and treatment protocols.

Direct engagement through sales representatives who visit clinics, offering samples and providing detailed product information.

Sponsorships for medical conferences and seminars to foster relationships with specialists and establish brand credibility.

2. Consumer-Oriented Marketing

With the rising awareness among women regarding reproductive health, direct-to-consumer marketing has become essential. Pharmaceutical companies utilize several approaches to reach end-users:

Awareness Campaigns: Conducting awareness programs through health talks, radio shows, and social media platforms to educate women about gynecological health, available treatments, and family planning options.

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Promotional Offers: Offering discounts, free samples, or loyalty programs through local pharmacies, making products more accessible to price-sensitive consumers in Jalna.

Collaboration with NGOs: Partnering with local non-governmental organizations (NGOs) and community health workers to promote awareness of gynecological health issues and medications, particularly in rural areas.

3. Advertising and Digital Marketing

The digital presence of pharmaceutical brands is becoming more influential. Online platforms like social media, health blogs, and local e-commerce websites are effective channels for reaching the tech-savvy population of Jalna, promoting gynecological products with targeted advertisements and health content.

Pricing Strategies and Product Positioning for Gynecological Products in Jalna

Pricing and product positioning are critical elements in the pharmaceutical market for gynecological products in Jalna, where a combination of affordability and brand perception influences consumer choices.

Pricing Strategies

Given the diverse socio-economic conditions in Jalna, pricing strategies need to be flexible to cater to both urban and rural populations. For gynecological products, a tiered pricing approach is commonly used:

Affordable Generics: Offering generic versions of popular medications at lower prices to cater to price-sensitive consumers.

Branded Products: Positioning premium, branded gynecological products at higher price points by emphasizing their superior quality, efficacy, and safety.

Discounts and Offers: Implementing promotional pricing strategies such as discounts, coupons, and buy-one-get-one offers, especially in smaller towns and rural areas to increase accessibility.

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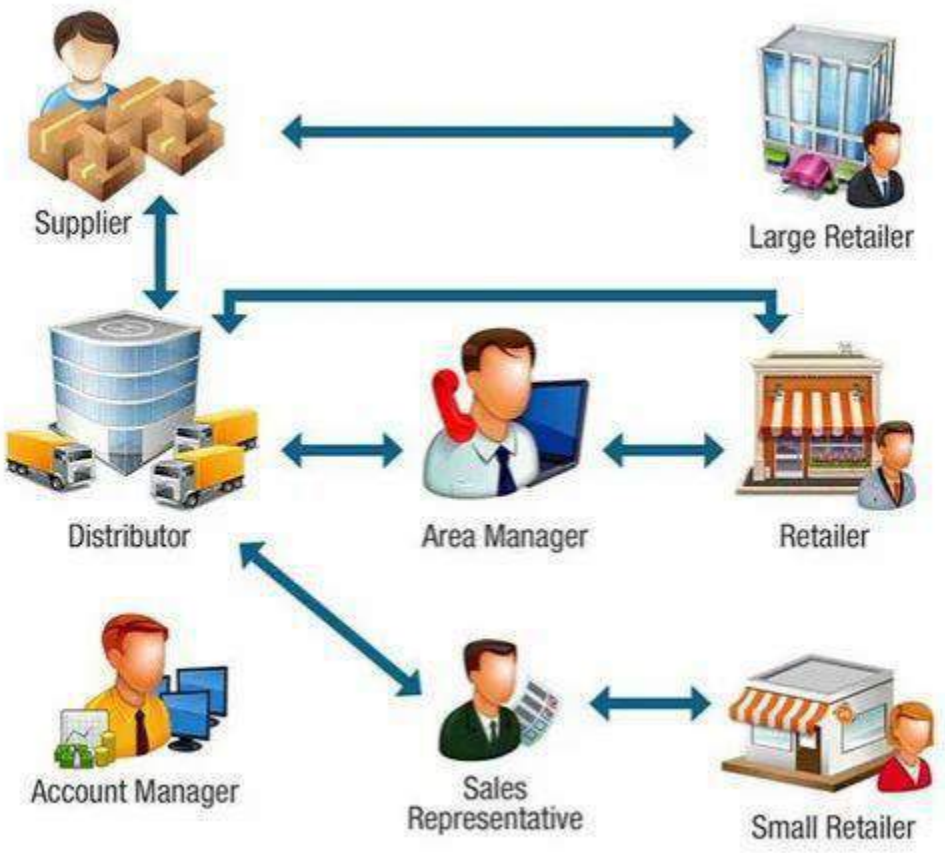
Product Positioning

The positioning of gynecological products in Jalna focuses on both functional and emotional benefits. Companies position their products as solutions to common women's health issues, such as contraception, fertility, and hormonal imbalances. The key is to balance affordability with quality, ensuring that the product meets the region's healthcare needs while being perceived as reliable and accessible. Leveraging local advertising channels and health awareness campaigns also plays a significant role in positioning gynecological products in the minds of consumers.

By adopting these strategies, pharmaceutical companies can effectively compete and establish a strong foothold in Jalna's competitive gynecological products market.

Distribution and Sales Channels for Gynecological Products in Jalna



The distribution and sales channels for gynecological products in Jalna are essential for ensuring that these products reach the intended consumers, including women and healthcare professionals.

Pharmacy and Retail Stores

Local pharmacies and retail outlets are the primary distribution channels in Jalna. These stores, both independent and chain pharmacies, offer a wide variety of gynecological products, such as contraceptives, hormonal therapies, and pregnancy supplements. Ensuring good relationships with pharmacy owners and regular stock replenishment is vital for market penetration.

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Healthcare Institutions and Clinics
Sales to hospitals, clinics, and specialized gynecological centers play a significant role in reaching patients who require prescribed medications. Pharmaceutical companies often supply gynecological products directly to these institutions through medical representatives who work closely with healthcare providers.

Direct Sales and Online Channels
The increasing penetration of digital platforms in Jalna has paved the way for online sales. E-commerce websites and health platforms enable the direct sale of gynecological products, offering convenience and discreet purchasing options for consumers. Additionally, sales representatives often engage in direct marketing to promote products, ensuring that they are available in local medical stores and clinics.

Distribution Partnerships
Many pharmaceutical companies rely on regional distributors who manage the logistics of product availability across various areas in Jalna. These partnerships ensure that products are readily available in both urban and rural parts of the region.

Effective distribution strategies and partnerships ensure the widespread availability of gynecological products, enabling better access and convenience for consumers in Jalna.

Regulatory and Compliance Factors for Gynecological Products in Jalna
The pharmaceutical industry in Jalna, like the rest of India, operates under stringent regulatory frameworks designed to ensure the safety, efficacy, and quality of medical products, including gynecological preparations. Key regulatory and compliance factors include:

Drugs and Cosmetics Act, 1940
Pharmaceutical companies must adhere to the Drugs and Cosmetics Act, which governs the manufacture, sale, and distribution of drugs in India. This ensures that gynecological products meet the necessary quality standards and are registered with the Central Drugs Standard Control Organization (CDSCO).

National and State-Level Licensing
Pharmaceutical manufacturers and distributors in Jalna must hold valid licenses issued by both state and national regulatory authorities. Local licenses are required for the sale and distribution of gynecological products through pharmacies and healthcare institutions.

Advertising and Promotion Guidelines
The promotion of pharmaceutical products, including gynecological preparations, is regulated by the Advertising Standards Council of India (ASCI). Companies must ensure that advertising is truthful, non-deceptive, and complies with ethical standards. This includes avoiding misleading claims about the efficacy of products and ensuring that all promotional materials are approved by the relevant authorities.

Pharmacovigilance and Reporting
Pharmaceutical companies must have mechanisms in place for reporting adverse drug reactions and ensuring the safety of gynecological products. Regular inspections and audits ensure compliance with Good Manufacturing Practices (GMP) and quality control standards.

Adhering to these regulatory and compliance factors is critical for ensuring the smooth operation of pharmaceutical sales and marketing in Jalna, promoting consumer safety, and maintaining the integrity of the healthcare system.

Training and Education for Pharmaceutical Sales Representatives in Jalna
Training and education for pharmaceutical sales representatives (PSRs) are crucial to ensure they effectively promote gynecological products in Jalna. The success of sales and marketing efforts relies heavily on the knowledge and skills of PSRs, who interact directly with healthcare professionals and consumers.

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Product Knowledge and Medical Understanding
Sales representatives undergo rigorous training to gain a comprehensive understanding of gynecological products, including their therapeutic uses, side effects, contraindications, and benefits. They are educated on the scientific and clinical aspects of the products to ensure they can provide accurate information to doctors and pharmacists.

Sales Techniques and Communication Skills
PSRs are trained in effective sales techniques, including negotiation, relationship-building, and product positioning. They also focus on developing strong communication skills to convey the product's value propositions to healthcare providers, ensuring they can address queries and concerns effectively.

Regulatory Compliance and Ethical Marketing
Given the highly regulated nature of the pharmaceutical industry, sales representatives in Jalna are educated on industry regulations, ethical marketing practices, and the importance of compliance with guidelines set by bodies such as the Drugs and Cosmetics Act and the Advertising Standards Council of India (ASCI).

Continuous Professional Development
Regular refresher courses, workshops, and medical seminars help keep PSRs updated on the latest developments in gynecology, new product launches, and evolving market trends. These programs ensure that representatives can maintain their competitive edge in a dynamic market like Jalna.

Proper training empowers sales representatives to effectively market gynecological products, build trust with healthcare professionals, and drive sales growth in the region.

Consumer Behavior and Physician-Prescription Patterns in Jalna
In Jalna, consumer behavior in the pharmaceutical market, particularly for gynecological products, is shaped by awareness, accessibility, and affordability. Women in the region are becoming more proactive about their health, seeking treatment for reproductive health issues, family planning, and hormonal imbalances. Consumers often rely on recommendations from healthcare professionals, such as gynecologists and general practitioners, for the choice of products. Physician-prescription patterns are influenced by the effectiveness, safety, and brand reputation of the products. Additionally, the increasing adoption of digital platforms for healthcare consultations is altering consumer behavior, allowing for a broader range of information about gynecological treatments.

Challenges in Pharmaceutical Sales and Marketing in Jalna
Pharmaceutical sales and marketing in Jalna face several challenges. One significant challenge is the price sensitivity of the population, particularly in rural areas, where access to branded products can be limited. Another issue is the low level of awareness regarding advanced gynecological treatments, such as hormone therapy and fertility medications. In addition, regulatory hurdles, strict advertising guidelines, and limited access to healthcare professionals in remote areas hinder marketing efforts. Furthermore, the fragmented healthcare infrastructure in Jalna poses logistical challenges in ensuring consistent product availability.

Opportunities for Growth in the Pharmaceutical Market
Despite the challenges, there are significant opportunities for growth in Jalna's pharmaceutical market. Increasing healthcare awareness, coupled with a rise in the number of healthcare facilities, creates demand for gynecological products. The growing awareness of women's health issues, driven by educational initiatives and government programs, opens doors for new product introductions. Additionally, the rising adoption of digital healthcare services offers opportunities for online sales and marketing of gynecological products, allowing for broader outreach.

CONCLUSION
The pharmaceutical market for gynecological products in Jalna presents both challenges and opportunities. Effective marketing and sales strategies, including targeting both healthcare professionals and consumers, are essential for success. With increased healthcare awareness, regulatory compliance, and strategic pricing, the region holds significant potential for growth in the pharmaceutical industry. Companies that can adapt to local market conditions, educate consumers, and engage healthcare professionals will find success in Jalna's dynamic market.

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APPROACHES OF IN VITRO CULTIVATION OF BAMBUSA VULGARIS

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ABSTRACT
Bamboo species are a valuable source of renewable raw material, with Bambusa vulgaris being an economically significant species. However, there are certain constraints to large-scale cloning of adult-selected genotypes. This study aims to investigate the in vitro cloning of Bambusa vulgaris in several culture systems. Compared to in vitro approaches, vegetative multiplication through separation of culm, rhizome, and rooting of stem cuttings is rather slow. Bambusa vulgaris, or common bamboo, is grown in vitro, or in a controlled laboratory environment, using plant tissue or cells. This review discusses a few methods for cultivating Bambusa vulgaris in vitro.
KEY WORDS: *Bambusa Vulgaris, micropropagation, Somatic embryogenesis, in vitro seed germination, shoot tip culture, callus induction.*

INTRODUCTION

Common bamboo, or Bambusa vulgaris, is a natural species of bamboo found in South-east Asia. It is one of the bamboo species that is grown and distributed the most throughout the world. Because of its ability to outcompete local plants and its quick development, Bambusa vulgaris is regarded as an invasive species in some areas.

Bamboo is a stem, sometimes referred to as a culm, with the majority of its woody content found in the upper ground portion. It also features a cylindrical, hollow, and straight structure made up of internodes and nodes. The diameter decreases as the thickness of the culm wall increases from the bottom to the top.

Bamboo has been utilized in traditional medicine for ages, primarily in Asia. Several bamboo species possess pharmacological characteristics, including, Anti-inflammatory, anti-microbial, antioxidant, cardioprotective, neuroprotective, anti-diabetic, immunomodulatory, anti-ulcer, and anti-aging properties

[1]

Cultivation for Bambusa vulgaris demands careful consideration of environment and soil.
Maintenance includes temperature, suitable humidity, soil pH, and proper propagation method.
In vitro culture of Bambusa vulgaris includes cultivating bamboo tissues or cells in a controlled laboratory environment. In vitro cultivation procedures include seed sterilisation and germination, node culture, somatic embryogenesis, suspension culture, and so forth.

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[2]

An approximate estimate of 9.5 million tonnes of bamboo is produced in India each year, of which 4.5 million tonnes are used to make paper. The versatile species of bamboo, which has significant economic potential, is rapidly disappearing due to indiscriminate and unplanned harvesting. There is still much to learn about the unusual gregarious and monocarpic flowering habit that is followed by the death of the mother clump and all of its offspring. The traditional method of propagating seeds is unreliable because of the seeds' quick viability loss, infection, and damage from pests and diseases during storage in warm, humid climates, as well as the unpredictable flowering cycle that might potentially yield techniques by means of culm, rhizome, roots, or stem cuttings is rather low. Research has always been done on the propagation of bamboo using both traditional and tissue culture methods. Regeneration of plantlets through somatic embryogenesis A variety of explants were used to observe different species. Various stages of somatic embryo development have also been documented in vitro flowering in various bamboo species. Histological and biochemical investigations have been used to determine the time of embryogenic calli development, embryoid formation, gemination of somatic embryos, and flowering in in vitro grown shoots. This article provides an overview of micropropagation.

[3]

- ***Disinfection of Mature Explanted***

mature explants infested with disease Because of internal contaminations in bamboo, it can be challenging to establish aseptic cultures from mature explants; cultures may exhibit symptoms of contamination even after 8 weeks or after being cultured for extended periods of time. Fungal and bacterial contaminations could not be controlled by standard sterilisation techniques. Benlate and bavistin (50–500 ppm) were used with anti-fungal medicines such as tetracycline, chloromycetin, rifamycin, and streptopenicillin to treat the explants. About 50% of sterile cultures were obtained after treatment with benlate (100 ppm each)

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for 60 minutes, followed by HgC12 (0.1%). (Personal observation). After disinfection, contaminated cultures may occasionally be used in bavistin. For disinfection, several toxicides and fungicides were also employed.[4]

- ***Aseptic Culture Establishment from seed***

The majority of research on the micropropagation of different bamboo species comes from seed sources. Mature bamboo seeds were dehusked, rinsed in 0.1 % (v'.v) "Teepol" (Qualigen, India) detergent solution for IO minutes, and then rinsed with running tap water for 2O minutes. The samples were subjected to four thorough rinses in sterile double-distilled water after being surface sterilised for 25 milliseconds using a 0.2% (w/v) aqueous solution of mercuric chloride. The entire excised zootic seed was utilised as an experimental specimen._ Seeds were carefully inoculated into liquid MS medium supplemented with 2% (w/v) sucrose after being surface-stain-treated for ten minutes with either a 0.05% solution of mercuric chloride, chlorine water, or sodium hypochloride.Typically, a 0.1-0.5% (w/v) aqueous solution of mercuric chloride or 5- 10% sodium hypochloride could be used to disinfest the majority of explants from seeds and seedling sources for IO to 20 minutes. This washed down with many rinses (2–6) using sterile distilled water. Without the use of growth regulators, seeds were cultivated on Skoog 25 (MS) and basal Murashige medium. After gelling the medium with 0.8% (w/v) agar (BDH,England), 20 ml of the molten medium was poured into each 25 x 50 mm culture tube that had been filled with non-absorbent cotton and covered with a single layer of cheese cloth. For 15 minutes, the media were steam sterilised at 104 kPa. For germination, the cultures were maintained in the dark at 25 ± 2°C. 4

1. Micro propagation of Bambusa vulgaris using internode explant

The preservation of natural behaviours is necessary for the conservation of bamboo variety, and production through ex-situ conservation is currently not a feasible alternative [6-7]. Although the macro proliferation strategy for propagation is a significant advancement, the need for seeds remains a constraint. As a result, contemporary conservation techniques like micropropagation offer a substitute for the quick regrowth of new plants in species like bamboo.

Using a sterile blade, the inter-nodal area of the stem (Bambusa vulgaris Schrad. ex Wendl) was chopped up to three inches. To get rid of the wax and dust, the top layers of the explant were wiped off. After that, the internode explant was cleaned for ten minutes under running tap water. The explant was submerged in fungicide (Bavistin 1%) for 10 minutes before being rinsed with sterile distilled water twice or three times. The explant was further cleansed with distilled water containing 1% of detergent for five minutes. Following a one-minute surface disinfection with 70% ethanol, the explants were treated with 0.1% aqueous mercuric chloride (HgCl2) for five minutes, and they were then thoroughly washed four to five times with sterile distilled water under aseptic condition

- ***Prepration of MS Media***

Getting MS Ready Media Growth conditions and the medium of culture for this investigation, MS (Murashige and Skoog 1962) medium containing 2% (w/v) sucrose was utilized. BAP (0.3 mg/L) was added to the medium along with 3 mg/l of NAA, 2,4-D, and IAA, respectively. Before the medium gelled with 1% agar, the pH was brought to 5.6. The prepared media (Hi-media, Qualigens, and SD fine chemicals, India) were the chemicals employed in this investigation. Each of the 50 ml of Murashige and Skoog was poured into a 150 ml sterilized conical flask (Borosil) and sealed with a cotton plug that wasn't absorbent.

- ***Storage of Prepared Media***

Keeping Prepared Media Stored Following preparation, the media were autoclaved, allowed to come to room temperature, and then kept in a 6°C refrigerator. The quantity of cultural media utilized in the Culture Jar Each conical flask contained 20 cc of semi-solid culture media for the typical propagation plantlet regeneration experiment.

- ***Establishment of Shoot***

Culture MS media containing and without 0.1% activated charcoal was used to cultivate surface-sterilized immature and semi-hard wood shoots. The explants that survived were then moved to regeneration media. Over the course of four weeks, the percentages of browning and survivals, as well as the quantity of shoot buds begun, new leaves developed, and callus formation, were noted. After that, the cultivated explants were kept at 25 ± 20C in the plant tissue culture environment with cool white fluorescent lamps providing a 16-hour photoperiod. There was 50–55% relative humidity.[5]

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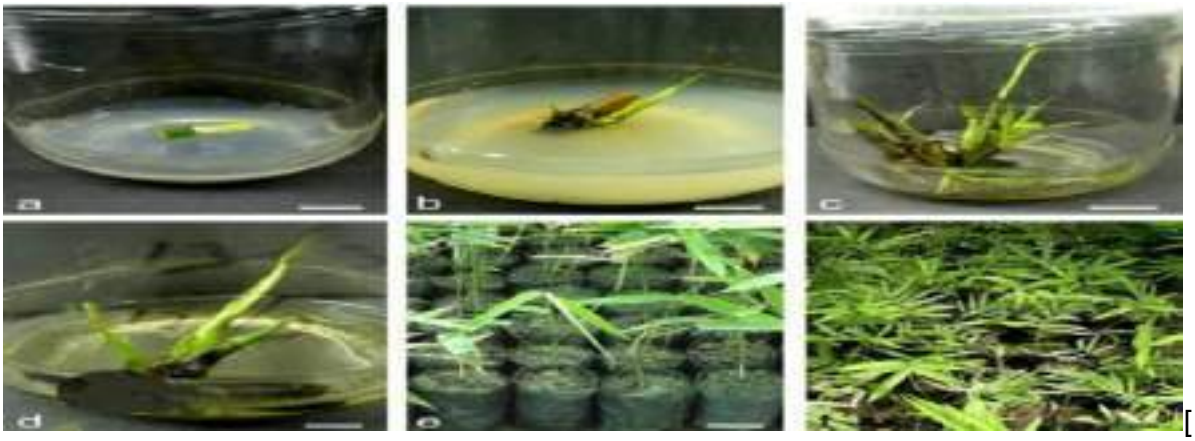

[6]

Table 1. Culture condition required for *in vitro* cultivation of *Bambusa vulgaris* Schrad. ex Wendl

Ex–plant	Temp.	Moisture	Light period	Time of regenretion
Inter node	25± 2	50-55	16 hours	3 Week

[5]

2.Somatic Embryogenesis

In callus cultures produced from nodal explants of in vitro-grown seedlings and excised mature zygotic embryos of bamboo species, plant regeneration by somatic embryogenesis was accomplished. Numerous research on in vitro shoot multiplication using various explants have been conducted. Plant regeneration and somatic embryogenesis from Bambusa zygotic embryo explants

- ***Material and Methods***

Plant matter and processing of explants. Mature Bambusa vulgaris seeds were gathered from trial crops. After the seeds were dehusked, they were rinsed for ten rains in a 0.1% (v/v) detergent solution called "Teepol" from Qualigen, India, and then for twenty rains under running water. The seeds were thoroughly cleaned four times in sterile double distilled water after being surface sterilized for 25 rains using a 0.2% (w/v) aqueous solution of mercuric chloride. Seeds were cultivated on basic MS (Murashige and Skoog 1962) medium without growth regulators.

0.8% (w/v) agar (BDH, England) was used to gel the medium. Then, 20 ml of the molten media was poured into each 25 x 150 mm culture tube, which was then sealed with a single layer of cheesecloth and filled with non-absorbent cotton. The media were steam sterilized for 15 minutes at 104 kPa.7

- ***Storage Condition***

Keeping prepared media stored following conditions, for germination, the cultures were stored in air-light containers under low or no light.7

- ***Establishment***

One node per nodal segment (1.0-1.5 cm) was measured. Semisolid MS media with different concentrations and combinations of Kn, BAP, NAA, IBA, and 2,4-D ranging from 0.0 - 3.0 mg/l was used to implant nodal tissue and excised zygotic embryo explants. Calli (about 200 mg + 20 mg) were routinely subculture every 4 weeks on fresh callusing medium or regeneration medium (1/2 MS + 0.5 mg/1Kn + 10 rag/1 Ads + 2.0 mg/l 2,4-D). Callus was routinely initiated from nodal explants and excised zygotic embryos on MS +0.25 mg/l Kn + 3.0 mg/12,4-D in species. Before being autoclaved and poured into culture tubes, all media were brought to a pH of 5.7 using either 0.1N NaOH or 0. I N HC1. 7

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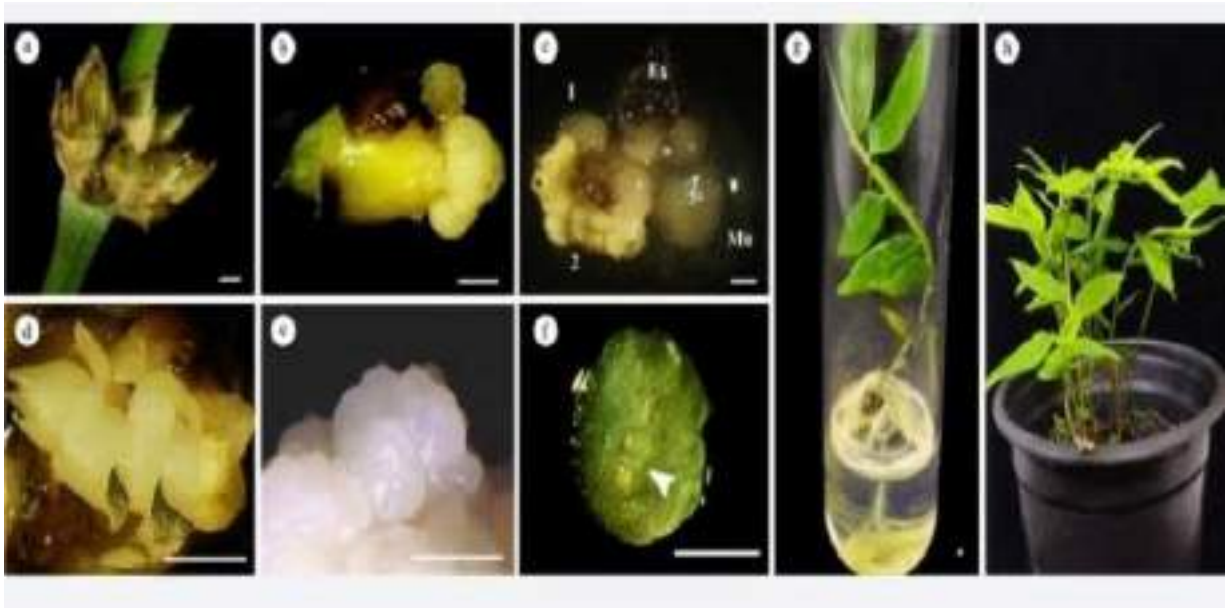

[8]

3. In Vitro Seed Germination of Bamboo

There is a lot of variances in bamboo's ability to stay viable and dormant in soil, and its demographic traits are still mostly understood when it comes to seed regeneration. Due to the lengthy intermast time, it would be challenging to store a lot of seeds for large-scale planting until the following flowering cycle is repeated. Since endogenous levels of auxins and abscisic acid (ABA) in seeds have been discovered to be one of the key variables related to the reduction in seed viability in stored bamboo seeds, seed viability is often quite poor in bamboos. Bamboo seeds have a brief lifespan; they can germinate in three to seven days, lose viability in one to two months, and their ability to do so varies with the season.[9]

- ***Material and Methods***

Procedures vegetation Caryopses, which are single-seeded propagation units of Poaceae, are formed when the test is united with a thin pericarp. For this experiment, seeds were purchased. The seeds were ageing; they were more than six months old. The seeds are 5-7.5 mm long, broadly oval, dark brown in hue, and rounded at the base with a pointy end. The seeds were stored in the Institute's seed bank in addition to being germinated.[9]

- ***Culture Establishment***

The glumed seeds, or explants, were meticulously prepared by floating them in water. This allowed for the separation of debris and empty seeds. After the dehusked seeds were gently shaken for 45 minutes, they were treated with a broad-spectrum antibiotic, streptomycin sulphate, 0.25% (w/v), and bavin 0.25% (w/v) as an antifungal treatment. The seeds were rinsed in 0.01% (v/v) Tween 20 for 10 minutes. The last stages of surface sterilization were carried out in a laminar flow using 0.1% (w/v) HgCl2 and 15% sodium hypochlorite for ten minutes each. After every treatment, the items were repeatedly washed in autoclaved distilled water for a minimum of three times.[9]

- ***Germination***

Sterile MS media medium (pH 5.6–5.8) was used to inoculate the transplants. Different quantities and combinations of plant growth regulators, such as 6-benzylaminopurine (BAP) and kinetin (KN), were added to the medium. Depending upon the necessity for initiation media or proliferation media 2.0-3.0% (w/v) sucrose was used as a carbon source with 0.75% (w/v) agar. For every treatment, three duplicates containing ten seeds each were obtained.[9]

- ***Transplantation and Acclimatization***

To lessen the likelihood of fungal contamination, plantlets were treated with an aqueous solution of bavistin after being carefully cleaned with lukewarm water and a sable hair brush to remove any remnants of agar adhering to the roots. Plantlets were then moved to a potting mix consisting of sand, soil, and FYM: :(1:1:1), and they were housed for a week in a greenhouse in a polytunnel with low light intensity and high humidity. Watering them frequently and misting them with Hogland's solution every seven to ten days was considered proper care. Following each week, data on growth performance and survival % were recorded.[9]

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Fig. 2—(a) Morphology of seed showing rounded base with a pointed end, dark brown in colour about 5 mm long, (b) initiation of germination by emergence of radicle (R) about 2 mm long, (c) micropylar end showing emergence of radicle and plumule (P), (d) radicle showing numerous root hairs.

[9]

4. Shoot tip Culture of Bambusa Vulgaris

Small-scale production can benefit from the enormous amount of material required for propagation by culm cuttings (single, double, triple, and whole node cuttings), as the right stage of material is only available for a brief period of time. Furthermore, this approach works well for producing clonal planting material on a modest scale. Every bamboo plant has a node on its segmented axis that contains a bud or a branch, and the branches themselves have a bud in their axil. The goal of the little research on its vegetative propagation has been to develop as many of these buds as possible into plant material (Banik, 1994). Numerous bamboo species have been effectively vegetatively propagated by the use of adventitious rooting in culm/branch cuttings (Agnihotri et al.,2009) Clonal propagation through shoot proliferation from field grown mature nodal shoot explants have been described with different effectiveness in many bamboo species viz; 54 species from 15 genera of bamboo.

- M***aterials and Procedures***

Plants from the greenhouse were taken.

Plant Materials and Culture Medium

Young, healthy B. vulgeris nodes were surface-sterilized for one minute using 70% ethanol, then treated for fifteen minutes with a 0.2% sodium hypochlorite solution (v/v), and then rinsed five times with sterile distilled water. The seeds were solidified with 0.8% agar and cultivated in MS (Murashige and Skoog 1962) with vitamins supplied with 3% sucrose as a carbon source.[10]

Culture Conditions for the growth of roots and shoot regeneration:

Similar to this, about one week old nodes were positioned vertically on MS medium supplemented with varying doses of BAP (0.5, 1.0, 1.5, 2.0, and 2.5 mg/l) + Kinetin for shoot induction. Healthy node explants were sectioned into 1 cm in length and inoculated into shoot induction medium. Cool white fluorescent light with a 16-hour photoperiod and an intensity of 40 εmol m-2 s-1 were used to incubate the cultures at 26 ± 0.5 °C. Every experiment was run in triplicate, with roughly 50 explants per treatment. An appropriate nutritional medium was standardized in order to compare the morphogenic response of internode explants towards varying concentrations of benzyl aminopurine (BAP) and kinetin. Following a 4-week incubation period under the same conditions,

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each explant was graded according to the quantity of responsive explants displaying shoot regeneration. Extended shoots measuring 2-4 cm were placed in MS medium that contained varying amounts of indole-3-butyric acid (IBA; 0.5, 1.0, 1.5, 2.0, and 2.5 mg/l) as well as 2.5 mg/l of charcoal to aid in rooting.[10]

Growth and Elongation of node

In synthetic media, node development and elongation are mostly dependent on the external supply of nutrients and plant growth regulators. The establishment of a precise tissue culture technique for effective in vitro organogenesis in bamboo made it possible to study the critical function that phytohormones play in plant regeneration.

Fig. 1. *In vitro* propagation of bamboo shoot: [A] Shoot initiation in MS+BAP; [B] and [C] Shoot induction in MS+kinetin+BAP.

[10]

5. Callus Induction

- **Initiation of callus from seed source**

Callus initiation from the seed source There have been reports of callus induction indifferent ex plants produced from several different species of bamboo. After two weeks of inoculation, callus was started from excised mature zygotic embryos and nodal segments formed from 10-day-old in vitro-grown seedlings on MS basal media supplemented with different combinations of kinetin and 2,4-dichlorophenoxyacetic acid (2,4-D). Incubating cultures in the dark resulted in a higher callus proliferation rate. The ideal concentrations of 2, 4-D and Kn for inducing callus varied little between species. The callus was first creamy white, friable, and nodular. The rate of callus growth slowed down and the callus turned brownish as the auxin concentration increased.[11]

- ***Report and Conclusion***

As the country's economy grows swiftly and has a high potential, the demand for bamboo has accelerated the depletion of its rootstock. Bamboo has a high capacity for carbon sequestration and is used to mitigate climate change and environmental issues. Similarly, it provides an alternative source of forest. As a result, it plays a significant role in conservation biology and has emerged as a top priority. With understanding of conservation biology and the environment, individuals must meet massive market demands and utilize finite resources. Harvesting from resources necessitates the production of a significant number of bamboo plantlets via micropropagation in order to cover plant stock gaps. Different methods of production are explained in this review

This protocol's excellent rates of shoot multiplication, rooting, and plant survival in the field indicate its potential to fulfil the expanding demand for disease-free, high-quality plant material

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PADDY STRAW AS A BIOFUEL FEEDSTOCK: RECENT ADVANCEMENTS AND FUTURE PROSPECTS

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ABSTRACT
Paddy straw, an abundant lignocellulosic agricultural residue, has garnered significant attention as a sustainable feedstock for biofuel production. Traditional disposal methods, such as open burning and field incorporation, contribute to environmental degradation, including air pollution and greenhouse gas emissions. This review comprehensively examines the recent advancements in converting paddy straw into various biofuels—namely bioethanol, biogas, and biodiesel. Emphasis is placed on technological innovations in pretreatment methods, conversion processes, and integrated biorefinery approaches over the past decade. The findings highlight the evolution of methodologies that enhance efficiency and sustainability, offering insights into future prospects for utilizing paddy straw as a versatile biofuel resource.
KEYWORDS: *Paddy straw; Rice straw; Biofuel; Bioethanol; Biogas; Pretreatment; Biorefineries*

1. INTRODUCTION

1.1 Background and Significance

Rice cultivation is a major agricultural activity worldwide, resulting in the production of substantial quantities of paddy straw. Global paddy straw production is estimated to be in the hundreds of millions of tons annually, posing significant management challenges (Liu & Wu, 2016). Traditionally, farmers dispose of paddy straw through open burning or field incorporation. These practices contribute to severe environmental repercussions, including air pollution and the emission of greenhouse gases such as CO_2, CH_4, and N_2O (Soam et al., 2017; Trivedi et al., 2017). The release of particulate matter adversely affects human health and exacerbates climate change (Connor et al., 2020).

1.2 Emerging Environmental Concerns

The environmental impact of traditional paddy straw disposal methods has become increasingly evident. Open burning leads to the release of pollutants that contribute to smog and respiratory illnesses (Sophal, 2020). Field incorporation, while initially considered beneficial for soil organic matter enhancement, has been linked to increased methane and nitrous oxide emissions due to anaerobic decomposition under certain conditions (Launio et al., 2016; Janz et al., 2019). These concerns underscore the urgency for sustainable disposal alternatives.

1.3 Objectives of the Review

In response to these challenges, research efforts have intensified over the past decade to explore the conversion of paddy straw into biofuels, aligning with global sustainability goals. This review aims to:

- Assess advancements in biofuel production from paddy straw between 2015 and 2024.
- Highlight technological innovations in pretreatment methods, conversion processes, and integrated biorefinery concepts.
- Identify future research directions to enhance the feasibility and efficiency of biofuel production from paddy straw.

2. CONVERSION PATHWAYS FOR PADDY STRAW BIOFUELS

Paddy straw's lignocellulosic composition makes it a suitable feedstock for producing various biofuels through different conversion technologies.

2.1 Bioethanol Production

2.1.1 Early Developments (2015–2018)

Initial research focused on overcoming the recalcitrance of paddy straw's lignocellulosic structure to enhance fermentable sugar yields:

- **Enzymatic Hydrolysis and Fermentation:** Juanssilfero et al. (2015) improved glucose availability through simultaneous saccharification and fermentation (SSF) using cellulase enzymes.
- **Microbial Strains Optimization:** Swain and Krishnan (2015) employed *Candida tropicalis* for fermenting hydrolyzed sugars, achieving moderate ethanol yields.

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- **Consolidated Bioprocessing (CBP):** Liu et al. (2016) improved CBP efficiency by combining enzyme production, hydrolysis, and fermentation in a single step.
- **Pilot-Scale Implementations:** Kapoor et al. (2017) demonstrated the feasibility of dilute acid pretreatment and enzymatic hydrolysis at a pilot scale, yielding high sugar concentrations suitable for industrial applications.
- **Genetic Engineering of Microorganisms:** Engineered strains of *Saccharomyces cerevisiae* and *Zymomonas mobilis* capable of fermenting pentoses have increased ethanol yields (Xie et al., 2018).
- **Adaptive Laboratory Evolution (ALE):** Chen et al. (2018) enhanced microbial strain robustness under industrial conditions through ALE, improving overall process performance.

2.1.2 Technological Innovations (2019–2023)

Advancements in recent years have focused on improving efficiency and reducing costs:

- **Process Integration:** Integrated hydrolysis and fermentation have streamlined production, reducing operational costs (Kumar et al., 2023).

2.2 Biogas Production

2.2.1 Advancements in Anaerobic Digestion (2015–2021)

Efforts have been made to optimize anaerobic digestion processes to enhance methane production:

- **Co-Digestion Strategies:** Shen et al. (2018) showed that co-digesting paddy straw with nitrogen-rich substrates like pig manure balanced nutrient content, enhancing biogas yields.
- **Two-Stage Digestion Systems:** Chen et al. (2021) found that separating hydrolysis and methanogenesis phases improved methane yields and process stability.
- **Digestate Recirculation:** Recirculating digestate was found to improve microbial community dynamics, leading to increased methane production (Chen et al., 2021).

2.2.2 Novel Approaches (2018–2024)

Recent innovations have focused on reactor design and enhancing microbial activity:

- **Nanobubble Water Pretreatment:** Wang et al. (2024) used nanobubble water to increase microbial accessibility, boosting methanogenesis efficiency.
- **Bioaugmentation and Nutrient Supplementation:** Introducing specialized microbial consortia and micronutrients has optimized microbial activity, enhancing biogas yields (Shen et al., 2023).
- **Advanced Reactor Designs**: Li et al. (2022) developed internal circulation reactors that maintain optimal conditions for continuous biogas production.
- **Anaerobic Membrane Bioreactors (AnMBR):** Incorporating membranes has increased biomass retention and methane production rates (Luo et al., 2018).

2.3 Biodiesel and Bio-Oil Production

2.3.1 Exploration of Thermochemical Conversion (2016–2018)

Research into thermochemical processes has expanded the range of biofuels derived from paddy straw:

- **Pyrolysis for Bio-Oil Production:** Fang et al. (2016) investigated the pyrolysis of paddy straw to produce bio-oil, suitable for fuel applications after upgrading.
- **Microbial Oil for Biodiesel:** Nam et al. (2018) explored cultivating oleaginous microorganisms on paddy straw hydrolysates to produce lipids convertible to biodiesel.
- **Integrated Co-Production Systems:** Processes that produce both bioethanol and biodiesel from paddy straw have been developed to enhance economic viability (Fang et al., 2016).

3. ADVANCES IN PRETREATMENT TECHNOLOGIES

Effective pretreatment is essential for overcoming the recalcitrant nature of paddy straw's lignocellulosic matrix.

3.1 Evolution of Pretreatment Strategies (2016–2020)

Early pretreatment methods faced challenges such as high costs and environmental concerns:

- **Hydrotropic Pretreatment:** Devendra and Pandey (2016) used hydrotropes for lignin removal without significant cellulose loss, reducing environmental impact.
- **OrganoCat Pretreatment:** Morone et al. (2017) developed a catalyst-based method achieving high delignification with minimal sugar degradation.
- **Ionic Liquid Pretreatment:** An et al. (2015) explored renewable ionic liquids derived from biomaterials, effectively dissolving lignin and enhancing subsequent hydrolysis.

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- **Glycerol Thermal Pretreatment:** Gabhane et al. (2020) demonstrated that glycerol pretreatment resulted in higher sugar yields in an eco-friendly manner.

3.2 Recent Innovations (2021–2023)

Recent pretreatment advancements aim to improve efficiency and sustainability:

- **Recyclable Ionic Liquids:** Wei et al. (2021) focused on solvent recovery in ionic liquid pretreatments, reducing costs and environmental footprint.
- **Electrochemical Pretreatments:** Sun et al. (2022) introduced electrochemically produced NaOH-H_2O_2 pretreatment, enhancing efficiency while reducing chemical handling risks.
- **Supercritical CO_2 Pretreatment:** Kumar et al. (2023) demonstrated that supercritical CO_2 is an eco-friendly method for lignin removal, enhancing hydrolysis efficiency.
- **Biological Pretreatment with Engineered Fungi:** Rani and Dhoble (2023) improved selectivity and efficiency in lignin degradation using genetically engineered fungi.

4. DEVELOPMENT OF INTEGRATED BIOREFINERIES

Integrated biorefineries aim to maximize the value derived from paddy straw by producing multiple products, thereby improving economic viability.

4.1 Fractional Utilization and Co-Product Generation

- **Fractionation Techniques:** Sun et al. (2016) fractionated paddy straw into cellulose, hemicellulose, and lignin, facilitating the production of xylooligosaccharides, high-purity lignin, and fermentable sugars.
- **Sequential Production Processes:** Zhao et al. (2018) combined ethanol fermentation with anaerobic digestion of residues, enhancing overall biomass utilization and energy recovery.

4.2 Pilot Projects and Demonstrations (2022–2023)

- **Zero-Waste Biorefineries:** Le et al. (2022) developed a pilot-scale biorefinery producing bioethanol, lignin, silica, and nutrients, achieving high recovery rates and energy efficiency.
- **Economic and Environmental Benefits:** Integrated biorefineries reduce waste, lower production costs, and align with circular economy principles (Singh & Basak, 2019).

5. FUTURE RESEARCH DIRECTIONS

Advancements in technology and interdisciplinary approaches are essential for the continued progress of paddy straw biofuel production.

- **Artificial Intelligence and Machine Learning:** AI and machine learning models are being developed to optimize process parameters, enhance yields, and predict system performance (Liu et al., 2016).
- **Advanced Enzyme Technologies:** Development of specialized enzyme mixtures has improved hydrolysis efficiency (Li et al., 2022). Wang et al. (2024) explored nanobiocatalysts to increase enzyme stability and activity.
- **Genetic Engineering and Synthetic Biology:** Xie et al. (2018) enhanced biofuel yields by genetically modifying microorganisms for better substrate utilization and inhibitor tolerance.
- **Process Intensification and Integration:** Combining pretreatment, hydrolysis, and fermentation into a single or continuous process reduces costs and increases efficiency (Liu et al., 2016).
- **Enhancing Economic Viability:** Producing co-products such as biochemicals, bioplastics, and animal feed can improve the economic feasibility of biorefineries (Le et al., 2022).

6. CONCLUSION

Significant progress has been made in the conversion of paddy straw into biofuels over the past decade. Innovations in pretreatment technologies, enzymatic hydrolysis, anaerobic digestion, and integrated biorefinery concepts have enhanced the feasibility and efficiency of biofuel production. These advancements contribute to environmental sustainability by reducing pollution and greenhouse gas emissions, while also offering economic benefits through waste valorization and rural development. Continued research is essential to address remaining challenges, such as process scalability, cost reduction, and integration with existing energy infrastructures. The prospects for paddy straw as a versatile biofuel feedstock are promising, with the potential to significantly contribute to renewable energy portfolios and sustainable development goals.

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FORMULATION AND EVALUATION OF HERBAL LOTION

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ABSTRACT
Liquid preparations called lotions are designed to be applied externally without creating friction. They are applied directly to the skin using an absorbent substance, like gauze soaked in it or cotton wool. The need for natural materials and natural extracts in cosmetics preparations was sparked by customers' desire for herbal products and the usage of natural herbs and their products for their aromatic value. Aloe vera is the most widely used medical plant in the world and the oldest known medicinal plant. Lotion formulation involves a number of procedures, including cutting the leaf's tip and base, extracting the mucilage portion in a mixing jar, grinding it thoroughly, adding vitamin E, pasteurizing the product, and cooling it. Following that, the gel was created. Next, the measured amount of gel was taken and used to formulate lotion by mixing it with the measured amount of ingredients. After a while, lotion was ready.
KEYWORDS : *Aloe vera, Herbal lotion, Herbal cosmetic, pH, Skin*

INTRODUCTION

The term "Herbal Cosmetics" refers to products that are mixed with a variety of approved cosmetic substances to create a basis, and then use one or more herbal ingredients to deliver specific cosmetic benefits. The need for natural materials and natural extracts in cosmetic preparations was sparked by customers' desire for herbal products and the usage of natural herbs and their products for their aromatic value.Liquid preparations called lotions are designed to be applied externally without creating friction. They are applied directly to the skin using an absorbent substance, like gauze soaked in it or cotton wool. Lotions can be used locally for protecting, calming, or cooling effects. Compared to body butter, body lotion has more water. Because it is an oil-in-water emulsion, producers disperse oil into the water. Body lotions made using this technique are lighter than body butter, making application simpler.Depending on their intended use, body lotions can differ slightly from one another. While some varieties are intended for more general use on the body, others are exclusively targeted at the face.

Advantages of Lotion

- It can also be used on broken skin.
- No metabolism first pass
- Localized therapeutic impact
- Portable and easy to use
- Self-medication can be done.
- Better for people who have trouble swallowing

Disadvantages of Lotion

- Poor drug permeability to deeper skin layers.
- less stable than solid dose forms.
- emulsion or suspension lotions require shaking the container before use.
- babies can ingest if applied to their hands.

Applications

cooling, hydrating, smoothing, and softening the skin Scabicidal, local anesthetic, antiseptic, humectant, astringent, antiacne, anti-inflammatory, cleansing, protective, antipyretic, Germicide, Paraciticide, antifungal, Fairness, wrinkle prevention, and anti-aging

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METHOD OF PREPARATION

Ingredients used in Herbal Lotion -

1. Aloe vera gel
2. Coconut milk
3. Honey
4. Almond oil
5. Glycerine
6. Rose water
7. Tomato
8. Vitamin E
9. Lavender oil

1.Aloe Vera Gel

- is used as a moisturizer, to treat burn wounds, and to lessen acne and pimples.
- Reduces scarring, pigmentation, redness, and skin irritation; it also acts as an antifungal and anti-inflammatory.
- It is rich in beta-carotene and vitamin Ç. As a result, it has anti-aging qualities; it also has antibacterial and anti-inflammatory qualities; it has cooling qualities; and it is abundant in minerals and antioxidants that promote healing. Additionally, it has calming and hydrating properties.
- The cooling properties of aloe vera provides a cooling sensation and prevents sunburn from developing.
- This drug is used as a moisturizer to treat or avoid minor skin irritation as well as dry, rough, scaly, and itchy skin.

2.Coconut Milk

- When applied directly to dry skin, coconut milk's high fat content can provide a great moisturizing effect. It also serves as a sealant to hydrate and look in moisture.
- It has the smoothest skin cells, is readily absorbed, and the fats keep your skin supple.
- It is the body's perfect moisturizer, leaving the skin textured and smooth.
- Coconut milk acts as a moisturizer.
- It lowers inflammation and encourages wound healing.

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- It has antifungal and antibacterial qualities.
- It possesses antioxidant qualities.

3.Honey

- As a natural antibacterial and anti-inflammatory, honey aids in the healing of acne outbreaks and guards against further infections.
- Additionally, honey lessens acne's redness and swelling.
- Honey helps to minimize fine lines and wrinkles by moisturizing the skin's outermost layers.
- It is used as an agent to cure wounds.
- Honey combats bacteria because it is an antibacterial substance.
- Honey can be very hydrating and prevent bacterial infections.
- It reduces pores, combats bacteria, and maintains youthful, smooth skin.
- Honey has a long shelf life and works well with a variety of chemicals, making it a great preservative for aloe.
- Mostly made up of sugar, honey also contains a variety of vitamins, minerals, iron, zinc, amino acids, and antioxidants. Honey is used for its antibacterial, anti-inflammatory, and antioxidant qualities, among other health benefits.

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4.Almond Oil

- Almond oil is a hydrating emollient that can help smooth and hydrate skin.
- Since almond oil is lightweight and non-irritating, it is often safe for sensitive skin.
- It might have antioxidant properties.
- It might have an anti-inflammatory effect.
- It might raise levels of healthy cholesterol.
- It might possess antimicrobial properties.
- It might possess antifungal qualities.
- It might have an immune-boosting effect.
- Make the skin clear and bright by reducing the rough and dry skin.
- It aids in the development of smooth and soft skin and provides you with incredibly hydrating skin without making it feel heavy.

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5.Glycerine

- A moisturizer is glycerin.
- It relieves itchy and dry skin.
- It addressed scars and acne.
- It aids in the reduction of wrinkles.
- It possesses anti-aging properties.
- It serves as a cleanser.
- It increases the permeability of the skin.

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6. Rose Water

- Rose water contains anti-aging properties and can calm your skin.
- Rose water is an excellent face spray.
- Fragrances can be made with it.
- One of the most effective ingredients for a face treatment is rose water.
- Rose water has many anti-inflammatory properties.
- In addition to lowering itching and redness, it has a cooling effect.
- It eases inflammation of the skin.
- It moisturizes and hydrates the skin.
- It aids in preserving the pH balance of the skin.
- It enhances the smoothness and texture of the skin

7.Tomato

Lycopersicum esculantum, the tomato, is a member of the Solanaceae family. The tomato is one of the most well-liked and extensively cultivated vegetable crops worldwide.LycopeneTrusted Source is a carotenoid that is present in tomatoes and other fruits. This organic substance is what gives tomatoes their red hue.Vitamin C and antioxidants included in them may help boost your immune system.They also contain the following nutrients:

- Pottasium
- Vitamin A
- Vitamin B
- Magnesium

- It cuts down on superfluous oil.
- Dead skin is removed.
- It keeps acne at bay.
- It makes skin more radiant.
- It alleviates inflammation of the skin.
- It postpones the aging indications.
- It tightens the pores.
- The tomato face wash that clarifies blemishes

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EXTRACTION PROCESS OF TOMATO

1. Fresh tomatoes were chopped and blended in a mixer.
2. To obtain tomato concentrate, a portion of the water was distilled off at 60 °C with reduced pressure and disposed away.
3. A sufficient volume of saturated water was added to the concentrate, which was kept out of the light at room temperature and agitated for two hours.
4. Two hours later, the residue was removed and the extract was collected.
5. After filtering the extract, the filtrate was gathered.

PREPARATION OF ALOE VERA GEL

1. First, gather the raw stuff.
2. Clean the leaf and cut off the base and tip.
3. A part of the leaf is cut.
4. Empty the leaves' mucilage into a mixing jar.
5. Add the agar-agar powder after heating it.
6. Unpasteurized juice is ground or homogenized.
7. Mix thoroughly after adding vitamin E.
8. Store and package the generated gel.

FORMULATION TABLE

Sr. No.	Name of Ingredients	Quantity (ml)
1	Aloe vera gel	10 ml
2	Coconut milk	5 ml
3	Honey	5 ml
4	Tomato	3 ml
5	Almond oil	2 ml
6	Rose water	2 ml
7	Vitamin E	2 Capsule
8	Glycerin	3 ml
9	Lavender oil	2-4 Drops

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METHOD OF PREPARATION OF HERBAL LOTION

1. Weigh each component in accordance with the recipe.
2. Alovera gel was placed in a different, clean beaker and swirled until it became somewhat creamy.
3. After that, tomato extract and honey were added and combined.
4. Next, glycerin, almond oil, lavender oil, and vitamin oil from capsules were added to another beaker.
5. After that, the oils solution was gradually added to the first beaker and properly mixed.
6. After combining all the ingredients, coconut milk and rose water were added according to consistency.

EVALUATION TEST FOR HERBAL LOTION

1. Organoleptic character
2. Homogenicity
3. PH determination
4. Stability test
5. Determination of spredability
6. Irritancy test
7. Washability

1. Organoleptic Character

Colour – Yellowish
Odour -Pleasant
Texture –Smooth
State – Semi-solid

2. Homogenicity

Visual appearance and tactile tests were used to determine the uniformity of the formulation.

3. PH determination

A digital PH meter was used to measure the PH after 0.5 g of cream had been dissolved in 50 ml of distilled water.

4. Stability Test

The formulation was put in the middle of the petri dish, and the plates were then incubated for 72 hours at 37°C to monitor the microbial development.

5. Determination of spredability

The sample was sandwiched between two glass slides and squeezed for five minutes with a 100g weight to achieve a consistent thickness. The pan was given more weight. The measure of spreadability was the amount of time needed to separate the two slides, or the amount of time it took for the upper glass slide to pass over the lower slide. The following formula was used to calculate it:

Spreadability-m*I/t
m-Weight tide to upper slide ,l - Length moved
on the glass slide , t-time taken.

6.Irritancy Test

On the dorsal surface of the left hand, mark the area (2 cm2). After applying the cream to that location, the time was recorded. After that, it is examined for irritability, erythema, and edema for up to 24 hours and reported.

7.Washability

For ten minutes, a dollop of lotion was applied to the hand's skin and let to run under the force of the tap water. It was noted when the lotion was totally gone.

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EVALUATION TABLE

Sr.No.	Test	Observation
1	Appearance	Lotion type
2	Colour	Yellowish
3	Odour	Pleasant
4	PH	5
5	Spreadibility	Easily spreadable
6	Irritancy test	Non irritable and non allergic to the skin
7	Washability test	Easily washable from the skin by using water
8	Stability test	No microbial growth is observed after 5 months

RESULT AND DISCUSSION

After being made, the herbal lotion was evaluated based on a number of criteria. The color of the herbal composition was yellowish. Throughout the trial, the pH ranged between 5 and 6, which is within the typical range for skin pH, and the lotion did not cause any skin irritation when applied. Under typical storage circumstances, the preparation remained stable. These findings showed that the topical region was not negatively impacted by the herbal lotion. This herbal concoction has been shown to have anti-aging and anti-inflammatory properties.

CONCLUSION

In this study, a herbal lotion formulation was created and assessed based on its physiological parameters (pH, spdiability, ease of removal, and irritancy test) as well as its organoleptic qualities (color, odor, and appearance).The current study focuses on herbal extracts. Give the skin the nutrition it needs to stay healthy. There are many naturally occurring herbs that can be used as antioxidants in skincare and cosmetic preparations. In comparison to commercially available cosmetics, the current study found that herbal cosmetics are extremely safe and do not cause any harmful or negative effects. By using herbal lotion, we can prevent skin issues.

This study unequivocally revealed the several drawbacks of allopathic lotion, including sensitivity, high cost, and adverse effects. Simple W/O techniques and minimal equipment are needed to manufacture the herbal lotion of crude pharmaceuticals with special qualities. The study's findings indicated that the poly formulation with F2 formulation outperforms other herbal formulations and represents the potential of herbal formulation in the future. whereby herbal lotion was effectively made, described, and assessed in a number of ways.

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COMPREHENSIVE OVERVIEW ON GUIDELINES FOR SOLID DOSAGE FORM SUBMISSION AS PER CDSCO IN INDIA

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ABSTRACT

Central Drugs Standard Control Organisation (CDSCO) and Regulation of Solid Dosage Forms in India. The Central Drugs Standard Control Organisation (CDSCO) serves as the apex regulatory authority in India for the approval, regulation, and quality control of pharmaceutical products, including solid dosage forms such as tablets, capsules, and powders.

Solid dosage forms, being the most common pharmaceutical formulations, are subject to rigorous regulatory oversight. CDSCO establishes standards for manufacturing practices, product testing, and marketing approvals to ensure compliance with Good Manufacturing Practices (GMP) and pharmacopeial standards. Its responsibilities include licensing of manufacturing units, approval of new drugs,

T. This framework not only safeguards public health but also promotes the growth of India's pharmaceutical industry in the global market., The regulatory efforts of CDSCO have been instrumental in fostering public trust by ensuring the availability of high-quality and affordable solid dosage forms in India.

KEYWORDS: *Drugs and Cosmetics Rules, 1945, Pharmaceutical Regulatory Authority, Good Manufacturing Practices (GMP), Central Licensing Authority, State Licensing Authority, New Drug Approval (NDA), Quality Control (QC), Pharmacovigilance Solid Dosage Forms Keywords*
Tablets, Effervescent tablets, Enteric coating, Disintegration testing, Active Pharmaceutical Ingredient (API), Excipients, Formulation Development, Bioavailability, Bioequivalence, Regulatory License, Product Registration, Quality Assurance (QA), Clinical Trials,

INTRODUCTION TO CDSCO

The Central Drugs Standard Control Organization (CDSCO) is India's national regulatory authority responsible for regulating pharmaceuticals, medical devices, and cosmetics. It operates under the Ministry of Health and Family Welfare, adhering to the provisions of the Drugs and Cosmetics Act, 1940, and its subsequent amendments. CDSCO plays a pivotal role in ensuring the availability of safe, effective, and high-quality medicines to the Indian population. Headquartered in New Delhi, CDSCO oversees multiple zonal, sub-zonal, and port offices across the country, facilitating smooth regulatory operations. Its responsibilities include granting approvals for new drugs, clinical trials, and fixed-dose combinations, along with licensing blood banks, vaccines, and large-volume parenterals. Additionally, CDSCO regulates medical devices, ensuring compliance with national and international safety standards CDSCO's work extends beyond approvals to monitoring post-marketing safety through pharmacovigilance programs. It collaborates with global organizations like the World Health Organization (WHO) to align Indian drug regulations with international best practices. By ensuring adherence to Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP), CDSCO maintains the integrity of the Indian pharmaceutical market while supporting research, innovation, and public health safety. In this presentation, we will explore the comprehensive drug approval process managed by CDSCO, which includes general considerations, data submission guidelines, inspections, and compliance functions, all aimed at maintaining a balance between public health and industry growth.

General Considerations on CDSCO

The Central Drugs Standard Control Organization (CDSCO) operates under the provisions of the Drugs and Cosmetics Act, 1940, and its associated rules. The organization ensures that all pharmaceutical products marketed in India meet stringent safety, efficacy, and quality standards. Several general considerations guide CDSCO's regulatory activities to maintain public health while promoting the growth of the pharmaceutical sector.

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Compliance with Regulatory Framework:
CDSCO ensures that drug approvals align with the Drugs and Cosmetics Act, 1940, and its rules. The regulatory framework provides a legal foundation for the approval process, setting clear requirements for drug manufacturing, marketing, and clinical trials.

Evaluation of Preclinical Data
CDSCO reviews detailed preclinical study data, including toxicity studies, pharmacological effects, and safety evaluations, to ensure that the drug is safe to proceed for human trials. These studies provide the foundation for understanding the risk-benefit profile of the drug.

Assessment of Clinical Trials
The organization requires comprehensive clinical trial data from Phases I, II, and III. These trials evaluate the drug's safety, efficacy, and dosing in human populations. Special emphasis is placed on ensuring that these trials are conducted ethically and comply with Good Clinical Practices (GCP).

Good Manufacturing Practices (GMP)
Compliance with GMP is critical to ensure the consistent quality of drugs. CDSCO conducts inspections of manufacturing units to verify adherence to GMP guidelines, focusing on processes, hygiene, and equipment standards.

Local Relevance of Clinical Data
CDSCO mandates those clinical trials include data specific to the Indian population to account for genetic, dietary, and environmental differences that might influence a drug's safety and efficacy.

Post-Marketing Surveillance
CDSCO emphasizes post-marketing safety monitoring (Phase IV studies) to identify any adverse effects or risks that may arise once the drug is widely used. This helps in safeguarding public health and maintaining trust in the regulatory system.

Ethical Considerations
All activities under CDSCO, including clinical trials and inspections, are carried out with a focus on protecting human participants' rights and safety. Ethics committees play a significant role in monitoring trials and ensuring transparency.

Risk-Benefit Analysis
Before granting approval, CDSCO performs a thorough risk-benefit analysis, ensuring that the potential therapeutic benefits of a drug outweigh its risks. This step is critical in making informed decisions about the approval and use of new drugs.

Adherence to International Guidelines
CDSCO aligns its regulatory practices with global standards, such as those set by the World Health Organization (WHO) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). This alignment ensures that Indian drug approvals are internationally accepted.

Stakeholder Collaboration
CDSCO works closely with pharmaceutical companies, research organizations, and global regulators to ensure effective communication and transparency throughout the drug approval process.
By adhering to these considerations, CDSCO ensures that every drug introduced into the Indian market is safe, effective, and of the highest quality, contributing to public health and industry development.

Guidelines on Data Required for Approval for Marketing of New Drugs
The approval process for marketing new drugs in India is a rigorous procedure regulated by the Central Drugs Standard Control Organization (CDSCO). It ensures that every new drug introduced to the market is safe, effective, and of high quality. To achieve this, CDSCO requires a comprehensive set of data at every stage of the approval process. Below are the key guidelines governing the data submission requirements:

Preclinical Data
Before initiating clinical trials, drug manufacturers must submit detailed preclinical data. This includes:

Toxicology Studies: Assessing the drug's safety through acute, sub-acute, and chronic toxicity studies in animals.
Pharmacology Studies: Evaluating the drug's mechanism of action, therapeutic efficacy, and pharmacodynamics (effect of the drug on the body).

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Pharmacokinetics: Data on absorption, distribution, metabolism, and excretion (ADME) in animal models.

Genotoxicity and Carcinogenicity: Studies to determine whether the drug poses risks of genetic mutations or cancer development. This data is crucial for determining whether a drug is safe for human testing.

Clinical Trial Data (Phase I, II, III)
To gain approval, manufacturers must provide detailed data from clinical trials conducted in accordance with **Good Clinical Practices (GCP)**.

Phase I Trials: These are conducted on a small group of healthy volunteers to assess safety, tolerability, pharmacokinetics, and pharmacodynamics.
Phase II Trials: Conducted on a larger group of patients to evaluate the drug's efficacy, dosing, and safety profile.
Phase III Trials: Large-scale trials conducted on diverse patient populations to confirm therapeutic efficacy, monitor adverse effects, and compare the drug to existing treatments.
CDSCO also mandates that a portion of the clinical trials include Indian participants to ensure the drug's suitability for the local population.

Manufacturing Information
The manufacturer must provide a detailed description of the drug's manufacturing process, including:

Raw Materials and Active Pharmaceutical Ingredients (APIs): Details on the sourcing, quality, and characterization of materials.
Batch Manufacturing Records: Documentation of the process to ensure consistency in production.
Stability Studies: Data showing that the drug remains stable and effective under various environmental conditions, such as temperature and humidity.
Good Manufacturing Practices (GMP): Compliance with GMP guidelines must be demonstrated to ensure product quality.

Bioavailability and Bioequivalence Studies
For certain drugs, particularly generic drugs or fixed-dose combinations, bioavailability and bioequivalence studies must be submitted to prove that the new drug behaves similarly to a previously approved drug in terms of absorption and efficacy.

Safety and Efficacy Data
A detailed analysis of the drug's risk-benefit profile is required, including:

- Adverse event reports during clinical trials.
- Comparisons to similar drugs already on the market.
- Evidence of long-term safety and therapeutic benefits.

Regulatory Forms and Documents
CDSCO requires the submission of specific forms and documents, including:

Form 44: The primary application for approval of new drugs.

Common Technical Document (CTD): A standardized format used internationally, which includes quality, safety, and efficacy data.

Detailed investigator brochures and reports from ethics committees approving the trials.

Pharmacovigilance Plan
Manufacturers must outline a pharmacovigilance plan, detailing how they will monitor and report adverse drug reactions (ADRs) once the drug is marketed. This ensures ongoing safety assessments during the post-marketing phase.

Local Clinical Trial Waiver
In certain cases, a waiver for conducting local clinical trials may be granted. This applies when:

- The drug is already approved in other countries with stringent regulatory standards.
- It addresses unmet medical needs or rare diseases.
- In such cases, CDSCO reviews existing global clinical trial data, though local trials may still be required later.

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Post-Marketing Surveillance (Phase IV Trials)
Manufacturers are required to submit plans for conducting Phase IV trials, which monitor the drug's real-world safety and efficacy after it has been approved and marketed.

Ethical and Legal Compliance
All submitted data must comply with ethical and legal standards. This includes approvals from ethics committees, adherence to GCP, and ensuring patient confidentiality during trials.

Approval of Solid Dosage Forms
The approval process for solid dosage forms (such as tablets, capsules, and powders) by the **Central Drugs Standard Control Organization (CDSCO)** involves stringent evaluations to ensure that these formulations meet safety, efficacy, and quality standards. Solid dosage forms are one of the most widely used drug delivery systems due to their convenience, stability, and cost-effectiveness. Below is a detailed explanation of the key aspects of the approval process:

Preformulation Studies
Before seeking approval, manufacturers conduct extensive preformulation studies to gather data on the physical and chemical properties of the active pharmaceutical ingredient (API). This includes:
Solubility and Dissolution: Ensuring the API dissolves properly for absorption in the body.

Stability Studies: Assessing how the API behaves under various conditions (e.g., temperature, humidity).

Compatibility Studies: Ensuring the API is compatible with excipients used in the formulation.
These studies form the foundation for designing a robust and effective solid dosage form.

Manufacturing Process
CDSCO requires detailed documentation of the manufacturing process to ensure consistency and compliance with Good Manufacturing Practices (GMP). This includes:

Granulation: Dry or wet granulation processes used to prepare the drug.
Compression: The process of forming tablets or encapsulating powders.
Coating: Information on coatings (e.g., enteric or sustained-release) that modify the drug's release profile.
Packaging: Details on primary and secondary packaging to maintain product integrity during storage and distribution.
Each step must be validated to ensure product consistency and reproducibility.

Quality Control and Testing
Comprehensive quality control (QC) testing of solid dosage forms is critical for approval. The tests include:

1. **Uniformity of Dosage Units**: Ensuring each tablet or capsule contains the same amount of API.
2. **Dissolution Testing** : Determining the rate at which the drug dissolves in the gastrointestinal tract.
3. **Hardness and Friability Testing**: Ensuring tablets can withstand mechanical stress during handling and transport.
4. **Moisture Content Analysis** : Testing for residual moisture, which can affect stability.
5. **Microbial Limits**: Ensuring the dosage form is free from harmful microbial contamination.

These tests ensure that the product meets the desired specifications for safety, potency, and stability.

Fig.1. Quality Control and Testing

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Bioavailability and Bioequivalence Studies
For approval, manufacturers must submit data on bioavailability (BA) and bioequivalence (BE):

1. **Bioavailability**: Demonstrates how well the drug is absorbed and becomes available in the bloodstream.
2. **Bioequivalence**: Required for generic solid dosage forms to ensure they are equivalent to the innovator drug in terms of efficacy and safety.
   These studies are crucial, especially for extended-release or controlled-release formulations
3. **Stability Testing**
   Manufacturers conduct stability studies to demonstrate that the solid dosage form remains effective and safe under varying environmental conditions. These tests are conducted as per **International Council for Harmonisation (ICH)**guidelines:
4. **Long-Term Stability Testing**: Conducted over months to years at controlled temperature and humidity
5. **Accelerated Stability Testing**: Conducted at higher temperatures to predict shelf life quickly. Data from stability studies is used to determine the drug's expiration date and storage conditions.

Regulatory Documentation
Manufacturers must submit a complete dossier to CDSCO, including:

Form 44: Application for approval of new solid dosage forms.
Batch Manufacturing Records (BMR): Documentation of production details.

Certificate of Analysis (CoA): A detailed report of the QC tests conducted on the final product.

Common Technical Document (CTD): A globally accepted format containing quality, safety, and efficacy information.
Proper documentation ensures transparency and compliance with regulatory standards.

Post-Approval Requirements
After approval, manufacturers must comply with CDSCO's post-marketing surveillance requirements. This includes:

Phase IV Studies: Monitoring the real-world safety and efficacy of the solid dosage form.

Periodic Safety Update Reports (PSURs): Regular reports on adverse drug reactions (ADRs) and other safety concerns.

Pharmacovigilance Plan: Ensuring effective monitoring of adverse effects and safety signals.
Variations and Amendments
If manufacturers make changes to the formulation, manufacturing process, or packaging after approval, they must seek CDSCO's approval for these variations. For example

- Changes to excipients or API sourcing.
- Modifications in tablet size, shape, or coating.

Inspection and Compliance Function of CDSCO
The Inspection and Compliance Function of the Central Drugs Standard Control Organization (CDSCO) in India is responsible for ensuring that drugs, medical devices, and cosmetics comply with regulatory standards for safety, efficacy, and quality. This function plays a vital role in safeguarding public health by ensuring that pharmaceutical and medical products on the market meet established standards.

Key Functions of the Inspection and Compliance Unit
Inspection of Manufacturing Units:
CDSCO conducts inspections of pharmaceutical manufacturing facilities to verify compliance with Good Manufacturing Practices (GMP) and other relevant standards. The goal is to ensure that drugs are produced consistently in a quality-controlled environment. Inspections may also cover the manufacturing of medical devices and cosmetics.

Monitoring of Drugs and Medical Devices
The department inspects drugs and medical devices at various stages of production, importation, and sale. This includes assessing the safety and efficacy of drugs before approval and after they are available in the market.

Compliance checks are also performed to ensure that companies are adhering to labeling, packaging, and advertising regulations.

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Import and Export Compliance
The CDSCO inspects imported pharmaceutical products and medical devices to ensure that they meet Indian standards and regulations. This also involves monitoring the export of drugs and medical devices from India to ensure international compliance.

The CDSCO may also issue certificates for products meant for export.

Enforcement of Standards
The Inspection and Compliance function ensures that all pharmaceutical and medical device products in the market meet the standards set by the Drugs and Cosmetics Act, 1940, and the Medical Devices Rules, 2017.

Non-compliance can lead to enforcement actions such as product recalls, penalties, or suspension of licenses.

Surveillance and Post-Market Monitoring
The department monitors the safety of drugs and medical devices post-market by tracking adverse drug reactions (ADRs) and complaints from consumers and healthcare professionals.

This helps in identifying potential risks associated with products that may not have been apparent during clinical trials.

Regulatory Actions
If a violation is detected, CDSCO has the authority to take regulatory actions, including issuing show cause notices, suspending or revoking licenses, or initiating legal proceedings against manufacturers or distributors.

Collaboration with Other Regulatory Authorities
CDSCO collaborates with other national and international regulatory bodies, such as the World Health Organization (WHO) and the U.S. Food and Drug Administration (FDA), to ensure consistent global standards for pharmaceuticals and medical devices.

Key Responsibilities of CDSCO
Regulation of Drugs and Cosmetics
Approval of Drugs: CDSCO is responsible for the approval of new drugs before they can be marketed in India. This includes evaluating clinical trial data, safety, and efficacy of new pharmaceutical products.

Licensing and Control: The organization issues licenses for the manufacture, sale, and distribution of drugs, cosmetics, and medical devices, ensuring compliance with the Drugs and Cosmetics Act, 1940, and the Medical Devices Rules, 2017.

Quality Control: CDSCO ensures that drugs and cosmetics meet quality standards by enforcing the Drugs and Cosmetics Act and conducting inspections and testing.

Regulation of Medical Devices
CDSCO regulates medical devices under the Medical Devices Rules, 2017. This includes ensuring the safety and effectiveness of devices before and after they enter the market.

The organization also oversees the approval process for medical devices, including diagnostic kits, surgical instruments, and implantable devices.

Monitoring and Enforcement
Surveillance and Post-Market Monitoring: CDSCO monitors drugs and medical devices after they are released into the market to identify any adverse reactions, defects, or quality issues. This is done through mechanisms like pharmacovigilance programs.

Enforcement of Standards: CDSCO ensures compliance with regulations and standards, and takes enforcement actions against manufacturers, distributors, or retailers who violate these standards. Actions can include product recalls, fines, suspending licenses, or legal proceedings.

Regulation of Clinical Trials
CDSCO oversees the conduct of clinical trials in India, ensuring they are conducted ethically and with the safety of participants as a priority. It regulates the approval of clinical trials and monitors their progress.

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The organization also ensures that trials are conducted following the guidelines set by the Central Ethics Committee and the Indian Council of Medical Research (ICMR).

Drug Import and Export Control
CDSCO regulates the import and export of drugs, medical devices, and cosmetics, ensuring that imported products meet Indian standards before being allowed into the market. Similarly, it oversees the export of Indian pharmaceutical products to foreign markets.

The organization also issues **Free Sale Certificates** to facilitate international trade.

Pharmacovigilance
CDSCO manages the **Pharmacovigilance Programme of India (PvPI)**, which tracks the safety of drugs once they are in use. This system collects data on adverse drug reactions (ADRs) and helps in identifying potential safety issues.

The goal is to take proactive measures to prevent harm to public health.

Regulation of Ayurvedic, Siddha, Unani, and Homeopathic Medicines
CDSCO is also responsible for the regulation of traditional medicines like Ayurveda, Siddha, Unani, and Homeopathy under specific regulations. This includes ensuring that these products meet safety and efficacy standards.

Public Health and Safety:
CDSCO works to ensure the overall public health and safety by regulating the availability of safe and effective medicines. It also plays a role in addressing public health emergencies by approving vaccines, treatments, and medical devices for urgent use.

Training and Capacity Building
CDSCO organizes training programs for its own staff as well as for pharmaceutical and medical device manufacturers, focusing on compliance, quality assurance, and regulatory affairs.

Collaboration with International Regulatory Bodies
CDSCO collaborates with international organizations such as the World Health Organization (WHO), U.S. FDA, European Medicines Agency (EMA), and other regulatory authorities to harmonize drug regulations and standards globally.

New Drug Approval by CDSCO
Pre-Clinical Trials
Before a drug can be tested on humans, it must undergo pre-clinical studies, usually conducted in laboratory settings or on animals. These studies assess the drug's safety profile, toxicity, pharmacokinetics (how the drug is absorbed, distributed, metabolized, and excreted), and pharmacodynamics (how the drug works in the body).

The results of pre-clinical studies are submitted to CDSCO as part of the application for permission to conduct clinical trials.

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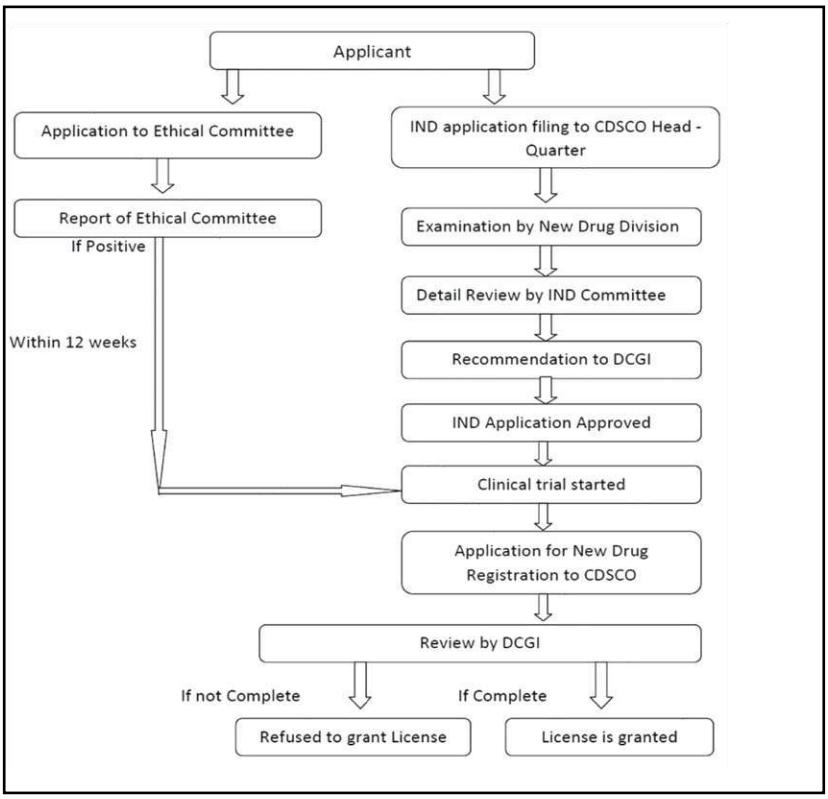

FIG.2. Flow chart of Drug Approval in India

Clinical Trials Application

A pharmaceutical company wishing to develop a new drug submits an **Investigational New Drug (IND) application** to CDSCO. This application includes detailed information about the drug, the pre-clinical studies, and the proposed clinical trial protocol.

The CDSCO evaluates the application, and once approved, the company can proceed with clinical trials in humans, which are typically conducted in three phases:

Phase I (Human Safety Trials): This phase involves testing the drug on a small group of healthy volunteers to assess safety, dosage, side effects, and absorption.

Phase II (Efficacy and Safety): This phase tests the drug on a larger group of patients who have the condition the drug is intended to treat. The goal is to assess the drug's efficacy and gather more data on its safety.

Phase III (Large-Scale Testing): Phase III trials involve even larger groups of patients to confirm the drug's effectiveness, monitor side effects, and compare it to existing treatments or a placebo. This phase is the final step before seeking approval for the drug.

Review of Clinical Trial Data:

Once the clinical trials are completed, the pharmaceutical company submits the results to CDSCO for review. The data submitted include detailed reports on the drug's safety, efficacy, side effects, and manufacturing processes.

CDSCO evaluates the clinical trial data to determine whether the benefits of the drug outweigh its risks, and whether it meets the required standards for public use.

Approval of New Drug

If CDSCO is satisfied with the clinical trial data and other requirements, it grants **approval** for the drug to be marketed in India. This approval is based on the drug's **safety, efficacy, and quality**.

For biologics, vaccines, and other complex drugs, additional specific guidelines and processes may apply.

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Labeling and Packaging Review
After approval, CDSCO also ensures that the labeling and packaging of the drug comply with the regulatory requirements, including clear information on the dosage, side effects, warnings, and expiration dates. This ensures that healthcare providers and consumers have access to accurate information about the drug.

Good Manufacturing Practices (GMP) Compliance
CDSCO ensures that the manufacturer complies with **Good Manufacturing Practices (GMP)**, which are set standards to ensure that drugs are consistently produced with quality controls. The manufacturing facility is inspected for GMP compliance before approval.

Post-Approval Surveillance
After a new drug is approved, it is subject to **post-marketing surveillance** or **pharmacovigilance**. This includes monitoring adverse drug reactions (ADRs) and conducting ongoing studies to detect any potential long-term effects that were not apparent during clinical trials.

If new safety concerns arise, CDSCO has the authority to take regulatory actions, such as withdrawing the drug from the market, issuing warnings, or revising its usage instructions.

Accelerated Approval
In certain cases, such as for drugs addressing unmet medical needs or public health emergencies (e.g., vaccines for pandemics), CDSCO may grant **accelerated approval**. This allows the drug to be marketed more quickly based on early-stage evidence, with continued monitoring for safety and efficacy.

Key Regulatory Frameworks for New Drug Approval

- **Drugs and Cosmetics Act, 1940:** This is the primary legislation governing the regulation of drugs and cosmetics in India.
- **New Drug and Clinical Trial Rules, 2019:** These rules, under the Drugs and Cosmetics Act, set the guidelines for conducting clinical trials and the approval process for new drugs.
- **The Medical Device Rules, 2017:** For drugs that may also be considered medical devices (such as drug-eluting stents or diagnostic kits), these rules apply.

Solid Dosage Forms – Forms 10, 11, and 40

In the context of the **Drugs and Cosmetics Act** and the regulations enforced by the **Central Drugs Standard Control Organization (CDSCO)** in India, **Forms 10, 11, and 40** refer to specific regulatory documents related to the **manufacturing, licensing, and distribution of solid dosage forms** (such as tablets, capsules, and powders).
These forms are part of the regulatory framework designed to ensure the quality, safety, and efficacy of pharmaceutical products in India.

Form 10: Application for License to Manufacture Drugs (Other than Blood and Blood Products)
Purpose: Form 10 is used by manufacturers seeking to obtain a **license for the manufacturing of drugs**, including solid dosage forms (tablets, capsules, etc.), under the provisions of the **Drugs and Cosmetics Act, 1940**.

Scope: This form applies to the **manufacturing of any drug** (including solid dosage forms), and the manufacturer must meet the relevant **Good Manufacturing Practices (GMP)** as stipulated by the CDSCO.

Details Required

- Name and address of the manufacturing company.
- The specific drugs or dosage forms being manufactured.
- Manufacturing processes and equipment used.
- Quality control measures.
- Compliance with the regulations under the Drugs and Cosmetics Act.
- After submission of Form 10, the CDSCO or the concerned State Drug Authority may inspect the manufacturing unit to ensure that it meets all the required standards before granting the manufacturing license.

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Form 11: Application for License to Sell or Distribute Drugs
Purpose: Form 11 is used by entities seeking a license to **sell or distribute** drugs, including solid dosage forms, in India.

Scope: This form applies to companies or individuals who want to distribute or retail pharmaceutical products, such as tablets or capsules, that have already been manufactured and approved.

Details Required

- Information about the applicant (individual or company).
- List of the drugs to be sold or distributed, including solid dosage forms.
- Details of premises, storage conditions, and distribution methods.
- Compliance with the Drugs and Cosmetics Act and any other applicable regulatory requirements.

The approval of Form 11 ensures that only licensed distributors or retailers are allowed to sell or distribute drugs in India, and that they meet proper storage, handling, and distribution standards.

Form 40: Application for License to Manufacture or Import Drugs (For Clinical Trials)
Purpose: Form 40 is used when an entity seeks a license to **manufacture or import drugs** for **clinical trial purposes**. This form specifically applies to drugs that are being tested in clinical trials, including those in solid dosage forms.

Scope: It is an essential document for obtaining permission to manufacture or import drugs for use in clinical trials before they are introduced to the market.

Details Required:

- Name and details of the applicant (company or individual).
- Drug details, including formulation (e.g., tablets, capsules).
- Purpose of the clinical trial, including the clinical trial protocol.
- Approval from an ethics committee.
- Compliance with the **Indian Good Clinical Practice (GCP)** guidelines and the **Drugs and Cosmetics Act**.

The approval of Form 40 allows entities to manufacture or import drugs (including solid dosage forms) specifically for clinical trials. These trials must adhere to ethical standards and follow proper procedures to ensure safety and efficacy before the drug can be marketed.

Summary of Forms 10, 11, and 40:

- **Form 10**: For obtaining a **manufacturing license** to produce drugs, including solid dosage forms, in compliance with GMP.
- **Form 11**: For obtaining a **license to sell or distribute** drugs, including solid dosage forms, ensuring proper distribution practices.
- **Form 40**: For obtaining a **license to manufacture or import** drugs for **clinical trial purposes**, including solid dosage forms, under specific conditions.

Permission to Approval
In the context of drug regulation in India, permission to approval refers to the process through which the Central Drugs Standard Control Organization (CDSCO) grants permission for the approval of drugs, including new drugs, generic drugs, and drugs for clinical trials, ensuring they meet safety, efficacy, and quality standards before being marketed or used in the country.

The term "permission to approval" can refer to several stages in the regulatory process, particularly for new drug approval and clinical trial approval. Below, we will explain the key stages involved in obtaining permission for the approval of drugs:

1.Permission to Conduct Clinical Trials (Investigational New Drug - IND)
Before a new drug can be approved for sale and marketing in India, it must first undergo clinical trials to demonstrate its safety and efficacy. To conduct these trials, pharmaceutical companies must seek permission from the CDSCO.

Application for Clinical Trial Permission (Form CT-04)
Companies must submit an application (Form CT-04) to CDSCO to seek approval for conducting clinical trials. This includes detailed documentation about the drug, proposed clinical trial protocol, and ethical considerations.

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The application must also include pre-clinical study data (such as animal testing results) to demonstrate that the drug is safe to test in humans.

Ethical Approval
The clinical trial must also receive approval from an independent ethics committee or institutional review board (IRB) that reviews the proposed trial protocol, ensuring that it meets ethical standards and protects the rights of participants.

Permission from CDSCO
Once the application is reviewed and found to meet regulatory and ethical standards, CDSCO grants permission to proceed with the clinical trials in India. This is often referred to as **permission to conduct clinical trials**.
In the case of drugs addressing urgent medical needs (such as for a public health emergency), the process may be expedited.

2. Permission for New Drug Approval
Once clinical trials are completed, pharmaceutical companies need to obtain permission for the approval of a new drug before it can be marketed to the public.

Application for New Drug Approval (Form 44 or Form 45):
After completing the clinical trials, the company submits an application (Form 44 or 45) to CDSCO for the approval of the new drug, including all clinical trial data (Phase I, II, and III results), pharmacological information, and manufacturing details.
The company also submits information on the drug's labeling, packaging, and proposed indications.

Review of Data
CDSCO thoroughly reviews the clinical trial results, including the safety, efficacy, and potential side effects of the drug. This involves a scientific and regulatory evaluation of the drug's clinical trial data, the manufacturing process, and the risk-benefit profile.
The review also includes input from experts and committees, such as the Drugs Technical Advisory Board (DTAB) and the Subject Expert Committee (SEC).

Grant of Permission for Approval
If the data meets the required safety and efficacy standards, CDSCO grants permission for the drug to be marketed in India. This permission is typically given in the form of a drug approval license.
The drug then becomes available for sale in the Indian market, subject to post-market surveillance for safety and adverse reactions.

3. Permission for Import of Drugs
Drugs that are to be imported into India must also undergo a permission process.

Application for Import License
Companies seeking to import drugs into India, including foreign-manufactured solid dosage forms, need to submit an application to CDSCO for an import license. The application includes documentation about the drug's origin, manufacturing process, and approval from the regulatory authority in the country of origin.

Approval from CDSCO
If CDSCO is satisfied with the drug's regulatory compliance in the foreign market and that the drug meets Indian standards, it grants the **import permission**.

The drug is then allowed to be imported and sold in India, subject to regulatory compliance with Indian labeling, packaging, and safety standards.

4. Permission for Market Authorization
After obtaining approval for clinical trials and new drug approval, a company must also obtain permission for **market authorization** to officially launch the drug in the market.

Market Authorization Application (Form 46):
A pharmaceutical company submits an application (Form 46) to CDSCO to seek permission for **market authorization**.

The application includes documentation on manufacturing details, labeling, packaging, and the post-marketing surveillance plan.

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Review and Granting Market Authorization:
CDSCO reviews the application and, if all requirements are met, grants the market authorization. This means the drug can officially be sold in the Indian market.

Regulatory Framework for Permission and Approval
The permission and approval processes are governed by the **Drugs and Cosmetics Act, 1940**, and the **Drugs and Cosmetics Rules, 1945**, as well as the **New Drug and Clinical Trial Rules, 2019**.
These processes ensure that only drugs that are proven to be safe, effective, and of good quality are available to the public, and that clinical trials are conducted in an ethically responsible manner.

Summary of Permission to Approval Process:
1. **Clinical Trial Permission:** Approval to conduct clinical trials in India after submitting necessary data.
2. **New Drug Approval Permission:** After successful clinical trials, permission to market a new drug in India.
3. **Import Permission:** Permission for importing drugs into India.
4. **Market Authorization Permission:** Final approval for the drug to be available on the market after ensuring all regulatory requirements are met.

This **permission to approval** process ensures rigorous scrutiny of new drugs, protecting public health and safety while promoting access to effective treatments.

Application for New Drugs
The application for new drugs is a critical step in the process of introducing a new pharmaceutical product to the market in India. This process is governed by the Drugs and Cosmetics Act, 1940, and the New Drug and Clinical Trial Rules, 2019, and is overseen by the Central Drugs Standard Control Organization (CDSCO). The objective is to ensure that new drugs are safe, effective, and of high quality before they are approved for public use.

Steps Involved in the Application for New Drug Approval
Pre-Clinical Research and Development
Pre-clinical studies (animal testing and laboratory studies) are carried out to assess the safety, toxicity, and pharmacokinetics of the new drug before it can be tested in humans.

The results from these pre-clinical studies are used as part of the application to demonstrate that the drug is safe for human trials.

Application for Permission to Conduct Clinical Trials
Before submitting an application for marketing approval, the applicant (usually the drug manufacturer or sponsor) must first obtain permission to conduct **clinical trials** in India.

Form CT-04 is used to seek approval from the CDSCO to conduct clinical trials, which are typically conducted in three phases:

Phase I: Testing in healthy volunteers to assess safety and dosage.
Phase II: Testing in patients with the targeted condition to evaluate efficacy and side effects.
Phase III: Large-scale testing in patients to confirm the drug's effectiveness and monitor long-term safety. After receiving approval for clinical trials, the sponsor conducts the trials and gathers data on the drug's safety and efficacy.

Submission of New Drug Application (NDA): After the completion of clinical trials, the company submits a formal New Drug Application (NDA) to the CDSCO for marketing approval. This application includes comprehensive data and documentation, such as:

Clinical Trial Data: Results from all three phases of clinical trials, including safety, efficacy, adverse events, and statistical analyses.

Pharmacology and Toxicology Data: Information about the drug's mechanism of action, toxicity studies, and animal trial results.

Manufacturing Information: Detailed information about the drug's manufacturing process, including quality control measures and Good Manufacturing Practice (GMP) compliance.

Proposed Labeling and Packaging: The drug's intended use, dosage instructions, contraindications, warnings, and other labeling information.

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Pharmacokinetics and Pharmacodynamics: Data on how the drug is absorbed, metabolized, and eliminated from the body, as well as how it interacts with the body's systems.

Post-Marketing Surveillance Plan: A plan for monitoring the safety of the drug once it is on the market.

Regulatory Review by CDSCO
The CDSCO, with the help of expert committees like the Drugs Technical Advisory Board (DTAB) and the Subject Expert Committee (SEC), reviews the NDA to ensure the drug meets the required safety, efficacy, and quality standards.
The review process includes:

Evaluation of Clinical Data: A thorough analysis of the clinical trial results to assess the drug's safety and efficacy.

Manufacturing and Quality Control: A review of the drug's manufacturing processes, quality control measures, and compliance with GMP.

Labeling and Packaging Review: Ensuring that the drug's labeling and packaging comply with regulatory requirements.

Grant of Marketing Authorization:
If the CDSCO is satisfied with the data and finds the drug to be safe and effective, it grants **marketing authorization**. This approval allows the drug to be sold in India.

The approval typically includes conditions for the sale of the drug, such as dosage, indications, labeling requirements, and post-marketing surveillance.

Post-Marketing Surveillance and Adverse Drug Reaction (ADR) Monitoring:
After the drug is launched in the market, it is subject to post-marketing surveillance to monitor its long-term safety and efficacy. The CDSCO uses the Pharmacovigilance Programme of India (PvPI) to track adverse drug reactions (ADRs) and take necessary actions if new safety concerns arise.

In some cases, the drug may be subject to further studies or a risk-benefit review based on real-world data.

Regulatory Actions
If any issues arise after the drug is marketed, such as new safety concerns or failure to meet quality standards, the CDSCO has the authority to take regulatory actions. These actions can include:

- Suspending or revoking the approval.
- Issuing warnings or advisories.
- Mandatory recall of the drug.

Forms Used for New Drug Approval
Form 44 (for **new drugs**) and **Form 45** (for **fixed-dose combination drugs**) are used to submit the application for new drug approval to CDSCO.

Form 44: This is used when applying for approval of a **new chemical entity** (NCE) or new drug that has not been marketed in India before.

Form 45: This form is for applications related to fixed-dose combinations (FDCs) of existing drugs that have not been marketed as a combination in India before.

Special Considerations for New Drugs
Fast-Track Approval:
For drugs addressing critical health needs (such as vaccines for pandemics or treatments for serious diseases), CDSCO may grant **fast-track approval** to expedite the review process.
This allows the drug to be approved more quickly while still ensuring safety and efficacy.

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Biological and Biosimilar Drugs

The approval process for **biological drugs** (e.g., vaccines, monoclonal antibodies) or **biosimilars** may involve additional regulatory considerations. Specific guidelines under the **Biologics and Biosimilars Guidelines** are followed, with a focus on ensuring that the biologic is similar to an already approved reference product.

Summary of the Application for New Drug Approval

1. **Pre-Clinical Testing**: Initial safety and efficacy studies.
2. **Clinical Trials**: Approval to conduct trials and gather data on human safety and efficacy.
3. **New Drug Application (NDA)**: Submission of clinical data, manufacturing details, labeling, and post-marketing plans.
4. **Regulatory Review**: Evaluation of the application by CDSCO and expert committees.
5. **Marketing Authorization**: Approval for the drug to be marketed in India, subject to regulatory conditions.
6. **Post-Marketing Surveillance**: Ongoing monitoring for safety and efficacy.

DISCUSSION

1. Role in Regulation

CDSCO regulates the approval process for new drugs and ensures compliance with standards for the manufacturing of solid dosage forms.

It works under the Ministry of Health and Family Welfare, ensuring drugs meet the Drugs and Cosmetics Act, 1940, and associated rules.

Solid dosage forms are assessed for stability, bioavailability, dissolution, and uniformity during approval.

2. Quality Control Mechanisms

It ensures compliance with Good Manufacturing Practices (GMP) outlined in Schedule M of the Drugs and Cosmetics Rules, 1945.

Manufacturers must submit detailed documentation and samples for testing and analysis by CDSCO-approved laboratories.

3. Testing Parameters

Dissolution testing: To ensure the drug releases appropriately in the body.

Content uniformity: Ensuring consistent potency in each unit of the solid dosage form.

Stability studies: Testing the product's shelf life under various conditions.

Impurity profiling: Ensuring no harmful impurities are present.

4. Pharmacovigilance

CDSCO monitors the post-market performance of drugs through the Pharmacovigilance Programme of India (PvPI) to identify any adverse reactions or quality issues in solid dosage forms.

5. Challenges

Counterfeit or substandard drugs.

Lack of uniform compliance among small-scale manufacturers.

Ensuring consistent implementation of standards across India's vast pharmaceutical industry.

Results of CDSCO Oversight

1. Improved Drug Quality

Regulatory enforcement has led to stricter adherence to manufacturing standards.

Significant reduction in the circulation of substandard solid dosage forms in the market.

2. Increased Market Transparency

Online platforms like Sugam facilitate efficient drug approval processes and improve transparency in regulatory operations.

3. Enhanced Public Health Outcomes

With better quality control, incidences of drug-related adverse events have reduced, improving patient safety and therapeutic efficacy.

4. Global Recognition

Indian pharmaceutical companies have gained international recognition, with many CDSCO-regulated facilities meeting USFDA and WHO standards.

CONCLUSION

The Central Drugs Standard Control Organization (CDSCO) plays a crucial role in regulating drugs, medical devices, and cosmetics in India, ensuring they meet safety, efficacy, and quality standards. Through its comprehensive processes for drug approvals, inspections, and post-market surveillance, CDSCO supports both public health and the growth of the pharmaceutical sector. Its collaboration with international organizations and adherence to global standards strengthens India's regulatory framework, ensuring that the population has access to safe and effective medicines. By enforcing robust compliance mechanisms, CDSCO not only protects consumers but also ensures the integrity of the pharmaceutical and medical device markets in India.

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AN POLYHERBAL TRANSDERMAL PATCH ACTING AS ANTIPYRETIC AND ANALGESIC IN EFFECT

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[5]Co-Guide

ABSTRACT

The development of polyherbal transdermal patches offers a novel approach to delivering therapeutic agents for managing fever (antipyretic) and pain (analgesic). This study focuses on formulating and evaluating a polyherbal transdermal patch using natural plant extracts with proven antipyretic and analgesic properties. Key ingredients include herbal extracts like Azadirachta indica *(Neem),* Curcuma longa *(Turmeric), and* Zingiber officinale *(Ginger), chosen for their synergistic pharmacological effects. The transdermal patch is designed to ensure sustained release of active compounds through the skin, enhancing bioavailability and reducing gastrointestinal side effects associated with oral administration.*

The patches were prepared using a solvent casting method, employing biocompatible polymers such as hydroxypropyl methylcellulose (HPMC) and ethyl cellulose for controlled drug release. The formulations were evaluated for physicochemical properties, including thickness, weight uniformity, tensile strength, drug content, and in-vitro release profile. Ex-vivo skin permeation studies and in-vivo antipyretic and analgesic efficacy were conducted to assess the therapeutic potential of the patches.

KEYWORDS:- *Polyherbal Formulation,Transdermal Drug Delivery ,Antipyretic,Analgesic, Herbal Medicine ,Pain Relief ,Controlled Release*

1. INTRODUCTION

The development of transdermal drug delivery systems has emerged as a promising alternative for administering therapeutic agents, offering controlled and sustained release while bypassing first-pass metabolism. Polyherbal formulations, leveraging the synergistic effects of multiple plant-based compounds, have gained significant attention due to their enhanced therapeutic potential and minimal side effects. This study focuses on the design and evaluation of a polyherbal transdermal patch with dual antipyretic and analgesic effects. The integration of multiple herbal extracts, each known for its fever-reducing and pain-relieving properties, aims to provide a holistic and effective solution for managing symptoms associated with fever and pain. The polyherbal transdermal patch offers several advantages, including improved patient compliance, ease of application, and sustained drug release, ensuring prolonged therapeutic efficacy. This research explores the formulation, characterization, and pharmacological evaluation of the patch, highlighting its potential as a novel alternative to conventional oral or injectable antipyretic and analgesic therapies. By combining traditional herbal knowledge with advanced transdermal technology, the study seeks to bridge the gap between natural medicine and modern pharmaceutical innovation, catering to the growing demand for effective, safe, and non-invasive treatment modalities.

2. GENERAL MECHANISM ACTION OF TRANSDERMAL PATCH

The general mechanism of action of a **transdermal patch** involves delivering drugs or active compounds through the skin and into the systemic circulation or localized tissues. This method is non-invasive and ensures controlled, sustained release of medication. Here's a step-by-step overview of how transdermal patches work:

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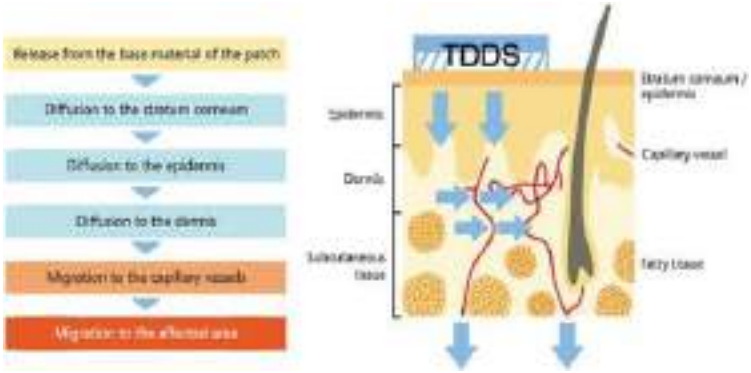

2.1 Application to the Skin

- The patch is applied to clean, dry, and hairless skin, ensuring optimal contact between the adhesive layer of the patch and the skin surface.

2.2 Drug Release from the Patch

- The active compounds in the patch are stored in a reservoir or dispersed in a matrix system.
- Depending on the design of the patch, the drug is released either:
    - **Diffusion-controlled**: Gradual release as the drug diffuses through the polymer layer.
    - **Membrane-controlled**: A semipermeable membrane regulates the release rate of the drug.
    - **Matrix-controlled**: The drug is embedded in a polymer matrix and released gradually as it migrates to the skin surface.

2.3 Penetration into the Skin

- The released drug interacts with the skin surface and penetrates the outermost layer, the **stratum corneum**.
- Penetration is influenced by:
    - **Drug properties**: Lipophilicity, molecular size, and solubility.
    - **Patch design**: Inclusion of permeation enhancers (e.g., menthol, camphor).
    - **Skin condition**: Hydration level, temperature, and barrier integrity.

2.4 Diffusion Through Skin Layers

- The drug diffuses through the **epidermis** and **dermis**, where blood capillaries are located.
- In localized formulations (e.g., analgesic patches), the drug primarily acts on tissues near the site of application without significant systemic absorption.

2.5 Absorption into Systemic Circulation

- For systemic effects, the drug enters the capillary network in the dermis and is carried into the bloodstream.
- This allows the drug to bypass the **first-pass metabolism** in the liver, enhancing bioavailability compared to oral administration.

2.6 Sustained and Controlled Release

- The patch provides a continuous and controlled release of the drug over hours or days, maintaining steady plasma levels and avoiding the peaks and troughs seen with oral or injectable routes.

Key Components of a Transdermal Patch

1. **Backing Layer**: Protects the patch from external environment and ensures structural integrity.
2. **Drug Reservoir or Matrix**: Contains the active ingredients and regulates their release.
3. **Adhesive Layer**: Ensures the patch adheres to the skin and may contain the drug.
4. **Release Liner**: Protects the adhesive layer before application and is removed during use.
5. **Permeation Enhancers** (optional): Facilitate drug penetration through the skin.

Advantages

- **Non-invasive**: Avoids needles or invasive procedures.

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- **Sustained Drug Release**: Reduces dosing frequency.
- **Bypass First-Pass Metabolism**: Enhances drug efficacy and reduces dosage.
- **Patient Compliance**: Convenient and easy to use.

Limitations

- **Skin Barrier**: The stratum corneum limits the penetration of large or hydrophilic molecules.
- **Irritation**: Prolonged use may cause skin irritation or sensitivity.
- **Limited Drugs**: Only suitable for drugs with specific physicochemical properties (e.g., low molecular weight, lipophilicity).

3. CLASSIFICATION OF TRANSDERMAL PATCH

3.1 SINGLE-LAYER DRUG IN ADHESIVE PATCH

Single-layer transdermal patches are comprised of one layer: combined drug and adhesive. A single-layer patch is applied to the skin, where it sticks and deploys the drug.

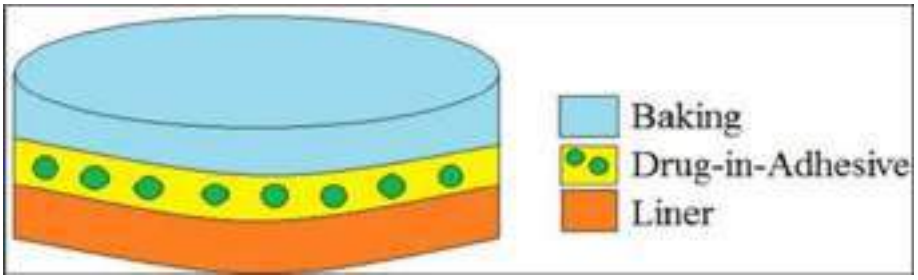

Fig. Single-Layer Drug In Adhesive Patch

3.2 MULTILAYER DRUG IN ADHESIVE PATCH

Multilayer transdermal patches are similar to the single-layer system in that adhesive layers release the drug, except BOTH adhesive layers contain drugs. Typically, multilayer transdermal adhesives deploy solutions over a longer period of time because the width of the layers determines how quickly the drug reaches the skin.

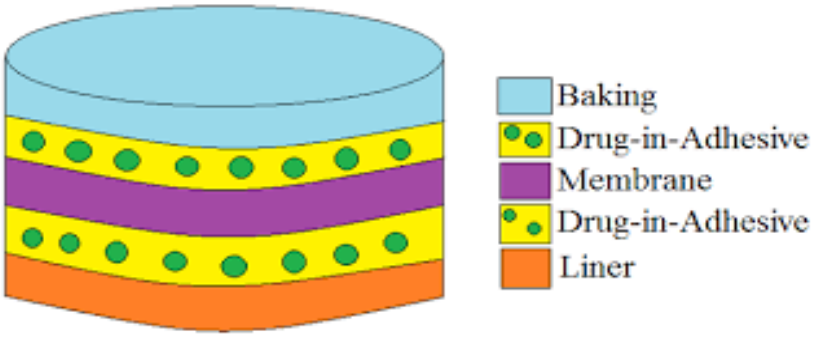

Fig. Multilayer Drug In Adhesive Patch

3.3 RESERVOIR PATCH

Transdermal reservoirs are liquid layers containing the drugs which are gradually delivered to the skin through a rate-controlling membrane. These reservoir patches allow for more controlled delivery rates, but the initial drug release can be a slight burst. In addition, if the membrane is damaged, there is a risk of sudden release into the skin.

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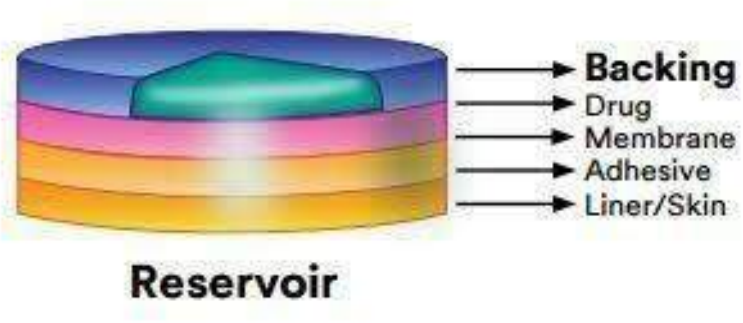

Fig. Reservoir Patch

3.4 MATRIX PATCH:

A transdermal matrix patch includes an adhesive polymer matrix containing the drug, which is gradually released into the skin. Unlike the rate-controlling membrane in a reservoir patch, the formulation of its drug and polymer matrix dictates the rate of drug delivery. The active ingredient is distributed evenly throughout the patch, so there is less risk of accidental release.

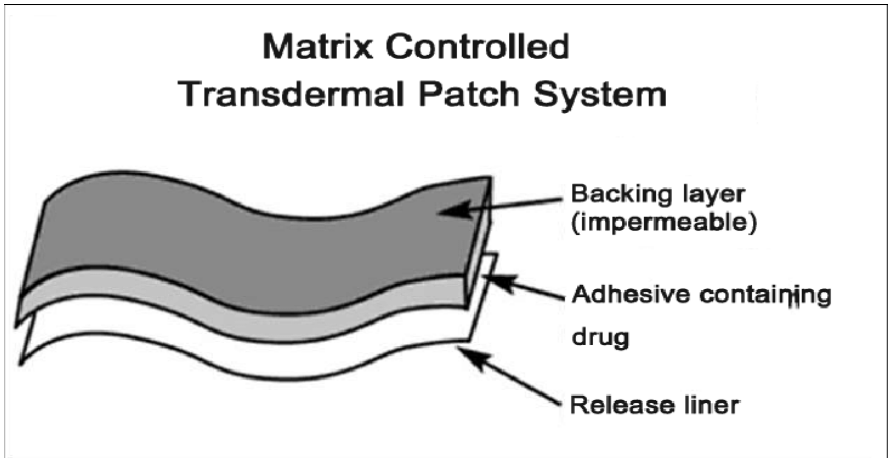

Fig. Matrix Patch

3.5 MICRONEEDLE PATCH

Microneedle patches are transdermal patches with microscopic needles that penetrate the epidermis deep enough to help drugs enter the bloodstream. Despite the needles, they are painless and can deliver drugs more effectively for faster absorption. Needles are typically preloaded with drug solutions, assembled separately, and then placed onto the adhesive patch. For example, Strouse creates adhesive patches for medical devices like microneedles but doesn't manufacture the needles. Instead, manufacturers often use automated systems to attach the preloaded needles to the patch.

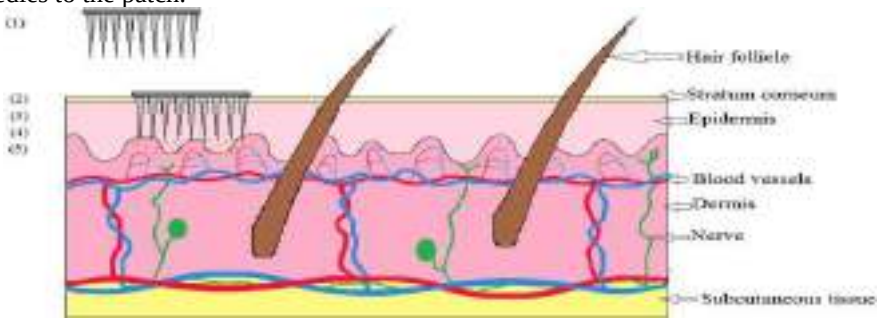

Fig. Microneedle Patch

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3.6 IONTOPHORESIS PATCH

Iontophoresis patches are medical devices that use small electrical currents to deliver charged substances to the skin. This substance is often applied directly to a designated spot on the patch before use and can consist of tap water for milder uses.

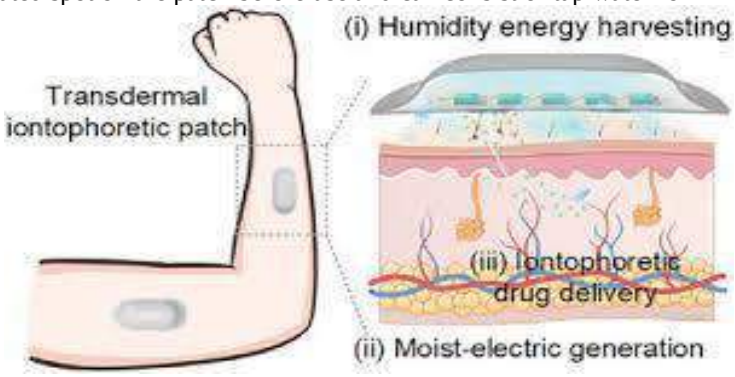

Fig. Iontophoresis Patch

4. POLYHRERBAL TRANSDERMAL PATCH

A polyherbal patch is a transdermal drug delivery system designed to deliver multiple herbal bioactive compounds through the skin into the systemic circulation. It is formulated by incorporating extracts or active constituents of two or more medicinal plants into a suitable adhesive matrix, allowing for controlled and sustained release of the therapeutic agents.

Polyherbal patches leverage the synergistic effects of various herbs to enhance therapeutic efficacy, providing benefits such as analgesic, antipyretic, anti-inflammatory, or antimicrobial effects. These patches offer non-invasive administration, improved patient compliance, and the avoidance of gastrointestinal side effects often associated with oral herbal formulations.

PLANTS ACTING AS ANALGESIC AND ANTIPYRETIC IN EFFECT:

SR.NO.	PLANTS
1	NEEM
2	GINGER
3	TURMERIC
4	BOSWELLIA SERRATA
5	EVENING PRIMROSE OIL
6	BLACKCURRANT SEED OIL
7	LICORICE
8	CAT'S CLAW
9	DEVIL'S CLAW
10	KARPURA
11	PEPPERMINT SATVA
12	CAPSACIN

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4.1 NEEM

Neem (Azadirachta indica), a well-known medicinal plant in traditional medicine systems, plays a vital role when incorporated into polyherbal transdermal patches. Neem's pharmacological properties contribute significantly to the patch's overall therapeutic efficacy, particularly in antipyretic and analgesic applications.

Fig, Neem

- **Antipyretic Effect**

Neem exhibits strong antipyretic properties, helping reduce fever. This effect is attributed to its ability to modulate inflammatory mediators, such as prostaglandins, which play a role in fever pathogenesis.

- **Analgesic Effect**

Neem possesses analgesic properties that help alleviate pain. The active compounds, such as nimbidin and nimbolide, are known to suppress pain signals by inhibiting inflammatory pathways, reducing the release of pain-inducing mediators like bradykinin and prostaglandins.

4.2 GINGER:

Ginger (Zingiber officinale), a widely used medicinal herb, significantly enhances the therapeutic potential of polyherbal transdermal patches, particularly in antipyretic and analgesic applications. Its bioactive constituents, such as gingerols, shogaols, and zingerone, exhibit a range of pharmacological effects that make it a valuable component in these patches.

Fig. Ginger

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- **Analgesic Effect**

Ginger's potent analgesic properties are primarily due to its ability to inhibit pro-inflammatory mediators like prostaglandins and leukotrienes. The suppression of cyclooxygenase (COX) and lipoxygenase (LOX) pathways helps alleviate pain, making it an effective natural pain reliever.

- **Antipyretic Effect**

Ginger has shown effectiveness in reducing fever by modulating the production of inflammatory cytokines, such as interleukin-1 (IL-1) and tumor necrosis factor-alpha (TNF-α), which are involved in fever induction.

4.3 TURMERIC

Turmeric (Curcuma longa) is a cornerstone of traditional medicine, valued for its extensive therapeutic properties. Its primary bioactive compound, **curcumin**, is renowned for its anti-inflammatory, analgesic, and antipyretic effects, making it an essential ingredient in polyherbal transdermal patches targeting fever and pain relief.

Fig. Turmeric

- **Analgesic Effect**

Curcumin exhibits significant analgesic properties by modulating pain pathways. It inhibits enzymes like cyclooxygenase-2 (COX-2) and reduces the production of pain-inducing mediators, such as prostaglandins, providing natural pain relief.

- **Antipyretic Effect**

Turmeric helps reduce fever by suppressing the release of pro-inflammatory cytokines like interleukin-6 (IL-6) and tumor necrosis factor-alpha (TNF-α), which play a key role in fever pathogenesis.

4.4 BOSWELLIA SERRATA

Boswellia serrata, commonly known as Indian frankincense, is a renowned medicinal plant used extensively for its potent anti-inflammatory, analgesic, and antipyretic properties. Its active constituents, particularly **boswellic acids**, play a crucial role in enhancing the therapeutic efficacy of polyherbal transdermal patches.

Fig. Boswellia Serrata

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- **Analgesic Effect**

Boswellic acids inhibit pain pathways by targeting enzymes like 5-lipoxygenase (5-LOX), which are involved in the synthesis of leukotrienes, key mediators of pain and inflammation. This action effectively reduces pain associated with inflammatory conditions.

- **Antipyretic Effect**

Boswellia has been observed to reduce fever by modulating inflammatory cytokines such as tumor necrosis factor-alpha (TNF-α) and interleukin-1 beta (IL-1β), which are associated with febrile responses.

4.5 EVENING PRIMROSE OIL

Evening primrose oil (Oenothera biennis), derived from the seeds of the evening primrose plant, is rich in essential fatty acids such as gamma-linolenic acid (GLA) and linoleic acid. Its unique composition provides various therapeutic benefits, making it a valuable component in polyherbal transdermal patches aimed at managing pain, inflammation, and fever.

Fig. Evening Primrose Oil

- **Analgesic Effect**

Evening primrose oil is effective in alleviating pain associated with inflammation and other conditions, thanks to its ability to modulate nerve signaling and inflammatory mediators.
The oil's fatty acids contribute to reducing nerve sensitivity, providing natural pain relief.

- **Antipyretic Effect**

By regulating inflammatory pathways, evening primrose oil can indirectly assist in lowering fever, especially when inflammation is a contributing factor.

4.6 BLACKCURRANT SEED OIL

Blackcurrant seed oil (Ribes nigrum) is a nutrient-rich oil containing essential fatty acids, primarily gamma-linolenic acid (GLA), alpha-linolenic acid (ALA), and stearidonic acid (SDA). These bioactive components contribute to its potent anti-inflammatory, analgesic, and skin-nourishing properties, making it a valuable ingredient in polyherbal transdermal patches designed for pain and fever management.

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Fig. Blackcurrant Seed Oil

- **Analgesic Effect**

Blackcurrant seed oil reduces pain through its anti-inflammatory effects and by modulating neural pathways responsible for pain perception.

GLA is a precursor to prostaglandin E1 (PGE1), which helps alleviate discomfort by reducing nerve hypersensitivity.

- **Antipyretic Effect**

By controlling the release of fever-inducing cytokines, blackcurrant seed oil indirectly assists in reducing fever, especially when associated with inflammation.

4.7 LICORICE

Licorice (Glycyrrhiza glabra) is a versatile medicinal plant known for its powerful anti-inflammatory, analgesic, and antioxidant properties. Its active compounds, such as glycyrrhizin, glabridin, and liquiritigenin, make it a valuable addition to polyherbal transdermal patches for managing pain, fever, and inflammation.

Fig. Licorice

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- **Analgesic Effect**

Licorice possesses natural analgesic properties, which help alleviate pain by reducing inflammation and suppressing the release of pain-inducing mediators such as prostaglandins and bradykinin.
Liquiritigenin is particularly effective in modulating pain signaling pathways.

- **Antipyretic Effect**

Licorice aids in reducing fever by modulating inflammatory mediators and supporting the body's natural ability to regulate temperature.
Its soothing properties help in managing fever-related discomfort.

4.8 CAT'S CLAW

Cat's Claw (Uncaria tomentosa), a medicinal plant native to the Amazon rainforest, is valued for its potent anti-inflammatory, immunomodulatory, and analgesic properties. Its bioactive compounds, including oxindole alkaloids, quinovic acid glycosides, and polyphenols, make it an effective component in polyherbal transdermal patches for managing pain, inflammation, and fever.

Fig. Cat's Claw

- **Analgesic Effect**

The anti-inflammatory action of Cat's Claw indirectly contributes to pain relief by reducing inflammation-associated pain.
Its alkaloids and glycosides help modulate pain signaling pathways, providing natural analgesic effects.

- **Antipyretic Effect**

Cat's Claw assists in lowering fever by reducing inflammation and the release of pyrogenic (fever-inducing) cytokines.
Its immunomodulatory properties support the body's natural mechanisms for temperature regulation.

4.9 DEVIL'S CLAW

Devil's Claw (Harpagophytum procumbens), a plant native to Southern Africa, is widely recognized for its potent anti-inflammatory and analgesic properties. Its active constituents, particularly harpagoside and iridoid glycosides, make it an ideal component in polyherbal transdermal patches designed for managing pain, inflammation, and fever.

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Fig. Devil's Claw

- **Analgesic Effect**

Harpagoside, the primary active compound in Devil's Claw, helps alleviate pain by inhibiting inflammatory pathways and reducing the production of pain-inducing mediators such as prostaglandins.
Its ability to target musculoskeletal pain, particularly in conditions like arthritis and back pain, makes it effective for transdermal applications.

- **Antipyretic Effect:**

By modulating inflammatory cytokines such as TNF-α and interleukins, Devil's Claw indirectly assists in lowering fever, especially when associated with inflammation.

4.10 KARPURA

Karpura (camphor) is a widely used compound in traditional and modern medicine. Its incorporation into polyherbal transdermal patches can influence the formulation in several ways:

Fig. Karpura

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- **Analgesic Effect**

Camphor has natural anti-inflammatory and analgesic effects, making it valuable in patches designed for pain relief or treating localized inflammation. It works by desensitizing sensory nerves and improving blood circulation.

4.11 PEPPERMINT SATVA

The analgesic and antipyretic effects of Peppermint Satva (Mentha piperita extract) make it a valuable component in polyherbal transdermal patches designed for pain relief and fever management. Here's how these effects manifest and contribute to the efficacy of the patch:

Fig. Peppermint Satva

- **Analgesic Effect**

Menthol, the primary bioactive component of peppermint satva, activates TRPM8 receptors in sensory neurons. These cold-sensitive receptors produce a cooling sensation, which soothes pain and discomfort.

Menthol desensitizes nociceptors (pain receptors), reducing the perception of pain. This is particularly effective for:

- Musculoskeletal pain (e.g., arthritis, backache).
- Neuropathic pain (e.g., neuralgia).
- Localized acute pain (e.g., sprains, strains).

Antipyretic Effect

Menthol exerts vasodilation by relaxing vascular smooth muscles, which helps in heat dissipation. This cooling action is beneficial in reducing body temperature during fever.

The cooling effect on the skin promotes a subjective sense of temperature reduction, enhancing comfort for febrile patients.

4.12 CAPSACIN

Capsaicin, a bioactive compound derived from chili peppers (*Capsicum species*), is widely recognized for its analgesic and potential antipyretic effects. When incorporated into a polyherbal transdermal patch, it can contribute significantly to pain relief and fever management. Here's an in-depth look at its effects and role in such formulations:

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Fig. Capsacin

- **Analgesic Effect**

Desensitization of Pain Receptors: Capsaicin works by activating TRPV1 (transient receptor potential vanilloid 1**)** channels on nociceptors (pain-sensing nerve fibers). This causes an initial burning or tingling sensation, followed by the depletion of substance P, a neuropeptide involved in transmitting pain signals to the brain. The result is long-term desensitization and relief from pain.
Endorphin Release: Capsaicin can stimulate the release of endorphins, the body's natural painkillers, enhancing its analgesic effects.

- **Antipyretic Effect**

Induction of Vasodilation: Capsaicin increases blood flow to the skin's surface, promoting heat dissipation and providing a cooling effect, which may help alleviate fever symptoms.
Sweat Induction: It can stimulate sweat glands, aiding in temperature regulation.

5. GENERAL PROCEDURE OF FORMULATION OF POLYHERBAL TRANSDERMAL PATCH:

The formulation of a herbal transdermal patch involves careful selection of ingredients, preparation of the base, and incorporation of herbal actives to ensure effective drug delivery. Below is the general procedure for the formulation:

5.1 Pre-Formulation Studies

- **Selection of Herbal Extracts**
  - Choose herbal ingredients with desired therapeutic properties (e.g., analgesic, antipyretic).
  - Ensure the extracts have the appropriate molecular weight, lipophilicity, and stability for transdermal delivery.
- **Characterization**:
  - Evaluate solubility, stability, and compatibility of the herbal extracts with other components.
  - Identify the need for **permeation enhancers** (e.g., menthol, camphor) to improve skin penetration.

5.2 Selection of Polymers:

- Select suitable polymers to form the patch matrix or reservoir, such as:
  - **Natural polymers**: Gelatin, chitosan, alginate.
- **Synthetic polymers**: Polyvinyl alcohol (PVA), ethyl cellulose, hydroxypropyl methylcellulose (HPMC).
- Properties to consider:
- Biocompatibility.
- Controlled release characteristics.
- Adhesiveness and flexibility.

5.3 Preparation of Polymer Matrix:

- Dissolve the polymer(s) in a suitable solvent (e.g., water, ethanol) or a mixture of solvents.
- Adjust the viscosity and consistency of the polymer solution for optimal patch formation.

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5.4 Incorporation of Herbal Extracts
- Add the herbal extracts or oils to the polymer solution under gentle stirring.
- Ensure uniform dispersion of the active ingredients.
- Use stabilizers or emulsifiers, if necessary, to enhance stability.

5.5 Addition of Plasticizers
- Add plasticizers (e.g., glycerin, polyethylene glycol) to improve flexibility, elasticity, and durability of the patch.
- The concentration of plasticizers should balance mechanical strength and adhesive properties.

5.6 Incorporation of Permeation Enhancers
- Add permeation enhancers (e.g., menthol, eucalyptus oil, camphor) to facilitate the penetration of active ingredients through the skin.
- Ensure compatibility with herbal extracts and other components.

5.7 Casting the Solution
- Pour the prepared solution onto a **flat, leveled surface** (e.g., glass plate or silicone mold).
- Spread the solution uniformly using a spreader or applicator to achieve a consistent thickness.

5.8 Drying
- Allow the film to dry under controlled conditions:
  - Temperature: 40–60°C (to avoid degradation of herbal actives).
  - Duration: 24–48 hours or until the solvent completely evaporates.
- Use an oven, hot air blower, or vacuum drying method.

5.9 Cutting and Sizing
- Cut the dried film into patches of desired size and shape (e.g., square, rectangle, circular).
- Ensure uniformity in thickness and active ingredient content across all patches.

5.10 Backing and Adhesive Layers
- Attach a **backing layer** (e.g., aluminum foil, polyester film) to protect the patch.
- Apply an **adhesive layer** if not already included in the polymer matrix. The adhesive should be biocompatible and non-irritating.

5.11 Evaluation of the Patch
Perform quality control tests to ensure efficacy and safety:
1. **Physical Appearance**: Check for uniformity, color, and smoothness.
2. **Thickness Measurement**: Ensure consistency across batches.
3. **Drug Content Uniformity**: Analyze the distribution of herbal actives.
4. **Moisture Content**: Determine stability under storage conditions.
5. **Tensile Strength**: Evaluate flexibility and mechanical strength.
6. **Folding Endurance**: Assess the patch's ability to withstand repeated folding without breaking.
7. **Adhesion Test**: Check the adhesive strength to ensure it adheres well to the skin.
8. **In Vitro Drug Release**: Evaluate the rate and extent of active ingredient release.
9. **Skin Permeation Studies**: Confirm the ability of the patch to deliver herbal actives through the skin.

5.12 Packaging and Storage
- Pack the patches individually in airtight, moisture-resistant pouches.
- Store under controlled conditions (temperature, humidity) to maintain stability.

CONCLUSION

Polyherbal transdermal patches acting as **antipyretic** and **analgesic** agents represent an innovative, non-invasive approach to managing pain and fever. By combining the therapeutic properties of herbal extracts like **capsaicin**, **peppermint satva**, and **karpura (camphor)**, these patches offer synergistic effects that enhance their efficacy while minimizing side effects associated with systemic medications.

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The transdermal delivery system ensures controlled and sustained release of active compounds, providing prolonged therapeutic action and maintaining steady plasma concentrations. Furthermore, bypassing the gastrointestinal tract avoids issues like first-pass metabolism, making these patches a safe and efficient alternative. Their formulation, which includes permeation enhancers and biocompatible polymers, allows effective penetration through the skin's barrier, targeting localized pain or systemic conditions like fever. Additionally, the inclusion of natural cooling agents like menthol improves user comfort, compliance, and overall experience. With advancements in technology and thorough evaluation of their safety, efficacy, and stability, polyherbal transdermal patches hold significant potential as holistic, patient-friendly solutions in modern herbal medicine. Future research and development can further optimize these formulations, ensuring their widespread adoption in clinical and over-the-counter applications.

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OVERVIEW ON DIFFERENT TYPES OF METHODS OF EXTRACTION

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ABSTRACT

This study explores various extraction techniques used to isolate bioactive compounds from plant materials, highlighting maceration, percolation, Soxhlet extraction, microwave-assisted extraction (MAE), and ultrasound-assisted extraction (UAE). The choice of method, solvent, and conditions significantly affects extraction yield, efficiency, and the nature of compounds obtained. Maceration, though cost-effective and simple, requires extended time, while Soxhlet extraction is more efficient but demands laboratory setups. MAE and UAE offer advanced alternatives with shorter extraction times, higher yields, and reduced solvent usage. Comparative analyses of extraction methods using soursop leaves and boldo leaves demonstrate varying efficiencies, with modern techniques like MAE and UAE providing notable advantages in extraction time and compound recovery. The findings underscore the evolution of extraction methods toward greater efficiency, cost-effectiveness, and sustainability.

KEYWORDS: *Extraction methods Maceration, Percolation, Soxhlet extraction, Microwave-assisted extraction (MAE), Ultrasound-assisted extraction (UAE), Solvent extraction, Phytochemicals, Solvent selection, Soursop leaves, Boldo leaves.*

INTRODUTION

Methods of extraction are essential techniques in chemistry, biochemistry, and various industries to separate and isolate desired compounds from mixtures. Each method leverages the unique physical or chemical properties of the components, such as solubility, boiling point, or density, to achieve separation. From simple mechanical techniques to advanced solvent and chromatographic methods, extraction allows for the purification, analysis, and production of substances in forms ready for use or study. These techniques play a crucial role in fields like pharmaceuticals, food and beverage production, environmental science, and natural product isolation, offering tailored solutions to different types of mixtures and compound. Sample preparation is most often a necessity as even the simplest samples are frequently unsuitable for direct analysis because of excessive dilution or concentration of the target analytes or incompatibility with instrument operation procedures

METHODOLOGY & MATERIAL

EXTRACTION

Extraction is the process of separating a substance from a mixture by transferring it from one source to another. Extraction may be defined as the removal of soluble constituents from a solid or liquid or semi-solid with means of suitable solvent.

It may be defined as the treatment of the plant or animal tissues with appropriate solvent, which would dissolve the constituents. medicinally active Extraction is the method of removal of a soluble fraction in the form of a solution from an insoluble matrix with the help of a suitable solvent

Extraction methods include solvent extraction, distillation method, pressing and sublimation according to the extraction principle. Solvent extraction is the most widely used method

Extraction Procedure

The general techniques of medicinal plant extraction include maceration, infusion, percolation, digestion, decoction, hot continuous extraction (Soxhlet), aqueous-alcoholic extraction by fermentation, counter current extraction, microwave-assisted extraction, ultrasound extraction (sonication), supercritical fluid extraction, and distillation techniques (water distillation, steam distillation, phytonic extraction (with hydro fluorocarbon solvents). For aromatic plants, hydro water and steam distillation), hydrolytic maceration followed by distillation, expression and effleurage (cold fat extraction) may be employed. Some of the latest extraction methods for aromatic plants include headspace trapping, solid phase micro extraction, protoplast extraction, micro distillation.

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Effect of extracted plant phytochemical depends on

- The nature of the plant material
- Its origin
- Degree of processing
- Moisture content
- Particle size

The basic parameters influencing the quality of an extract are

- Plant part used as starting material
- Solvent used for extraction
- Extraction procedure

The variations in different extraction methods that will affect quantity and secondary metabolite composition of an extract depend upon

- Type of extraction
- Time of extraction
- Temperature
- Nature of solvent
- Solvent concentration
- Polarity
- Plant material
- Plant based natural constituents

Choice of solvents

For Successful determination of biologically active compounds from plant material is largely dependent on the type of solvent used in the extraction procedure.

A property of a good solvent in plant extractions includes:

- Low toxicity
- Ease of evaporation at low heat
- Promotion of rapid physiologic absorption of the extract
- Preservative action, Inability to cause the extract to complex or dissociate

The factors affecting the choice of solvent are:

- Quantity of phytochemical to be extracted
- Rate of extraction
- Diversity of different compounds extracted
- Diversity of inhibitory compounds extracted
- Ease of subsequent handling of the extracts
- Toxicity of the solvent in the bioassay process
- Potential health hazard of the extractants

The choice of solvent is influenced by what is intended with the extract. Since the end product will contain traces of residual solvent, the solvent should be nontoxic and should not interfere with the bioassay. The choice will also depend on the targeted compounds to be extracted.

Variation in extraction methods usually depends upon:

- Length of the extraction period,
- Solvent used,
- pH of the solvent
- Temperature
- Particle size of the plant tissues
- The solvent-to-sample ratio

The basic principle is to grind the plant material (dry or wet) finer, which increases the surface area for extraction thereby increasing the rate of extraction. Earlier studies reported that solvent to sample ratio of 10:1 (v/w) solvent to dry weight ratio has been used as ideal [1].

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Solvents used for active component extraction are:

- Water
- Ethanol
- Methanol
- Chloroform
- Ether
- Acetone

Water	Ethanol	Methanol	Chloroform	Ether	Acetone
Anthocyanins Starches Tannins Saponins Terpenoids Polypeptides Lectins	Tannins Polyphenols Polyacetylenes Flavonols Terpenoids Sterols Alkaloids	Anthocyanins Terpenoids Saponins Tannins Xanthoxyllines Totarol Quassinoids Lactones Flavones Phenones Polyphenols	Terpenoids Flavonoids	Alkaloids Terpenoids Coumarins Fatty acids	Phenol Flavonols

Table1: Solvents used for active component

DIFFERENT TYPES METHODS OF EXTRACTION

- Maceration
- Percolation
- Decoction

RECENTLY MOST USED METHODS

- Soxhlation Extraction
- microwave assisted extraction
- Ultrasound-assisted Extraction

Maceration

In this process, the whole or coarsely powdered crude drug is placed in a stoppered container with the solvent and allowed to stand at room temperature for a period of at least 3 days.

It is very simple and the chipest because it only requires a simple container as the place for extraction, but this method requires long time for extraction process[2].

This method can be done anywhere, the number of raw materials, the selection of solvents and the correct extraction time are things that affect the effectiveness of this method[3].
It could be used for the extraction of thermolabile components[4].

Solvents used

Water, hexane, vegetable oils, ethanol, methanol & glycerine

Categories obtained by extraction

Alkaloids, Terpenoids, Tannins, Flavonoids, Essential oils, Saponins, Glycosides, Phenolic compound, Resins, Vitamins, & Minerals

Form of drug

Solid-liquid type ⟶ Amorphous solids with solvents

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Fig.1. Maceration Extraction Apparatus

Percolation

Percolation is more efficient than maceration because it is a continuous process in which the saturated solvent is constantly being replace by fresh solvent.

This is more frequently used method to extract phytochemicals for the preparation of tinctures and fluid extracts. It allows the process to stand for approximately 4 hours in a closed container[5].

Solvents Used

Water, hexane, chloroform, ethyl alcohol, 75% ethanol, 55%alcohol & petroleum ethers

Categories obtained by extraction

Carbohydrates, Vasopressin, Alkaloids, Terpenoids, Flavonoids, & Sterols

Form of drug

Solid-Solid ⟶ Amorphous solid, Crystalline solid

Fig.2. Percolation Extraction Apparatus

Decoction

The decoction extraction method is a traditional technique used to extract active compounds from plant materials, particularly in herbal medicine. It involves boiling plant material in water for a specific period to draw out soluble substances

The extract from decoction contains a large number of water-soluble impurities. A decoction cannot be used for the extraction of thermolabile or volatile components.

This process is mainly used for vegetable drugs of hard and woody nature having thermostable water-soluble constituents[6].

Solvents used:

Water, hexane, ethanol, methanol

Categories obtained by extraction:

Alkaloids, flavonoids, and tannins

Form of drug:

Solid- solid & solid-liquid ~~Amorphous solid~~

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Fig.3. Decoction Extraction Apparatus

Soxhlation Extraction
It is very useful tool for preparative purposes in which the analyte is concentrated from the as a whole or separated from particular interfering substance, Solvent extraction of solid samples which is commonly known as solid liquid extraction.

It is one of the oldest methods for solid sample pretreatment Soxhlet extraction has been the most frequently used technique for isolation of organic compounds from environment for the last twenty year[8].

In this method, the finely ground crude drug is placed in a porous bag or "thimble" made of strong filter paper, which is placed in chamber E of the Soxhlet apparatus.

The extracting solvent in flask A is heated, and its vapors condense in condenser D.

The condensed extractant drips into the thimble containing the crude drug, and extracts it by contact. when the level of liquid in chamber E rises to the top of siphon tube C, the liquid contents of chamber E siphon into flask A.

This process is continuous and is carried out until a drop of solvent from the siphon tube does not leave residue when evaporated. The advantage of this method, compared to previously described methods, is that large amounts of drug can be extracted with a much smaller quantity of solvent.

This effects tremendous economy in terms of time, energy and consequently financial inputs.
At small scale, it is employed as a batch process only, but it becomes much more economical and viable when converted into a continuous extraction procedure on medium or large scale [7].

Solvents used
Ethanol, Methanol, Acetone, Hexane, Ethyl acetate, and Dichloromethane (DCM).

Categories obtained by extraction
Mentha oil, tannins, resin, eugenin.

Form of drug
Solid ⟶ Flowers, stems, leaves.

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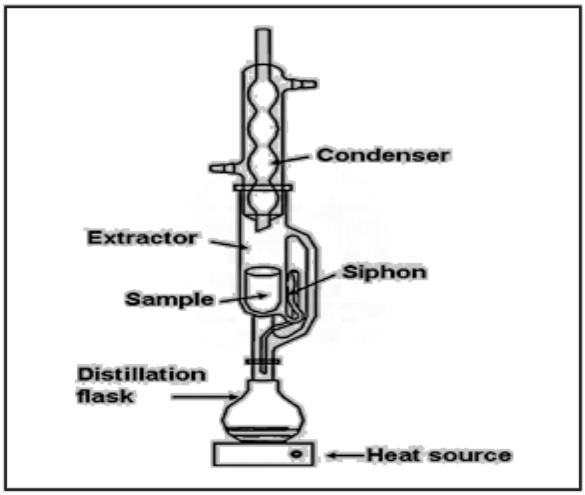

Fig. 4. Soxhlet Apparatus

Microwave Assisted Extraction

It is an advanced technique used to extract bioactive compounds from various matrices such as plant food, or environmental samples. This method uses microwave energy to heat the solvent and the sample, which enhance mast transfer and reduce extraction time. Compared to conventional extraction method microwave assisted extraction offers several advantages including shorter extraction time, lower solvent consumption and improves yield of desired compounds.

Microwave interacts with polar molecules in the solvent and the sample, causing them to rotate and align with the rapidly alternating electromagnetic field.

This leads to the generation of heat to molecular friction and enhances the solvent ability to penetrate the matrix, there by improving the extraction efficiency [8].

Solvents used

Ethanol, Methanol, Acetone, Hexane, Ethyl acetate, and Dichloromethane (DCM), Petroleum ether, Dimethyl formamide (DMF), Dimethyl sulfoxide (DMSO), Acetonitrile, Butanols,

For nonylphenol ⟶ Dichloromethane, acetone-petroleum ether (1:1) [10]tial oils, Flavones, Terpenoids Phenones, Polyphenols.

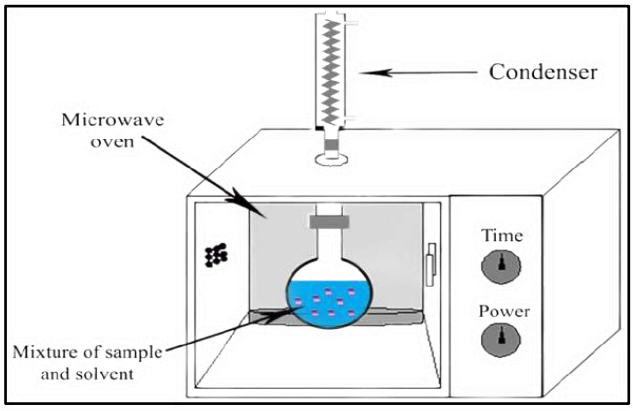

Fig.5. Microwave Oven

Ultrasound-assisted Extraction

Ultrasounds are electromagnetic waves with higher frequencies than sound waves audible to the human ear.

The range of ultrasound utilized is from 20 kHz to 2000 kHz. It travels through a medium involving expansions and contractions following the wave nature.

The mechanical effect of acoustic cavitation from the ultrasound increases the surface area of contact between solvents and plant samples and the permeability of cell walls. The bubble formation, its growth and collapse is termed as cavitation.

Some studies observed that frequency used can modify and favorably influence the extraction of compounds from the sample.

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Although the process is useful in some cases, like extraction of rauwolfia root, its large-scale application is limited due to the higher costs.
One disadvantage of the procedure is the occasional but known deleterious effect of ultrasound energy (more than 20 kHz) on the active constituents of medicinal plants through formation of free radicals and consequently undesirable changes in the drug molecule [9,10].

Solvents used
Ethanol, Methanol, Acetone, hexane, Ethyl acetate, Isopropanol, Acetonitrile.

Categories obtained by extraction
Polysaccharides, Pectin, Caffeine and polyphenols.

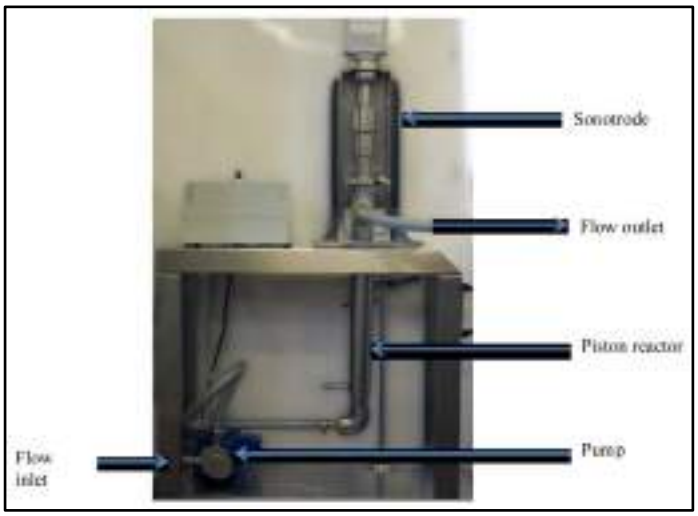

Fig.6. Ultrasonic pilot continuous

RESULT & DISCUSSION

Percolation and maceration are two distinct methods used in the extraction of active compounds from plant materials, often in pharmacology, perfumery, or the preparation of tinctures. While both involve soaking plant materials in a solvent, they differ in procedure and efficiency. **Table** 1[26].

Table 1: Difference between maceration and percolation procedures.

Maceration	Percolation
A process of becoming softened by soaking in a liquid	A process of liquid slowly passing through a filter
Main purpose is to obtain softer substances in a liquid medium	Main purpose is to extract particular substance into liquid
Results in liquid with waste and has to be purified further	Results in liquid that only contains desired substances dissolved in it. Hence no further purification is required
Takes long time	Takes less time
Do not require equipment	Takes less time Requires equipment's such as filter

Soxhlet extraction has for more than a century demonstrated its advantages, which have surpassed in most cases its shortcomings. Table 1, Table 2, and Table 3 show the results of the work of several researchers who extracted soursop leaves by the maceration method, soxhletation method, and MAE

Table 2. Results of soursop leaf extraction by maceration method.

Weight (g)	Solvent	Immersion Time (days)	Yield (%)	Active Compound	References
5000	Methanol	1	10	Acetogenins	[11]
500	Methanol	2	7.26	Alkaloid and sterols	[12]
6.5	Methanol	5	6.6	Acetogenins and Alkaloid	[10]

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1000	Ethanol 98%	3	12.5	Phenolics and Flavonoid	[13]
1981	Ethyl Acetate	4	4.1	Terpenoid	[14]
1190	Distilled water	1	32.96	Alkaloid	[15]
1000	Distilled water	2	3.62	Tannins and Polyphenolic	[16]

Table 2. Results of soursop leaf extraction by soxhletation method.

Weight (g)	Solvent	Immersion Time (days)	Yield (%)	Active Compound	References
60	Methanol	72	29.13	Phenolics and Flavonoid	[17]
201	Methanol	6	24.9	Flavonoid	[18]
0.03	Water	16	4	Flavonoid	[9]

Table 3. Results of soursop leaf extraction by MAE.

Weight (g)	Solvent	Immersion Time (days)	Yield (%)	Active Compound	References
20	Ethanol 70%	600	33.98 %	Phenolic	[19]
Unknown	Ethanol	850	20g	Unspecified / whole extract content	[20]

Based on the research results in Table 2, Table 3, and Table 4, it can be seen that the maceration method is the easiest method to do and uses cheaper equipment, but requires a long extraction time.

Soxhletation method is a method that is generally carried out on a laboratory scale because it uses tools that are usually found in a laboratory. Both of these methods are conventional methods that need to be developed. One of the new methods is MAE which offers a shorter extraction time because it uses electromagnetic waves. This MAE method is a modification of the soxhletation extraction method which obtains a heat source from electromagnetic waves by using a microwave.

Table for comparison of conventional and ultrasound assisted extraction method on boldo leaves

Table 4. Summary and comparison of extractions [27].

Method of extraction	Time of extraction (min)	Yield of extraction (% of leaves Boldo solubilized in the extract)	Boldine (µg of boldine/g of boldo leaves)
UAE	30	21.8	100
Conventional	30	18.0 5	1.7
UAE	120	26.7	148
Conventional	120	21.5	99.5

CONCLUSION

The pharmacopoeial standards in the Ayurvedic Pharmacopoeia of India are insufficient to ensure the quality of plant materials, as the materials received in manufacturing facilities are often unsuitable for effective microscopic examination. Consequently, quality assessment should rely on chemical methods, instrumental techniques, and thin-layer chromatographic analysis to ensure the proper quality of plant materials. Non-standardized extraction procedures can lead to the degradation of phytochemicals in plants, resulting in variations and a lack of reproducibility. It is crucial to produce batches with as consistent quality as possible, within a narrow range, and to develop and adhere to optimal extraction processes.

There are three methods for extracting active compounds from soursop leaves: maceration with solvent immersion, soxhlet extraction using a solid-liquid extraction system, and microwave-assisted extraction (MAE) with electromagnetic waves. Each method has its own advantages and disadvantages. Among these, MAE is the most efficient, yielding 33.98%.

In the case of the maceration method, polar solvents were found to extract higher phenolic yields from olive leaves compared to non-polar solvents, indicating that most phenolic compounds in olive leaves are polar. MAE with polar solvents, especially water, offers a comparable phenolic content yield to that of maceration with alcoholic solvents. MAE is advantageous over conventional

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methods, such as maceration, because it reduces extraction time, increases efficiency, requires less labor, and provides high selectivity, making it a preferred method for extracting phenolic compounds from olive leaves.

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OVERVIEW ON QUALITY CONTROL TEST OF PRIMARY AND SECONDARY PACKAGING MATERIAL

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ABSTRACT

The quality is normally understood as an index or measurement. It is the degree of excellence, a degree of conformation to standard. It is also the distinctive inherent features, property and virtue. Quality Control or Quality evaluation is the operational techniques to fulfill the requirement of quality. Testing is considered to be as a tool for the quality evaluation through the measurement of different qualitative parameters with respect to physical, Chemical, mechanical and optical properties of packaging materials. Pharmaceutical package is an integral part of Pharmaceutical product. An ideal package protects the product from harmful effects of environmental gases, moisture, microbes etc. Primary package is in direct control with the product and secondary package is the package which surrounds the primary package. Containers are tested by many methods of which commonly used test for glass are Crushed glass test, Whole-Container test, Chemical resistance of test, Water Attack Test etc. Similarly test. Closure materials are tested by Transparency test Penetrability Fragmentation test Self seal ability test, Extractive test etc. The requirement of packaging material testing is set according to specification of regulatory agencies like WHO GMP, USFDA and ICH guidelines. [01,03,09]

KEY WORDS : *Blister package, Closures, Primary package, Glass, ,Secondary package*

1.INTRODUCTION

Packaging is a process by which the pharmaceuticals are suitably packed so that they should retain their therapeutic effectiveness from the time of packaging till they are consumed. Packaging may be defined as the art and science which involves preparing the articles for transport, storage display and use. Pharmaceutical packaging is the means of providing protection, presentation, identification, information and convenience to encourage compliance with a course of therapy. The commonly used packaging materials are Container, Closure, Carton or Outer and Box. The containers may be made of glass, plastic, matel or paper. The material for closure may include Cork, Glass, Plastic, Metal or rubber. pharmaceutical packaging is the means of providing protection, presentation, identification, information and convenience to encourage compliance with a course of therapy.

2. DEFINATION

2.1) Primary Packing Material

- Packaging that directly protects or houses the product is known as primary packaging.
- Primary packaging is the packaging that comes in direct contact with the product itself. A cereal box wouldn't be considered primary packaging, but the bag inside the box would, since it's the part that actually holds the contents of the box. The material which Comes in direct contact with the product..
- Primary packaging is the first layer of protection for your product. It's in direct contact with the product and designed to protect it from damage, tampering, or spillage.

Example :- Bottles, Vials, Ampoules, Tin, etc . [05,08]

2.1.1) Types of Primary Packaging

- Flexible Packaging
- Rigid Packaging
- Semi-rigid Packaging

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2.1.1.1) Flexible Packaging :- Flexible packaging uses materials like foil, cellophane, and paper. It's often used for food items like chips, candy, and personal care products like shampoo and conditioner. Flexible packaging is easy to mold around a material.

1. Pouches: Stand-up, flat-bottom, or spout pouches for liquids, powders, or solids.
2. Bags: Paper, plastic, or foil bags for snacks, coffee, or tea.
3. Sachets: Small, single-dose packets for pharmaceuticals, cosmetics, or food.
4. Wraps: Flexible wrapping materials (e.g., plastic, paper, or foil) for snacks or food.
5. Labels: Adhesive labels for product identification.

2.1.1.2) Rigid Packaging :- Rigid packaging uses more complex materials that keep their shape like glass, metal, and plastic. Rigid packaging can be used for products that need protection from impact or temperature changes, such as electronics, beverages, and pharmaceuticals.
1. Bottles: Glass or plastic containers for liquids, tablets, or capsules.
2. Jars: Glass containers for food, cosmetics, or pharmaceuticals.
3. Cans: Metal containers for food, beverages, or chemicals.
4. Tubs: Rigid plastic containers for food, cosmetics, or pharmaceuticals.
5. Vials: Glass containers for pharmaceuticals or laboratory samples. [07,09]

2.1.1.3) Semi-rigid Packaging :- Semi-rigid packaging is a hybrid of flexible and rigid packaging, and uses shape-holding materials like foam and cardboard. Semi-rigid packaging materials can easily be bent or molded, and are usually used for products that need some protection from impact like eggs or wine bottles.
1. Trays: Plastic or paper-based packaging for food, pharmaceuticals, or medical devices.
2. Blister Packs: Pre-formed plastic and foil packaging for tablets or capsules.
3. Clamshells: Hinged plastic packaging for food, cosmetics, or pharmaceuticals.
4. Foldable Containers: Paperboard or plastic containers for food, cosmetics, or pharmaceuticals.
5. Thermoformed Containers: Molded plastic packaging for food, pharmaceuticals, or medical devices. [12]

2.1.2) Functions of Primary Packaging

- Protection
- Presentation
- Branding
- Information

2.1.2.1) Protection :- Products need protection from the elements, tampering, and damage. Primary packaging keeps your product safe from when it leaves the factory until it reaches the customer.
1. Physical Protection: Prevents damage from shock, vibration, temperature, and humidity.
2. Chemical Protection: Shields contents from chemical reactions, contamination, or degradation.
3. Microbiological Protection: Prevents contamination from bacteria, viruses, or fungi.
4. Moisture Protection: Controls humidity levels to maintain product integrity

2.1.2.2) Presentation :- The way your product looks is important to customers. Primary packaging should be eye-catching and make your product look its best. Well-packaged products are more likely to sell than poorly-packaged ones.[13]

2.1.2.3) Branding :- Primary packaging is often the first thing customers see, meaning it's an excellent opportunity to make a good impression and build brand awareness. Your packaging should be consistent with your branding across all channels, from your website to your social media accounts.[15,17]

2.1.2.4) Information :- Products like food and pharmaceuticals need specific information on the packaging, such as nutrition facts or expiration dates. It's important that this information is legible and easy to find.

2.2) Secondary packing material

- Secondary packaging is generally used to group a certain amount of products together into a cohesive unit that's easy to identify. The SKU, or Stock Keeping Unit, makes it easy for vendors to identify the movement of stock as well as inventory. Secondary packaging makes it possible to group products so that they can be more easily tracked.
  Its design protects multiple products during shipping and storage, and can also be used for branding and marketing purposes. [20,25]
  Example :- Cardboard boxes,Plastic Containers,Shrink Wrap,etc

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2.2.1) Types of Secondary Packaging

- Wrapping
- Boxes
- Containers

2.2.1.1) Wrapping :- Wrapping is a type of secondary packaging that uses materials like paper, plastic, or fabric to enclose a product or group of products. These materials are commonly used for products that need protection from the elements, like food items or personal care products

2.2.1.2) Boxes :- Boxes are a type of packaging that uses materials like cardboard or paperboard to enclose a product or group of products. They're often used for products that need protection from impact, like electronics or glassware.[16,17]

2.2.1.3) Containers :- Containers are a type of packaging that uses materials like plastic or metal to enclose a product or group of products. They're normally used for products that need protection from the elements or tampering, like pharmaceuticals or cosmetics

2.2.2) Functions of Secondary Packaging

- Protection
- Stacking
- Branding

2.2.2.1) Protection :- Secondary packaging protects your products from damage during shipping and storage. It's often made from sturdy materials like cardboard or plastic that can withstand impact.Most secondary packaging contains multiple layers of protection to further protect your products. These layers of protection are most commonly created with foam or bubble wrap
1. Shock Absorption: Cushioning against impacts and vibrations
2. Moisture Protection: Barrier against humidity and water
3. Dust Protection: Prevention of contamination

2.2.2.2) Stacking :- Secondary packaging is often designed to stack on top of each other to improve efficiency during shipping and storage. The stacking feature is especially important for fragile products that need protection from the elements.[27]
1. Stability: Prevents shifting or toppling
2. Load Containment: Secures products during transport

2.2.2.3 Branding) :- Secondary packaging can be used for branding and marketing purposes as it's an opportunity to make a good impression and build brand awareness. Your packaging should be consistent with your branding across all channels. It can feature unique shapes or patterns to entice customers, though the primary purpose of secondary packaging is to hold mass quantities.
1. Visual Identity: Logo, colors, and design consistency
2. Product Differentiation: Distinct packaging for brand recognition
3. Marketing Messaging: Communication of product benefits
4. Brand Storytelling: Emotional connection with customers [25]

2.3) Characteristics of Packaging Material

1. It must be a non –toxic
2. It must be a FDA approved
3. It must be not reactive with the product
4. Material must be protect the preparation from environmental condition
5. It must be not impart to the odor or taste to the product

3. PRINCIPAL INSTRUMENTAL TECHNIQUES EMPLOYED FOR PACKAGING MATERIAL

i. Spectrophotometry
ii. Chromatographic Methods
iii. Thermal analysis techniques
iv. Gas transmission analysis
v. Leak detection
vi. Physical test methods
vii. X-ray Fluorescence Analysis

3.1) Spectrophotometry :

1. Spectrophotometry (UV-Vis, NIR, IR): Measures absorption, transmission, or reflection of light to identify molecular structures, contaminants, and material properties.

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2. Fourier Transform Infrared Spectroscopy (FTIR): Analyzes molecular vibrations for material identification, contamination detection, and chemical analysis.
3. Raman Spectroscopy: Detects molecular vibrations for material identification, contamination detection, and chemical analysis.

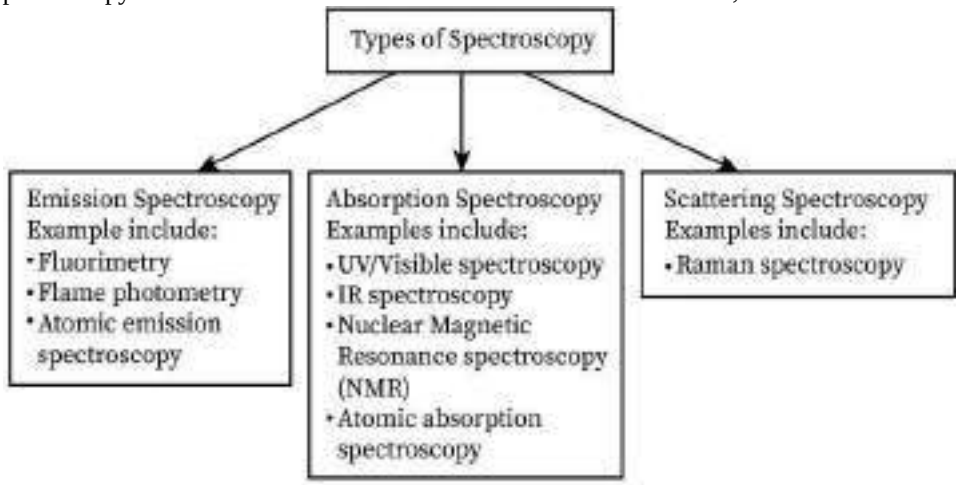

Fig.1 Types of spectroscopy

3.2) Chromatographic Methods

Chromatographic methods separate, identify, and quantify packaging material components. Here are common chromatographic techniques:

3.2.1) Liquid Chromatography (LC)

1. High-Performance Liquid Chromatography (HPLC): Analyzes complex mixtures, additives, and contaminants.
2. Ultra-High-Performance Liquid Chromatography (UHPLC): Provides faster separation and higher resolution.
3. Liquid Chromatography-Mass Spectrometry (LC-MS): Identifies and quantifies molecular structures

3.2.2) Gas Chromatography (GC)

1. Gas-Liquid Chromatography (GLC): Separates volatile compounds.
2. Gas-Solid Chromatography (GSC): Separates gases and volatile compounds.
3. Gas Chromatography-Mass Spectrometry (GC-MS): Identifies and quantifies molecular structures.

3.2.3) Other Chromatographic Techniques

1. Thin-Layer Chromatography (TLC): Separates and identifies compounds on a stationary phase.
2. Paper Chromatography: Separates and identifies compounds on paper.
3. Size-Exclusion Chromatography (SEC): Separates polymers based on molecular size.
4. Ion Chromatography (IC): Separates and identifies ions. [33,36]

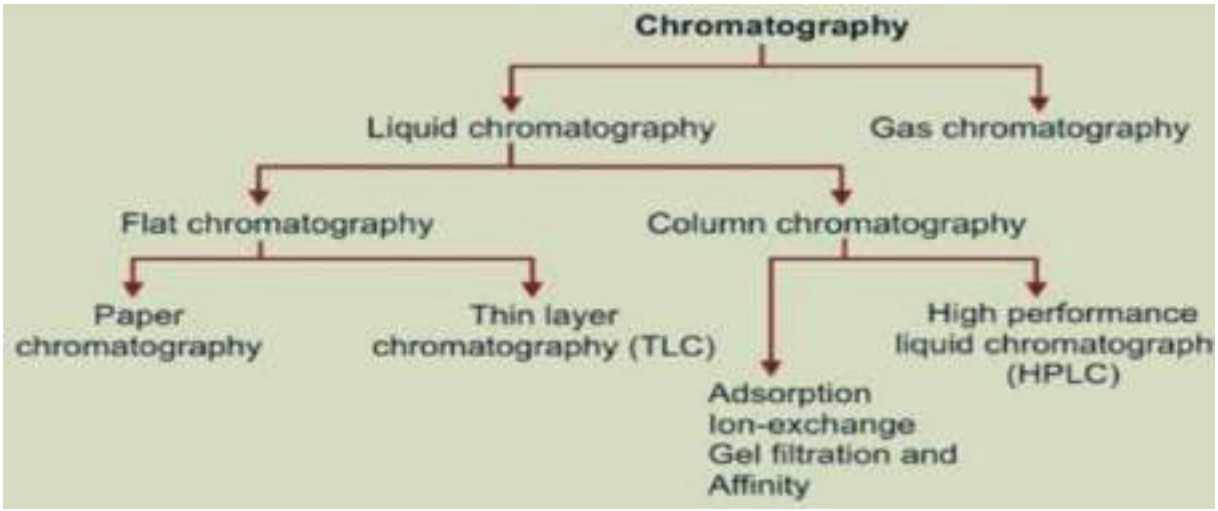

Fig.2 Classification of chromatography

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3.3) Thermal analysis techniques
Thermal analysis techniques analyze packaging materials' thermal properties, stability, and behavior. Here are common techniques:

3.3.1) Calorimetric Methods
1. Differential Scanning Calorimetry (DSC): Measures heat flow, melting points, and glass transition temperatures.
2. Differential Thermal Analysis (DTA): Measures temperature differences between samples and references.

3.3.2) Thermogravimetric Methods
1. Thermogravimetry (TG): Measures mass changes during heating or cooling.
2. Thermogravimetric Analysis (TGA): Measures mass loss, moisture content, and degradation.

3.3.3) Mechanical Methods
1. Dynamic Mechanical Analysis (DMA): Measures mechanical properties, stiffness, and damping.
2. Thermal Mechanical Analysis (TMA): Measures expansion, contraction, and softening.

3.3.4) Other Techniques
1. Thermal Conductivity Measurement: Measures heat transfer properties.
2. Heat Deflection Temperature (HDT): Measures temperature-induced deformation.
3. Vicat Softening Temperature: Measures temperature-induced softening.
4. Dielectric Analysis (DEA): Measures electrical properties.

3.4) Gas transmission analysis :
Gas transmission analysis measures the passage of gases (O2, CO2, N2, H2O) through packaging materials. Techniques:

3.4.1) Methods
1. Oxygen Transmission Rate (OTR): Measures oxygen permeability (ASTM D3985).
2. Carbon Dioxide Transmission Rate (CTR): Measures carbon dioxide permeability (ASTM D5826).
3. Water Vapor Transmission Rate (WVTR): Measures moisture permeability (ASTM F1249).
4. Nitrogen Transmission Rate (NTR): Measures nitrogen permeability.
5. Gas Permeability Testing: Measures gas flow through materials (ISO 2556).

3.5) Leak Detection
1. Vacuum Leak Detection: Detects leaks using vacuum pressure.
2. Pressure Decay Testing: Measures pressure changes.
3. Helium Leak Detection: Uses helium gas to detect leaks.
4. Hydrogen Leak Detection: Uses hydrogen gas to detect leaks.

3.6) Physical Test Methods
1. Tensile Strength Testing: Measures material strength (ASTM D882).
2. Flexural Testing: Measures flexibility (ASTM D790).
3. Impact Testing: Measures impact resistance (ASTM D1709).
4. Compression Testing: Measures compression strength (ASTM D695).
5. Thickness Testing: Measures material thickness (ASTM D374).
6. Density Testing: Measures material density (ASTM D1895).

3.7) X-ray Fluorescence Analysis (XRF) :
1. Elemental Analysis: Identifies elemental composition.
2. Material Identification: Verifies material authenticity.
3. Contamination Detection: Detects impurities.
4. Coating Thickness Measurement: Measures coating thickness. .[24,25]

4. QUALITY CONTROL OF PRIMARY PACKAGING MATERIAL

4.1) CONTAINERS

- A container for a pharmacopoeial article is intended to contain a drug substance or drug product with which it is, or may be in direct contact. The closure is a part of the container.
- Containers must be chosen with care and after taking into consideration the nature of the articles and the likely effects of transportation and storage, even for short periods of time.

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- A container should be designed so that the contents may be removed in a manner suitable for the intended use of the article in it. It should also provide an adequate degree of protection, minimize the loss of constituents and should not interact physically or chemically with the contents in a way that will alter their quality to an extent beyond the limits given in the individual monograph, or present a risk of toxicity.

4.1.1) Quality Control tests of Container

4.1.1.1) Airtight Container

These types of containers protect the container from environmental hazards. If these containers are intended to be opened on more than one occasions then they remains airtight after reclosure. These are also known as hermetic sealed containers.A container that is impermeable to solids, liquids and gases under ordinary conditions of handling, storage and transport. If the container is intended to be opened on more than once, it must be so designered that it mains airtight after re-closure.

4.1.1.2) Hermetically Sealed container :- A container that is impervious to air or any other gas under normal conditions of handling, shipment, storage and distribution, e.g. sealed glass ampoule, gas cylinder etc.

4.1.1.3) Light-resistant container :- A container that protects the contents from the effects of actinic light by virtue of the specific properties of the material of which it is made. These containers protect the contents from light (UV light). These are made up of the materials which do not allow the UV light to pass from them to contents. For e.g : Amber colored glass containers.

4.1.1.4) Single-Dose Container :- A container that holds a quantity of the preparation intended for total or partial use as a single administration. This type of container contain single dose of medicament example are: Glass ampoules,Vials etc.

Fig.3 Single Dose Container

Fig.4 Multi Dose Container

4.1.1.5) Sealed container :- A container closed by fusion of the material of the container.

4.1.1.6) Tamper-evident container :- A container fitted with a device or mechanism that reveals irreversibly whether the container has been opened.

4.1.1.7) Multidose container :- A container that holds a quantity of the preparation suitable for two or more doses. As the name indicates these type of containers holds more than single dose and their contents are withdrawn at various intervals e.g Vials etc.

4.1.1.8) Tightly-closed container :- A tightly-closed container protects the contents from contamination by extraneous liquids, solids or vapours, from loss or deterioration of the article from effervescence, deliquescence or evaporation under normal conditions of handling, shipment, storage and distribution. A tightly-closed container must be capable of being tightly re- closed after use.

4.1.1.9) Well-closed container :- These type of containers provide the protection from foreign particles and loss during transportation, sale etc. A well-closed container protects the contents from extraneous solids and liquids and from loss of the article under normal conditions of handling, shipment, storage and distribution.[39,40]

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4.1.2) Primary Package for solid dosage

4.2.2.1) Strip Package : In this the contents are sealed in a packet. The Package is made up of two layers of film. A strip containing many pockets and each pocket contains single dose of medicament..

4.2.2.2) Blister Package : It is made up of base layer (PVC layer) with cavities which contain Pharmaceutical product. This type of Package provides greater protection than strip package. The lid is made up of aluminium or paper foil. The package is sealed by combining lid and base with the application of heat and pressure.

Fig.5 Tablet Blister

4.1.3) Primary Package for semi solid dosage

Semi- Solid dosage forms include creams, pastes, ointments etc. the containers used for semi-solid dosage forms includes collapsible tubes etc. Plastic Containers are also very popular now a days. Another type of products are also available in market for e.g Pressurized products. For these types of products the package made up of stainless steel, aluminium etc. is used. The package used must be strong enough to withstand pressure built up in the container.

Fig.6 Semi Solid Dosage

4.2 GLASS CONTAINERS

Glass containers may be colourless or coloured. Neutral glass is a borosilicate glass containing significant amounts of boric oxide, aluminum oxide, alkali and/or alkaline earth oxides. It has a high hydrolytic resistance and a high thermal shock resistance. Soda-lime-silica glass is a silica glass containing alkali metal oxides, mainly sodium oxide and alkaline earth oxides, mainly calcium oxide. It has only a moderate hydrolytic resistance.

According to their hydrolytic resistance, glass containers are classified as:

– Type I glass containers which are of neutral glass, with a high hydrolytic resistance, suitable for most preparations whether or not for parenteral use,

– Type II glass containers which are usually of soda-lime- silica glass with high hydrolytic resistance resulting from suitable treatment of the surface. They are suitable for most acidic and neutral, aqueous preparations whether or not for parenteral use,

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Fig.7 Glass Container

4.2.1) Quality Control Test For Glass Container

4.2.1.1) Crushed–Glass Test :

This test is official in USP. The container is crushed and sieved to produce uniform particles of which a definite weight of taken. The control of the particle size and weight of powder ensures that a constant surface area is exposed to the solution. This test can be used for determining the nature of a glass or for distinguish between two types of glasses, such as neutral or surface – treated.[44,45]

Fig.8 Crushed Glass Test

4.2.1.2) Whole-Container Test

This test is official in European, British and International Pharmacopoeias. it is used in the USP for treated soda-lime containers only. The containers are simply filled with the test solution and exposed to the test conditions. Glassware may pass the whole container test more easily because the surface layer of a container is smooth and less reactive.

4.2.1.3) Chemical Resistance Of Glass Containers

USP and IP provide two tests to determine the chemical resistance of glass containers.

4.2.1.3.1) Powdered Glass Test : The principle involved in the powdered glass test estimate the amount of alkali leached from the powdered glass which usually happens at the elevated temperatures.

Fig.9 Powdered Glass Test

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.Procedure:-

Sample containers are rinsed with purified water and dried.

I

The containers are grinded in a mortar to a fine powder

and passed through sieve no. 20 and 50.

I

10gm of the sample is washed with acetone and dried.

I

50 ml of purified water is added to the dried sample and autoclaved

at 121°C for 30 min's and cooled and decanted.

I

The decanted liquid is titrated with 0.02 N H_2SO_4 using methyl red as indicator.

4.2.1.3.2) Water Attack Test : This test is used only with containers that have been exposed to sulphur dioxide fumes under controlled humidity conditions. Now the glass becomes chemically more resistant. The principle involved in the water attack test is to determine whether the alkali leached form the surface of a container is within the specified limits or not. Since the inner surface is under test entire container (ampoule) has to be used.

Procedure :–

Rinse thoroughly with high purity water.

|

Fill each container to 90%of its overflow capacity with water and is autoclaved at 121^0C for 30min

|

cooled and the liquid is decanted which is titrated with 0.02N

sulphuric acid using methyl red as an indicator.

|

The volume of sulfuric acid consumed is the measure of the

amount of alkaline oxides present in the glass containers.

4.2.1.3.3) Hydrolytic Resistance Of Glass Containers:- The hydrolytic stability of glass containers for pharmaceutical use is expressed by the resistance to the release of soluble mineral substances into water under the prescribed conditions of contact between the inner surface of the container or glass grains and water.

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Procedure:–

Rinse each container at least 3 times with CO2 free water

and fill with the same to their filling volume.

|

Fill & Cover the vials and bottles and keep in autoclave.

|

Heat to 100^0C for 10min and allow the steam to issue from the Vent cork Rise the temp from 100^0C to 121^0C over 20min.

|

Maintain the temp at 121^0C to 122^0C for 60min. Lower the temp from 121^0C to 100^0C over 40min venting to prevent vacuum.

|

Remove the container from autoclave, cool and combine the liquids being examined. Measure the volume of test solution into a conical flask and titrate with 0.01M HCl using methyl red as an indicator.

|

Perform blank with water and the difference between the titration

represents the volume of HCl consumed by the test solution.

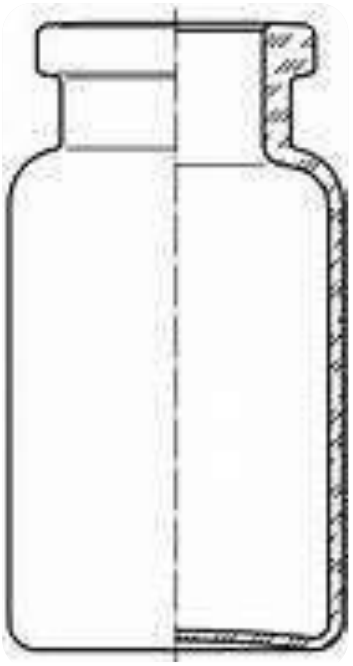

Fig.10 Hydrolytic Resistance Tets

4.2.1.3.4) Arsenic Test :

This test is for glass containers intended for aqueous parenterals. This procedure is designed to determine the presence of trace amounts of arsenic (As) by converting the arsenic in a substance under test to arsine, which is then passed through a solution of silver diethyldithiocarbamate to form a red complex.

Procedure

Wash the inner and outer surface of container with fresh distilled water for 5min.

|

Prepare test for hydrolytic resistance for an adequate no. of samples to produce 50ml.

|

Pipette out 10ml soluteion from combined contents of all ampoules to the flask.

Fig.11 Arsenic Test

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|

Add 10ml of HNO3 to dryness on the water bath,dry the residue in an oven at 130^{0}C

for 30min cool and add 10ml hydrogen molybdate reagent.

|

Swirl to dissolve and heat under water bath and reflux for 25min.

|

Cool to room temp and determine the absorbance at 840nm.Do the blank with 10ml hydrogen molybdate.

|

The test solution should not exceed the absorbance obtained by repeating the determination using 0.1ml of arsenic standard solution (10ppm) in place of test soln.

4.2.1.3.5) Thermal Shock Test

Thermal shock testing is the process through which a product is quickly transferred between two extreme temperatures to gauge its durability and identify potential breaking points.

This testing is meant to mimic, in an accelerated environment, the wear and tear a product will encounter in usual conditions or standard use.

Procedure:–

Place the samples in upright position in a tray.

|

Immerse the tray into a hot water for a given time and transfers to cold water bath, temp of both are closely controlled.

|

Examine cracks or breaks before and after the test.

|

The amount of thermal shock a bottle can withstand depends on its size, design

and glass distribution.

|

Small bottles withstand a temp differential of 60 to 80^{0}C and 1 pint bottle 30 to 40^0

A typical test uses 45^{0}C temp difference between hot and cold water.

Fig.12 Thermal Shock Test

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4.2.1.3.6) Internal Bursting Pressure Test

Burst is a condition where internal pressure exceeds pressure loading. Burst can happen in several situations, such as well control, pressure test casing/tubing, pumping operation, etc.

The most common instrument used is American glass research increment pressure tester.

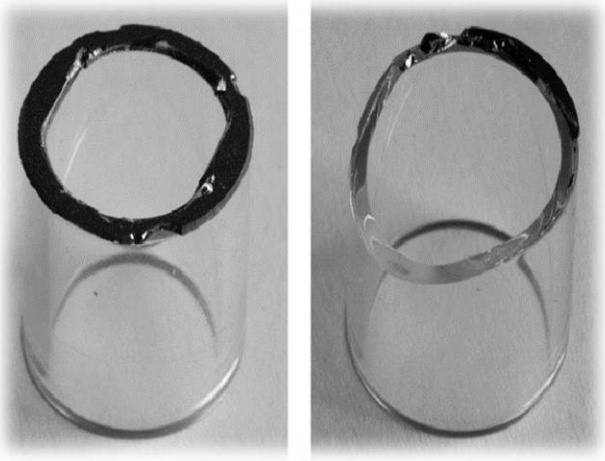

Fig.13 Internal Bursting Test

Procedure:–

The test bottle is filled with water and placed

inside the test chamber.

|

A scaling head is applied and the internal pressure automatically raised by a series of increments each of which is held for a set of time.

|

The bottle can be checked to a preselected pressure level and the

test continues until the container finally bursts.

4.2.1.3.7) Leakage Test:– A leak test is a procedure used to determine if an object, product, or system functions within a specified leak limit. A leak occurs when a gas or liquid flows through an object via an imperfection or manufacturing defect such as a hole, crack or weak seal. These imperfections create high- and low-pressure zones within a product, forcing the gas or liquid to flow from the high-pressure area to the low-pressure area. The primary leak test method discussed in this article uses pressurized air to identify leaks.

Procedure:–

10 containers are filled with water and fitted with intended closures.

I

They are kept inverted at room temperature for 24 hours.

I

The test is said to be passed if there is no sign of leakage from any container.

Fig.14 Leakage Test

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4.3 PLASTIC CONTAINERS

Plastic containers for pharmaceutical products are made from plastics based on the following polymers: polyethylene (low or high density), polypropylene, polyvinyl chloride, polystyrene and to a lesser extent polyethylene terephthalate. Plastic containers are containers made exclusively or partially of plastic. Plastic containers are ubiquitous either as single-use or reuseable/durable plastic cups, plastic bottles, plastic bags, foam food containers, Tupperware, plastic tubes, clamshells, cosmetic containers, up to intermediate bulk containers and various types of containers made of corrugated plastic. [47,50]

Fig.15 Plastic Container

4.3.1) Quality Control Test For Plastic Container

4.3.1.1) Physico-chemical Tests :- The sample is extracted in the required extraction media at 70 ± 2°C (water and alcohol) or 50 ± 2°C (hexanes) for 24 ± 2 hours. Other extraction times and temperatures may be used if requested, but the USP General Chapter 661 limits may not be applicable.

For general plastics, all four analyses are recommended using a water extraction. The ROI test is not required when the nonvolatile residue does not exceed 5 mg.

i} Buffering capacity: This test measures the amount of acid or base that is added to the extract which causes a significant change in ion activity (pH).

ii} Nonvolatile residue (NVR): This test quantifies any substances in the extract which do not volatilize at or above a temperature of 105°C.

iii} Residue on ignition (ROI): This test quantifies any substances from the nonvolatile residue test which do not volatilize at or above 600°C in the presence of sulfuric acid. An NVR test must be performed prior to an ROI test.

iv} Heavy metals: This test detects metallic impurities found in the extract that are colored by the sulfide ion. The metals which normally respond to this test are lead, mercury, bismuth, arsenic, antimony, tin, cadmium, silver, copper, and molybdenum. The total amount of heavy metals cannot exceed 1 part per million (ppm).[52,54]

4.3.1.2) Biological Test :- Policies and ethics Bioplastics or bio-based plastics are made from biological sources, a small portion of the worldwide plastic market, and need more research and commercialization.

The USP has provided its procedures for evaluating the toxicity of plastic materials .

i} Implantation test: Implanting small pieces of plastic material intramuscularly in rabbits.

ii} Systemic injection test: Injecting eluates using sodium chloride injection, with and without alcohol intravenously in mice and injecting eluates using poly ethylene glycol 400 and sesame oil intraperitoneally in mice.

iii} Intracutaneous test: Injecting all four eluates subcutaneously in rabbits. The reaction from test samples must not be significantly greater than nonreactive control samples.

Fig.16 Biological Test on Rabbit

4.3.1.3) Opthalic Test :

Ophthalmic preparations are designed to be instilled on the anterior surface (topical route) of the eye, administered intraocularly (inside the eye), periocularly (subtenon or juxtascleral) or in conjunction with ophthalmic devices

4.3.1.4) Leakage Test : Air leak testing is a common method used for leak testing. It is a flexible test method that can be used to leak test a wide variety of parts and applications.

Fig.17 Opthalmic Test on Rabbit

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Procedure:–

10 containers are filled with water and fitted with intended closures.

↓

They are kept inverted at room temperature for 24 hours.

↓

The test is said to be passed if there is no sign of leakage from any container

4.3.1.5) Clearity Of Aqueous Extract :

Procedure:–

A suitable container is taken at random, and unlabeled, unmarked and nonlaminated

portions is selected.

I

These portions are cut into strips, none of which has a total surface area of 20cm2 .

I

The strips are washed free from extraneous matter by shaking them with at

least two separate portions of distilled water for about 30 secs.

I

The processed sample is taken in to the flask, previously cleaned with chromic acid

and rinsed with distilled water.

I

250ml of distilled water is added to the flask, covered and autoclaved at 121 °C for 30 mins.

4.5 METAL CONTAINERS

The materials used for various pharmaceutical drug delivery systems include tin plated steel, mild steel, stainless steel, tin free steel, aluminum and its various alloys..Tin is frequently used in the production of aerosolcans by electroplating it onto sheet steel to improvecorrosion resistance and facilitate soldering. Incontrast; aluminum is used in its pure form as foil.Often, aluminum foil is used as an impermeable layerin a multilayer laminate that may include paper and plasticsas well. Aluminum foil can be formed intorigid containers, semi rigid containers, blister construction,or laminates.. Examples of metals used for this purpose include mainly aluminium, lead, tin etc.[60]

Fig.18 Metal Container

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Plastic containers are containers made exclusively or partially of plastic. Plastic containers are ubiquitous either as single-use or reuseable/durable plastic cups, plastic bottles, plastic bags, foam food containers, Tupperware, plastic tubes, clamshells, cosmetic containers, up to intermediate bulk containers and various types of containers made of corrugated plastic. [47,50]

5. QUALITY CONTROL OF SECONDARY PACKAGING MATERIAL

5.1 PAPER, PAPERBOARD, AND CARDBOARD

The most common applications of paper, paperboard, and cardboard are in blister lidding stock and in over-the-counter (OTC) outer packaging. Because paper, paperboard, and cardboard offer virtually no moisture or gas barrier, they are typically part of the secondary pharmaceutical container.. More commonly, when paper is involved in critical packaging functions, it is the only one component of a multicomponent system that offers optimal environmental protection to the drug environment. .Although paper does not offer high shear strength, its relatively high tensile strength makes it an easy barrier to overcome if one intends to do so, but is an exceedingly confounding one for a child. Paper also simplifies printing on the blister itself. Other uses of paper, paperboard, and cardboard are as secondary packaging or for shipping packaging (e.g., corrugated cardboard)

Fig.19 Paper board Box Container

5.2 CLOSURES

The closure is normally the most vulnerable and critical component of a container as far as stability and compatibility with the product is concerned. This is the most critical component of a container. An effective closure system prevents the loss of material from the container, prevents the environmental contamination of the product, prevents the microbs to enter inside he container.[56,58]

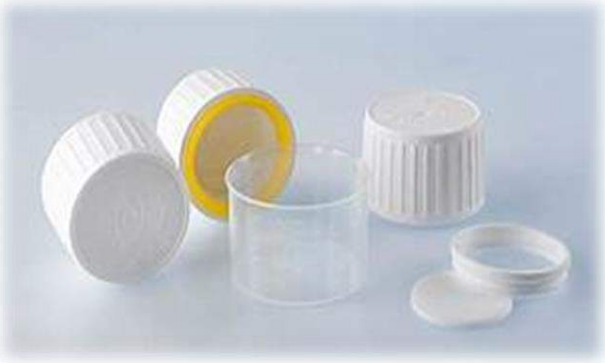

Fig.20 Closures

Closures are devices used for opening and closing containers. The term closure includes caps, lids, plugs, and covers. Each type of closure refers to the component found at the opening of a container used for sealing product inside. Closures are used in every industry to seal products ranging from food to chemicals. Closures are designed to pair with a variety of containers such as bottles, jars, tubes, pails and more. Different types of closures are selected based on the end user's product application such as resealing for reuse or dispensing a specific amount of product.[59]

Types of closures:-

1. Thread screw cap
2. Lug cap
3. Crown cap
4. Pilfer proof closures

5.2.1) QUALITY CONTROL OF CLOSURES

5.2.1.1) Penetrability test : This is measured to check the force required to make a hypodermic needle penetrate easily through the closure. It is measured by using the piercing machine. The piercing force must not exceed a stated value. If it exceeds that stated value, the hypodermic needle can be damaged as a result of undesirable hardness of the closures.[77,79]

5.2.1.2) Fragmentation test: This test is performed on 20 closures. Each closure is penetrated with hypodermic needle in a piercing machine five times within a limited area and needle is washed to transfer any fragment present. The contents are filtered through coloured paper that contrasts with the rubber and the fragments counted. On an average there should not be more than three fragments per unit.

5.2.1.3) Self sealability test: Applicable to multidose containers fill 10 vials with water close them with prepared closures and secure with a cap. For each closure use a new hypodermic needle and pierce 10 times each time at different site immerse the vials

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upright in methylene blue (0.1%) solution and reduce external pressure for 10 minutes. Restore the atmospheric pressure and leave the vials immersed for 30 minutes. Rinse the outside of the vials. None of the vials contains any trace of coloured solution.

5.2.1.4) Extractive test: In this test, the closure is boiled with water for four hours under reflux and the water evaporated to dryness. The residue must not exceed the specified amount.

5.2.1.5 Compatibility test: This test is performed to check the compatibility of the rubber closures with various types of the substances, since it is necessary to ensure that there is no interaction between the contents of the bottle and the closure.

5.2.1.6) Light absorption : Filter solution A through membrane filter. Measure the light absorbance of filtrate in the range 220 to 360 nm using a blank solution (prepared in the same manner as solution A). The absorbance is not more than2.

7. W.H.O GUIDELINES FOR QUALITY CONTROL OF PACKAGING MATERIALS

1. All the containers and closures intended for use shall comply with the pharmacopoeial and other specified requirements.
2. Suitable sample sizes, specifications, test methods, cleansing procedures and sterilization procedures shall be to suitability of packaging materials.
3. Plastic granules should also comply with the pharmocopeial requirements including physio-chemical and biological tests.
4. All the containers and closure shall be rinsed prior to sterilization with water for injection according to written procedure.
5. The design of the closures, containers and stoppers shall be as such as to make an airtight seal when fitted to the bottles.

10. CONCLUSION

The testing of packaging materials is almost requirement for any pharmaceutical industry. The material of a package affects quality, stability and efficacy of drug product. Thecost of material of a package should be as low as possible without compromising the quality of product. It should pass the specifications of tests before it reached the local markets and made available to the consumers of product. The type of test followed should be according to requirements of regulatory agencies.

Ensuring the quality and integrity of primary and secondary packaging materials is crucial for the safety, efficacy, and stability of pharmaceutical and medical devices. A comprehensive quality control program involves various tests to evaluate material properties, performance, and biocompatibility.

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A REVIEW ON HERBAL EXCIPIENTS IN NOVEL DRUG DELIVERY SYSTEMS

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ABSTRACT
Due to advances in drug delivery technology, currently, excipients are included in novel dosage forms to fulfil specific functions and in some cases, they directly or indirectly influence the extent and/or rate of drug release and drug absorption. Recent trends towards use of plant based and natural products demand the replacement of synthetic additives with natural ones. Today, the whole world is increasingly interested in natural drugs and excipients. These natural materials have many advantages over synthetic ones as they are chemically inert, nontoxic, less expensive, biodegradable, improve the shelf life of product and widely available. This article gives an overview of natural excipients which are used in conventional dosage forms as well as novel drug delivery systems.
KEYWORDS:- *Natural excipients, gums, mucilage, polysaccharides, starch, volatile oil*

INTRODUCTION

The term excipient was derived from Latin word, excipients, which means to receive, to gather, to take out. The quality of formulation depends on active pharmaceutical ingredient (API), production processes and the excipients used. These excipients contribute in a great way to the performance of the API and maintain the safety, efficacy of the product[1].

Excipients are primarily used as diluents, binders, disintegrants, adhesives, glidants and sweeteners in conventional dosage forms like tablets and capsules[2]. As the establishment of toxicity and approval from regulatory authorities poses a problem with synthetic excipients, of late more interest is being shown by researchers in herbal excipients. The drawback posed by heavy metal contamination often associated with herbal excipients is superseded by their lack of toxicity, easy availability, and economic considerations in pharmaceutical industry as compared to their synthetic counterparts.

Present day consumers look for natural ingredients in food, drugs, and cosmetics as they believe that anything natural will be more safe and devoid of side effects.

The traditional view that excipients are inert and do not exert any therapeutic or biological action or modify the biological action of the drug substance has changed and it is now recognized that excipients can potentially influence the rate and/or extent of absorption of a drug. As herbal excipients are non-toxic and compatible, they have a major role to play in pharmaceutical formulation. Hence, this article gives an overview of natural excipients which are used in conventional dosage forms as well as novel drug delivery systems[1-3].

Pharmaceutical Excipients

Pharmaceutical excipients can be defined as nonactive ingredients that are mixed with therapeutically active compound(s) to form medicines. The ingredient which is not an active compound is regarded as an excipient. Excipients affect the behavior and effectiveness of the drug product more and more functionality and significantly. The variability of active compounds, excipients and process are obvious components for the product variability [4].

Classification of Excipients

Excipients are commonly classified according to their application and function in the drug products:

- Binders, Diluents
- Lubricants, Glidants, Disintegrants
- Polishing Film formers and coatings agents

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- Plasticizers, Colorings
- Suspending agents Preservatives, antioxidants
- Flavorings, Sweeteners, Taste improving agents
- Printing inks, Dispersing agents Gums [4]

Advantage of Herbal Excipients

- Biodegradable – Naturally occurring polymers produced by all living organisms. They show no adverse effects on the environment or human being.
- Biocompatible and non-toxic – Chemically, nearly all of these plant materials are carbohydrates in nature and composed of repeating monosaccharide units. Hence, they are non-toxic.
- Economic - They are cheaper and their production cost is less than synthetic material.
- Safe and devoid of side effects – They are from a natural source and hence, safe and without side effects.
- Easy availability – In many countries, they are produced due to their application in many industries[5].

Disadvantages of Herbal Excipients

- Microbial contamination – During production, they are exposed to external environment and hence, there are chances of microbial contamination.
- Variation – Synthetic manufacturing is controlled procedure with fixed quantities of ingredients while production of natural polymers is dependent on environment and various physical factors.
- The uncontrolled rate of hydration- due to differences in the collection of natural materials at different times, as well as differences in region, species, and climate conditions the percentage of chemical constituents present in a given material may vary.
- Slow Process – As the production rate is depends upon the environment and many other

factors, it can't be changed. So, natural polymers have a slow rate of production.

- Heavy metal contamination – There are chances of Heavy metal contamination often associated with herbal excipients [5, 6].

Gums and Mucilage

Gums are pathological products formed following injury to the plant or owing to unfavorable conditions, such as drought, by a breakdown of cell walls (extra cellular formation; gummosis). Mucilage's are generally normal products of metabolism, formed within the cell (intracellular formation) and/or are produced without injury to the plant. Gums readily dissolve in water, whereas, mucilage form slimy masses. Mucilage's are physiological products[7].

Classification is based on source

(a) Marine origin/algal (seaweed) gums: agar, carrageenans, alginic acid, and laminarin;
(b) Plant origin:
i. shrubs/tree exudates: gum arabic, gum ghatti, gum karaya, gum tragacanth, and khaya and albizia gums;
ii. Seed gums: guar gum, locust bean gum, starch, amylose, and cellulose;
iii. Extracts: pectin, larch gum;
iv. Tuber and roots: potato starch;
(c) Animal origin: chitin and chitosan, chondroitin sulfate, and hyaluronic acid;
(d) Microbial origin (bacterial and fungal): xanthan, dextran, curdian, pullulan, zanflo, emulsan, Baker's yeast glycan, schizophyllan, lentinan, krestin, and scleroglucan.

Guar Gum

Guar gum derived from the seeds of Cyamopsis tetragonolobus (Family Leguminosae) is a naturally occurring galactomannan polysaccharide. It is made up of a linear chain of β -D- mannopyranose joined by β -(1–4) linkage with α -D-galactopyranosyl units attached by 1, 6- links in the ratio of 1:22 .

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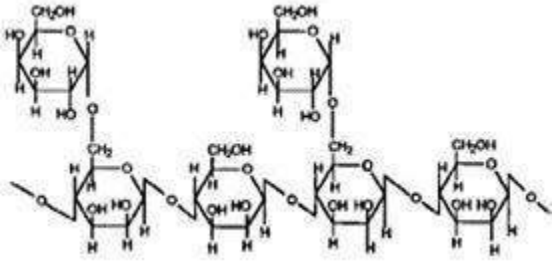

Fig. 1: **Structure of guar gum**

Guar gum is used in colon-delivery systems due to its drug release retarding property and susceptibility to microbial degradation in the large intestine. Selective delivery of 5–ASA to the colon can be achieved using guar gum as a carrier in the form of acompression coating over the drug core[8].

Further, guar gum-based matrix tablets of rofecoxib were prepared for their intended use in the chemoprevention of colorectal cancer. In vivo studies showed delayed Tmax, prolonged absorption time and decreased Cmax indicating that rofecoxib was not released significantly in stomach and small intestine, but was delivered to colon resulting in a slow absorption of the drug and making it available for local action in human colon[9].

Guar gum, in the form of three-layer matrix tablets, is a potential carrier in the design of oral controlled drug delivery systems for highly water-soluble drugs such as trimetazidine dihydrochloride [10].

Gum Acacia

Gum acacia or gum arabic is the dried gummy exudate obtained from the stemand branches of Acacia senegal (Linn.) Willdenow and other related species of acacia (Family Leguminosae). The gum has been recognized as an acidic polysaccharide containing D-galactose, L-arabinose, L-rhamnose, and D-glucuronic acid. Acacia is mainly used in oral and topical pharmaceutical formulations as a suspending and emulsifying agent, often in combination with tragacanth. It is also used in the preparation of pastilles and lozenges and as a tablet binder[11].

Sustained release of ferrous sulfate was achieved for 7 h by preparing gum Arabic pellets. Release was further sustained for more than 12 h by coating the pellets with polyvinyl acetate and ethylene vinyl acetate, respectively. The gel layer acts as a barrier and retards the rate of diffusion ofFeSO4 through the pellet[12].

Gum arabic was used as an osmotic, suspending and expanding agent in the preparation of a monolithic osmotic tablet system (MOTS) with two orifices on both side surfaces. Water-insoluble naproxen was selected as the model drug. The optimal MOTS were found to be able to deliver naproxen at a rate of approximately zero order up to 12 h in pH 6.8. Cumulative release at 12 h is 81%, and is independent of environment media and stirring rate. Therefore, these MOTS can be used in the oral drug-controlled delivery field, especially for water-insoluble drugs[13].

Karaya Gum

Karaya gum is obtained from Sterculia urens (Family sterculiaceae) is a partially acetylated polymer of galactose, rhamnose, and glucuronic acid [11]. Swellable hydrophilic natural gums like xanthan gum and karaya gum were used as release-controlling agents in producing directly compressed matrices. Drug release from xanthan and karaya gum matrices depended on agitation speed, solubility and proportion of drug. Both xanthan and karaya gums produced near zero order drug release with the erosion mechanism playing a dominant role, especially in karaya gum matrices [14]. Park etal.,[15] showed that mucoadhesive tablets prepared by karaya gum for buccal delivery, had superior adhesive properties as compared to guar gum and was able to provide zero-order drug release, but concentrations greater than 50% w/w may be required to provide suitable sustained release.

Xanthan Gum

Xanthan gum is a high molecular weight extra cellular polysaccharide produced by the fermentation of the gram- negative bacterium Xanthomonas campestris. The primary structure of this naturally produced cellulose derivative contains a cellulosic backbone (β -D-glucose residues) and atrisaccharide side chain of β -D-mannose-β -D-glucuronic acid-α -D-mannose attached with

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alternate glucose residues of the main chain. The terminal D-mannose residue may carry a pyruvate function, the distribution of which is dependent on the bacterial strain and the fermentation conditions. The non-terminal D-mannose unit in the side chain contains an acetyl function. The anionic character of this polymer is due to the presence of both glucuronic acid and pyruvic acid groups in the side chain[11](fig. 2)

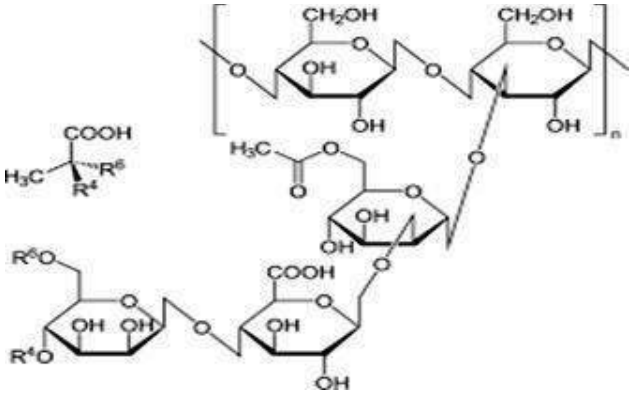

Fig. 2: Structure of xanthan gum

In one of the trials, xanthan gum showed a higher ability to retard the drug release than synthetic hydroxypropylmethylcellulose [16].

Compaction and compression properties of xanthan gum pellets were evaluated and drug release from tablets made of pellets was characterized. Two types of pellets were prepared by extrusion- spheronization. Formulations included xanthan gum, at 16% (w/w) and diclofenac sodium or ibuprofen, at 10% (w/w) among other excipients. Physical properties of pellets and tablets were analyzed. Pellets showed close compressibility degrees (49.9% for pellets comprising diclofenac sodium and 48.5% for pellets comprising ibuprofen). The release of the model drug from both type of tablets revealed different behaviors. Tablets made of pellets comprising ibuprofen released the model drug in a bimodal fashion and the release behavior was characterized as Case II transport mechanism (release exponent of 0.93). On the other hand, the release behavior of diclofenac sodium from tablets made of pellets was anomalous (release exponent of0.70) .

For the latter case, drug diffusion and erosion were competing mechanisms of drug release[17].
Tragacanth: This gum is obtained from the branches of Astragalus gummifer, Family Leguminosae. Tragacanth when used as the carrier in the formulation of 1- and 3-layer matrices produced satisfactory release prolongation either alone or in combination with other polymers [18].

Table 1:Some Recently Investigated Natural Gums and Mucilage

Common name	Botanical name	Family	Pharmaceutical applications
Agar	*Gelidiumamansii*	Gelidaceae	Suspending agent, emulsifying agent, gelling agent in suppositories, surgical lubricant, tablet disintegrates, medium for bacterial culture, laxative [19]
Albizia gum	*Albizia zygia*	Leguminosae	Tablet binder, coating materials in compression-coated tablets[20]
Abelmoschus gum (Orka gum)	*Abelmoschus esculentus*	Malvaceae	Suspending agent, disintegrant in low concentrations (4%) [21], poor floating capacity in sustained release tablet but with HPMC shows better results. Okra polysaccharide as a microbially triggered material for colon targeted tablet formulation [22]

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Tamarind Seed Polysaccharide	*Tamarindus indica*	Fabaceae	Microspheres preparation (size range of 230-460µm). In another study, Diclofenac sodium matrix tablets containing TSP[23]
Locust Bean Gum (Carob gum)	*Ceratoniasiliqua*	Leguminosae	Controlled release agent[24]
Fenugreek mucilage	*Trigonella foenum-graceum*	Leguminosae	Better release retardant[25]
Hibiscus mucilage	*Hibiscus rosasinensis*	Malvaceae	Sustained release[26]
Almond gum	*Prunus amygdalus*	Rosaceae	emulsifying, thickening, suspending, adhesive, glazing, and stabilizing properties. Drug release increased[27]
Neem gum	*Azadirachta indica*	Meliaceae	Controlled release agent[28]
Aloe Mucilage	*Aloe barbadensis*	Liliaceae	Controlled release agent[29]
Cashew Gum	*Anacardium occidentale*	Anacardiaceae	Gelling property, Controlled release agent[30]
Moringaoleifera gum agent.	*Moringa oleifera*	Moringaceae	Gelling property, Binding agent, Controlled release
Acacia	*Acacia Senegal*	Combretaceae	Suspending agent, emulsifying agent, binder in tablets, demulcent and emollient in cosmetics Osmotic drug delivery[31]
Bhara gum	*Terminalia bellerica roxb*	Combretaceae	Microencapsulation[32]
Cactus mucilage	*Opuntia*	----	Gelling agent in sustained drug delivery[33]
Gellan gum		----	Ophthalmic drug delivery, sustaining agent, beads, hydrogels, floating in-situ gelling, controlled release

Polysaccharides in Pharmaceuticals

Natural polysaccharides are extensively used for the development of solid dosage forms. These polymers of monosaccharides (sugars) are inexpensive and available in a variety of structures with a variety of properties. They are highly stable, safe, non-toxic, and hydrophilic and gel forming in nature. Pectins, starch, guar gum, amylase and karaya gum are a few polysaccharides commonly used in dosage forms. Non-starch, linear polysaccharides remain intact in the physiological environment of the stomach and the small intestine, but are degraded by the bacterial inhabitants of the human colon which make them potentially useful in targeted delivery systems to the colon[40].

Pectins

Pectins are non-starch, linear polysaccharides extracted from the plant cell walls. They are predominantly linear polymers of mainly (1-4)-linked D-galacturonic acid residues interrupted by 1,2- linked L-rhamnose residues with a few hundred to about one thousand

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building blocks per molecule, corresponding to an average molecular weight of about 50,000 to about 1,80 00040. Being soluble in water, pectin is not able to shield its drug load effectively during its passage through the stomach and small intestine.

Focus was shifted to the development of less soluble derivatives of pectin which get degraded by the colonic microflora. To overcome the drawback of high solubility of pectin, mixed films of pectin with ethyl cellulose were investigated as a coating material for colon-specific drug delivery. Polymeric hydrogels are widely used as controlled-release matrix tablets. Sungthongjeen et al.,[41]investigated the high-methoxy pectin for its potential value in controlled-release matrix formulations.

A very low solubility pectin-derivative (pectinic acid, degree of methoxylation (4%) was found to be well suited as an excipient for pelletization by extrusion/spheronization.

Musabayaneet al., [42] investigated the suitability of amidated pectin as a matrix patch for transdermal chloroquine delivery to mask the bitter taste when orally administered. In relation to the food industry, folic acid incorporated microcapsules were prepared using alginate and combinations of alginate and pectin polymers to improve stability of folic acid[43].

In relation to cosmetics, using citronellal as a model compound, pectin gel formulations were evaluated for controlled fragrance release by kinetic and static methods. Pectin/calcium microparticles are promising materials for controlled fragrance release[44].

Alginates

Alginates are natural polysaccharide polymers isolated from the brown seaweed (Phaeophyceae). Alginic acid can be converted into its salts, of which sodium alginate is the major form currently used. A linear polymer consisting of D-mannuronic acid and L-guluronic acid residues arranged in blocks in the polymer chain, these homogeneous blocks (composed of either acid residue alone) are separated by blocks made of random or alternating units of mannuronic and guluronic acids. Alginates offer various applications in drug delivery, such as in matrix type alginate gel beads, in liposomes, in modulating gastrointestinal transit time, for local applications and to deliver the bio molecules in tissue engineering applications[45] (fig. 3)

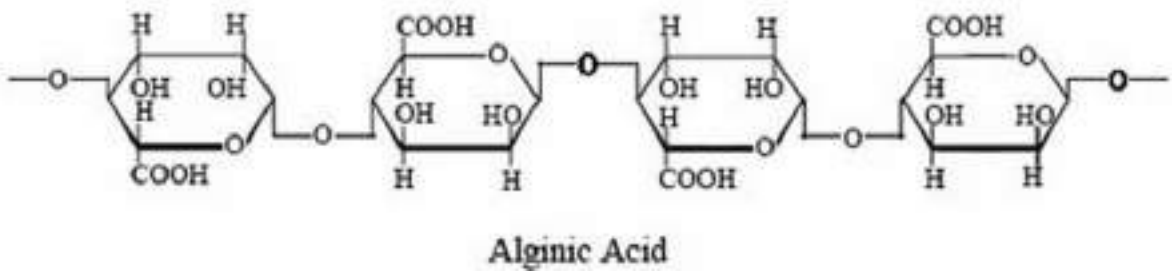

Fig. 3: Structure of Alginic acid

Bioadhesive sodium alginate microspheres of metoprolol tartrate for intranasal systemic delivery were prepared to avoid the first- pass effect, as an alternative therapy to injection, and to obtain improved therapeutic efficacy in the treatment of hypertension and angina pectoris.

A new insert, basically consisting of alginates with different hydroxyethylcellulose content was developed to maintain a constant drug level over a certain period in the eye, which cannot be achieved by conventional eye drop application [46]. To achieve 24 h release profile of water soluble drugs, sodium alginate formulation matrices containing xanthan gum or zinc acetate or both were investigated.

The helical structure and high viscosity of xanthan gum possibly prevent zinc ions from diffusing out of the ranitidine HCl sodium alginate-xanthan gum-zinc acetate matrix so that zinc ions react with sodium alginate to form zinc alginate precipitate with a cross-linking structure. The cross-linking structure might control a highly water-soluble drug release for 24 h[47].

In a comparative study, alginate formulation appeared to be better than the polylactide-co-glycolide (PLG) formulation in improving the bioavailability of two clinically important antifungal drugs-clotrimazole and econazole. The nanoparticles were prepared by the emulsion-solvent-evaporation technique in case of PLG and by the cation-induced controlled gelification in case of alginate[48].

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Volatile Oils

Volatile oils are generally mixtures of hydrocarbons and oxygenated compounds derived from these hydrocarbons. Many oils are terpenoid in origin; some of them are aromatic derivatives mixed with terpenes (e.g. cinnamon and clove). A few compounds (e.g. thymol and carvacrol) although aromatic in structure, are terpenoid in origin [49].

Starches

It is the principal form of carbohydrate reserve in green plants and especially present in seeds and underground organs. Starch occurs in the form of granules (starch grains), the shape and size of which are characteristic of the species, as is also the ratio of the content of the principal constituents, amylose and amylopectin [50]. Many starches are recognized for pharmaceutical use (fig. 4). These include maize (Zea mays), rice (Oryza sativa), wheat (Triticum aestivum), and potato (Solanum tuberosum)[51].

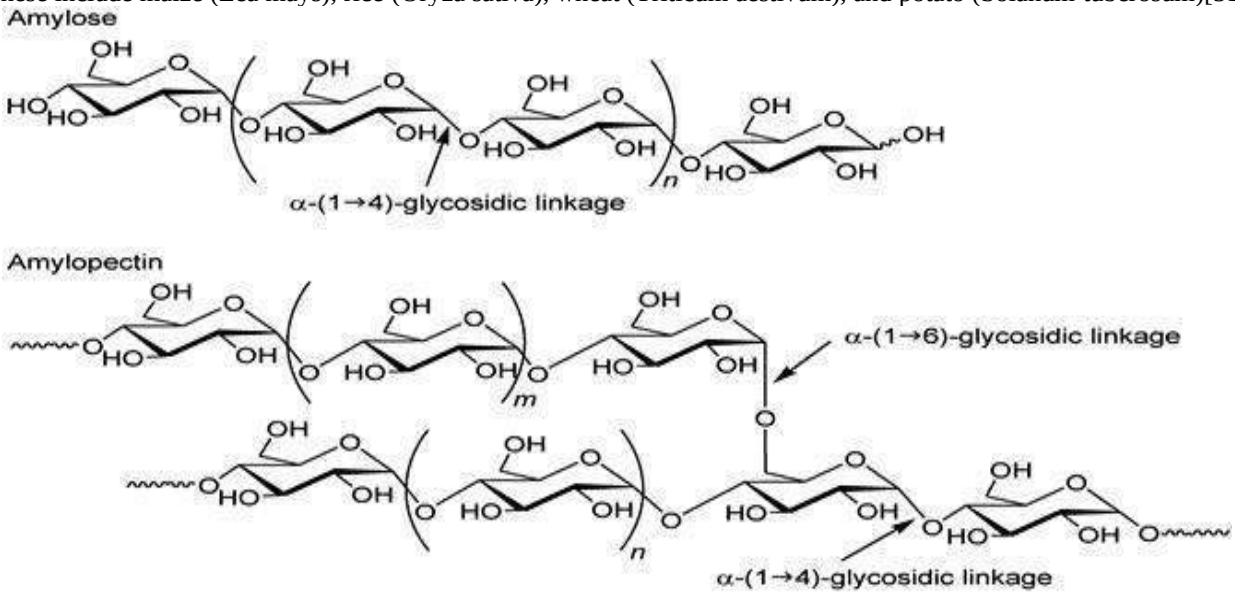

Fig. 4: Structures of (A) amylopectin or α- amylase and (B) β-amylose

Modified starch was tested for general applicability of a new pregelatinized starch product in directly compressible tablet controlled-release matrix systems. To deliver proteins or peptidic drugs orally, microcapsules containing a protein and a proteinase inhibitor were prepared[52].

Acetylating of starch considerably decreases its swelling and enzymatic degradation. Thus, starch-acetate (SA) based delivery systems were tested for controlled drug delivery [53].

Menthol

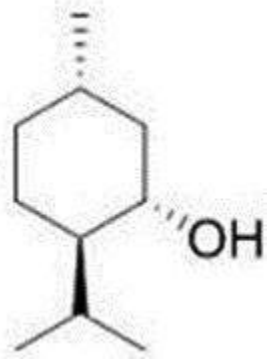

Fig. 5: Menthol

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Menthol is obtained by steam distillation of the flowering tops of Mentha piperitabelonging to the family Labiatae. A membrane - moderated transdermal therapeutic system (TTS) of nimodipine [54]using 2%w/w hydroxypropyl methylcellulose (HPMC) gel as a reservoir systemcontaining menthol as penetration enhancer and 60%v/v ethanol-water as solvent systemwas prepared.

Menthol was tested for improving the bioavailability of poorly water-soluble ibuprofen in the rectum with poloxamer [55]. Terpenes such as menthol, cineole and propylene glycol (PG) were tested as chemical enhancers to improve the skin penetration of propranolol. Release and skin permeation kinetics of propranolol from film preparations were examined in in vitro studies using a Franz-type diffusion cell. In vitro skin permeation studies showed that cineole was the most promising enhancer among the enhancers examined [56].

Caraway

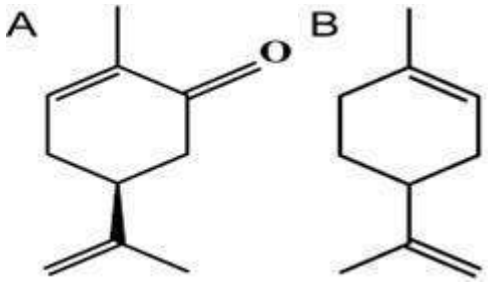

Fig. 6: a) Carvone b) Limonene

Caraway fruit consists of the dried, ripe fruits of Carum carvi (Umbelliferae) . The volatile oil consists of the ketone carvone (fig. 6) and the terpene limonene [49]. In another attempt, it was concluded that the limonene-based TTS of nicorandil provided the desired plasma concentration of the drug for the predetermined period with minimal fluctuations and improved bioavailability.

CONCLUSION

Today the stress is on patient compliance and to achieve this objective there is a spurt in the development of NDDS. As the herbal excipients are promising biodegradable materials, these can be chemically compatible with the excipients in drug delivery systems. In addition, herbal excipients are non-toxic, freely available, and less expensive compared to their synthetic counterparts. They have a major role to play in pharmaceutical industry. Therefore, in the years to come, there is going to be continued interest in the natural excipients to have better materials for drug delivery systems.

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A COMPREHENSIVE REVIEW ON THE EVALUATION TECHNIQUES AND STANDARDIZATION PARAMETERS OF CRUDE DRUG – CASSIA ANGUSTIFOLIA

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ABSTRACT

Cassia angustifolia, a member of the Fabaceae family, is known for its traditional medicinal value in treating various illnesses caused by pathogens. This study aims to evaluate the phytochemical properties and in vitro antimicrobial activity of Cassia angustifolia extracts, ranging from non-polar to polar solvents. Results indicate that the extracts contain significant amounts of secondary metabolites, with methanol proving to be the most effective solvent for extracting these compounds. All extracts contain detectable levels of phenols and flavonoids, with methanol extracts showing the highest concentrations, followed by water, acetone, and hexane extracts. The extracts also exhibit antimicrobial activity against various pathogenic bacteria and fungi, with methanol extract displaying the strongest effect, followed by water, acetone, and hexane extracts. Further research is recommended to enhance the development of plant-based drugs from Cassia angustifolia.

KEYWORDS: *Cassia angustifolia, secondary metabolites,HPTLC, antioxidant activity.*

INTRODUCTION

Cassia angustifolia, commonly known as senna, belongs to the Leguminosae family and is widely used for treating constipation in both Eastern and Western countries[1,2].The laxative properties of senna are attributed to the presence of two anthraquinone glycosides sennoside A and sennoside B. Additionally, C. angustifolia contains various other compounds, including rhein-8-diglucoside, sennosides C and D, rhein, rhein-8-glucoside, aloe-emodin, anthrone diglucoside, and naphthalene glycosides such as tinnevellin glycoside and 6-hydroxy musizin glycoside. It also includes kaempferol (a flavonoid), phytosterols, resin, and calcium oxalate [3,4].

Historically, the first variety of senna was discovered along the Nile River in Egypt and Sudan. Today, it is commercially cultivated in regions like Kutch (Gujarat) and Jodhpur (Rajasthan) in India. Senna can be grown as a perennial crop with a cultivation duration of approximately 2-3 years [2].

Taxonomical Classification [5]

Kingdom	Plantae
Sub division	Spermatophyta
Division	Magnoliophyta
Class	Magnoliopsida
Sub class	Rosidae
Order	Fabales
Family	Fabaceae/Leguminoceae
Genus	Cassia
Species	Angustifolia

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Medicinal Uses

Cassia angustifolia, commonly known as senna, is used medicinally for various treatments. It is effective in treating splenic enlargements, anemia, typhoid, and cholera as a febrifuge. Additionally, it serves as a blood purifier, an anthelmintic, and a remedy for constipation [5].Senna has also been included in the Indian Pharmacopoeia (I.P.) as a purgative due to the presence of active compounds such as rhein, aloe-emodin, kaempferol, and isorhamnetin [6].

MATERIALS & METHODS

Collection of Plant Material

Leaves of Cassia angustifolia were collected from the Seshachalam forest and authenticated by Dr. K. Madhava Chetty, Assistant Professor in the Department of Botany at Sri Venkateswara University (SVU), Tirupati, Andhra Pradesh. The collected plant material was thoroughly washed first with running water, followed by distilled water. The leaves were then separated from the stems, chopped, and left to dry under shade. The dried material was stored in sterilized polythene bags for further study [7].

Extraction Technique

The dried leaf material was powdered and subjected to sequential extraction using a Soxhlet apparatus with solvents of varying polarities, including hexane, acetone, methanol, and water [8].

The extracts were concentrated using a rotary evaporator, then dried and weighed to calculate the extractive yield. Finally, the dried crude extracts were stored in airtight bottles for further analysis [9].

Powdered drug was used for moisture content, ash values, swelling index, and fluorescence studies were carried out by treating 0.5 g of powdered drug with different reagents and observation in color was made in visible light, UV light of short (254 nm), and long wavelength (365 nm) under UV chamber. Photomicrography was performed using Olympus C7070 camera [10].

For Antioxidant Study: Preparation of plane material extraction: Cassia angustifolia leaves were grinded to fine powder by using electrical blender. The fine powder of 20 g was weighed separately and transferred to 250 ml of different solvent (petroleum ether, methanol and distilled water) were subjected to orbital rotary shaker for 24 h at 25 ºC at a speed of 150 rpm. Then the samples were centrifuged for 15 min at 2000 rpm at room temperature and are filtered through what man no 1 filter paper. The crude extracts of petroleum ether and methanol was evaporated through rotary evaporator at 60 ºC and 70 ºC respectively under constant pressure. While, aqueous extract was evaporated on hot plate at 100 ºC for 2 hours. The Crude plant extracts were stored at 4 ºC until further usage [11].

For HPTLC, 0.5 g of powdered seed samples from four different regions (DehraDun, Hyderabad, Jodhpur, and Mumbai) were separately refluxed with 5 ml of 50% methanol for 5 minutes on a water bath, then filtered. The filtrate was concentrated, and the extract was prepared in a known volume [12].

For analysis, 25 µl of each test solution was applied on a 10 x 10 cm precoated silica gel 60-F254 Merck TLC glass plate using a Camag Linomat IV applicator. Alongside the seed samples, Sennoside A (0.1 mg) and Sennoside B (0.55 mg) standards in isopropyl alcohol were also applied. The plate was developed to a distance of 8.7 cm at room temperature (33°C) using a solvent system of toluene: ethyl, acetate: methanol in the ratio of 85:15:0.5.

After development, the plate was sprayed with anisaldehyde–sulfuric acid reagent and heated at 120°C for 10 minutes, following the protocol by Wagner et al. (1984).

A fingerprint profile was then obtained using a Desaga Video Documentation Unit (Providoc II). Quantitative estimation of Sennosides A and B was performed with a Camag densitometric scanner.

Phytochemical Analysis

Preliminary Qualitative Screening of Cassia angustifolia

Standard screening tests were conducted on extracts of Cassia angustifolia to determine the presence or absence of various secondary metabolites.

The analysis included testing for alkaloids, steroidal compounds, phenolic compounds, flavonoids, saponins, tannins, and anthraquinones, following established procedures [13].

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1)Detection of Alkaloid
Extract was dissolved individually in dilute Hydrochloric acid and the resultant solution was clarified by filtration

Mayer's Test: Filtrate was treated with Mayer's reagent (Potassium Mercuric Iodide). Formation of a yellow colour precipitate indicates the presence of alkaloids

Wagner's Test: Filtrate was treated with Wagner's reagent (Iodine in Potassium Iodide). Formation of brown / reddish precipitate indicates the presence of alkaloids.

Dragendroff's Test: Filtrate was treated with Dragendroff's reagent (solution of Potassium Bismuth Iodide). Formation of red precipitate indicates the presence of alkaloids.

Hager's Test: Filtrate was treated with Hager's reagent (saturated Picric Acid solution). Presence of alkaloids confirmed by the formation of yellow coloured precipitate.

2) Detection of Phenols
Ferric Chloride Test: The filtered solution of extract was treated with three drops of freshly prepared 1% Ferric Chloride and Potassium Ferro cyanide. Formation of bluish- green colour is taken as positive.

3) Detection of Flavonoids
Alkaline Reagent Test: The Extract was treated with few drops of Sodium Hydroxide solution. Formation of intense yellow colour, which becomes colourless on addition of dilute HCl, indicates the presence of flavonoids.

Lead Acetate Test: The Extract was treated with few drops of Lead Acetate solution. Formation of yellow colour precipitate indicates the presence of flavonoids.

4) Detection of Anthraquinones
Free Anthraquinones Test (Borntrager's test): The extract of the plant material (equivalent to 100 mg) was shaken vigorously with 10 ml of Benzene, filtered and 5 ml of 10% Ammonia solution was added to the filtrate. The mixture was shaken and the presence of a pink, red, or violet colour in the ammonia (lower) phase indicates the presence of free anthraquinones.

5) Detection of Phytosterols
Salkowski's Test: The extract was dissolved in 2 ml Chloroform in a test tube. Concentrated Sulfuric Acid was carefully added unto the wall of the test tube to form a lower layer. A reddish brown colour at the interface indicates the presence of a steroid ring.

6) Detection of Terpenoids
The extract was added to 2 ml of Acetic Anhydride and Concentrated H_2SO_4. Formation of blue, green rings indicate the presence of terpenoids.

7) Detection of Tannins
Ferric Chloride Test: The extract was dissolved in water and the resultant solution was clarified by filtration to which 10 % Ferric Chloride solution was added to the clear filtrate. This was observed for a change in colour to bluish black.

Lead Acetate Test: The extract was dissolved in water and to that 10 % Lead Acetate solution was added. Appearance of yellow precipitate confirms presence of tannins.

Potassium Dichromate Test: The extract was dissolved in water and to it a strong potassium dichromate solution was added. Yellow colour precipitate indicates presence of tannins and phenolic compounds.
8)Detection of Reducing Sugars
Extract was dissolved individually in 5 ml distilled water and filtered. The filtrate was used to test for presence of carbohydrates.

Fehling's Test: Filtrates were hydrolysed with dilute HCl, neutralized with alkali and heated with Fehling's A & B solutions. Formation of red precipitate indicates the presence of reducing sugars.

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Keller Kiliani test (for deoxy sugars in cardiac glycosides): Fifty (50) mg of each extract was dissolved in 2 ml chloroform. H2SO4 was added to form a layer and presence of colour at interphase was noted. Brown ring at interphase is characteristic of deoxysugars in cardenolides.

Pharmacognostic evaluation of the plant:
The plant material was used for quantitative determination of physicochemical values. ash values, loss on drying, and extractive values of Cassia angustifolia [14].

Antioxidant Study
The antioxidant activities of aqueous and organic extracts of C. angustifolia and gallic acid were evaluated using the DPPH free radical scavenging test, based on IC50 values. IC50 represents the concentration required to inhibit 50% of DPPH free radicals. A lower IC50 value indicates higher antioxidant potential in the plant extracts [15].

To conduct the test, different extracts of C. angustifolia and standards were measured for absorbance at 517 nm, and the percentage of DPPH scavenging was calculated.

The extracts displayed dose-dependent antioxidant activities; as concentrations increased, so did their scavenging effectiveness.

The crude medicinal plant extract was diluted in methanol at concentrations of 5%, 10%, and 20%. For each concentration, 2 ml of the plant extract was added to 0.5 ml of 0.2 mmol/L DPPH ethanolic solution, with ascorbic acid used as a control. Each sample was tested in triplicate.
The reaction mixtures were incubated in the dark for 30 minutes, after which antiradical activity was measured with a UV spectrophotometer at 517 nm.

The DPPH scavenging effect was calculated as follows:

DPPH scavenging effect = ((A0 – A1)×100% /A0))
Where the AO of the control at 30 minutes, A1 the absorbance of the sample at 30 minutes [16].

RESULTS & DISCUSSION

Macroscopic Characteristics
Senna leaves are delicate and grayish-green with a specific odor and a mucilage-like, slightly bitter taste. The compound leaves consist of 5-8 pairs of oval-lanceolate leaflets, each measuring about 1.5-6.0 cm in length and 0.5-1.5 cm in width.. Senna produces the leaflets possess short and stout petioles, which may rarely break [4,17].The flowers of the Senna plant are large and yellow medium-sized, oblong-shaped pods containing flat, yellowish seeds [2].

Fig.1. Flower & Leaf of Cassia Angustifolia

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Fig.2. Leaves of Senna

Miroscopical Evaluation

The transverse section (T.S.) of the leaf shows an isobilateral structure, featuring paracytic stomata, nonlignified unicellular trichomes with warty walls, a fibrovascular bundle lined with abundant prisms of calcium oxalate, a 4-5 tiered palisade layer, and sclerenchyma. These structures are observed in the T.S. of the Cassia angustifolia leaf, as represented in the figure 3 above [17].

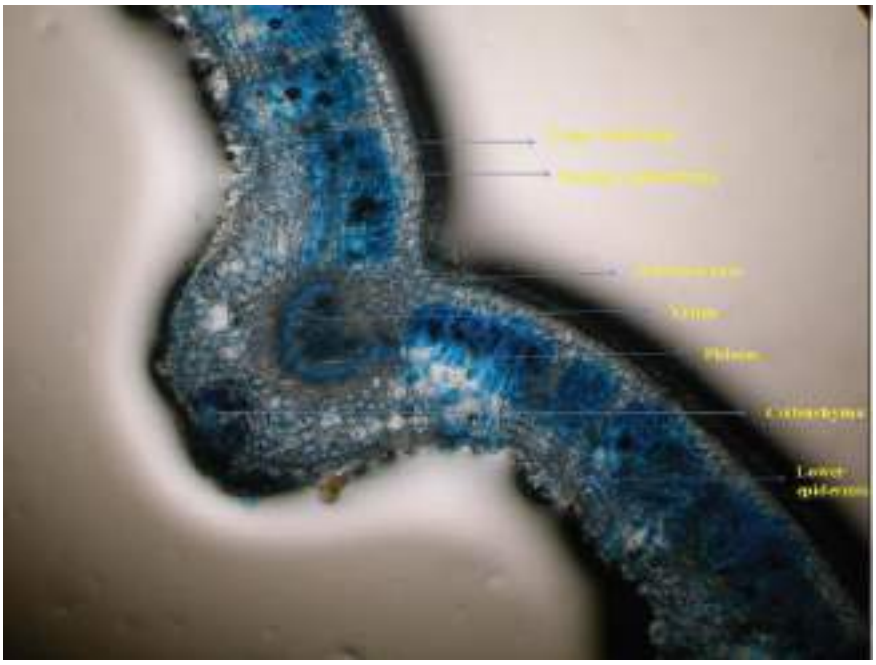

Fig.3.The transvers section of leaf of cassia angustifolia

Preliminary Screening

A preliminary qualitative analysis of the extracts provided initial information about the presence or absence of various metabolites in the plant extracts in table1 below.

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S.r. No.	Tests	Hexane Extract	Acetone Extract	Methanol. Extract	Water Extract
01.	***Alkaloids*:**				
	1. Mayer's Test	-	+	+	+
	2. Wagner's Test	-	+	-	+
	3. Dragendrof'fs Test	-	+	+	+
	4. Hager's Test	+	+	-	+
02.	***Phenolics*:**				
	1. Fecl2 Test	-	+	+	+
03.	***Flavonoids*:**				
	1. Leadacetate Test	-	+	+	+
	2. NaoH Test	+	+	+	-
	Anthraquinones:				
	1. Borntrager's Test	-	-	-	-
04.	***Phytosterols:***				
	1. Salkowski Test	+	+	+	+
05.	***Tannins:***				
	1. Fecl2 Test	-	+	+	+
	2. Lead acetate Test	-	+	+	+
	3. Pot. Dichromate Test	-	+	+	+
	4. Saponin Froth Test	-	-	+	-
06.	***Coumarin:***				
	1. NaOH Test	-	-	-	-
07.	***Reducing Sugars:***				
	1. Fehling' s Test	+	+	+	+
	2. Keller-Killani Test	+	+	+	+

(-): Negative (+): Positive

Table 1: Comparative Analysis of Phytochemical Analysis of Whole Arial Part Extracts of Cassia angustifolia .

The phytochemical screening results for hexane, acetone, methanol, and water extracts of Cassia angustifolia were summarized in the table above.These results revealed the presence of phenolics, steroids, alkaloids, flavonoids, and reducing sugars in all extracts of Cassia angustifolia. Polar solvent extracts (acetone, methanol, and water) showed the presence of tannins. Other metabolites, such as anthraquinones, saponins, anthocyanins, leucoanthocyanins, and coumarins, were completely absent in both nonpolar and polar extracts of Cassia angustifolia [13].

Physicochemical Parameters

The Cassia angustifolia (Linn.) leaf's physicochemical parameters are summarized below in table 2.

Analysis revealed a total ash content of 11.2%, indicating a significant presence of mineral and earthy components.

Further breakdown showed that 1.5% was acid-insoluble ash, while 4.7% was water-soluble ash, suggesting the presence of acidic compounds, sugars, and inorganic substances.

Moreover, drying the leaf at 105°C resulted in a 1.90% weight loss, indicating its moisture content [18].

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Table 2. Phisiochemical parameters of Cassia Angustifollia

Sr.No	Parameters	Values (%w/w)	Values (%w/w)	Values (w/w)	Mean±SD (% w/w)
01.	Total ash value	11.2	11.5	11.0	11.23±0.25
02.	Water-insoluble ash value	6.5	6.75	6.1	6.45±0.32
03	Water-soluble ash value	4.7	4.5	4.2	4.46±0.25
04.	Acid-insoluble ash value	1.5	1.3	1.4	1.4±0.1
05.	Loss on drying	1.90	1.8	1.9	1.86±0.05

Table 3. Extractive values of cassia angustifolia

Sr.No.	Solvent	Value (% w/w)	Value (% w/w)	Value (% w/w)	Mean±SD (% w/w)
01.	Water	16.5	16.9	16.4	16.6±0.26
02.	Ethanol	3.8	3.9	3.6	3.7±1.75
03.	Chloroform	0.8	0.9	0.8	0.83±0.05
04.	Petroleum ether	1.5	1.6	1.7	1.6±0.1
05.	Methanol	3.0	3.2	3.5	3.2±0.25

Successive extractive values of the Cassia Angustifolia using solvents Water, ethanol, chloroform, petroleum-ether and water, were determined and showed in table 3 found to be 16.6±0.26 %(w/w), 3.7±1.75 %(w/w), 0.83±0.05 %(w/w), 1.6±0.1 %(w/w) and 3.2±0.25 %(w/w) respectively [18].

Estimation of cassia Angustifolia By TLC (Thin Layer Chromatography):

Chromatographic parameter

Chromatography was performed by on glass packed silica gel 60 Gf254 HPTLC layers (20 cm ×20cm : 03mm layer thickness) prepared using a camag The plate Sample and standard compounds 1 and 2 of known concentration were applied at 8nm wide bands using Camag linomat automated TLC applicator with nitrogen flow from syringe [19].

Detection and Quantification

After completion of sample application the plate was developed in a camag twin through glass tonk presatu
rated with mobile phase of 2-propanol:ethyl acetate : water: formic aid (17:19:12:2) for one hour

The TLC runs were performed under laboratory Conditions of 25-27°C and 60% of relative humidity. After that played were taken off and dried by drier [20].

Sennosides A and B were quantified using a c TLC scanner model 3 equipped with camag loincasis software applying the following conditions:Slit width 6×0.5nm,wavelength 3500 nm absorption reflection scan mode.The identification of sennoside A and Sennoside B in formulations was confirmed bysuperimposing the UV spectra of samples and standards within Rf window [19,20].
The Rf value of sennoside A and Sennoside B is 0.991 and 0.997 respectively

Chemical Standardization through HPTLC

HPTLC studies were conducted to develop a characteristic gross HPTLC fingerprint profile that could serve as a marker for the quality evaluation and standardization of the drug.

In this study, eight chemical marker components were identified, with Rf values of 0.10, 0.21, 0.27, 0.32, 0.52, 0.58, 0.62, and 0.64, each displaying a characteristic color in all seed samples collected from different geographical zones across the country. (showed in table 3 and figure 4.)

Sennosides, the primary active components in Cassia angustifolia, have been previously studied in the leaves and pericarp of the fruit, though no data exists on their concentration in seeds. Because this study focused on the medicinal and commercial value of seeds, the

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percentage of sennosides was also measured. It was observed that sennoside B concentration was notably high in most of the samples [21,22].

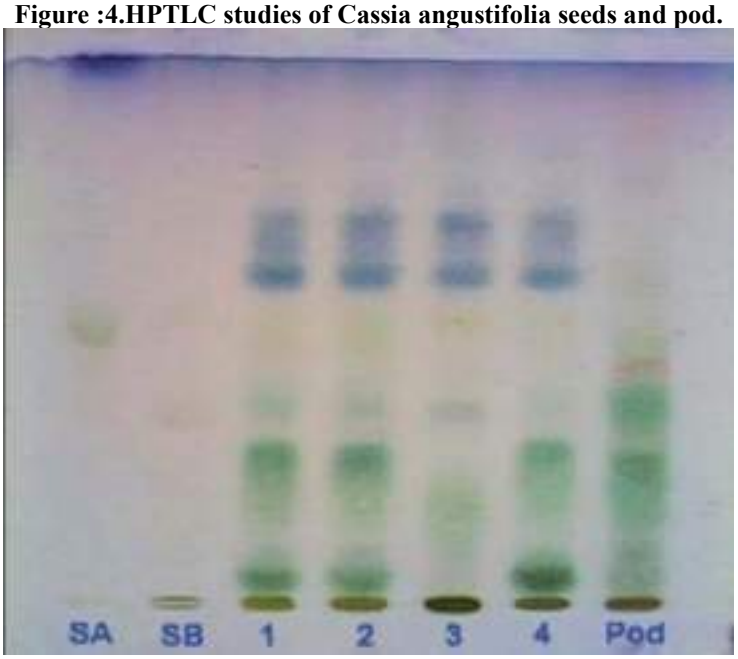
The plate in UV 254 and visible light after spraying with detecting. Reagent showed the presence of sennoside A and sennoside B at Rf of 0.52 and 0.32 respectively, in all of the seed samples [23].

Sennoside A and B, when qualitatively estimated,were found to be present in all the seed samples though their quantity varied from one region to another, possibly due to geographical variations.

The effect of different geographical zones on the concentration of sennosides (A and B) was also studied and showed in table below.

The concentration of sennoside A varied from 0.21% to 2.13% in seeds of different regions, while sennoside B showed a wide range of variation from 1.34% to 8.52% [21].

Figure :4.HPTLC studies of Cassia angustifolia seeds and pod.



(SA; Sennoside-A; SB; Sennoside-B; 1-Bombay; 2-Dehradun; 3-Hyderabad; 4-Jodhpur; Pod- Pod sample from Mumbai) Solvent system: Butanol: Acetic acid: Water (6:1:2)

Hyderabad seeds possessed a maximum of sennoside A (2.13%), which was least in the Bombay seeds,limited to just 0.219%. On the contrary, sennoside B was found to be maximum in the case of Jodhpur seeds(8.52%), which was about 7-times more than the seeds of Bombay, (i.e., 1.34%). Hyderabad seeds also possessed an appreciable concentration of sennoside B, 7.4%, while in Dehradun seeds the concentration was 3.95% [21,22].

Table 4: Quantitative HPTLC estimation of sennosides in C. angustifolia seeds of different zones in visible light after spraying

REFERENCE STANDARDS	MUMBAI		HYDERABAD		DEHRADUN		JODHPUR	
	Rf value	Colour	Rf value	Colour	Rf value	Colour	Rf value	Colour
	0.1	Green	0.1	Green	0.1		0.1	Green
	0.21	Yellowish green	0.21	Yellowish green	0.21	Yellowish green	0.21	Yellowish green
	0.27	Green	0.27	Green	0.27	Green	0.27	Green
Sennoside A	0.32	Greyish blue	0.32	Greyish blue	0.32	Greyish blue	0.32	Greyish blue

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Sennoside B	0.52	Light green	0.52	Light green	0.52	Light green	0.52	Light green
	0.58	Blue	0.58	Blue	0.58	Blue	0.58	Blue
	0.62	Blue	0.62	Blue	0.62	Blue	0.62	Blue
	0.64	Blue	0.64	Blue	0.64	Blue	0.64	Blue

TABLE 5 : Percentage concentration of sennoside A and B in seed samples of different geographical regions.

	DEHRADUN	HYDERABAD	JODHPUR	MUMBAI	PODS MUMBAI
Sennoside A	1.000%	2.134%	1.856%	0.219%	1.247%
Sennoside B	3.951%	7.446%	8.526%	1.348%	3.793%

Antioxidant Study

Radical scavengers present as antioxidants in products may directly react and quench with peroxide radicals and terminate the peroxidation chain reaction and improve the quality and stability of food product [24].

Cassia angustifolia has only high antioxidant potential at 5% concentration with petroleum ether and aqueous extracts, and the remaining concentration showed low antioxidant activity listed in table 6 [25].

The stable DPPH radical has been used to evaluate antioxidants for their radical quenching capacity.
The antioxidant activity of the plant extracts was examined on the basis of the scavenging effect on the stable DPPH free radical activity [26].

Table 6 : Antioxidant activity of plant extracts:

Sr.no	Solvent Extract	Conc. (µg/ml)	A. b (nm)	IC50%	Std. Ascorbic acid A. b (nm)
01.	Petroleum ether	5 10 15	0.405 0.376 0.360	24.015 74.439 86.327	0.533
02.	Methanol	5 10 15	0.117 0.252 0.291	78.048 82.868 88.947	1.471
03.	Distilled water	5 10 15	0.328 0.600 1.095	38.416 59.211 58.412	2.633

CONCLUSION

The present study conducted preliminary phytochemical and physicochemical investigations on Cassia angustifolia (C. angustifolia), focusing on its significant secondary metabolites, which are responsible for various pharmacological activities. These investigations are essential for drug identification and exploration of bioactive constituents in medicinal herbs. The phytochemical analysis of the ethanolic extract revealed the presence of flavonoids, glycosides, carbohydrates, and tannins, which contribute to multiple pharmacological effects, including anti-inflammatory, chemoprotective, antioxidant, antidiabetic, antianxiety, and antidepressant activities.

The identification and authentication of Cassia angustifolia seeds were carried out through macroscopic and microscopic studies, further confirmed by similar HPTLC profiles. Quantification of sennosides A and B revealed variations based on geographic location, with sennoside A ranging from 1.00% to 2.14% and sennoside B from 1.34% to 3.95%.

The antioxidant potential of Cassia angustifolia extracts was assessed using the DPPH free radical scavenging assay at three different concentrations (5, 10, and 20 µg/ml), demonstrating that this medicinal plant is a promising candidate as an antioxidant. This study supports the need for further in-depth assays of traditional herbal medicinal plants for potential use in pharmacological preparations

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HERBAL DRUG USED IN THE TREATMENT OF DIABETES MELLITUS

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ABSTRACT

Herbal drugs have gained significant attention in the treatment of diabetes mellitus due to their perceived safety and potential efficacy. This review explores the current landscape of herbal remedies used in managing diabetes, focusing on their mechanisms of action, clinical effectiveness, and safety profiles. Various herbs such as bitter melon, fenugreek, ginseng, and cinnamon have been studied for their antidiabetic properties, often targeting insulin sensitivity, glucose metabolism, and pancreatic function. Despite promising findings from preclinical and some clinical studies, rigorous scientific validation and standardization of herbal therapies remain essential to establish their efficacy and safety. Challenges including variability in active compounds, bioavailability issues, and potential herb-drug interactions necessitate caution in their use alongside conventional treatments. Nevertheless, herbal drugs represent a valuable adjunct or alternative in diabetes management, highlighting the need for further research to elucidate their full therapeutic potential.

KEYWORDS: *Medical Plant, India, Antioxiant, Diabetes.*

INTRODUCTION

Diabetes is a metabolic complaint marked by changes in the metabolism of proteins, lipids, and glucose that lead to hyperglycemia and inadequate insulin action or conflation. The Indian Council of Medical Research has linked it as one of the recalcitrant conditions for which diabetic remedy calls for a relief drug. Diabetes mellitus is a significant issue in the ultramodern world.The biochemical parameters of the poly herbal expression in diabetes calculated,including,hemoglobin,glycosylated,hemoglobin, high viscosity lipoprotein, low viscosity lipoprotein, glucose, urea, creatinine, serum cholesterol, and serum triglycerides. This product doesn't have a hypoglycemic effect, indeed if it did well in an oral glucose forbearance test. (1)

Biochemical markers significantly improved when herbal products were administered to diabetic rats. The current investigation suggests that the herbal material has anti-diabetic properties. The aging population, urbanization, increased rates of obesity, and physical inactivity are the main contributors to the diabetes epidemic, which is affecting an increasing number of people. Calculate the number of people with diabetes and the burden of the disease. Logical planning and resource allocation are essential for both diabetes prevention and treatment both now and in the future. Diabetes is a metabolic disorder characterized by insufficient production of insulin by the body, a hormone required for the conversion of sugar, starches, and other carbs into energy.[(2)]

Anomalous blood glucose levels are a hallmark of diabetes. In our everyday lives, we may come across a multitude of herbal plants. Both healthy and sick people consume these herbs as a food or source of nourishment. Plans based on herbs are readily available, affordable, and safe to consume raw or cooked. All other cures are subordinate to herbal medications.[(3)]

Due to the increased negative effects of many synthetic medications, particularly those used to treat diabetes, and their widespread use, herbal use has been increasingly popular in the past ten years. Glucagon-like peptide-1 (GLP-1), biguanide, sulfonylurea, thiazolidinediones, a-glucosidase inhibitors, dopamine-2 agonists, dipeptidyl peptidase 4 (DPP-4), and sodium-glucose cotransporter-2 (SGLT 2) inhibitors are only a few examples of the synthetic medication kinds that are available on the market.

However, prolonged ingestion will result in adverse effects such as cancer, hepatitis, allergies, etc. As a result, more people are turning to natural medicine for the treatment of disease because it is less hazardous than manufactured medications. "Let food be your medicine, and medicine be your food," was a saying we used to have. We now know that using natural sources to treat diseases will have many advantages because they are safer to eat.[(4)]

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Among the nations that have developed natural drug development is China, specifically with regard to traditional Chinese medicine (TCM). In China, a number of herbal remedies, including Panax ginseng, Momodica charantia, Lagenaria siceraria, and Psidium guajava, have been licenced for the treatment of diabetes. More than thirty TCM products, including Yuquan Wan, Xiaokeling Pian, Tangniaoling Pian, etc., are currently produced in China. These items have two or more natural ingredients that work synergistically. TCM products therefore have a substantial effect in reducing diabetes, up to 1.2 times more so than western medications. The main issue is that there is no set protocol for TCM consumption by diabetics. In light of this, a review of a few chosen herbals is essential as it will clarify everything before combining them to make products that resemble TCM.

It is hoped that the herbs would supplement or take the place of the prescribed synthetic diabetic medications. Therefore, the present review will examine various herbal remedies that may be used to treat diabetes, taking into account factors such as toxicity, potency, mechanism of action, and types of active compounds. Worldwide, these herbal plants have been utilised extensively in the treatment of diabetes. This review aims to evaluate several herbal plants as potential future prospects for TCM drugs with antidiabetic properties.[5]

Edidemioloy of Diabetes Mellitus

In developing nations, where many individuals with diabetes and pre-diabetes are still unidentified, the prevalence of diabetes and pre-diabetes is rising. When people with pre-diabetes lose even a small amount of weight, adopt a healthy balanced diet, and increase their physical activity levels, they can typically reverse the disease and their chances of developing diabetes by as much as 60%. The World Health Organisation estimates that in 2005, there were about 1.6 billion overweight adults and at least 400 million obese adults globally. By 2015, those numbers were expected to rise to 2.3 billion and 700 million, respectively.

Types of Diabetes Mellitus

Type 1 Diabetes: Previously known as juvenile onset diabetes or insulin-dependent diabetes mellitus (IDDM), type 1 diabetes may make up five to ten percent of all instances of diabetes that are diagnosed. Compared to Type 2 diabetes, Type 1 diabetes has less clearly identified risk factors; however, autoimmune, genetic, and environmental variables all have a role in the development of this form of diabetes.

Type 2 Diabetes: Previously known as adult-onset diabetes or non-insulin-dependent diabetes mellitus (NIDDM), type 2 diabetes is mostly caused by insulin resistance or abnormalities in insulin production. Between 76% and 85% of all instances of diabetes that are diagnosed are thought to be type 2 diabetes. Diabetes type 2 risk factors comprise advanced age, obesity, diabetes in the family, a history of gestational diabetes, reduced glucose tolerance, inactivity, and race/ethnicity.

Introduction of Herbal Medicine

How do herbal medicine work?

Every herbal plant has a unique active ingredient that has a medicinal effect. Many active chemicals are present in medicinal plants, and it is possible that these compounds combine to provide the intended synergistic therapeutic effect. A plant's active ingredients are influenced by the kind of environment it grew in (temperature, insects, soil quality), as well as by how and when it was harvested and processed. These factors are also crucial for the effectiveness of herbal medicine.

How are herbal medicine used?

The study of botany and the application of medicinal plants is called herbal medicine. Herbal medicine refers to the use of plants as a basis for medical treatment throughout most of human history. Together, these active chemical ingredients generate therapeutic effects and reduce the likelihood of any one component causing negative effects. A variety of herbs are frequently combined to increase potency, promote synergistic effects, and lessen toxicity. Herbalists have a lot of considerations to make when recommending herbs. For instance, the plant's genus, species, and diversity; its environment; and its handling, storage, and processing methods.

Classification of Antidiabetic Agent: Oral Hypoglycemic agent:

A. Drug acting by the release of insulin
B. Drug acting by other Mechanism
C. Biguanides :-E.g Metformin and Phenformin
D. Thiazolidinediones :-E.g Adiponectine
E. Alpha-Glucosidase inihibators
F. Exenatide and liraglutide
G. Dpp-4 Inihibators
H. Amylin Derivativess
I. D2 Agonist

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Common Herbal Drug Interaction in diabetes

Aloe Vera

Fig.1 Aloe vera

Aloe (Aloe Vera L., Liliaceous family) is used in health and beauty products and also has laxative, anti-inflammatory, antioxidant, and anti-cancer properties.[6] Lignin, salicylic acid, carbohydrates, vitamins, minerals, enzymes, and amino acids are among its seventy-five active components.[7] Aloe-emodin, aloe acid, anthranol, barb loin, manna and its derivatives, alkaline phosphates, amylase, bradykinase, carboxypeptidase, catalase, cyclooxidase, cyclooxygenase, lipase, oxidase, phosphoenolpyruvate, carboxylase, superoxide dismutase, 8-C-glusoly-(2′-O-cinnamoly), and 7-O-methlyal Auxins, Gibberellins, Calcium, Chlorine, Chromium, Copper, Iron, Magnesium, Steroids, Mannose, Glucose, L-Rhamnose, Aldopentose, Vitamin A, B12, C, E, Choline, and Folic acid have all been identified. Animal models with diabetes that received oral Aloe Vera leaf gel extract for 21 days showed improved glycoprotein metabolism.[8] Evidence suggests that aloe vera can be utilised to regulate the metabolism of glucose. Even so, studies on Aloe Vera have demonstrated its hypoglycemic properties. People who are susceptible to type 2 diabetes are becoming more numerous. On the one hand, basic, easily accessible treatments are required.[9]

Fenugreek

Fig.2 Fenugreek

Reducing the prevalence of prediabetics is a great way to lessen T2DM's impact on the planet. Our objective is to discover novel, highly efficacious therapeutic agents that are affordable, low-toxic, and able to be often provided to prevent the advancement of type 2 diabetes in the prediabetic population.[10] Therefore, using dietary supplements that might modify glucose homeostasis and potentially improve lipid properties would be excellent. While several herbs have been touted for their potential to prevent diabetes, fenugreek seeds (Trigonella foenumgraecum) rank among the best in terms of safety and efficacy, according to a substantial body of research and traditional usage.[11] Fenugreek seeds are excellent for those with diabetes and are a fantastic source of fibre. Research over the past 20 years has shown that fenugreek seeds can assist people with diabetes lower their blood glucose levels. Improved glucose tolerance in human volunteers and a drop in fasting blood glucose levels were indicative of its anti-diabetic efficacy.[12] Nutraceuticals containing fenugreek are advertised as having the ability to reduce blood sugar levels. For individuals who already exhibit abnormalities in their handling of glucose, an inexpensive, low-risk intervention centred on diet may be helpful in order to normalise the patient's metabolic environment. One dietary supplement that has shown promise in this regard is

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fenugreek. The hypoglycemic and hypolipidemic effects of fenugreek have been investigated in T2DM animal and human models; prediabetics have not been the subject of any research.[13]

Ginger

Fig.3 Ginger

Ginger, a widely used spice worldwide, is actually the subterranean rhizome of the Zingiber officinale plant, which belongs to the Zingiberaceae family. It has long been used as a herbal remedy for a variety of ailments, such as pain, cold-induced syndromes, nausea and vomiting, constipation, and indigestion (dyspepsia).[14] More lately, it was found that because it can scavenge hydroxyl and superoxide anion radicals, ginger possesses anti-inflammatory, anti-cancer, and anti-clotting properties. Ginger is known to contain a variety of compounds, including sesquiterpenes like beta-bisabolene and (-)-zingiberene, monoterpenes like geranial, volatile oils like gingerols, and the shogaols that result from their dehydration. Moreover, phytochemical research has shown that gingerol, shogaol, zingerone, and paradol are the main ingredients in ginger. 6-gingerol and 6-shogaol are said to be the two primary gingerols and shogaols present in the rhizome.[15] Ginger pretreatment stopped the development of hypoinsulinemia and produced hyperglycemia. Ginger has been shown by several researchers to reduce cholesterol. Other research indicates that the body's response to ginger varies depending on the dose concentration of its constituents. greater research may provide greater insight into ginger's efficacy in treating and preventing metabolic disorders, even though the validity of some published experimental investigations on its anti-oxidative, anti-diabetic, and hypolipidemic properties is questionable.[16] The goal of the study was to find out how supplementing with ginger powder affected the levels of malondialdehyde (MDA), apo B, apo A-I, apo B/A-I, haemoglobin A1c (HbA1c), and fasting blood sugar (FBS) in type 2 diabetes patients' serum.[17]

Garlic

Fig.4 Garlic

Garlic is one of the first cultivated plants in history and is used as a food and traditional medicine. Garlic extract has been demonstrated to benefit human health due to its antibacterial, antioxidant, anticarcinogenic, antimutagenic, antiasthmatic, immunomodulatory, and prebiotic properties. Previous research has demonstrated that in those with severe hypertension, it can control blood pressure and avoid cardiovascular events.[18] While the effects are still being studied, it might also help with primary

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prevention of colorectal cancer and cardiovascular mortality. Right now, one of the drugs with the most extensive research has been garlic extract. Many excellent randomised controlled trials (RCTs) have been carried out over the years to investigate its efficacy in treating type 2 diabetes.[19] Garlic's potential as a traditional food and medicine, as well as its many possible targets, wide distribution, low cost, and rare problems, were all to be demonstrated. However, because of the small sample size and unvalidated results, a comprehensive and quantitative study with high reliability is still needed.[20] To assess the safety and efficacy of supplements containing garlic in the management of type 2 diabetes mellitus (T2DM) on blood glucose levels and blood fluids, such as total cholesterol, triglycerides, HDL, and LDL regulation.[21]

CONCLUSION

Plants with medicinal properties are being used to treat a wide range of illnesses. Historically, people have employed plants for a variety of purposes. They meet more trustworthy standards when it comes to their use as a natural source of side-effect-free, longer-lasting medications. These characteristics have led to the increased use of plant-based medications in the treatment of diabetes in modern times. They come in the form of multi-herbal formulations, which are excellent for managing diabetes.

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DRUG THERAPY IN OBESITY CURRENT AND EMERGING TREATMENTS

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ABSTRACT
Obesity is a growing global health problem, leading to serious conditions like numerous chronic diseases, including type 2 diabetes, cardiovascular disease, and certain cancers. While lifestyle changes like diet and exercise are important, many people need medication to help with weight loss. Currently, several drugs are approved for treating obesity, including GLP-1 receptor agonists (e.g. naltrexone-bupropion,) and combinations like phentermine-topiramate. These medications help with weight loss by reducing hunger, increasing feelings of fullness, and improving metabolism. New treatments are also being developed, such as drugs that target different hormones or gene-based therapies, offering hope for even more effective solutions. This review covers the current obesity drugs, how they work, and what new treatments might be available in the future

KEYWORDS: *Amylin mimetics, Gherlin antagonist , GLP-1 receptor agonists,Leptin analogues,obesity*

1.INTRODUCTION[1]

Obesity are defined as abnormal or excessive fat accumulation that presents a risk to health.
The condition significantly increases the risk of developing chronic diseases, such as type 2 diabetes, cardiovascular disease, and certain cancers, resulting in substantial morbidity, mortality, and economic burden.
A body mass index (BMI) over 25 is considered overweight, and over 30 is obese.
These ranges of BMI are used to describe levels of risk:
1.Overweight (not obese), if BMI is 25.0 to 29.9.
2.Class 1 (low-risk) obesity, if BMI is 30.0 to 34.9.
3.Class 2 (moderate-risk) obesity, if BMI is 35.0 to 39.9.
4.Class 3 (high-risk) obesity, if BMI is equal to or greater than 40.0.

❖ **BMI Calculate Formula**

$$BMI = \frac{\text{Weight (in kilograms)}}{\text{Height}^2 \text{ (in meters)}}$$

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Fig.1 Obesity

Obesity is the modern epidemic, generally defined as a body mass index (BMI) of 30 kg/m² or higher, though a BMI of 27.5 kg/m² or more defines obesity in Indian populations. In 2022, 70 million adults in India were living with obesity, with nearly twice as many women as men: 44 million women and 26 million men. Among children aged 19 and under, 5.2 million girls and 7.3 million boys were obese.

Obesity costs India Rs 2.8 lakh crore a year, over 1% of its GDP, according to a study. Overweight and obesity, the two common lifestyle problems affecting nearly 17% of India's population, are estimated to be costing the country $35 billion (Rs 2.8 lakh crore) annually.

The obesity rate in India has risen significantly, from 1.2% in 1990 to 9.8% in 2022 for women, and from 0.5% to 5.4% in 2022 for men. A Lancet study reveals alarming obesity rates in India, with 70% of the urban population being overweight. India ranks third globally in obesity, following the US and China.

According to a report by IMARC, a market research company, the size of the weight management market in India reached Rs 1.72 lakh crore in 2022 and is expected to grow to Rs 3.15 lakh crore by 2028.

Globally, in 2022, 1 in 8 people were living with obesity. The global adult obesity rate has more than doubled since 1990, and adolescent obesity has quadrupled. In 2022, 2.5 billion adults (18 years and older) were overweight, of which 890 million were living with obesity.

A BMI of less than 18.5 suggests underweight, between 18.5 and 24.9 suggests a healthy weight range, between 25 and 29.9 may indicate overweight, and a BMI of 30 or higher may indicate obesity.

- **MEASUREMENT OF OBESITY**

1. BMI
2. Wait Hip Ratio
3. Skin Fold Thickness
4. Air Displacement Plethysmography
5. Total Body Electrical Conductivity

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➢ TYPES OF OBESITY[4]

1. Inactivity Obesity
2. Food and Stress Obesity
3. Anxiety Obesity
4. Venous Obesity
5. Gluten Obesity
6. Atherogenic Obesity

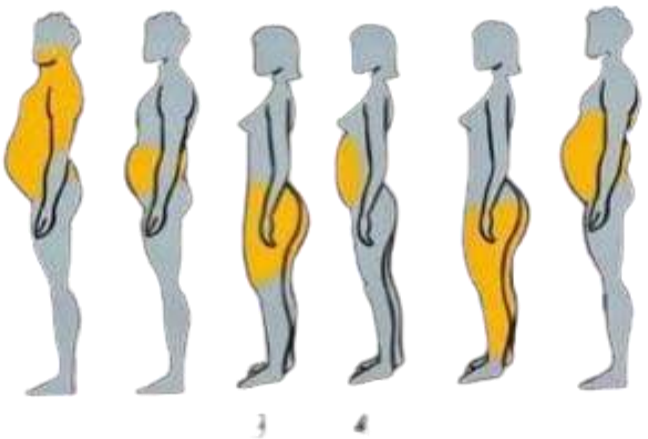

Fig.2 Types of Obesity

1. **Inactivity Obesity**
It is no secret that a lack of physical activity can cause you to become overweight. In this type of obesity, once-strong parts of the body quickly gain fat and become unhealthy.

2. **Food and Stress Obesity**
If you overeat, and particularly if you overindulge in unhealthy foods, you may suffer from food obesity.

Excessive sugar intake can also cause food obesity, which may lead to accumulation of fat around the middle part of the body.

3. **Anxiety Obesity**
Anxiety or depression can often lead to overeating and accumulation of fat in the body, since the body must constantly survive in fight-or-flight mode.

To treat this type of obesity, you must control your anxiety.

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4. **Venous Obesity**

Venous circulation is one obesity cause that is genetic in nature, rather than habitual in nature. This type of obesity is particularly common in pregnancy.

Exercise is the best solution for this problem.

5. **Gluten Obesity**

You are likely no stranger to the many health problems that gluten can cause. In fact, gluten can actually cause obesity.

This type of weight gain is most common in women.

6. **Atherogenic Obesity**

People whose fat tends to accumulate in the stomach area often suffer from Atherogenic obesity.

This is a particularly dangerous condition since it can affect your other organs and lead to breathing problems.

- **CAUSED BY OBESITY**

1.Types 2 Diabetes
2.Heart Disease
3.Hypertension
4.Stroke
5.Liver Disease

- **RISK FACTOR[5]**

Several Factors Are Responsible For Obesity :
1.Behavioral And Lifestyle Factors
2.Diseases
3.Mental Illness
4.Genetics

- **MANAGEMENT OF OBESITY[18]**

1.Healthy Eating
2 Exercise
3.Behavioral Changes
4.Medications
5.Bariatric Surgery
7.Monitor Progress

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2.LITERATURE SURVEY

1. Eka Molson et.al publish 1 February 2024: Obesity is a chronic disease associated with increased risk of obesity-related complications and mortality, the currently approved GLP-1 RA treatments.
2. P. Sumatran et.al 2 June 2024: The aim of this narrative review is to synthesize the available data describing the efficacy and safety of medications approved for obesity management and to provide an overview of upcoming agents in development.
3. Hae Woon et.al Jung 20 June 2024: In children and adolescents, the prevalence of overweight and obesity continues to increase, especially in classes II and III, and in younger toddlers and preschool aged children.
4. Mareana Abdel Malek et.al Published 30 May 2023: Substantial leaps have been made in the drug discovery front in tackling the growing pandemic of obesity and its metabolic co-morbidities.
5. David M. Williams et.al Published 15 April 2020: Whilst the prevalence of obesity continues to increase at an alarming rate worldwide, the personal and economic burden of obesity-related complications become severs more important.

3.AIM AND OBJECTIVE

❖ **AIM**

Drug Therapy In Obesity Current And Emerging Treatments

❖ **OBJECTIVES**

❑ Primary Objectives

1. To review the current landscape of pharmacological treatments for obesity.
2. To assess the efficacy and safety of emerging treatments.
3. To identify novel targets and mechanisms for obesity treatments.

❑ Secondary Objectives

1. To evaluate the clinical trials and regulatory approvals of current and emerging treatments.
2. To analyze the combination therapies and potential synergies.

❑ Specific Objectives

1. To examine the pharmacology and mechanisms of action of current treatments (e.g. Bupropion, phentermine-topiramate).
2. To investigate the efficacy and safety of emerging treatments (e.g., Amylin mimetics.)

4.PLAN OF WORK

Data Collection

Selection Criteria

a. Randomized controlled trials (RCTs), cohort studies, and meta-analyses focused on weight loss medications.
b. Studies that assess the impact on comorbid conditions, quality of life, and long-term weight management.
c. Pharmacokinetic and pharmacodynamic data on emerging therapies.

Data Analysis

Statistical analysis to compare the efficacy of different drugs based on weight loss outcomes (e.g., percentage of body weight lost, changes in BMI).

Safety analysis to evaluate the side effect profiles of existing and emerging treatments.
Subgroup analysis to identify which patient populations benefit the most from specific drug therapies.

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5.CURRENT AND EMERGING DRUG THERAPIES FOR OBESITY[8]:-

1. Bupropion/Naltrexone (Contrave, Mysimba)

Approved by the FDA in 2014, this combination of an opiate antagonist and a dopamine and noradrenaline reuptake inhibitor is intended for adults who are overweight or obese. It can lead to increased energy expenditure and reduced food intake.

Fig.3Bupropion/Naltrexone(Contrave,Mysimba)

2. Tirzepatide (Zepbound)

A dual agonist at GLP-1 and glucose-dependent insulinotropic peptide (GIP) receptors, this drug is administered as a weekly injection. It may reduce caloric intake, increase glucose and triglyceride uptake, and increase insulin sensitivity.

Fig.4 Tirzepatide (Zepbound)

3. Retatrutide

This drug has shown to be effective in reducing body weight and improving lipid profiles and blood pressure.

Other drugs that are currently approved for obesity treatment include: orlistat and phentermine/topiramate extended release.

Fig.5 Retatrutide

4. Orlistat

Orlistat is a selective inhibitor of pancreatic lipase, which thereby moderates the intestinal digestion and absorption of fat, approved for use both the FDA and EMA.

Fig.6 Orlistat

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Table 1 A comparison of approved weight loss therapies in obesity

Drug	Mechanism of action	Dosing	Approving bodies	Weight loss	Side effects
Naltrexone/bupropion	Dopamine and noradrenaline reuptake inhibitor (bupropion); Opioid receptor antagonist (naltrexone)	32 mg/360 mg 2 tablets Four times daily	FDA (2014) EMA (2015)	20-25% Body weight per year	Nausea/ vomiting, headache, dizziness
Tirzepatide (Zepbound)	Gastric inhibitory polypeptide) and GLP-1 (glucagon-like peptide-1) receptor agonist.	2.5 mg or 15 mg weekly	FDA (2022) EMA (2023)	12-22% Body weight per year	Nausea Vomiting Diarrhea
Retatrutide	GIP receptor agonist (gastric inhibitory peptide)	2.5mg or 5mg weekly	FDA (2022) EMA (2023)	15-20% Body weight per year	Nausea Vomiting Diarrhea
Orlistat	Pancreatic lipase inhibitor	60-120mg three times daily	FDA (1999) EMA (1998)	2.9-3.4% Body weight per year	Steatorrhea,fa ecal urgency

Compares the mechanism or action, dosing, efficacy and more common side effects of already approved drug therapies used to support weight loss in obesity.

➢ OTHER EMERGING THERAPEUTIC TARGETS[31]

1.Amylin Mimetics

Amylin is a neuroendocrine peptide co-secreted by pancreatic b-cells postprandially with insulin and acts to inhibit glucagon secretion, reduce gastric emptying and centrally induce satiety.

The amylin analogue pramlintide was licensed by the FDA in 2005 for patients with insulin-treated diabetes. Early studies reported that pramlintide use in people with insulintreated diabetes is associated with improved glycaemic control and may support weight loss by reducing food intake.

A subsequent trial in obese patients with either non-insulin treated T2D or without T2D found an additional mean weight loss of 3.7 kg versus placebo.

Co-administration of pramlintide with either the sympathomimetic sibutramine or phentermine was observed to result in 9.2 kg weight loss compared with placebo over 24 weeks,whereas pramlintide monotherapy resulted in just 1.5 kg additional weight loss.

2. Leptin Analogues

Leptin is a 167 amino acid secreted by white adipose tissue, which promotes satiety and increases energy expenditure via stimulation of hypothalamic POMC neurons and inhibition of neuropeptide Y neurons. Overfeeding and high total body fat stimulate release of leptin, whilst the fasting state and low-fat stores inhibit leptin secretion.

People with leptin gene mutations are obese secondary to pronounced hyperphagia and satiety and body weight can be regulated in people with these genetic mutations with leptin treatment.
As such,there is a good rationale for leptin analogues in the treatment of obesity.

3.Ghrelin Vaccines and Antagonists

Ghrelin is the only known orexigenic peptide hormone and is secreted by the stomach and proximal small intestine. Conversely to the hormone leptin, ghrelin stimulates neuropeptide Y neurons and inhibits hypothalamic POMC neurons .
As ghrelin induces hunger,inhibition of the ghrelin receptor represents an attractive therapeutic target in obesity.
Ghrelin receptor antagonists and vaccines have shown promise with reduced food intake and body weight in pre-clinical studies.

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6.EVALUATION TESTS[21]

1.Bupropion/Naltrexone (Contrave, Mysimba)

Fig.7 Bupropion/Naltrexone (Contrave, Mysimba)

Bupropion Tablet Evaluation Test

1. **Physical Appearance**
- **Shape, size, and color:** Check if the tablet looks as described (e.g., round, white, imprinted).
- **Surface quality:** Ensure tablets are smooth and free from cracks or chips.

2. **Weight Uniformity**
- **Test:** Weigh a sample of 20 tablets.
- **Pass Criteria:** The weight of each tablet should be close to the average (within ±5% of the average weight).

3. **Hardness Test**
- **Test:** Measure how hard it is to crush the tablet.
- **Pass Criteria:** The tablet should have enough strength to resist breaking, typically **4-8 kg**.

4. **Friability Test**
- **Test:** Tumble a sample of tablets to check if they break easily.
- **Pass Criteria:** Tablets should not lose more than **1%** of their weight.

5. **Disintegration Test**
- **Test:** Place tablets in water and see how long it takes for them to break apart.
- **Pass Criteria:** Tablets should disintegrate within **15-30 minutes**.

6. **Dissolution Test**
- **Test:** Measure how quickly the active ingredient (Bupropion) is released into a solution (mimicking stomach conditions).
- **Pass Criteria: >80%** of the drug should dissolve within **30 minutes**.

7. **Content Uniformity**
- **Test:** Check if each tablet contains the correct amount of Bupropion.
- **Pass Criteria:** The amount of Bupropion should be between **90-110%** of the stated dose.

8. **Stability Testing**
- **Test:** Store the tablets at different temperatures and check if they stay effective over time.
- **Pass Criteria:** The tablets should remain stable and not degrade significantly over their shelf life.

9. **Side Effects (Patient Monitoring*)***
- **Test:** Monitor patients for any unwanted effects (e.g., insomnia, dry mouth).
- **Pass Criteria:** Side effects should be manageable and not severe in most patients

➢ Sure! Here's a **simplified evaluation test** for **Bupropion tablets** in a pharmaceutical context. This focuses on basic quality control and performance tests to ensure the tablet is safe and effective:

➢ COMBINATION WITH MEDICATION[12]

A treatment plan for obesity typically includes a combination of diet, exercise, and lifestyle changes:-

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1. DIET

Fig.8 Diet

Reduce the number of calories you consume each day. A low-calorie diet can involve reducing your daily caloric intake by 500–1000 kcal/day. You can also try eating more slowly and being mindful of what and when you eat.

2. EXERCISE

Fig.9 Exercise

Get at least 150 minutes a week of moderate-intensity physical activity. This could include activities like walking, jogging, swimming, or tennis**.**

3. EVERYONE CAN TAKE STEPS TO:

A. Eat healthy foods and drink healthy beverages.
B. Get the recommended amount of physical activity.
C. Get enough sleep.
D. Manage stress.
E. Talk to your health care provider about whether weight is a health concern.

Your plan will likely include reducing the number of calories you eat each day, getting more physical activity, and adopting lifelong healthy lifestyle changes. The goal of your treatment plan is to reduce your risk of obesity-related complications and improve your quality of life.

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7. SCOPE OF THE STUDY

This review covers the current and emerging drug treatments for obesity. It looks at the medications that are already approved, such as GLP-1 receptor agonists (like bupropion-naltrexone) and combinations like prevention, focusing on how they help with weight loss and improve metabolic health. It also discusses new treatments being developed, including drugs that target different hormones or genes, offering hope for more effective solutions. The review aims to explain how these treatments work, their benefits, and their potential for helping people who struggle with obesity, especially those who haven't had success with diet and exercise alone. It also considers safety and how different therapies might work together in the future.

8.CONCLUSION

- The obesity pandemic continues to grow at an alarming rate. Because lifestyle modifications have been limited in their success in weight loss maintenance, pharmacotherapy plays an important role in achieving clinically significant weight loss and preventing the development or exacerbation of comorbid conditions.
- Obesity is a chronic, relapsing, multifactorial disease, which has become a serious threat to public health globally, and is associated with a higher incidence of a number of diseases, including CVD, T2DM and cancer.

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ROLE OF PHARMACISTS IN HEALTHCARE SERVICES, FOCUSING ON THEIR CONTRIBUTIONS TO PATIENT CARE, MEDICATION MANAGEMENT, AND INTERDISCIPLINARY HEALTHCARE TEAMS

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ABSTRACT

During the last few years, the pharmacy profession has expand significantly in terms of professional services delivery and now has been recognized as an important profession in the multidisciplinary provision of health care. The paper highlights the current scenario The Pharmacy profession in health care system. Pharmacist is a backbone that strengthens to health care system. Different roles of Pharmacist in different sectors of pharmacy profession like Industrial, academic s, community health, clinical research, drug design and discovery, developing NDDS etc. In nutshell pharmacist play an integral part of health care system. "Physician gives medicine to the patients but life to medicine given by pharmacist.

Global healthcare expenditure is escalating at an unsustainable rate. Money spent on medicines and managing medication-related problems continues to grow. The high prevalence of medication errors and inappropriate prescribing is a major issue within healthcare systems, and can often contribute to adverse drug events, many of which are preventable. As a result, there is a huge opportunity for pharmacists to have a significant impact on reducing healthcare costs, as they have the expertise to detect, resolve, and prevent medication errors and medication-related problems. The development of clinical pharmacy practice in recent decades has resulted in an increased number of pharmacists working in clinically advanced roles worldwide. Pharmacist-provided services and clinical interventions have been shown to reduce the risk of potential adverse drug events and improve patient outcomes, and the majority of published studies show that these pharmacist activities are cost-effective or have a good cost:benefit ratio. This review demonstrates that pharmacists can contribute to substantial healthcare savings across a variety of settings. However, there is a paucity of evidence in the literature highlighting the specific aspects of pharmacists' work which are the most effective and cost-effective. Future high-quality economic evaluations with robust methodologies and study design are required to investigate what pharmacist services have significant clinical benefits to patients and substantiate the greatest cost savings for healthcare budgets.

INTRODUCTION

The role of pharmacists has significantly expanded over the past few decades. As healthcare providers, pharmacists are increasingly involved in direct patient care, medication management, and chronic disease management. This paper explores the various dimensions of pharmacists' contributions to healthcare services.

Pharmacists have long been recognized as essential members of the healthcare team, playing a pivotal role in ensuring the safe and effective use of medications. Traditionally seen as dispensers of drugs, the role of pharmacists has evolved significantly over the years. In modern healthcare systems, pharmacists are now vital contributors to patient care, public health, and collaborative healthcare practices. Their expertise in pharmacotherapy, medication management, and patient education positions them as critical healthcare providers, directly influencing patient outcomes and the overall quality of care.

Pharmacists also contribute significantly to public health initiatives, such as vaccination programs, tobacco cessation, and the management of antimicrobial resistance. In recent years, advancements in technology, such as telepharmacy and the use of health informatics, have further enhanced the ability of pharmacists to reach and provide care for patients remotely.

Despite these advances, pharmacists face challenges, including regulatory restrictions, time constraints, and varying levels of recognition in different healthcare systems. However, as healthcare continues to evolve, pharmacists are increasingly being acknowledged for their critical role in ensuring medication safety, improving health literacy, and contributing to overall patient well-being.

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The focus of profession of pharmacy has shifted from technical, product oriented, functions to patient oriented, health outcomes counseling information and professional services. This shift, generally referred to as "Pharmaceutical Care", embarrasses the nation that pharmacist, working in collaboration with other health care providers, undertake responsibility for patient outcomes with respect to their drug therapy.

According to WHO "Health is complete physical, mental and social well-being and not merely absence of disease. According to ayurveda swath's health is defined as "well balance metabolism. Happy state of being senses and mind. In spite of short coming in the WHO difference the Concept of the health is wide and positive and provides an overall goal towards which nations. Should march. "Well Health "of citizens leads to socially and economically protective life that's. Why health for all every nation
1. Health is an integral part of the development
2. Health is intersect oral
3. Health is central to the concept of quality of life hence, health is world Wide social-goal. To achieve this goal every nation sets professional persons in healthcare System.

Pharmacists can enhance the health of individuals through the art and skill of compounding. Through compounding, the pharmacist partners with prescribers and patients to meet unique medication needs that are not met by commercially available products. Compounding is an age old art of the profession of pharmacy, which is utilized today to provide personalized medication therapies. In her commentary, Burch [8] describes patient care needs that can be met by compounding as well as reviews some of the regulations and best practices governing pharmaceutical compounding

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AIM AND OBJECTIVE

AIM

Role Of Pharmacists in healthcare services, focusing on their contributions to patient care, medication management, and interdisciplinary healthcare teams.

OBJECTIVE

- To explore the traditional and modern roles of pharmacists in healthcare services.
- To analyze the impact of pharmacists on patient outcomes, medication safety, and overall healthcare quality.
- To discuss the integration of pharmacists into interdisciplinary healthcare teams and their contributions to collaborative care.
- To assess the role of pharmacists in public health initiatives, such as vaccination campaigns, health education, and preventive care.
- To explore collaborative practices between pharmacists and other healthcare professionals in interdisciplinary teams.
- To identify challenges and opportunities for expanding the role of pharmacists in healthcare systems.
- To provide recommendations for policy and practice changes that can further integrate pharmacists into the healthcare team to improve patient outcomes.

Traditional Roles of Pharmacists

1. Dispensing Medications

Dispending medication refers to the process of providing patients with prescribed medication ,ensuring ,accurate and safe delivery Pharmacists have long been responsible for accurately preparing and dispensing medications prescribed by physicians. This includes verifying prescriptions, ensuring the correct dosage, and packaging the medications appropriately for patient use.

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Dispensing Medication Types:
1. Prescription medications
2. Over-the-counter (OTC) medications
3. Controlled substances
4. Specialty medications
5. Compounded medications

2. Compounding Medications

Compounding medication involves preparing customized medications for patients who require specific formulations, strengths, or delivery systems not commercially available.

In earlier times, pharmacists were heavily involved in the compounding of medications, which involved the preparation of customized medications by combining or altering ingredients to fit the specific needs of individual patients.

Types of Compounding:
1. Sterile Compounding: Preparing medications in a sterile environment, typically for injectable or intravenous administration.
2. Non-Sterile Compounding: Preparing medications for oral, topical, or other routes of administration.
3. Compounded Pharmaceuticals: Creating customized medications from raw ingredients.

3. Medication Supply Management

Medication supply management refers to the systematic process of procuring, storing, distributing, and controlling medications within healthcare settings.

Pharmacists traditionally have the responsibility to maintain an adequate supply of medications in their pharmacies. They manage the inventory, ensuring medications are stored correctly and are within their expiration dates.
1.Ensure medication availability and accessibility
2. Maintain medication quality and safety
3. Optimize medication inventory and reduce waste
4. Control medication costs and budget
5. Ensure compliance with regulations and standards.

4. Patient Counseling

Patient counseling is a communication process between a healthcare professional (e.g., pharmacist, nurse, physician) and a patient, focusing on educating and empowering the patient to manage their health, medications, and lifestyle.

While dispensing medications, pharmacists also provide basic patient counseling, informing patients about their medications' proper use and possible interactions with other drugs. This role has been essential for ensuring medication adherence and minimizing adverse effects.
1. Improve patient understanding of medications and treatments
2. Enhance medication adherence and compliance
3. Promote lifestyle modifications and healthy behaviors
4. Address patient concerns and questions
5. Foster a therapeutic relationship between patient and healthcare provider.

MEDICATION THERAPY MANAGEMENT (MTM) AND PHARMACOVIGILANCE

1. Definition and Concept

Medication Therapy Management (MTM) is a patient-centered service provided by pharmacists aimed at optimizing drug therapy and improving therapeutic outcomes. It involves a thorough review of a patient's medications, ensuring that they are appropriate, safe, and effective. MTM is designed for patients who are on multiple medications, have chronic diseases, or are at risk of adverse drug events (ADEs) due to complex medication regimens.

Medication Therapy Management (MTM) is a patient-centered service provided by pharmacists and other healthcare professionals to optimize medication use, improve health outcomes, and reduce healthcare costs.
MTM Process:
1. Patient selection and identification
2. Medication review and assessment
3. Identification of medication-related problems (MRPs)
4. Development of a care plan

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5. Implementation and monitoring
6. Follow-up and evaluation

Medication-Related Problems (MRPs):
1. Adverse reactions
2. Allergic reactions
3. Medication interactions
4. Dosing errors
5. Non-adherence
6. Ineffective therapy

Medication Therapy Review (MTR)

Medication Therapy Review (MTR) is a systematic process where a healthcare professional, typically a pharmacist, reviews a patient's medications to optimize therapy, improve health outcomes, and reduce medication-related problems**.**

A comprehensive review of all medications (prescription, over-the-counter, and herbal) a patient is taking. The goal is to identify and resolve any medication-related problems (e.g., drug interactions, improper dosage, unnecessary medications).

Types of MTR:
1. Comprehensive Medication Review (CMR)
2. Targeted Medication Review (TMR)
3. Focused Medication Review (FMR)
4. Medication Reconciliation Review (MRR)

Benefits:
1. Improved medication adherence
2. Enhanced patient safety
3. Reduced medication errors
4. Improved health outcomes
5. Cost savings
6. Improved patient satisfaction

Personal Medication Record (PMR): A detailed record of all medications a patient is taking, which can be shared with other healthcare providers and used by the patient for self-management.

A Personal Medication Record (PMR) is a comprehensive document that lists a patient's current medications, dosages, and instructions for use. Pharmacists play a crucial role in maintaining and updating PMRs to ensure accurate and safe medication management.

Components of a PMR:
1. Patient demographics
2. Medication list (prescription and over-the-counter)
3. Dosage and frequency
4. Route of administration
5. Duration of therapy
6. Allergies and sensitivities
7. Medical conditions
8. Laboratory results (relevant to medication therapy)

Medication-Related Action Plan (MAP): A Medication-Related Action Plan (MAP) is a personalized plan developed in collaboration with patients, pharmacists, and healthcare providers to manage medications, address medication-related problems, and improve health outcomes.

A patient-specific plan that outlines actionable steps for managing their medications, improving adherence, and achieving therapeutic goals.

Pharmacist's Role in MAP:
1. Conduct medication reviews and reconciliations
2. Identify MRPs and develop action plans
3. Collaborate with healthcare providers

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4. Educate patients on medication use and safety
5. Monitor and adjust MAPs as needed.

2. Benefits of MTM

Improved Patient Outcomes: MTM helps reduce hospitalizations and emergency room visits by preventing medication errors, improving adherence, and optimizing treatment regimens.

Cost Savings: By reducing adverse drug reactions, duplicate therapy, or unnecessary medications, MTM can lower healthcare costs for both patients and the healthcare system.

Enhanced Medication Adherence: Through counseling and education, pharmacists help patients understand the importance of taking their medications as prescribed, leading to better adherence.

Better Disease Management: Better disease management refers to a comprehensive approach to managing chronic conditions, focusing on preventing complications, improving quality of life, and reducing healthcare costs.

PHARMACOVIGILANCE

1. Definition and Purpose

Pharmacovigilance refers to the science and activities related to detecting, assessing, understanding, and preventing adverse effects or other drug-related problems. Its primary aim is to ensure the safety of medicines throughout their lifecycle, from development to post-marketing surveillance.

It plays a vital role in ensuring that the benefits of medications outweigh their risks, thus protecting public health.

Adverse Drug Reaction (ADR) Reporting: Pharmacovigilance is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

One of the most important tasks in pharmacovigilance is collecting and reporting adverse drug reactions. Pharmacists, as accessible healthcare professionals, play a key role in detecting and reporting these reactions to national or global databases (e.g., the World Health Organization's VigiBase or the FDA's MedWatch).

Adverse Drug Reaction (ADR) Reporting

1. Identification of adverse events
2. Collection and evaluation of data
3. Reporting to regulatory authorities
4. Analysis and assessment of ADRs
5. Implementation of risk management strategies

Benefits of ADR Reporting**:**

1. Improved patient safety
2. Enhanced drug efficacy and safety
3. Reduced medication errors
4. Informed regulatory decisions
5. Better public health outcomes

Risk Assessment and Management: Once a potential risk or adverse event is identified, pharmacovigilance teams assess its severity and frequency. Based on this, they develop strategies to manage or mitigate the risk (e.g., adjusting dosages, issuing warnings, or recalling the drug).

Risk Assessment:

1. Identification of potential risks
2. Evaluation of risk likelihood and impact
3. Prioritization of risks
4. Documentation of risk assessment

Regulatory Actions: Pharmacovigilance findings often lead to changes in drug labeling, restrictions on use, or in extreme cases, the withdrawal of a drug from the market.

Pharmacist's Role in Regulatory Action:

1. Medication Safety Surveillance
2. Adverse Event Reporting
3. Quality Control and Assurance
4. Compliance with Regulations
5. Patient Counselling and Education

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Education and Communication: Pharmacovigilance involves educating healthcare professionals and the public about drug risks and safety. This includes issuing safety alerts, providing updated prescribing information, and developing risk minimization plans.
Communication:
1. Patient Counselling: Medication information, side effects, interactions
2. Healthcare Provider Communication: Medication recommendations, therapy changes
3. Patient-Pharmacist Communication: Building trust, understanding
4. Inter professional Communication: Collaborative care, patient-centered care
5. Health Literacy: Clear, simple language, cultural sensitivity

The Role of Pharmacists in Multidisciplinary Teams

Pharmacists bring their expertise in pharmacology, medication management, and patient counseling to multidisciplinary teams. Their roles in such teams include:

A. Medication Expert

Therapeutic Decision-Making: Pharmacists provide recommendations on medication selection, dosing, and administration, ensuring that the chosen therapy is both effective and safe for the patient. This is especially critical in complex cases where polypharmacy (multiple medications) is involved.

Drug Interaction Prevention: Pharmacists review patients' medication lists to detect potential drug-drug, drug-food, or drug-disease interactions that may lead to adverse effects.

B. Medication Reconciliation

Pharmacists are responsible for conducting medication reconciliation at key transition points in care, such as hospital admission, transfer, and discharge. This ensures consistency in the medications patients receive, preventing medication errors, omissions, duplications, or inappropriate therapies.

C. Chronic Disease Management

Pharmacists assist in managing chronic conditions like diabetes, hypertension, asthma, and cardiovascular diseases by optimizing medication regimens, ensuring adherence, and monitoring therapeutic outcomes. In some cases, pharmacists may have collaborative prescribing authority to adjust medication doses or therapies.

D. Educators and Counselors

Pharmacists educate both patients and healthcare team members on proper medication use, potential side effects, and the importance of adherence. They also offer counseling on lifestyle changes, the use of medical devices (e.g., inhalers, and insulin pens), and the management of side effects.

E. Pharmacovigilance and Safety Monitoring:

As part of the healthcare team, pharmacists monitor and report adverse drug reactions and side effects, contributing to ongoing pharmacovigilance efforts. This allows for timely interventions and adjustments to therapy to avoid harm.

Pharmacist-Patient Interaction

Improved Medication Adherence: One of the most significant roles of the pharmacist is ensuring that patients take their medications correctly. Through regular interaction, pharmacists educate patients on the importance of adherence, the correct use of medications, and strategies to overcome challenges (e.g., side effects or complex dosing regimens).

Patient Education: Patient education is the process of informing and teaching patients about their health, medications, and self-care to promote informed decision-making and improved health outcomes.

Pharmacists educate patients about their health conditions, treatment options, potential side effects, and lifestyle modifications. This empowers patients to make informed decisions about their health and medications.

Building Trust: A strong, trusting relationship between pharmacists and patients enhances communication. Patients are more likely to disclose relevant information about their health, allowing pharmacists to provide better care.
Pharmacist's Skills:
1. Communication and interpersonal skills
2. Empathy and active listening
3. Cultural competence and awareness
4. Critical thinking and problem-solving
5. Adaptability and flexibility

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Communication Skills: Effective pharmacist-patient interaction relies heavily on the pharmacist's communication skills. Pharmacists must be able to explain complex medical information in simple, understandable terms, tailoring their communication style to meet the patient's needs.

Improving Communication Skills:
1. Practice self-awareness
2. Seek feedback
3. Engage in role-playing
4. Attend workshops and training
5. Join communication-focused groups
6. Read communication-related literature
7. Reflect on past interactions.

Active Listening: Pharmacists need to actively listen to patients' concerns, questions, and symptoms. This helps in identifying issues such as medication side effects, adherence challenges, or potential drug interactions.

Challenges and Barriers

A. High Workload in Community Pharmacies

Pharmacists, particularly in high-volume community pharmacies, often face heavy workloads and high patient volumes. This can reduce the time they have available for thorough counseling sessions, especially if their primary focus is on dispensing medications. Limited Time for Counseling: As a result of these time pressures, pharmacists may not always have enough time to engage in detailed consultations or address all patient concerns. This can lead to brief, transactional interactions that focus on medication dispensing rather than holistic patient care.

B. Hospital and Clinical Settings

In hospital settings, clinical pharmacists may also experience time constraints, especially when dealing with multiple patients across different departments. The complexity of medication regimens, combined with limited time, can make it challenging to offer in-depth consultations for each patient.

C. Side Effects and Fear of Medications

Concerns about potential side effects can discourage patients from adhering to their prescribed treatments. Some patients may discontinue medication use without consulting their pharmacist, leading to treatment failure or worsening health conditions.

D. Complex Treatment Regimens

Polypharmacy (the use of multiple medications) is common among patients with chronic conditions, particularly the elderly. Complex regimens, including multiple doses per day or different medications with specific administration requirements, can confuse patients and lead to non-adherence.

E. Financial Barriers

The cost of medications can also be a significant barrier to adherence. Some patients may ration their medications, take lower-than-prescribed doses, or skip doses altogether to save money. Pharmacists may not always have the opportunity to address these concerns during brief interactions.

F. Language Barriers

Language differences between pharmacists and patients can pose significant challenges, particularly in areas with diverse populations. Patients with limited proficiency in the dominant language may have difficulty understanding instructions or communicating their concerns. Without access to translators or multilingual materials, effective pharmacist-patient interaction is compromised.

Future Perspectives

1. Pharmacists as Primary Care Providers:
   There is growing recognition of the value pharmacists bring as direct care providers, particularly in the management of chronic diseases like diabetes, hypertension, and asthma. In the future, pharmacists are likely to take on more primary care roles, particularly in underserved areas where there is a shortage of healthcare providers.
2. Advanced Pharmacy Practice:
   As the healthcare system shifts toward preventive care, pharmacists will increasingly play a role in public health initiatives, such as health screenings, vaccinations, and smoking cessation programs. In addition to dispensing medications, pharmacists will focus on wellness and disease prevention.

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3. Growth of Telepharmacy:
   Telepharmacy services are expected to expand significantly, especially in rural or underserved areas where access to healthcare providers may be limited. Through telepharmacy platforms, pharmacists can provide virtual consultations, monitor chronic conditions, and offer medication therapy management (MTM) services to patients remotely.
4. Integration with Digital Health Tools:
   Future pharmacist-patient interactions will be enhanced by digital health tools like mobile apps, wearable health devices, and artificial intelligence (AI)--powered platforms. These tools can track patient health data, remind patients to take medications, and notify pharmacists of potential issues (e.g., missed doses, and adverse drug reactions).
5. Use of Artificial Intelligence (AI) and Big Data:
   AI tools can help identify trends in patient behavior, medication use, and potential risks, allowing pharmacists to intervene before problems escalate. For instance, predictive analytics could help pharmacists anticipate when patients are likely to miss doses or experience side effects, prompting timely counselling.
6. Personalized Medication Management:
   The future of pharmacist-patient interaction will focus on providing more personalized care. Pharmacists will increasingly tailor medication regimens to each patient's unique needs, preferences, and health conditions, rather than using a one-size-fits-all approach.

CONCLUSION

The future of pharmacist-patient interaction is characterized by greater collaboration, personalized care, and technological integration. Pharmacists are expected to take on more clinical roles, leveraging telepharmacy, digital health tools, and precision medicine to enhance patient outcomes. As the healthcare landscape evolves, pharmacists will play an increasingly central role in the management of chronic diseases, preventive care, and patient education, contributing to a more patient-centered, accessible, and effective healthcare system.

Pharmacist-patient interaction is fundamental to effective healthcare delivery. It improves medication adherence, reduces the risk of medication errors, and leads to better chronic disease management. Pharmacists, as accessible healthcare providers, play a key role in educating and empowering patients, enhancing the overall quality of care and patient satisfaction. By adopting personalized, empathetic, and culturally sensitive approaches, pharmacists can foster trusting relationships with patients, ultimately leading to better health outcomes.

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REVIEW ON SUSTAINED RELEASE NIFEDIPINE TABLET

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ABSTRACT

This study been designed to assess bioequivalence of the newly developed delayed-release oral tablets (test) 30 mg nifedipine compared to its marketed counterpart (30 ing: reference) in healthy adult Chinese volunteers. Methode We conducted randomised, open-label, four-period, crossover trials, including a fasting trial and a fed trial. The anhjects. administered the test or reference products in a 1:1 ratio at random throughout each period with 7 days washout period. Then in the next ansidon, they got the alternate products. Lipid chromatography-tandem mass spectrometry and WinNonlin software were used to evtluste the bioequivalence of nifedipine peak blood concentration (Cmax) and area under the concentration-time (AUC). Result A total of 46 subjecta participated in the fasting trial ami 48 subjects in the postprandial trial. In both auses the 90% CL of the geometrica ratios of Cmax, AUCU and AUCH were in the equivalence range (80-125%), When nifedipine was given concomitantly with a high-fat meal, tmax was approximately twofold earlier, absorption was approximately 4.8% less and Conax changed little compared to fasting conditions. In addition, no serious adverse events were observed in the subjects. Conclusion: This study confirus the hioequivalence of the test and reference formulations of nifedipine extended mlense tablets under fasting and postprandial conditions. Food giving kende much earlier Tmax, which is different from the results of other studies. The effect of food effect on the pharmacokinetics of nifedipine needs to be further explored

KEYWORDS: *Nifedipine, Matrix tablet, HPMC,Sustained release, HEC Ethyl cellulose, Eudragit RS100, Wet granulation.*

INTRODUCTION

Nifedipine (NFP) is a short-acting dihydropyridine calcium channel blocker1. Nifedipine can selectively blockL-type calcium channels on cardiac and smooth muscle cells, organize the inward flow of extracellular calciumions, reduce the intracellular calcium ion concentration, relieve the effect of vascular smooth muscle spasm,reduce peripheral vascular resistance, reduce myocardial oxygen consumption, and lower diastolic and systolicblood pressure in hypertensive patients2. At the same time, nifedipine can diastole the coronary arteries,and its application in small doses can have a very good anti-anginal effect. It is currently used clinicallyfor the prevention and treatment of various types of coronary artery disease and angina pectoris, is alsoindicated for various types of hypertension, and has good efficacy in persistent and severe hypertension3,4Nifedipine is almost completely absorbed from the gastrointestinal tract after oral administration and undergoes first-pass metabolism in the liver and intestinal wall, and its oral bioavailability reaches 43%-77%.Nifedipine is highly bound to plasma proteins, metabolized by the liver, and excreted primarily in the urine,with only less than 1% of the dose being excreted in its original form5Regular nifedipine tablets havelow and irregular bioavailability, and short-acting calcium antagonists cause increased sympathetic tone and reflex tachycardia, along with adverse effects such as headache, palpitations, flushing, and dizziness6-78. In contrast, nifedipine extended-release and controlled-release formulations do not have the ”sudden release” phenomenon of ordinary tablets, which can reduce the gastrointestinal stimulation of the drug and avoidthe adverse reactions caused by high peak blood concentrations, making the onset of nifedipine smooth and blood pressure control more stable9. Nifedipine extended-release tablets III, in the size of 30 mg, are capableof releasing nifedipine at a near-constant rate for 24 hours, similar to controlled-release tablets. Nifedipine extended-release tablets I and II are generally taken on an empty stomach, whereas nifedipine extendedrelease tablets III are not restricted by meal times because they are not affected by gastrointestinal motility or pH10.

NEED OF WORK

Sustained-release (SR) nifedipine tablets are designed to provide a controlled release of the drug over an extended period, which helps maintain a steady level of medication in the bloodstream. This formulation is particularly useful for treating conditions like hypertension (high blood pressure) and angina (chest pain) by:

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1**. Improved Blood Pressure Control**: Sustained-release nifedipine helps maintain a consistent effect over 24 hours, reducing the need for multiple doses and ensuring more stable blood pressure control.
2. **Fewer Side Effects**: By avoiding peak concentrations in the blood, sustained-release formulations can minimize side effects such as dizziness, headaches, or flushing that may occur with immediate-release versions.
3. **Convenience:** Patients may prefer the sustained-release form due to fewer doses per day, which can improve adherence to the prescribed regimen.
4. **Reduced Risk of Tachycardia**: The controlled release of nifedipine can help prevent sudden drops in blood pressure, reducing the risk of reflex tachycardia (a rapid heart rate) that can occur with immediate-release nifedipine.

PLAN OF WORK
for sustained-release (SR) nifedipine tablets typically involves a comprehensive approach, starting from formulation development to clinical use. Below is an outline for a work plan focusing on different stages of development, testing, and therapeutic application of SR nifedipine tablets.

1. Formulation Development
Objective: Design and optimize the sustained-release formulation of nifedipine.
Steps:
a. Choice of Release Mechanism: Select the appropriate mechanism of release (e.g., matrix system, osmotic pump, or coated systems).
b. Excipients Selection: Choose polymers, binders, and other excipients that control the rate of nifedipine release.
c. Drug-Excipient Compatibility: Conduct stability studies to ensure nifedipine is compatible with chosen excipients.
d. Formulation Trials: Prepare small batches to determine optimal drug loading, release profile, and tablet hardness.
e. Scale-Up: Increase batch size while maintaining consistent release properties.

2. Pre-Clinical Studies
Objective: Evaluate the pharmacokinetics, pharmacodynamics, and safety of the SR formulation.
Steps:
a. In Vitro Release Testing: Conduct dissolution testing using various media to simulate the gastrointestinal conditions.
b. Stability Testing: Test the formulation under various temperature and humidity conditions to assess shelf life.
c. Animal Studies: If necessary, perform animal studies to confirm the controlled release profile and assess systemic exposure.

3. Clinical Trials (Human Studies)
Objective: Ensure the safety and efficacy of SR nifedipine tablets in humans.
Phases:
a. Phase I (Safety and Pharmacokinetics):
b. Administer the formulation to a small group of healthy volunteers.Assess the pharmacokinetics, including half-life, Tmax (time to reach peak concentration), and Cmax (maximum concentration). Monitor for adverse effects.
c. Phase II (Efficacy and Dose-Response):
d. Test on patients with conditions like hypertension or angina.Evaluate the effectiveness of the sustained release in controlling blood pressure or preventing chest pain.
e. Phase III (Large-Scale Efficacy and Safety):
f. Conduct large-scale, multicenter trials to assess long-term safety and efficacy in a diverse patient population.Collect data on adverse events and side effects.

4. Regulatory Approval
Objective: Obtain regulatory approval for the SR nifedipine formulation.
Steps:
a. Compile Data: Gather all preclinical, clinical, and manufacturing data for submission to regulatory bodies (e.g., FDA, EMA).
b. Documentation: Ensure compliance with Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP).
c. Regulatory Submission: Submit the New Drug Application (NDA) or Marketing Authorization Application (MAA) for approval.
d. Manufacturing and Quality Control
e. Objective: Produce the SR nifedipine tablets on a commercial scale, ensuring quality and consistency.

Steps
a. Batch Production: Manufacture large-scale batches under GMP conditions.

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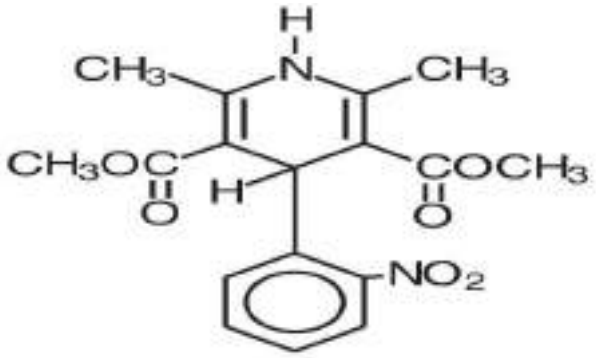
b. Quality Control (QC): Perform QC tests to ensure tablet uniformity, release profile, and stability.
c. Packaging: Package tablets in a manner that protects them from environmental factors like moisture or light, ensuring long shelf life.

6. Post-Marketing Surveillance (Phase IV)
Objective: Monitor the long-term safety and effectiveness of SR nifedipine tablets once they are on the market.
Steps:
a. Adverse Event Reporting: Collect data on any new adverse effects or long-term side effects.
b. Post-Market Studies: Conduct additional studies to observe the drug's effectiveness in real-world settings.
c. Patient Education: Provide information on how to use the medication safely and effectively, including possible interactions and side effects.

7. Patient Management Objective: Ensure the correct use of SR nifedipine tablets by patients.
Steps:
a. Dosing Instructions: Educate patients on proper dosing intervals (usually once or twice daily).
b. Monitoring: Regularly monitor patients' blood pressure and heart rate to ensure the drug's effectiveness and adjust the dosage if needed.
c. Follow-Up: Schedule periodic follow-up visits to track patient progress, especially for chronic conditions like hypertension and angina.

8. Marketing and Distribution
Objective: Ensure the widespread availability and accessibility of SR nifedipine tablets.
Steps:
a. Distribution Channels: Establish partnerships with wholesalers and pharmacies.
b. Promotion: Educate healthcare providers about the benefits of SR nifedipine for long-term treatment.
c. Global Reach: Depending on the regulatory approvals, expand distribution to other countries or regions.

DRUG PROFILE **STRUCTURE**



Uses:- Nifedipine is used to treat high blood pressure and to control angina (chest pain).
AVAILABLE FORMS OF DRUG
ROUTE: ORAL

AVAILABLE FORMS
TABLETS: 20mg, 30mg, 60 mg,90 mg
CAPSULES: 10mg, 20mg
concentration, minimizing side effects.
Enhanced Efficacy**:** Provides prolonged therapeutic effects

DRUG DESIGN
1. Selection of Formulation Approach
The sustained-release mechanism can be achieved using various approaches, each providing different release profiles. Common strategies include:

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Matrix Systems: The drug is dispersed in a hydrophilic or lipophilic polymer matrix, where the drug is gradually released as the matrix swells or erodes over time.

Hydrophilic Matrix (e.g., HPMC, Xanthan gum): This type of system forms a gel barrier around the tablet core as it comes in contact with water, controlling the drug release.

Hydrophobic Matrix (e.g., ethylcellulose): These systems rely on the drug's diffusion through the polymer matrix, which slowly releases the drug over time.

Reservoir Systems: A drug core is surrounded by a rate-controlling membrane, typically made of polymers such as ethylcellulose or cellulose acetate, which regulates the release rate of nifedipine. Osmotic Pump Systems: In these systems, the drug is released through a controlled orifice due to osmotic pressure. A semipermeable membrane surrounds the tablet, and water enters, causing the drug to be released at a controlled rate.

2. Selection of Drug Release Mechanism
Diffusion-Controlled Release: In a matrix or reservoir system, nifedipine is released via diffusion through the polymer.Swelling-Controlled Release: In a hydrophilic matrix, water uptake leads to the swelling of the polymer, which slows the drug release.
Erosion-Controlled Release: Some hydrophobic matrices will erode over time, slowly releasing the drug.Combination Systems: A combination of these mechanisms can be used to achieve the desired release profile.

3. Choice of Polymers
The choice of polymers is critical for controlling the release rate. Commonly used excipients include: Hydrophilic Polymers: Hydroxypropyl methylcellulose (HPMC), polyethylene oxide (PEO), or carbopol. These polymers swell in water, forming a gel that gradually releases the drug. Hydrophobic Polymers: Ethylcellulose, Eudragit, or cellulose acetate. These polymers can provide a more consistent release by slowing down the drug's diffusion.Other excipients: Pore-formers like sodium chloride or magnesium stearate may be used to enhance drug release through diffusion channels.

4. Tablet Core Design
Drug Loading: Nifedipine should be carefully loaded into the matrix to ensure uniformity in content and release characteristics. Granulation Process: Wet or dry granulation techniques may be used to ensure uniform distribution of the drug and excipients.Compression: The tablet should be compressed to an optimal hardness to ensure mechanical integrity, but not so hard as to inhibit drug release.

5. Optimization of Release Profile
To achieve the desired release profile, it's essential to optimize factors such as: Polymer concentration and ratio (hydrophilic to hydrophobic) Particle size of nifedipine (smaller particles tend to have faster release) Tablet hardness and porosity, which affect the rate of water uptake and drug release.Coating thickness (for membrane-controlled systems) or use of pore formers (for diffusion-controlled release).

6. Preformulation Studies: Before the final formulation, preformulation studies such as solubility, stability, and compatibility tests are conducted on nifedipine and the excipients to ensure that the drug and excipients do not interact in a way that compromises the drug's release or stability.

7. In Vitro Release Testing
In vitro dissolution testing is a critical step to evaluate the performance of the sustained-release tablet. The dissolution medium and test conditions (e.g., USP Apparatus II at 50 or 75 rpm) should mimic gastrointestinal conditions. The goal is to ensure that nifedipine is released at a controlled rate and meets the target profile for a once-daily dosage.

8. Stability Testing
The stability of the tablet needs to be assessed under accelerated conditions (e.g., 40°C/75% RH) to ensure the drug remains stable over time and the release profile is maintained**.**

9. Clinical Considerations
Therapeutic Range: Nifedipine is used to treat conditions such as hypertension and angina. Sustained-release formulations should maintain plasma concentrations within the therapeutic range for extended periods.Side Effects: The sustained-release form aims to minimize peaks and troughs in drug concentration, which can reduce side effects such as dizziness, flushing, or palpitations associated with nifedipine**.**

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10. Regulatory Requirements

Ensure the formulation complies with regulatory standards for sustained-release dosage forms, including the FDA's guidelines on controlled-release drug products.Perform necessary bioavailability and bioequivalence studies to demonstrate that the SR formulation provides therapeutic benefit. Summary of Key Design Considerations: Formulation strategy: Matrix, reservoir, or osmotic system.Polymers: Hydrophilic (e.g., HPMC) or hydrophobic (e.g., ethylcellulose) based on desired release profile.Tablet compression and hardness: Balanced to ensure mechanical integrity without compromising drug release.Dissolution testing: To optimize the release rate and ensure compliance with therapeutic goals.By carefully balancing the drug, excipients, and release mechanisms, it's possible to design a nifedipine sustain release tablet that provides controlled, consistent drug delivery over a prolonged period, improving therapeutic outcomes and patient adherence.

SAFATY ASSESSMENT

A safety assessment of sustained-release (SR) nifedipine tablets involves evaluating the potential risks associated with the drug's formulation, pharmacokinetics, and its clinical use. Nifedipine is a calcium channel blocker commonly prescribed for hypertension, angina, and other cardiovascular conditions. The sustained-release formulation aims to provide a steady, controlled release of the drug over an extended period, reducing the frequency of dosing and improving patient compliance.

Key factors in the safety assessment of sustained-release nifedipine include

1. Pharmacokinetic Considerations

Absorption and Bioavailability: Sustained-release formulations are designed to release the drug slowly, which impacts the peak plasma concentrations and the overall bioavailability. This slower absorption can reduce the risk of adverse events associated with rapid peaks in drug levels, such as hypotension or tachycardia. Steady-State Concentration: The controlled release allows for more consistent plasma concentrations, which can be beneficial for maintaining therapeutic effects while minimizing side effects. Risk of Dose Dumping: There is a potential risk of "dose dumping" where the sustained-release mechanism fails, leading to a rapid release of the drug. This can result in overdosing and heightened risks of adverse effects, such as hypotension, dizziness, or even heart failure.

2. Adverse Effects

Common Side Effects: The most common side effects of nifedipine, including SR formulations, are related to its vasodilatory effects and may include:

- Headache
- Dizziness
- Flushing
- Edema (particularly peripheral edema)
- Palpitations
- Gingival hyperplasia

Serious Side Effects: In rare cases, more severe side effects could include:

- Reflex tachycardia (due to vasodilation)
- Severe hypotension (especially with overdose or in patients with preexisting low blood pressure)
- Cardiac arrhythmias
- Acute myocardial infarction (with high doses or improper use)
- Exacerbation of heart failure (particularly in patients with existing heart conditions)

Tolerability: Sustained-release nifedipine may offer better tolerability compared to immediate-release formulations, as the slower onset of drug action can reduce the intensity of side effects like flushing or palpitations.

3.Patient-Specific Considerations

Renal and Hepatic Function: Nifedipine is metabolized by the liver, so patients with liver impairment may have altered drug metabolism, leading to increased plasma concentrations and a greater risk of side effects. Renal function can also impact the excretion of the drug. Cardiovascular Conditions: In patients with heart failure or aortic stenosis, nifedipine may exacerbate symptoms due to the drug's vasodilatory effects.

Drug Interactions: Nifedipine can interact with other medications, such as beta-blockers (increasing the risk of bradycardia), CYP3A4 inhibitors (increasing nifedipine plasma levels), and antihypertensive drugs (leading to excessive lowering of blood pressure).

4. Formulation Issues

Tablet Integrity: The safety of sustained-release tablets depends on the integrity of the formulation. If the tablet is damaged (e.g., crushed or chewed), it could lead to a rapid release of the drug, significantly increasing the risk of side effects and

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overdose.Bioequivalence: Different brands or generics of sustained-release nifedipine might have variations in how the drug is released, which could affect both efficacy and safety. It is important to ensure that the SR formulations are bioequivalent to prevent inconsistent therapeutic effects.

5. Long-Term Safety
Chronic Use: The long-term use of nifedipine SR tablets generally appears to be safe for most patients when prescribed appropriately. However, as with any chronic medication, regular monitoring for signs of adverse effects

EXESSIVE HYPERTENSION IN PATIENT WITH ANGINA
Excessive hypertension in a patient with angina while using sustained-release (SR) nifedipine tablets could be due to several factors related to the drug's pharmacodynamics, the patient's underlying conditions, or drug interactions. Here's a breakdown of potential causes and considerations:
1. Nifedipine and Blood Pressure Control
Mechanism of Action: Nifedipine is a calcium channel blocker that works by relaxing vascular smooth muscle, leading to vasodilation and, ideally, a reduction in blood pressure. In patients with angina, this helps reduce myocardial oxygen demand by lowering systemic vascular resistance and decreasing heart workload.Sustained-Release Formulation: The SR formulation is designed to provide a gradual release of the drug over time, helping maintain stable blood levels and preventing sharp fluctuations in blood pressure. This should ideally prevent both excessively high and low blood pressure.

2. Potential Reasons for Excessive Hypertension
Dose Adjustment Issues: If the initial dose of SR nifedipine is too low or inadequate for the patient's needs, it may not sufficiently lower blood pressure, particularly in a hypertensive patient. This could result in uncontrolled hypertension despite using the drug.
Tachyphylaxis or Tolerance: Although rare with SR nifedipine, some patients may develop tolerance over time, where the drug becomes less effective at controlling blood pressure. This might cause inadequate blood pressure lowering, especially in patients with higher baseline hypertension.

Dose Dumping or Absorption Issues: If the SR formulation fails due to improper tablet integrity (e.g., crushing, chewing, or improper dissolution), there could be rapid release of the drug, leading to a sudden drop in blood pressure followed by rebound hypertension as the body tries to compensate.

Inappropriate Use in Severe Hypertension: If the patient's hypertension is particularly severe or if they are on other medications that increase blood pressure (e.g., corticosteroids, sympathomimetics), SR nifedipine may not be sufficient as a sole agent to control the elevated pressure.

BETA-BLOCKER WITHDRAWAL
Beta Blocker Withdrawal with Sustained-Release Nifedipine Tablets
Beta blockers and calcium channel blockers like nifedipine are often prescribed for various cardiovascular conditions, such as hypertension, angina, and arrhythmias. Nifedipine belongs to a class of drugs known as calcium channel blockers, and when used in a sustained-release (SR) formulation, it provides a gradual release of the drug into the bloodstream over an extended period, which helps maintain a consistent therapeutic effect.

When discussing beta blocker withdrawal specifically, it’s important to note that beta blockers (e.g., metoprolol, atenolol) are a different class of drugs from nifedipine, but they are often prescribed together in cardiovascular conditions. Therefore, the withdrawal effects from beta blockers (if discontinued suddenly) and the management of nifedipine (particularly in its sustained-release form) must be understood within the broader context of cardiovascular treatment.

1. Beta Blocker Withdrawal
Beta blockers are commonly used to treat hypertension, arrhythmias, heart failure, and angina. They work by blocking the effects of adrenaline on beta receptors, slowing the heart rate and reducing the force of heart contractions, which ultimately lowers blood pressure. When beta blockers are stopped abruptly or reduced too quickly, it can lead to withdrawal symptoms. These may include: Rebound hypertension: Beta blockers have a blocking effect on the sympathetic nervous system. Discontinuing them suddenly can lead to an overreaction of the sympathetic system, resulting in a significant increase in blood pressure (rebound hypertension).

Tachycardia (rapid heart rate): The heart rate may increase significantly as the body’s natural sympathetic response is no longer moderated by the beta blockers.

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Angina or chest pain: Withdrawal may lead to increased workload on the heart, which can precipitate angina in individuals with underlying coronary artery disease.

Anxiety, sweating, and tremors can also be symptoms as the sympathetic nervous system is suddenly unopposed.
Increased risk of arrhythmias: The sudden loss of beta blockade may expose the heart to a higher risk of arrhythmias, especially in individuals with a history of heart disease.

Because of these potential risks, beta blockers should be tapered gradually under medical supervision if discontinuation is necessary.

2. Sustained-Release Nifedipine (SR Nifedipine) Overview
Nifedipine is a calcium channel blocker that works by inhibiting the influx of calcium ions into smooth muscle cells and cardiac muscle cells. This action causes vasodilation, which can lower blood pressure and relieve angina.

In the sustained-release (SR) formulation, nifedipine is designed to release the drug slowly over a prolonged period. This helps maintain a steady drug concentration in the blood and avoids peak concentrations that could cause adverse effects.

Key Points about SR Nifedipine:
It is used primarily for hypertension and angina.
SR nifedipine helps in managing these conditions with fewer fluctuations in blood drug levels.
Sudden cessation of SR nifedipine can lead to a rebound effect, but this is more commonly associated with the vasodilatory effects (e.g., sudden increases in blood pressure or worsening of angina) rather than direct withdrawal symptoms like those seen with beta blockers.

3. Impact of Beta Blocker Withdrawal on SR Nifedipine Therapy
While SR nifedipine itself does not cause withdrawal symptoms in the traditional sense, the withdrawal of beta blockers can impact how nifedipine works. Te effects of discontinuing a beta blocker while on nifedipine include:
Increased Heart Rate: Without the beta blocker to counteract the tachycardia caused by nifedipine, patients may experience a significant increase in heart rate, especially when they transition to standing or during physical activity.

Worsening Angina: In patients who use beta blockers for angina, withdrawing the beta blocker may increase the risk of angina attacks due to a combination of higher heart rate and potential rebound hypertension.

Rebound Hypertension: As mentioned, stopping beta blockers abruptly can cause an increase in blood pressure, which could exacerbate the hypertensive effects in a patient on SR nifedipine.

4. Management of Withdrawal Symptoms and Cessation of Beta Blockers
If beta blockers are being withdrawn in a patient on SR nifedipine, the withdrawal should be gradual. A tapering plan is usually recommended to minimize the risk of rebound hypertension, tachycardia, and arrhythmias.
Monitor heart rate and blood pressure closely during the tapering period.

If angina worsens during this process, additional medications or adjustments to nifedipine doses might be necessary.
In some cases, an alternative anti-hypertensive or anti-anginal therapy might be introduced to support the patient during the transition.

CLINICAL TRIALS AND ADVERSE DRUG REACTION
Adverse Drug Reactions (ADRs) in Clinical Trials for Sustained-Release Nifedipine Tablets
Sustained-release nifedipine is commonly used in the treatment of hypertension and angina, providing a more controlled release of the active ingredient compared to immediate-release formulations. While nifedipine is generally well-tolerated, clinical trials have identified a range of adverse drug reactions (ADRs) that can occur with its use. The side effects are typically dose-dependent and can vary in frequency and severity. Here's a detailed look at the clinical trial data for sustained-release nifedipine:

Common Adverse Drug Reactions
1. Cardiovascular
Peripheral edema (swelling): One of the most common side effects, especially in elderly patients. This occurs due to nifedipine's vasodilatory effect on peripheral blood vessels.

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Hypotension (low blood pressure): Due to its vasodilatory effects, nifedipine can lower blood pressure too much, leading to symptoms like dizziness, light-headedness, and fainting. This is more likely to occur if a patient is volume-depleted or is on high doses.

2. Gastrointestinal

Constipation: Although less common than with other calcium channel blockers, some patients may experience constipation

DO NOT USE NIFEDIPINE TABLET

There are several clinical situations where nifedipine tablets, particularly the sustained-release formulation, may not be recommended or should be avoided due to safety concerns. Here are some of the key reasons why nifedipine tablets might be contraindicated or should be used with caution:

1.Severe Hypotension (Low Blood Pressure):

Nifedipine is a calcium channel blocker that works by relaxing blood vessels, which can significantly lower blood pressure. In individuals with already low blood pressure or severe hypotension, nifedipine can exacerbate this condition, leading to life-threatening situations such as dizziness, fainting, or shock.

2. Acute Myocardial Infarction (Heart Attack)

Nifedipine should generally be avoided in patients who are experiencing a heart attack, particularly in the acute phase. There is a risk that it could worsen the heart's condition due to reflex tachycardia (increased heart rate), which might increase the oxygen demand of the heart, potentially leading to further ischemia (lack of blood flow to the heart).

3. Unstable Angina

Nifedipine should not be used in patients with unstable angina because its vasodilatory effects could lead to reflex tachycardia, which might worsen the angina symptoms. The condition could deteriorate, leading to more severe chest pain or a heart attack.

4. Severe Aortic Stenosis

Aortic stenosis, a condition where the aortic valve is narrowed, can be exacerbated by nifedipine, which dilates blood vessels. In such patients, the decrease in vascular resistance can lead to impaired blood flow to the coronary arteries, which could precipitate severe complications.

5. Hypersensitivity (Allergy) to Nifedipine or its Components

Individuals with a known allergy to nifedipine or any of the excipients in the formulation should avoid the drug. Allergic reactions could range from mild skin rashes to severe anaphylactic reactions, which can be life-threatening.

HOW TO TAKE SUSTAINED RELEASE NIFEDIPINE TABLET

When taking sustained-release nifedipine tablets, it's important to follow the prescribed instructions to ensure the medication works effectively and to minimize the risk of side effects. Here's how to take sustained-release nifedipine correctly:

1. Follow the Prescribed Dose and Schedule

Always take the medication exactly as prescribed by your healthcare provider. The typical dosing for sustained-release nifedipine will vary depending on your condition (e.g., hypertension, angina) and individual factors (e.g., age, other health conditions).
Don't adjust the dose on your own. If you feel that the dose is too high or too low, talk to your doctor.

2. Take with or without Food

Sustained-release nifedipine can generally be taken with or without food. However, taking it with food might help reduce some gastrointestinal side effects (like nausea) for some people.
If you experience stomach upset, try taking it with food to see if it helps.

3. Swallow the Tablet Whole

Do not crush, chew, or break the tablet. The tablet is designed to release nifedipine gradually over time, so crushing or breaking it could release too much of the drug at once, increasing the risk of side effects like severe low blood pressure or other adverse reactions.
Always swallow the tablet whole with a glass of water.

4. Take at the Same Time Every Day

To help remember to take your medication consistently, try to take your nifedipine tablet at the same time each day. This helps maintain a steady level of the drug in your system.

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5. Do Not Take More Than Prescribed
Never take more than the prescribed dose. Taking extra tablets or doses can lead to dangerous side effects such as severe hypotension (low blood pressure), tachycardia (fast heart rate), or other heart-related issues.
If you miss a dose, do not double the next dose. Instead, take the missed dose as soon as you remember, unless it's almost time for your next dose. In that case, just skip the missed dose and continue with your regular schedule.

6. Stay Hydrated
It's a good idea to stay well-hydrated when taking nifedipine, as dehydration can increase the risk of side effects like dizziness and hypotension.

7. Monitor Blood Pressure and Heart Rate
If you're taking nifedipine for hypertension or angina, it's important to regularly monitor your blood pressure and heart rate. Your doctor may ask you to check these regularly to ensure that the medication is working as expected.
Report any significant changes in your blood pressure or heart rate to your doctor.

8. Avoid Grapefruit and Grapefruit Juice
Grapefruit and grapefruit juice can interact with nifedipine and increase its concentration in the blood, which may increase the risk of side effects like low blood pressure or heart problems. Avoid consuming grapefruit products while taking nifedipine.

9. Stay Alert for Side Effects
Some people may experience dizziness, headache, or swelling while taking nifedipine. If you feel light-headed or dizzy, avoid standing up too quickly and be careful when driving or operating heavy machinery.

Peripheral edema (swelling in the ankles or feet) is a known side effect of nifedipine, especially in the lower extremities. If this becomes bothersome or severe, talk to your doctor.

10. Keep Regular Appointments
Regular follow-up appointments are important to monitor your response to the medication and to check for potential side effects. Your doctor may adjust your dose or change your medication if needed.

Key Points to Remember:
Do not crush or chew the sustained-release tablet.
Take as prescribed, and do not alter your dosage without consulting your doctor.
Monitor your blood pressure and heart rate, especially when starting the medication.
Stay hydrated and avoid grapefruit.
If you miss a dose, do not double the dose—just take the next scheduled dose.
By following these guidelines, you can help ensure that sustained-release nifedipine works effectively and safely for your condition. Always consult your healthcare provider if you have any questions or concerns about taking the medication.

CONCLUSION

In conclusion, sustained-release nifedipine tablets represent a significant advancement in the management of hypertension and angina by providing a controlled, prolonged release of the medication. This formulation not only helps maintain consistent blood drug levels, improving therapeutic outcomes, but also enhances patient compliance by reducing the frequency of dosing. While generally well-tolerated, careful monitoring of patients is essential to manage potential side effects, particularly in those with preexisting cardiovascular conditions. Ongoing research into the pharmacokinetics and long-term effects of sustained-release nifedipine will further refine its role in clinical practice and expand its therapeutic applications

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AYURVEDIC APPROACHES TO FUNDAMENTAL ORAL HEALTH CARE

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ABSTRACT

Oral health is an important part of a person's overall well-being and quality of life. Oral health includes a person's ability to confidently speak, smile, smell, taste, swallow and even convey different emotions through facial expressions. Altered oral health can cause pain, suffering, and decreased productivity and affects the self-esteem of a person. Improving oral health and hygiene benefits the entire system, i.e., the tissues of the mouth itself, the digestive system, and the deeper tissues that correlate with our oral health. Oral diseases are one of the leading causes of disability in India and affect all age groups irrespective of socio-economic factors. Ayurveda explains several practices or procedures of Dinacharya (daily regimen) like Dantadhavana, Jihvanirlekhana, Kavala, Gandusha, Pratisarana and Tambula Sevana which are fruitful in maintaining oral health/hygiene and preventing oral disorders. In addition to the procedures, Ayurveda describes various herbs with pharmacological effects, such as antimicrobial, anti-inflammatory, analgesic, anti-ulcer, etc., which are useful for maintaining oral health. These strategies and the use of such potential herbs can be practiced along with daily brushing and flossing to promote optimal oral health and hygiene.

KEYWORDS: *Ayurveda, Dinacharya, Oral hygiene, Hygiene.*

INTRODUCTION

Principles of *Ayurveda* aims at improving the health of the healthy and preventing the occurrence of diseases. *Shalakya-Tantra* which is among the eight branches of *Ashtang Ayurveda* deals with the diseases occurring above the clavicle i.e., with diseases and treatment of the Head, eyes, ear, nose, and oral cavity[1]. According to WHO, Oral health is a state of being free from chronic mouth and facial pain, oral and throat cancer, oral sores, birth defects such as cleft lip and palate, periodontal (gum) disease, tooth decay, and tooth loss, and other diseases and disorders that affect the oral cavity[2]. According to the Surgeon General's Report on Oral Health, oral health is a mirror that reflects our overall health and well-being[3]. The three *doshas* are present within the mouth in different locations and facilitate diverse functions. *Vata dosha* is present within the pores of teeth and facilitates in biting, chewing, and swallowing of food. *Pitta dosha* is present within the blood vessels which nourishes and protect the gums tissue. One of the *Kapha* sub-*doshas* called *Bodhaka Kapha* functions to moistens the mucous membrane of the mouth. The physical form of *Bodhaka Kapha* is saliva. *Bodhaka kapha* helps to prevent cavities by washing away bits of food and reduces the effect of acidic foods on teeth enamel. Oral diseases continue to be a major health problem worldwide. Oral health relates to the quality of life and general well-being of a person. There is a well-established link between oral diseases and the activities of microbial species that form a part of the microbiota of the oral cavity[4]. There is a global need for alternative prevention and treatment options that are safe, effective, and economical for the people. Despite this, numerous chemical agents which are commercially available can alter oral microbiota and have undesirable side effects such as vomiting, diarrhoea, tooth staining, etc. In the context of medications, prolonged or extensive use of certain medications such as oral contraceptive pills, Antiseizure medications, Antihypertensives, Antihistamines, Analgesics Diuretics, several antibiotics, Antacids, Antifungal agents containing sugar, etc., and regular use of toothpaste containing Sodium lauryl sulphate, may cause tooth discoloration, canker sores, and certain other oral health problems. Daily rules of conduct have been explained in *Ayurveda* texts under the headings *Dinacharya* and *Swasthavritta*. *Acharya Charak* has mentioned

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Dantapavana, Mukhaprakshalana etc. under the *Dinacharya prakaran* and has mentioned that oral health is an integral part of the daily regime or routine[5].

Numerous therapeutic procedures for maintaining oral health and basic oral hygiene include *Danta Dhavana* (Brushing), *Jihvanirlekhana* (Tongue Scrapping), *Sneha Gandusha* (Oil pulling), *Shiro & Mukha Abhyanga* (Head and Face Massage), *Nasya* (Application of oil in Nostrils), *Dhumapana* (Herbal smoke inhalation), *Mukhwas* (Mouth Freshener), *Kavala* (Gargle) in the mouth. The oral cavity plays a crucial role in daily activities and there are various diseases related to the oral cavity that are mentioned in *Ayurveda* described as sixty-five varieties of oral disorders that can arise in seven anatomical locations in and around the mouth[6]. Hence, this enlightens us about the importance of basic oral health and proper care of the oral cavity for the prevention of oral disorders.

AYURVEDA FOR THE BASIC ORAL HEALTH

Ayurveda is a science that gives prior importance to the preventive aspect and to the maintenance of health for healthy individuals. The understanding of maintaining oral health is better understood under the following headings.

A) *Dinacharya* (Daily Regime)

1) *Brahma Muhurta Uttishthe* and *Malatyag*

Last *yama* of night is said to be the *Brahma muhurta*. It starts approximately 96 minutes before sunrise and lasts for 48 minutes and ends 48 minutes before sunrise. In this time, *Vata dosha* is naturally dominant in the body and is the time to defecate if one feels the urge. *Mala visarjana* (Defecation) is an *Adharniya vega* of the body and it is under the control of *Apana vayu*. If a person wakes up in *Brahma muhurta*, it is considered as the best time for expelling *mala. Acharya Vagbhata* has mentioned that the suppression of the natural urge of defecation can cause *Mukha Vittapravarti* (Bad breath from the mouth)[7].

2) *Mukha Swasthya Rakshanartha Dantashodhana* (Brushing of Teeth)

Toothbrushing is an integral part of the daily regime and is useful in maintaining oral health. *Ayurveda* insists on the use of herbal brushes (*Dantonna*) which is a cost-effective, suitable, and furthermore beneficial way of cleaning the teeth. *Dantapavana* (Tooth brushing) daily helps in preventing halitosis (bad breath), clarity of the oral cavity, removal of the debris of food from the teeth, tongue, and mouth, and facilitates in salivary secretion and relishing your food. Most of the toothpaste present in the market contains calcium carbonate, sodium lauryl sulphate, sodium silicate etc. which has certain side effects on the oral cavity.

Dantashodhana in *Ayurveda*

- Material to be used:

Herbal twigs of different *rasa* are to be used depending on the *dosha, prakriti* of the person and on the seasonal availability of the twig. Certain twigs are mentioned which are best to use according to the *Rasa* of the herb.

Table 1 showing best twig to be used according to different *Rasa*[8]

RASA	BEST TWIG
MADHUR	MADHUK
KATU	KARANJA
TIKTA	NIMBA
KASHAYA	KHADIR

Chewing these stems is believed to facilitate salivary secretion and the anti-bacterial properties of these herbs is substantial in preventing plaque.

- Physical properties of the Twig

Acharyas have mentioned the qualities of prime herbal twigs that should be used for *Dantashodhana*. The twig to be used for brushing the teeth should be 12 *Angula* in length, the thickness of a little finger of the hand, straight, without knots and one end of the twig should be chewed which is used in brushing so that gums are prevented from any injury.

- Frequency

Twice a day, after waking up in the morning and before going to bed.

- Method

Dantshodhaka churna (Herbal powder) is taken in the twig and brushing is done in a circular manner and up-down motion by inserting the brush in the oral cavity preventing injury to the gums and then rinsing mouth with water.

3) *Dantashodhaka Churna Pratisarana* (Massaging of the gums and teeth)

In *Yog Ratnakar* text, use of *Churna, Kalka* or *Avelaha* is mentioned for the massage of teeth and gums. *Acharya Sushruta* has also described the use of *Dantashodhaka churna* which includes *Madhu, Trikatu, Dalchini, Tejapatra, Ela, Saindhav* mixed in sesame oil for the massaging of the teeth and gums. The herbal mixture is taken on the index finger and gums, teeth are gently massaged in

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a side-to-side motion and then the mouth is rinsed with water. Massaging of the teeth and gums facilitates improving blood circulation to the gums and is crucial in strengthening the gums[9].

4) *Jihvanirlekhana* (Tongue Scrapping)

Improper eating, poor digestion, or imbalance in the GIT system leads to the accumulation of toxic residue in the tongue. Proper removal of this toxic coating and stimulation of the tongue helps in stimulating taste perception and improves salivation which is helpful in digestion. Many phytonutrients that food contains are first interpreted by the receptors on the tongue. Hence, the presence of a coating on the tongue can interfere with this communication between the food and the body[10]. Proper digestion is essential to the body or if not can affect organs such as the liver, kidney, etc. The tongue should be scraped from back to front and the scraper should be made of materials like gold, silver, copper, tin, brass, etc. *Acharya Sushruta* has mentioned that the scraper should be 10 *Angula* in length and should be blunt and curved to prevent injury to the tongue and easy to use respectively.

5) *Sneha Gandusha* (Oil Pulling)

Gandusha is a procedure in which the oral cavity is filled completely with liquid medicine and is held for a specific period until there is lacrimation and nasal discharge[11]. *Sneha Gandusha* (Oil Pulling) is beneficial in preventing tooth decay, preventing bad odour, bleeding gums, cracked lips, and dryness of the throat, and facilitates in strengthening gums, teeth, and jaw[12]. *Ayurveda* describes that brushing is contraindicated in conditions like *Mukhapaka* (Mouth ulcers), *Shirashoola* (Headache), *Karnshoola* (Pain in ear), *Kasa* (Cough), *Shwasa* (Asthma), *Vaman* (Vomiting), *Hikka* (Hiccups) etc. Hence, Oil pulling is a better alternative in these conditions for cleaning the oral cavity. *Vagbhata* has mentioned that daily oil pulling with sesame oil is the best for the health. Oral mucosa has the capacity to absorb lipid-soluble substances as the buccal mucosa is lipophilic in nature. The viscosity of medicated oil inhibits bacterial adhesion in the oral cavity.

6) *Mukha Abhyanga* (Face Massage)

Massaging the face after oil pulling or preferably before bedtime should be done. After washing the face with water and drying it with a towel oil should be applied on the face using your fingertips and massage of the scalp, forehead, nose, cheeks, ears, and neck should be done gently[13]. This process helps in enhancing the functioning of the sense organs and enhances the blood circulation to the oral cavity.

7) *Tambula Sevana* (Application of Mouth Freshener)

The use of *Tambula* is beneficial in the prevention of bad breath, cleansing of the oral cavity, aids in digestion, stimulates the salivary flow in the mouth which neutralizes the acids and washes away the bacteria, and provides protection against dental erosion. Certain materials such as *Jayphala, Katuka, Lavanga, Kankola, Ela* and *Tambula patra* should be installed in the oral cavity[14]. The essential oils present in the *Tambula* leaves possess anti-bacterial, anti-fungal, antiseptic, antioxidant properties and contains substantial number of vitamins and minerals. Betel leaf chewing minimizes the pathogenic microbial organisms in the sub-gingival flora.

8) *Kavala* (Gargle)

Gargling after every meal is an integral part of the daily regime and it facilitates the removal of food debris from the oral cavity. After every meal, the oral cavity should be filled with half of its capacity with lukewarm water which should be briskly moved inside the mouth and then spitted out[15].

9) *Pratimarsha Nasya* (Application of the oil in nostrils)

The nose is considered as the way of entry to the head and medicines installed through the nasal route is useful in *Urdhwajatrugata Vikaras*[16]. Among various types of *Nasya*, *Pratimarsha Nasya* is incorporated into the daily regime for the prevention of disease and to promote oral health. Other types of *Nasya* are disease specific. 2 drops of sesame oil or *ghee* is to be administered into the nostrils preferably after tongue scraping or before bedtime with the help of little finger or dropper. *Nasya* helps in preventing supraclavicular disorders and is useful in the strengthening of the jaw and teeth[17].

10) *Dhoompana* (Inhalation of herbal smoke)

Part of the vitiated *kapha* situated in the head is effectively eliminated by *dhoompan*. Generally, there are 5 types of *dhoompan* which have been mentioned – *Prayogik, Snehik, Vairechanik, Vamaniya* and *Kasaghna*[18]. *Prayogik* is used for *Dinacharya* (Daily regime). It is to be used twice a day after application of oil in the nostrils. The herbal wick is lit, and the fire is put off. Smoke emitted is inhaled through one nostril at a time, closing the other and it is done alternatively. Every time the inhaled smoke is to be expelled through the mouth. *Dhoompana* provides firmness to the teeth, a pleasant smell, and clarity of the mouth. It also prevents loss of taste and exudations of mouth making it an effective method in the maintenance of basic oral health[19].

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B) ***Adharniya Vega Dharan*** **(Suppression of the natural urges)**

Acharya Vagbhata has described 13 types of *Adharniya vega* (Natural urges) which should not be suppressed and if does may lead to various disorders. In the context of oral health, it is described that suppression of the urge to defecate or urinate (*Purisha* and *Mutra Vega dharan*) may lead to Halitosis (bad breath from the mouth)[20]. Hence along with the procedures, *Ayurveda* also enlightens us about the knowledge of not suppressing the natural urges which may lead to a disturbance in basic oral health.

C) **Aspect of natural herbs for maintenance of oral health**

There are numerous natural herbs that can be used in maintaining oral health as well as in the prevention of oral disorders.

- *Amra patra* (Mango leaves) contains a significant amount of ascorbic acid, and phenolic acid and possess anti-bacterial property against the microflora in the oral cavity. It can be used as an effective adjuvant in maintaining oral hygiene[21].
- *Neem* leaves have numerous properties such as antibacterial, antifungal, and antioxidant properties[22] and contain therapeutic antiplaque agents. Oral rinse with a decoction of neem leaves is beneficial for oral health as well as in the management of periodontitis[23].
- *Amla* with its astringent and antioxidant properties helps in combating the inflammation of the oral cavity[24].
- Clove has a broad role in the oral aspect. Clove has antiseptic properties and is beneficial in sore gums and if applied to a cavity in a decayed tooth helps in relieving pain[25]. Like that, the use of peppermint oil also helps in combating the toothache and inflammation of the gums.
- Oral rinse with *Tulsi* decoction effectively reduces salivary streptococcal mutant counts[26].
- *Ghritakumari*/Aloe vera contains a polysaccharide of Acemannan (ACE) that has an effective role in dentin formation[27].
- Lemon solution is a natural source of citric acid. Its antibacterial effect is recommended as a root canal medication[28].
- *Triphala* can be used as a gargling agent in dental disorders as per *Acharya Sushruta*. 0.6% *Triphala* mouthwash has been shown to have significant anti-caries activity[29]. *Triphala* also has Antioxidant and Anti-microbial activity. The strong antioxidant activity of *Triphala* may be attributed to *Terminalia belerica* followed by *Phyllanthus emblica* and *Terminalia chebula*. Along with that, *Terminalia chebula* is valuable in the prevention and treatment of several diseases of the mouth such as dental caries, spongy and bleeding gums, gingivitis, and stomatitis. The extract of it could successfully prevent plaque formation on the surface of the tooth, as it inhibits sucrose-induced adherence and glucan-induced aggregation, the 2 processes that foster the colonization of organisms on the surface of the tooth. The extract of *T.chebula* also inhibit the growth and accumulation of *S. mutans* on the surface of the tooth. This would prevent the accumulation of acids on the surface of the tooth, and thus the further demineralization and breakdown of the tooth enamel[30].

CONCLUSION

Oral diseases are one of the most important problems related to public health and are on an accelerating pace in developing countries which indicates us about the importance of basic oral health. According to the Surgeon General's Report on Oral Health, oral health is a mirror that reflects our overall health and well-being. The aim of *Ayurveda* includes preventive healthcare which explains the importance of hygiene while emphasizing upon maintenance and promotion of positive health in peoples. Procedures mentioned in the daily regime as per *Ayurveda* like *Dantshodhana, Jihvanirlekhana, Sneha gandhusha, Tambula sevana* etc. and the herbal drugs which are mentioned for these regimes both are cost effective and can be performed without any trouble. Hence, these regimes should be adapted in the daily routine of an individual for the promotion of oral health and prevention of oral disorders. Along with that, some potent herbs mentioned can be used as an adjunct for the maintenance of oral health. To conclude this conceptual study, prior importance to oral health should be given in developing countries and the traditional knowledge of *Ayurveda* should be incorporated, encouraged, and could be integrated with modern dentistry in oral health maintenance and various oral health treatments.

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RESULTS OF MAMMOGRAPHIC SCREENING FOR INTRADUCTAL BREAST FORMATIONS

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SUMMARY
Intraductal carcinoma, or ductal carcinoma in situ (DCIS), is the preinvasive form of breast carcinoma. In most instances, it is clinically inapparent and is discovered incidentally during histologic examination of breast tissue identified as abnormal by mammography.
KEY WORDS: *ductal carcinoma in situ (DCIS), breast carcinoma, clinic and screening mammographic studie, calcifications.*

RELEVANCE

Currently, one of the most pressing problems not only in oncology but also in healthcare in general is the prevention of breast cancer (BC), which is due to the rapid, steady and widespread growth in the incidence of this form of cancer, which has taken first place in the structure of morbidity in women with malignant neoplasms (Bluekens AM et all 2012). This is due to the leading position of this tumor in women, outpacing other malignant neoplasms in frequency of occurrence (Bray F et all 2018). Despite a large number of studies devoted to improving the methods of diagnosis and treatment of BC, the results are far from always satisfactory.

Mammographic screening has reduced breast cancer-related mortality by 30% (Tagliafico AS et all, 2016). However, the sensitivity of mammography is about 70%, especially in women with dense breast tissue (Pisano ED et all, 2005). Current recommendations of the Society of Breast Imaging, the American College of Radiology, and the National Comprehensive Cancer Network require annual mammographic screening, starting at age 40 and older in cases of average oncological risk. For women with a high risk of breast cancer (more than 20% during life), MRI is recommended in addition to mammography (Riedl CC et all, 2015). For women with a BRCA1/2 gene mutation, with TP53 Li Fraumeni syndrome, or who received radiation therapy to the chest area before age 30, annual mammography and, possibly, MRI are recommended from the moment of identification. In the USA, women with dense breast tissue are warned about the advisability of additional screening (mammography + ultrasound / MRI) (Tagliafico AS et all, 2016). If calcification is detected during screening mammography, image magnification is recommended to determine the extent of the lesion. If calcification is associated with structural asymmetry of the mammary gland or the presence of a mass, additional examination using ultrasound is required to diagnose invasion.

To improve the primary screening of DCIS, it is recommended to conduct studies comparing the diagnostic efficiency of ultrasound and radiological methods of population screening. There is insufficient literature data on such a comparison today, which does not allow developing a single effective and adequate strategy for the preventive diagnosis of breast tumors.

MATERIALS AND METHODS OF RESEARCH

As a women, a total of 144 patients 77 of them had pain in the mammary glands of various ages, for the period from 2017 to 2022, were included, palpation of the mammary gland derivative, and pathological discharge from the nipple without the presence of hyperprolactinemia. 67 women aged 40 and older, mammography revealed mammary masses, and no subjective symptoms indicative of mammary gland pathology were included. The methods of clinic and screening mammographic studies.

RESULTS

During mammographic screening in women who were subsequently diagnosed with an intraductal formation, in 120 cases out of 144, a focal shadow was found that was suspicious of the formation of breast cancer. Thus, the sensitivity of standard mammography to intraductal formation was 83.33%, which is significantly higher than the sensitivity of clinical screening ($X2=29.72$, $p<0.001$). Moreover, the sensitivity of mammography was comparable both among the glands with a malignant neoplasm and with a benign one (80.77% and 83.90%, respectively, chi square=0.15, nd). Since the criterion for inclusion in the statistical analysis of the study was the presence of a verified intraductal formation, the specificity of the method was not evaluated. Comparison of the results of detection of intraductal neoplasms on the basis of mammography and on the basis of clinical signs revealed a significant weak relationship between these diagnostic approaches: the correlation coefficient was +0.42 for all cases ($p<0.01$), +0.39 for malignant neoplasms ($p<0.05$) and +0.42 for benign neoplasms ($p<0.01$).

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Among all cases of intraductal formations diagnosed in the course of this study, only 37% of cases showed the presence of clinical symptoms of the formation and mammographic signs. In 46% of cases, screening mammography revealed the formation against the background of a "silent" clinical course, which accounted for 55.83% of all mammographically "positive" cases. In 17% of cases, patients showed clinical signs of cancer without mammographic confirmation, which accounted for 31.17% of all clinically "positive" cases (Fig.1).

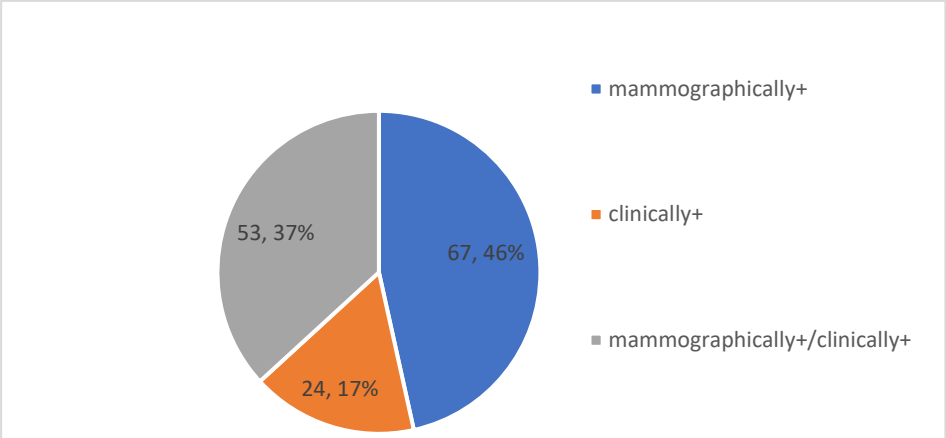

Fig-1 The frequency of occurrence of mammographically and clinically "positive" and "negative" cases of intraductal formations/

The frequency of occurrence of mammographically and clinically "positive" cases of intraductal formations in the groups with malignant and benign pathology did not differ (Table-1).

Table 1.

Frequency of occurrence of mammographically and clinically "positive" intraductal breast formations, depending on the presence of malignancy (relative percentage in the group is shown in parentheses)

Criteria	Breast cancer criterion (n=26)	Benign pathology (n=118)
Mammography+ (n=67)	10 (38,46%)	57 (48,31%)
Clinic+ (n=24)	5 (19,23%)	19 (16,10%)
Mammography+ / clinic+ (n=53)	11 (42,31%)	42 (35,59%)
X2	0.83 nd	

Calcinates are one of the important mammographic findings associated with intraductal formations. This phenomenon was found on 77 mammographic images (53.47% of all mammograms performed), while the presence of calcifications was more characteristic of malignancies (19 cases out of 26) compared to benign pathologies (58 cases out of 118): 73.08% and 49.15%, respectively (X2=4.90, p<0.05). Differentiation of calcifications by character into linear and lumpy. Showed that linear shadows of calcifications are associated with intra-ductal breast cancer (61.54% against 26.92% of lumpy formations), while in the case of benign pathology, lumpy calcifications are more often detected (50.85% against 19.49% of linear calcifications, X2 between breast cancer groups and benign pathology=19.18, p<0.001).

Thus, the analysis showed that the sensitivity of mammography in the aspect of detecting intraductal formations is 83.33%. In the aspect of differentiated detection of malignancy, informative mammographic signs turned out to be deformity of the X-ray pattern and detection of linear calcifications. The remaining mammographic characteristics did not differ in the case of malignant and benign pathology.

The sensitivity of such a mammographic sign as pattern deformity in the aspect of detecting intraductal breast cancer is 42.31% (11 out of 26), specificity is 85.59% (101 out of 118), and diagnostic value is 77.78% (112 out 144). The relative risk of detecting intraductal malignancy in patients with mammographic pattern deformity is 3.04 (absolute risk of intraductal breast cancer in patients with pattern deformity is 39.29%: 11 out of 28, in patients without pattern deformity-12.93%: 15 out of 116, X2e=9.97, p<0.01).

The sensitivity of calcification detection to the risk of ductal breast cancer is 73.08% (19 out of 26), the specificity is 50.85% (60 out of 118), and the diagnostic effectiveness is 54.86% (79 out of 144). The risk of ductal breast cancer in patients with breast calcifications diagnosed by mammography is 24.68% (19 out of 77), in the absence of calcifications-10.45% (7 out of 67, chi square=4.99, p<0.05), so the relative risk of breast cancer in the gland with mammographically detectable calcifications is 2.36.

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Detection of linear calcifications (39 cases out of 144) is characterized by sensitivity of 61.54% (16 out of 26), specificity-80.51% (95 out of 118), diagnostic significance – 77.08% (111 out of 144). The risk of ductal breast cancer in the case of linear calcifications detected during screening mammography is 41.03% (16 out of 39), without linear calcifications-9.52% (10 out of 105, X2=18.51, p<0.001), the relative risk of ductal breast cancer in the case of linear calcifications is 4.31. Thus, the detection of linear calcifications in the aspect of diagnosing ductal breast cancer, compared with the detection of calcifications of any form, is associated with an increase in specificity with a decrease in sensitivity.

CONCLUSIONS

1. The sensitivity of clinical physical screening for intraductal breast formations is 53.47%, the sensitivity of mammographic screening is 83.33%.
2. Mammographic markers of malignancy of an intraductal formations are deformation of the breast pattern (RR = 3.04, p < 0.01), the presence of calcifications (RR = 2.36, p < 0.05), in particular linear calcifications (RR = 4.31, p < 0.001).

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CARDIOVASCULAR CHANGES DURING MENOPAUSE TRANSITION

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ABSTRACT

Beginning with the commencement of irregular menstruation or missing periods and ending 12 months after the last menstrual period, this phase marks the shift from active reproduction to the cessation of considerable estrogen release due to the depletion of functioning ovarian follicles. Menopause is connected with alterations typical of cardiovascular aging. Cardiac disease has a wide range of impacts, including alterations in endothelial function, coronary artery physiology, and metabolic dysfunction, all of which lead to structural abnormalities in coronary morphology. Atherosclerosis is the leading cause of death. In earlier cross-sectional investigations, we discovered a significant incidence of metabolic cardiovascular risk factors in women before and after menopause, and we identified the menopausal transition as a key period for atherosclerosis acceleration. In the current longitudinal study, we evaluated changes in the primary cardiovascular risk variables in women after the transition to menopause.

INTRODUCTION

Menopause, which usually occurs between the ages of 45 and 55, is a normal biological process that signals the end of a woman's reproductive years. It is distinguished by the end of the menstrual cycle and a drop in hormone levels, especially progesterone and estrogen. The term "cardiovascular ageing" describes how the cardiovascular system ages, both structurally and functionally. These modifications may involve adjustments to the heart's operation, blood arteries, and general cardiovascular health. For women, the menopause is a crucial time in life that is marked by a number of physiological and hormonal changes. An increased risk of cardiovascular conditions such as heart failure, stroke, and coronary artery disease has been connected to these alterations. To effectively prevent, identify, and treat cardiovascular problems in menopausal women, it is imperative to comprehend how the menopause affects cardiovascular health. (1)

Creating a Connection Between the trouble of CVD and Menopause.

The majority of studies that have established a connection between the risk of cardiovascular disease and menopause have used the age at which women attain the ultimate menopause (p) as a proxy for menopause. Previous research collected menopause age retrospectively since a lengthy follow-up period was required.Although, this strategy is convenient, recollection bias has been a big worry . If characterizing changes as related to time relative to the date of the final menstrual period is the aim, then this bias presents a challenge. Nonetheless, meta-analyses produced reliable findings in research aimed at proving a connection between menopausal age and cardiovascular disease. (2)

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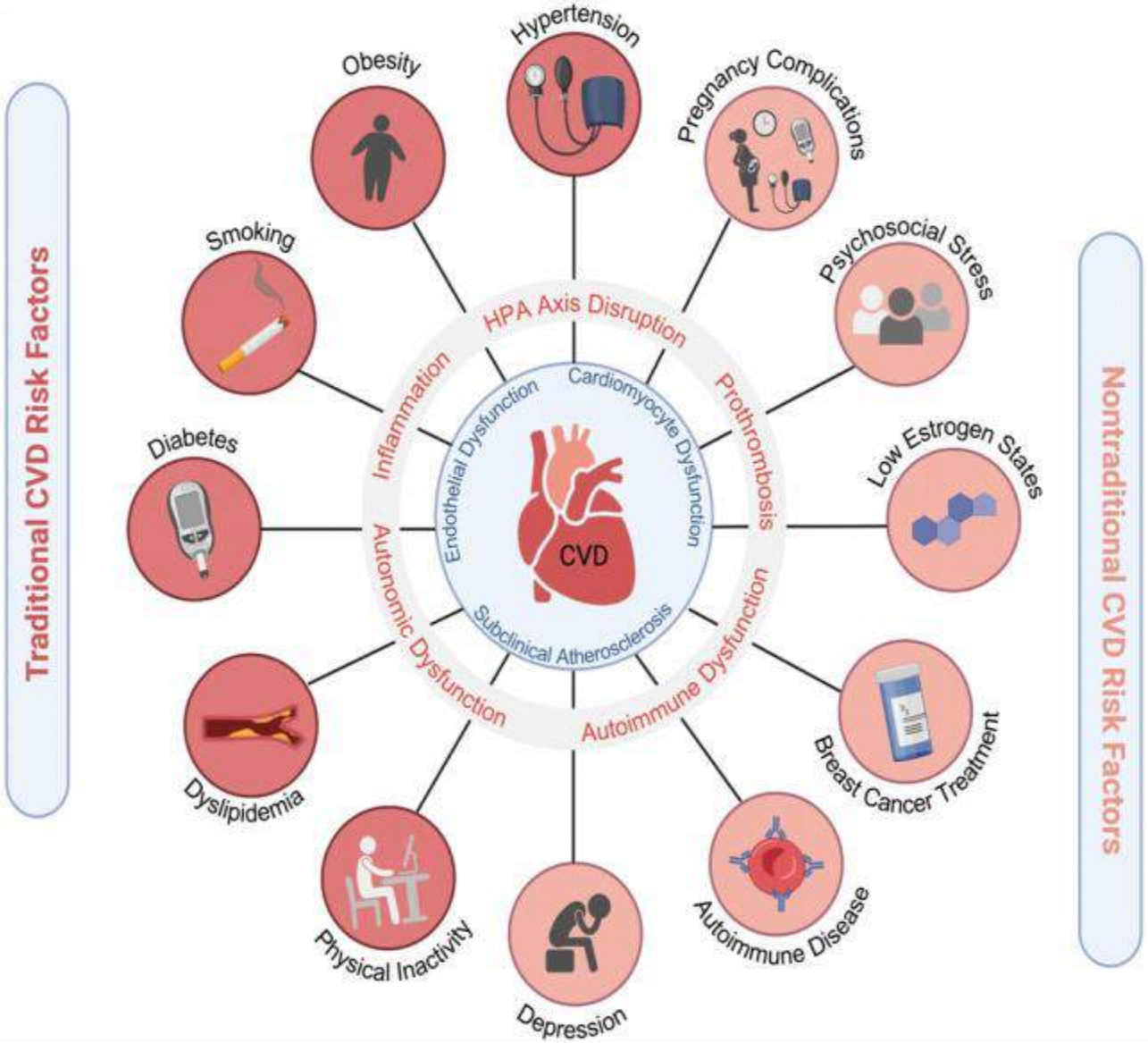

Fig.1 Cardiovascular trouble factors in women. There is a correlation between established and new trouble factors and increased atherosclerotic, thrombotic, and inflammatory stateswomen, which in turn increases the morbidity and mortality from CVD. Hypertensive diseases during gravidity, enhance diabetes, and preterm birth are samples of adverse pregnancy outcomes. Fig referred by. (3)

CORONARY ENDOTHELIAL FUNCTION AND VASCULAR AGING: is the term used to describe the adding hardening of the arteries together with a drop in the vessels' capacity to dilate. It develops in men and women in distinct ways. Unlike the progressive loss of vascular function associated with chronological aging, MP is characterized by rapid-fire vascular aging. Endothelial dysfunction and vascular aging are factors in the development of cardiovascular disease with menopause. Atherosclerosis and hypertension are two conditions that are eased by vascular aging. (4)

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CHANGES IN LIPID PROFILE: Women's lipid biographies are known to start changing during the perimeters, with increases in triglycerides (TD), LDL cholesterol, and total cholesterol (TC). A prospective disquisition of MP transition in Caucasian and non age women who weren't receiving hormone therapy was conducted as part of the disquisition of Women's Health Across the Nation (SWAN) design. It offered evidence that inimical lipid biographies and MP transition are related. It shown that, anyhow of the age at which the final menstrual period occurs, TC, LDL, and lipoprotein- B all increased in the time that followed. These are all associated with endothelial dysfunction and the development of atherosclerosis. Post-MP Carotid pillars are associated with elevated LDL levels during the peri-MP phase. These variations differ from the chronological aging 'linear differences. Over the MP transition, the line of HDL cholesterol or its suggested cardio protective effect isn't harmonious. Elevated HDL cholesterol has Its own independent cardio protective effect in youthful women. This could be as a result of the HDL patches' capability to stimulate cholesterol efflux, which is how HDL extracts cholesterol from supplemental cells. High HDL cholesterol in peri- and post-MP women may be associated with an increased threat of CVD. A measure of the health and remodeling of the highways is carotid India- media consistence, or IMT. The cIMT is higher in post-MP women with advanced HDL situations. Changes in the HDL particle quality throughout the MP transition could be the cause of this. (5)

HEART'S FAT DEPOTS: Directly covering the heart between the myocardium and visceral pericardium is called pericardia adipose tissue (EAT). EAT and PAT are now known to be novel risk factors for coronary heart disease. Pericardial adipose tissue (PAT) is situated out side the parietal pericardium and anterior to the EAT. Because these fat depots are so close to the heart, they might be more harmful than visceral fat. Compared to menopausal women, late primp/postmenopausal women had 20.7% higher PAT and 9.9%higher Eat in the SWAN cardiovascular fat ancillary trials. PAT might therefore be particular MP-specific CHD risk sign. (6)

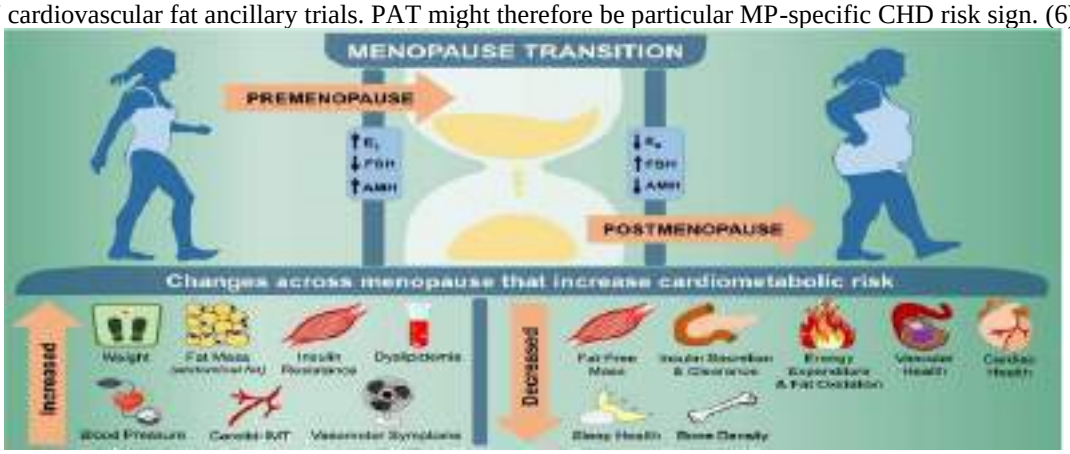

Fig.2 Correlated alterations in cardiometabolic risk with the transition to menopause. (7)

CVD SUBCLINICAL: Sub-clinical CVD may be indicated by markers such as IMT, coronary artery calcification (CAC), an indicator of atherosclerotic plaques, aortic calcification, and measurements of vascular stiffness such as aortic pulse wave velocity or flow-mediated dilation (a sign of endothelial function). These have the ability forecasts occurrences. A rise in IMT is a characteristic of late primp in women when their dyslipdemia and metabolic syndrome deteriorate. Additionally, there appears a connection between MP transition and the likely hood endothelial dysfunction. (6)

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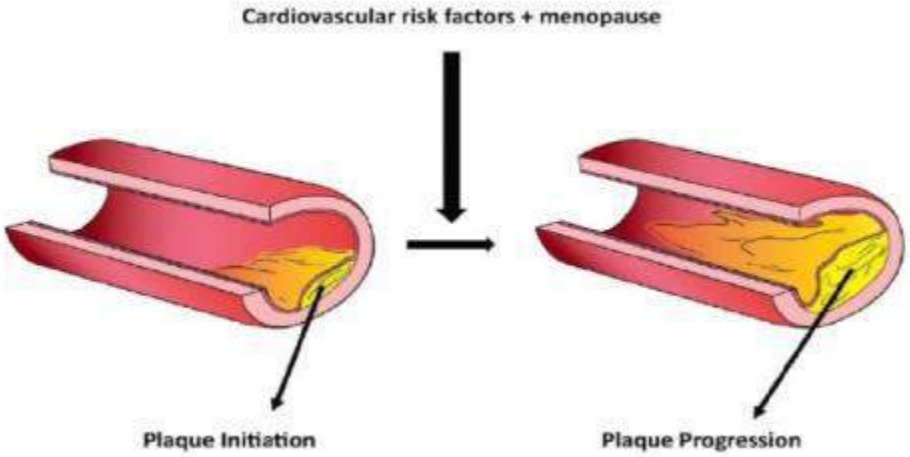

Fig. 3: Demonstrates how menopause and cardiovascular risk factors may have an effect on the development of atherosclerosis. (6)

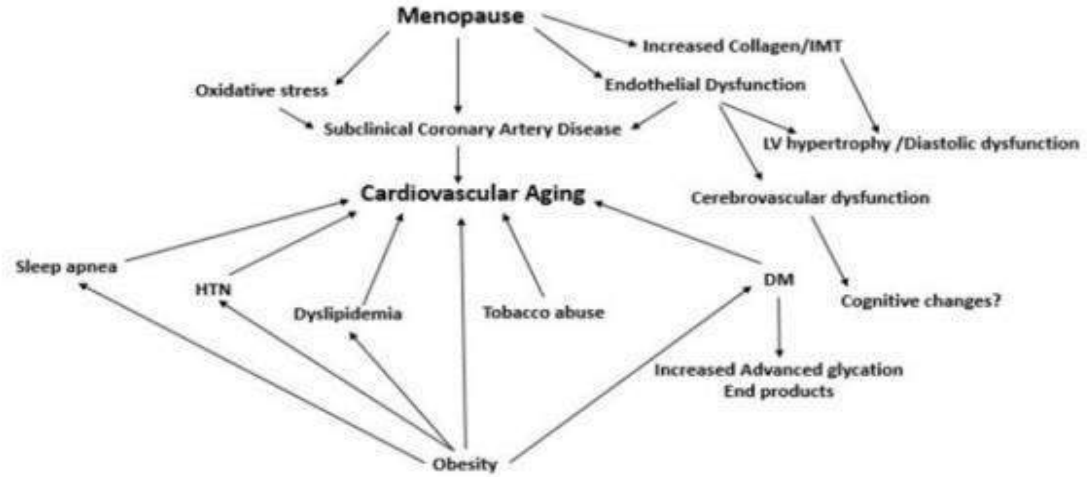

Fig.4: Demonstrates how cardiovascular risk factors are highlighted in the context of menopause. (6)

THE METABOLIC SYNDROME PREVALENCE: The co-existence of many metabolic risk factors, such as central obesity, dyslipidemia, hypertension, and impaired glucose tolerance, is known as metabolic syndrome.
The distribution and storage of fat are significantly influenced by estrogen. The accumulation of fat occurs in the thighs, buttocks, and hips prior to menopause. Because of chronologic aging, women tend to gain weight (total body fat) after midlife and beyond. However, there is a shift in the distribution of fat as well as the body composition (fat:lean body mass) in women who undergo the MP transition. (6), (8), (9).

MP AND OXIDATIVE STRESS: Aging and oxidative stress are closely related. Atherosclerosis can be caused by an excess of free radicals, such as Reactive Oxygen Species (ROS), and a decrease in antioxidant levels. This decrease, in conjunction with a progressive loss of estrogen in the female reproductive system, is strongly linked to a number of MP sequelae, including non-cardiac consequences like osteoporosis and heart disease and vasomotor abnormalities., (10), (9. Tchernof)

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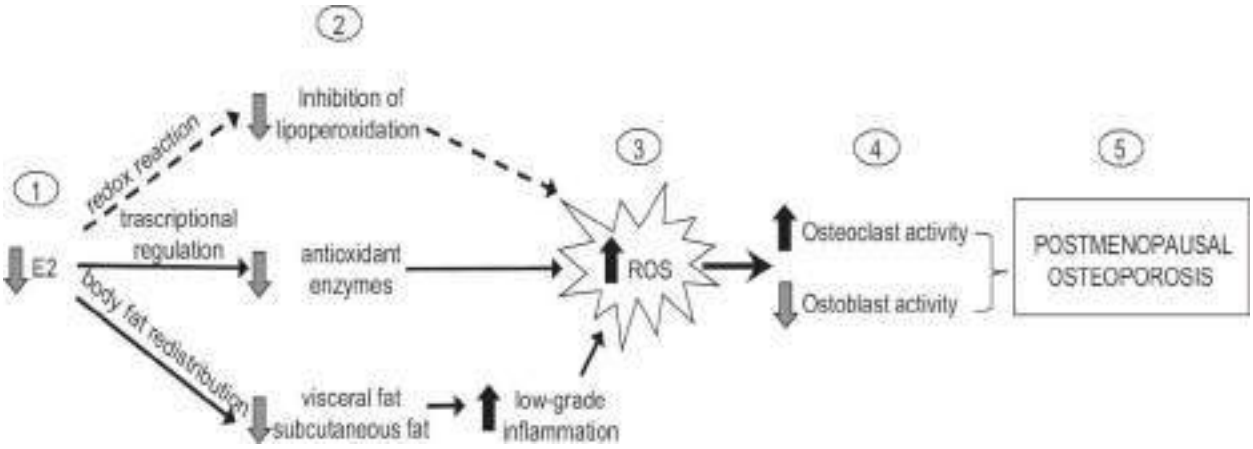

Fig.5 Oestrogen decline, oxidative stress, and postmenopausal osteoporosis: a cause-and-effect link. (11)**. Menopause-related reduction in oestrogens (E2). (1)resulting in a loss in systemic and local (bone) protection against reactive oxygen species assault.(2) This impact is attributed to the ability of 17β-oestradiol to act as a direct antioxidant and, most likely, upregulate the expression of antioxidant enzymes. It also contrasts the growth of pro-inflammatory visceral fat. Oxidative stress occurs when reactive oxygen species (ROS) levels rise uncontrollably.(3)This affects the equilibrium of bone production and resorption.(4) therefore boosting the latter activity and leading to the onset of post-menopausal osteoporosis.(5).**

The Decline of Estrogen and Cerebrovascular Illness: In the cerebrovascular system, estrogens reduce vascular tone and thereby enhance blood flow, whereas androgens increase tone. Another way that estrogens and androgens work is through increasing angiogenesis. Estrogen has the ability to lower inflammation and oxidative stress, which protects neurons by maintaining the blood-brain barrier and lowering oxidative stress. Changes in MP hormone levels may have a detrimental effect on cognition and contribute to cerebrovascular dysfunction in the presence of cardiovascular diseases. (12)

Handling Cardiac Symptoms During the Menopause Transition:- The main symptom of MP is called vasomotor symptom (VMS). reduction of the thermoneutral zone, causing mild variations in body temperature to trigger compensatory flushing and perspiration, ultimately resulting in hot flashes and nocturnal sweats. CV concerns have been connected to VMS. VMS also adds to a lower quality of life overall, irritation, difficulties concentrating, and poor sleep quality. Lifestyle adjustments, non-hormonal medicines and systemic hormone treatment may be indicated for the management of VMS. (13)

The treatment of moderate to severe VMS is the main use case for hormone therapy. The gold standard for treating VMS is hormone treatment. This could involve progesterone and estrogen therapy (EPT) for women who still retain their uterus or the use of estrogen alone (ET) for women who have had hysterectomy. Progestogens or the SERM bazedoxifene are two options for endometrial protection, which women with uteri require to prevent endometrial neoplasia. The use of systemic hormones, which can be administered orally (PO) or transdermally (T/D), is necessary for the management of VMS. Generally speaking, the shortest amount of time spent using the lowest dose of hormones required for symptom alleviation is advised.

Reduced HT dosages are linked to a decreased incidence of breast discomfort, unplanned vaginal bleeding, and venous thromboembolism (VTE). It may take 6–8 weeks for HT at lower dosages to start showing symptom alleviation. Oral conjugated equine estrogen (CEE) 0.3 mg, oral 17 beta-estradiol 0.5 mg, and estradiol patch 0.025 mg are some possible forms of estrogen. Oral progesterone, such as medroxyprogesterone acetate (MPA), may be prescribed if progestogens are necessary for the patient. (14)

Progestogens (natural or synthetic) can be used alone to treat VMS; however, they are less effective than estrogen therapy and have inadequate long-term safety data. Long-term use raises concerns about the potential of breast pathology. Progesterone formulations include oral MPA 10 mg/day, oral megestrol acetate 20mg, and micronized progesterone 300 mg nightly.

Tissue Selective Estrogen Complex (TSEC) is an FDA-approved treatment for VMS in women with a uterus that combines Bazedoxifene, a SERM (Selective Estrogen Receptor Modulator), and (CEE). It has the additional benefit of preventing osteoporosis. Bazoxifene provides endometrial protection. As a result, extra progestin is not recommended.

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The government-approved Bioidentical Hormone Therapy (BHT), which includes estradiol, estrone, and micronized progesterone formulations, is regulated for purity, safety, and efficacy. The FDA has not approved "Compounded BHT" products sold as BHT. There are special considerations here, particularly about safety. These are often manufactured by a pharmacist in a compounding pharmacy using the provider's prescription. The compounded BHT may contain a variety of hormones. As a result, the quality, efficacy, and safety of the components cannot be guaranteed. The concentration of hormones in these formulations is also unknown, as is their bioavailability. As a result, there is a risk of over- or underdosing. The dangers associated with compounded BHT are typically not disclosed.They may contain unapproved combinations of drugs and be administered by experimental means, such as hormone pellets, troches, or subdermal implants.

Compounded BHT should only be considered if patients are unable to tolerate FDA-approved hormones due to concerns such as component allergies or a lack of a dose or formulation. (15)

CONCLUSION

Menopause e is frequently a turning point in women's health around the world. Increasing evidence from experimental and clinical investigations suggests that cardio metabolic changes might occur during the menopausal transition, compounding the influence of aging on the risk of cardiovascular disease. The menopausal transition is associated with increased fat mass (mostly inter nuclear), insulin resistance, dyslipidemia, and endothelial dysfunction. Endogenous estrogen exposure throughout the reproductive years protects women from cardiovascular disease, which is lost approximately ten years following menopause. Women with vasomotor symptoms during menopause appear to have a worse cardio metabolic profile. Early management of the traditional risk factors of cardiovascular disease (i.e., hypertension, obesity, diabetes, dyslipidemia, and smoking) is essential; However, it is important to recognize in the reproductive history the female-specific conditions (i.e., gestational hypertension or diabetes, premature ovarian insufficiency, some gynecological diseases such as functional hypothalamic amenorrhea, and probably others) that could enhance the risk of cardiovascular disease. In this Review, the first of two papers, we provide an overview of the literature for understanding cardio metabolic changes and the management of women at higher risk in midlife (40-65 years), with a focus on identifying factors that can predict the occurrence of cardiovascular disease. We also present research on preventive non- hormonal measures in the context of cardio metabolic health. (6)

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A REVIEW ON DEMONSTRATION OF HPLC

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ABSTRACT

High-Performance Liquid Chromatography (HPLC) is a powerful analytical technique used for separating, identifying, and quantifying components in a mixture. This demonstration aims to showcase the principles and operation of HPLC in a laboratory setting. It involves the use of a liquid mobile phase that is pumped through a column packed with a stationary phase, where the sample mixture is separated based on the differential interactions between the analytes and the stationary phase. The separated components are then detected, typically by UV-Vis absorption or fluorescence, and quantified. This demonstration will highlight key aspects such as sample preparation, column selection, mobile phase optimization, and the role of detector systems in obtaining accurate results. By understanding the setup and operation of an HPLC system, users can effectively apply the technique to a wide range of applications, from pharmaceutical analysis to environmental monitoring.

1.INTRODUCTION

HPLC, developed in the late 1960s by Kirkland and others, integrates liquid chromatography principles into gas chromatography techniques for separating macromolecular substances like proteins and nucleic acids. Using stationary phases with smaller particle sizes under high pressure, HPLC achieves rapid separations within minutes to hours. Its four basic components are a high-pressure infusion system, sample loading system, separation system, and detection system. Today, HPLC is widely used in pharmaceuticals, biotechnology, environmental science, polymers, and the food industry.

Developed in the late 1960s by Kirkland and others, HPLC combines liquid and gas chromatography principles to separate macromolecules like proteins and nucleic acids. It uses small-particle stationary phases under high pressure for rapid separations. Key components include a high-pressure infusion system, sample loader, separation system, and detector. HPLC is widely applied in pharmaceuticals, biotechnology, environmental science, polymers, and food industries.

2.GENERAL PRINCIPLE OF HPLC

The separation principle of High-Performance Liquid Chromatography (HPLC) is based on the distribution of the analyte (sample) between a mobile phase (eluent) and a stationary phase (the packing material in the column). Depending on the chemical structure of the analyte, the molecules are delayed as they pass through the stationary phase. The specific intermolecular interactions between the sample molecules and the packing material determine their "on-column" retention time. As a result, different components of a sample are eluted at different times, achieving the separation of the sample's constituents. A detection unit (such as a UV detector) identifies the analytes as they exit the column. The signals are then processed and recorded by a data management system (software) and displayed in a chromatogram. After passing through the detector, the mobile phase can be directed to additional detectors, a fraction collection unit, or discarded as waste. In general, an HPLC system consists of the following components: a solvent reservoir, a pump, an injection valve, a column, a detector unit, and a data processing unit.

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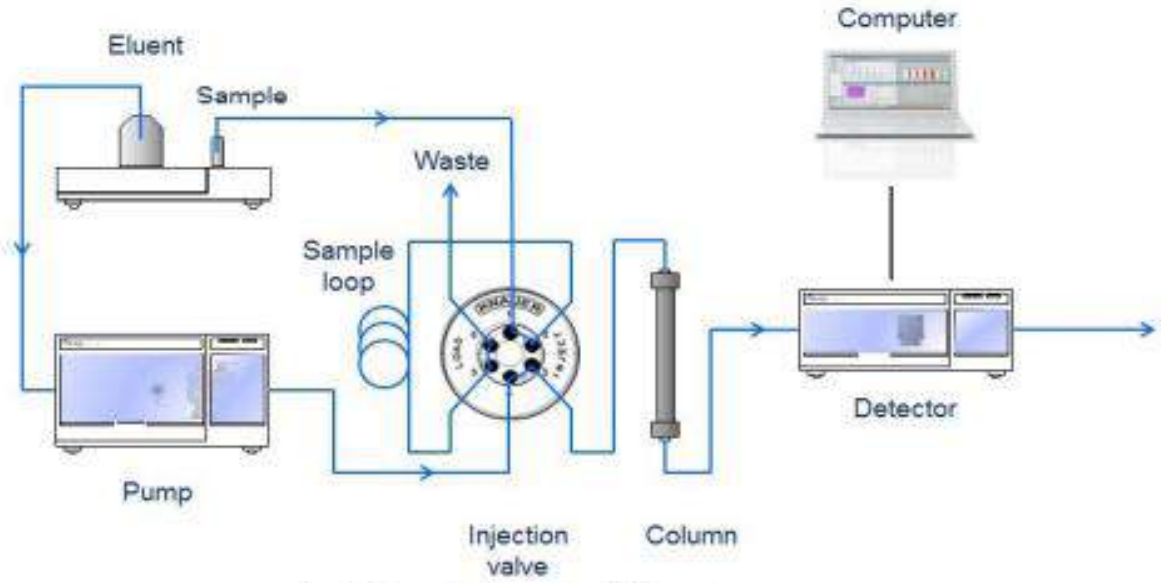
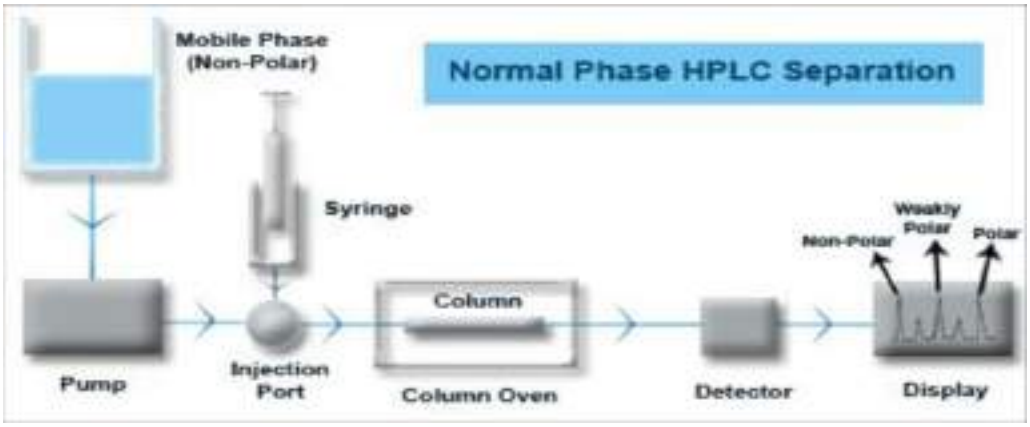


Fig. 1 Schematic layout of a HPLC system

3. TYPES OF HPLC

3.1 Normal Phase Chromatography:

Also known as Normal Phase HPLC (NP-HPLC), this technique separates analytes based on their polarity. It utilizes a polar stationary phase and a non-polar mobile phase. Polar analytes interact with and are retained by the polar stationary phase, with adsorption strength increasing as the analyte's polarity rises. These interactions result in longer elution times for more polar compounds**.**



3.2 Reversed Phase Chromatography

Reversed Phase HPLC (RP-HPLC or RPC) uses a non-polar stationary phase and a moderately polar aqueous mobile phase. The separation occurs through hydrophobic interactions between the non-polar stationary phase and relatively non-polar analytes, driven by the repulsive forces between the analyte and the polar mobile phase. The binding of the analyte to the stationary phase is influenced by the surface area contact between the non-polar part of the analyte and the ligand in the aqueous mobile phase.

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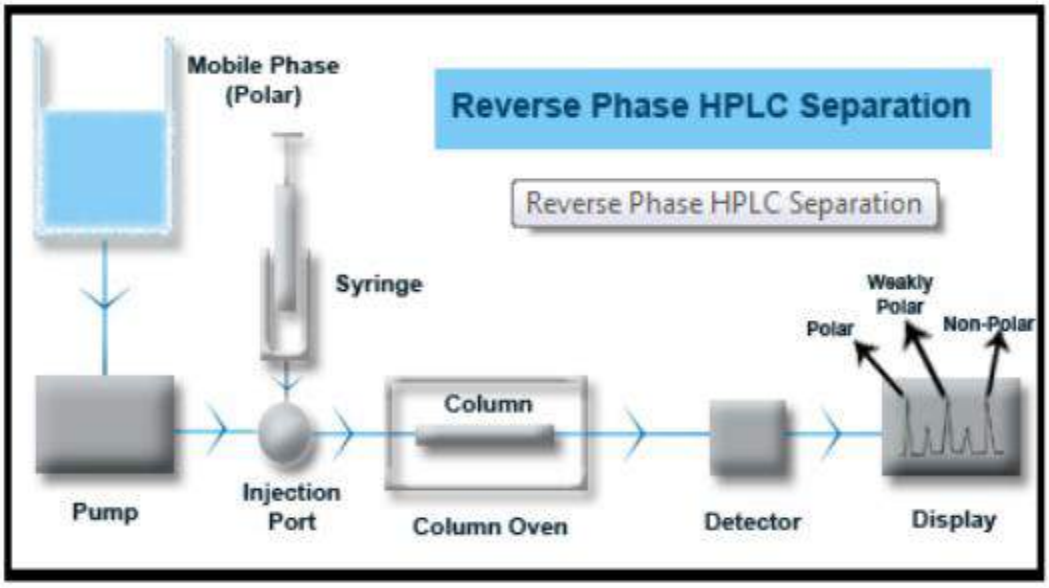
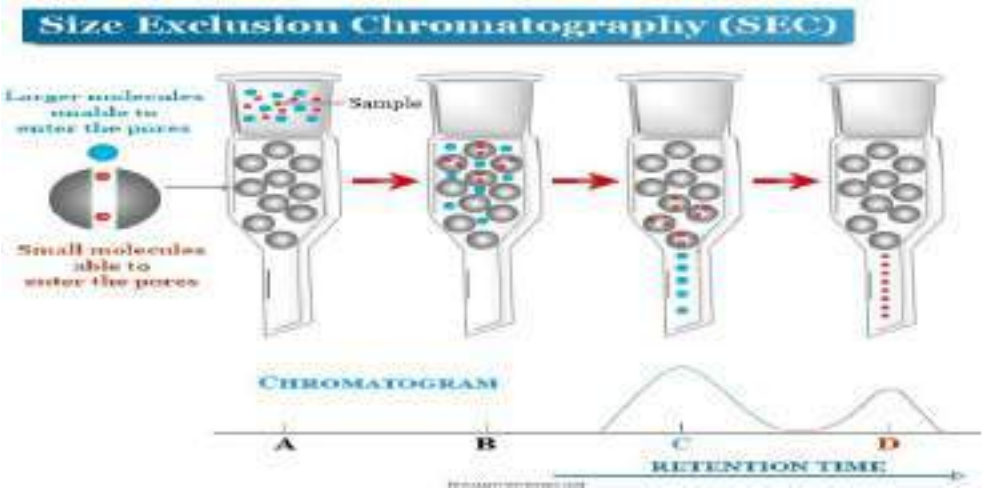


3 3. Size Exclusion Chromatography

Size Exclusion Chromatography (SEC), also known as Gel Permeation Chromatography (GPC) or Gel Filtration Chromatography, primarily separates molecules based on their size. It is commonly used to determine the molecular weight of polysaccharides, and to analyze the tertiary and quaternary structures of proteins and amino acids.



3.4 Ion Exchange Chromatography

Ion Exchange Chromatography relies on the interaction between charged solute ions and oppositely charged sites on the stationary phase. Ions with the same charge as the stationary phase are excluded. This technique is widely used for water purification, protein purification (such as in the isolation of proteins), and high-pH anion-exchange chromatography for carbohydrates and oligosaccharides.

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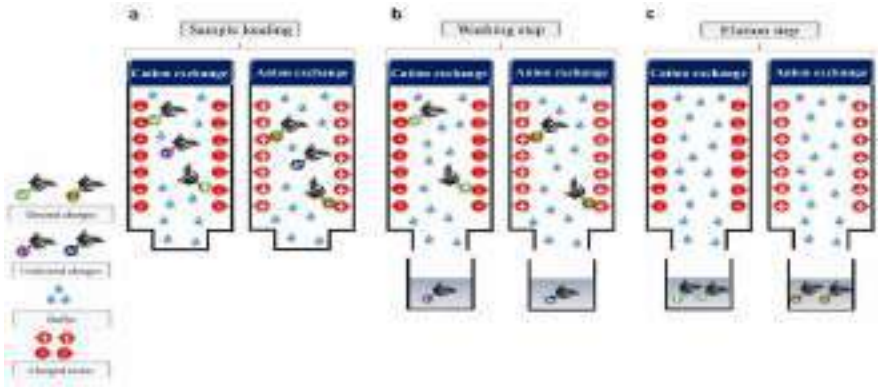


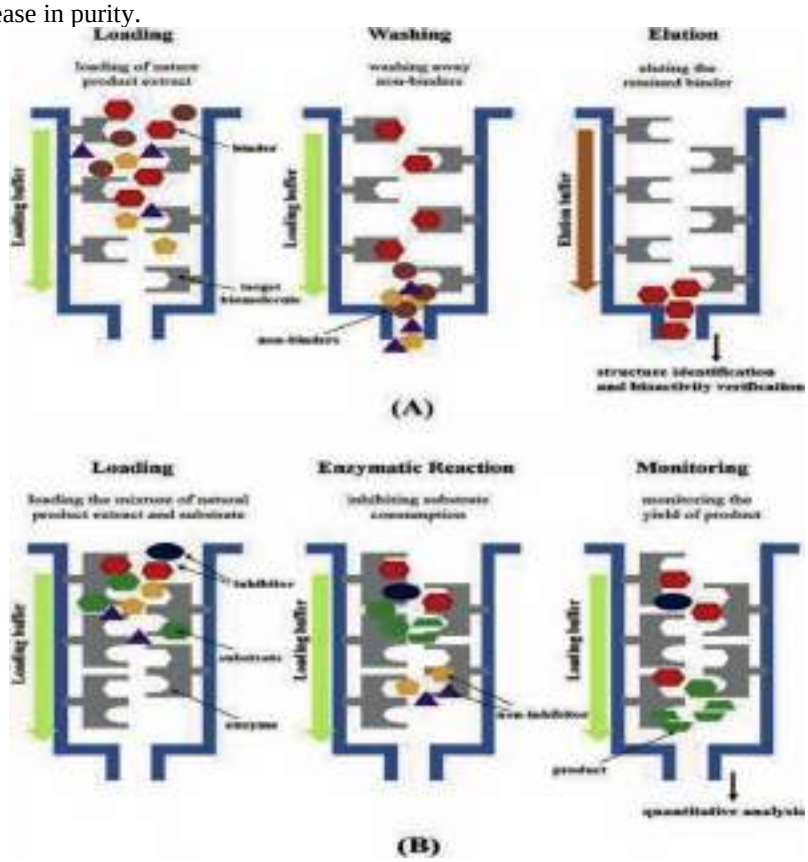
3.5 Bio-Affinity Chromatography

This method separates compounds based on the specific, reversible interactions between proteins and ligands. The ligands are covalently attached to a solid support matrix, which retains proteins that interact with these column-bound ligands. Proteins can be eluted from the column in two ways:

Biospecific Elution: By adding a free ligand to the elution buffer, which competes with the column-bound ligand.

Aspecific Elution: By altering the conditions (e.g., changing pH or salt concentration) to weaken the interaction between the protein and the column-bound ligand.

Due to the high specificity of the interaction, bio-affinity chromatography can achieve significant purification in a single step, often providing a 10- to 1000-fold increase in purity.



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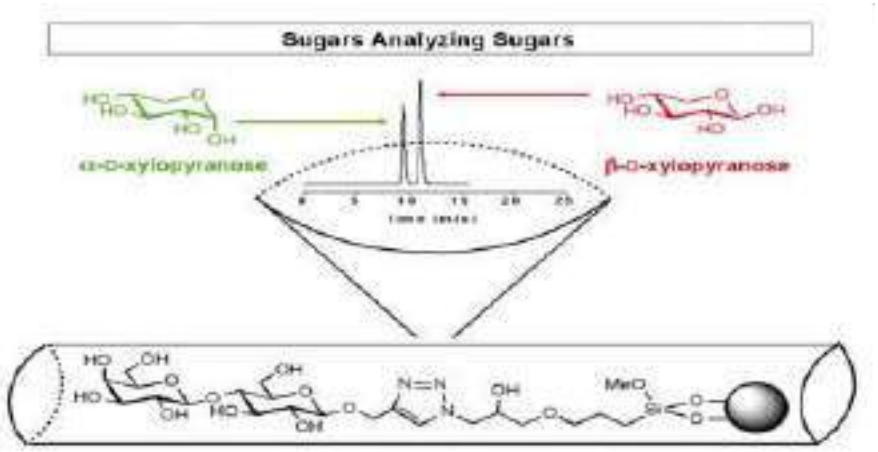
3.6 Hydrophilic Interaction Chromatography (HILIC)

Another chromatographic separation mode used in High-Performance Liquid Chromatography (HPLC) is Hydrophilic Interaction Chromatography (HILIC). This technique combines the principles of hydrophilic interaction liquid chromatography with the conventional HPLC approach. HILIC is specifically applied in certain HPLC columns for specialized analyses. In HILIC, the separation of biomolecules occurs based on their polar and hydrophilic interactions. This mode is particularly effective for the separation of small polar compounds using polar stationary phases.

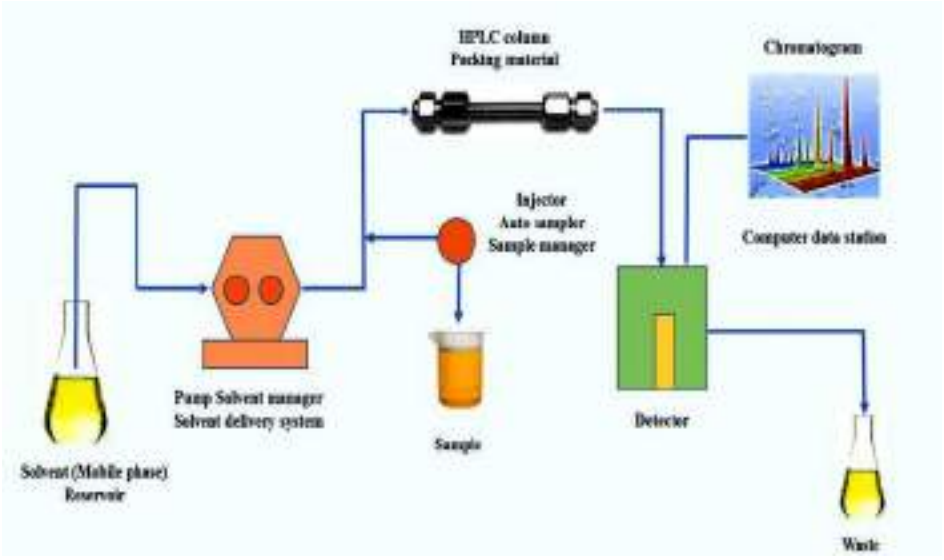


4. INSTRUMENTATION OF HPLC

Components of HPLC

1. Solvent Reservoir and Degassing system
2. Pumping System
3. Sample Injection System
4. Columns
5. Detectors
6. Data Handling System

FIG. High Performance Liquid Chromatography System



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4.1. Solvent reservoir and Degassing system

The mobile phase used in High-Performance Liquid Chromatography (HPLC) can consist of a mixture of organic solvents, an aqueous-organic mixture, or a buffer solution. The choice of mobile phase depends on the chromatographic technique and the type of detector employed. Specially refined commercial-grade solvents, which are purified to remove UV-absorbing impurities and particulate matter, are commonly used in HPLC. If other grades of solvents are considered, purification is essential because impurities, such as those with strong UV absorption, high polarity (e.g., traces of water or ethanol in chloroform), or those that affect the detector, can interfere with the separation process.

The solvent reservoir is typically a 1-liter glass bottle with a lid, connected to a PTFE (polytetrafluoroethylene) tube of 1/8 inch diameter to transfer the mobile phase from the reservoir to the degasser and pump. To avoid irregular pumping, contamination of the column, damage to seals and valves, or column blockages, the liquid entering the pump must be free from impurities like dust and particulate matter. Often, a stainless steel filter (with a pore size of 2 microns) is used in the PTFE tube within the reservoir, or an inline filter is employed to ensure the mobile phase is adequately purified before entering the system.

Degassing System ;

Generally, liquids dissolve some amounts of atmospheric gases (e.g., air or suspended air-bubbles) that cause some major practical problems in HPLC, specifically affecting the working of pump and the detector. These problems can be avoide d by degassing the mobile phase. Degassing is performed by:

1) External Vacuum Degassing
2) Helium sparging
3) Online Degassing
4) Filters

4.1.1 .External Vacuum Degassing

External Vacuum Degassing: In this method, the solvent is placed in a container and exposed to an ultrasonic bath while under vacuum, which is created using a vacuum pump. This process helps to remove dissolved gases from the solvents, making them suitable for use in HPLC. It is particularly effective for solvents that tend to absorb gases, such as carbon dioxide, and is also useful for eluents that are blanketed with an inert gas like helium. This technique is illustrated in the figure.

Fig. Instrumentation OF A Typical HPLC Unit

4.1.2 Helium Sparging

This technique involves bubbling helium through the solvent to remove other dissolved gases. The amount of helium and the duration of sparging need to be carefully controlled. Since helium is insoluble in the mobile phase, it escapes without affecting the chromatographic process. This method, known as helium sparging, can be performed either online, if the helium tank is integrated with the HPLC system, or offline. However, there are some limitations. Helium may selectively volatilize the more volatile solvents, potentially altering the composition of the premixed solvents. Additionally, helium is relatively expensive and requires large quantities for effective sparging.

4.1.3Online Degassing

This technique involves using a vacuum pump in conjunction with the HPLC system. A vacuum is applied to semi-permeable tubes through which the solvents flow, effectively removing dissolved air from the solvents. The expelled air is then directed to a waste collection container. This method is illustrated in the figure.

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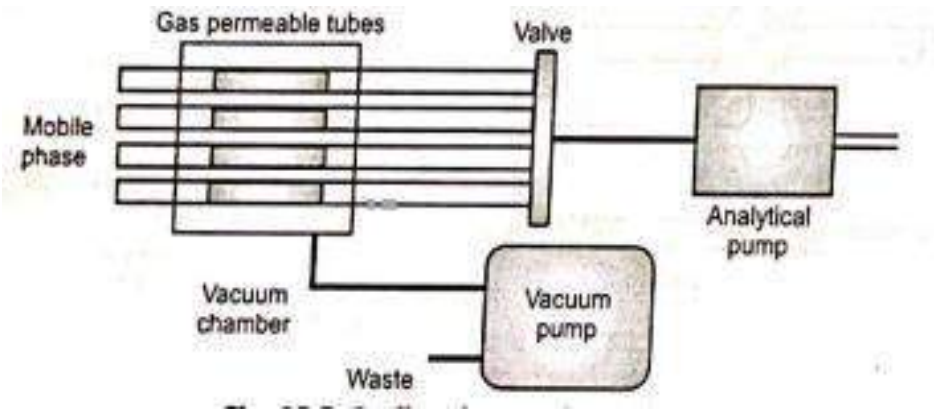

Fig. Online degassschematic

4.1.4 Filtration

In addition to the methods mentioned above, filters are also employed to remove dust and other impurities from solvents. Membrane filters with a pore size of 0.45 µm are commonly used. The mobile phase is filtered through these membranes using a Buchner funnel under vacuum, often followed by ultrasonication.

Other devices that may be used in the process include:
(a) A vacuum pumping system,
(b) A distillation system,
(c) Devices for heating and stirring the solvents, or
(d) A sparging device, where dissolved gases are removed from the solution by passing an inert gas with low solubility through fine bubbles.

Additionally, a filter may be used to remove particulate matter from solvents. An alternative method is to filter the solvent through a Millipore filter under vacuum before it is introduced into the solvent reservoir. The typical pore size for such filters is 0.2 µm, which effectively removes excess particles.

In Analytical HPLC, the mobile phase is pumped through the column at flow rates of 1-5 ml/min. The mobile phase can consist of a mixture of aqueous and organic solvents, or buffer solutions, depending on the chromatographic method and the type of detector used.

4.2 Pumping System

The liquid chromatographic pumps must meet the following requirements:

1. Ability to generate pressures up to 6000 psi (lb/in²),
2. Provide a pulse-free output,
3. Operate with flow rates ranging from 0.1 to 10 ml/min,
4. Achieve flow reproducibility of 0.5% or better,
5. Be resistant to corrosion from various solvents.

Although the high pressures in liquid chromatographic pumps do not pose an explosion risk due to the low compressibility of liquids, solvent leakage from a ruptured component could lead to fire or environmental hazards.

Based on the mechanism of working the pumps can be classified into:
1. Syringe Pump/Displacement pumps
2. Reciprocating piston pumps
3. Constant pressure pumps

4.2.1. **Syringe Pumps**

A syringe pump is made up of a large syringe with a plunger connected to a digital stepping motor or a precision screw drive. As the plunger moves, it pushes a fixed volume of solvent through the chromatograph at a constant, pulseless flow. These pumps are known

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for their smooth, pulseless solvent delivery. The flow rates are typically under 100 µl/min, and the flow is unaffected by viscosity or column back pressure. However, the runtime is limited by the syringe's volume, and no flow occurs during the refill step. It has limitations such as low solvent capacity (200-500ml) and it is not easy to change solvent during gradient elution.

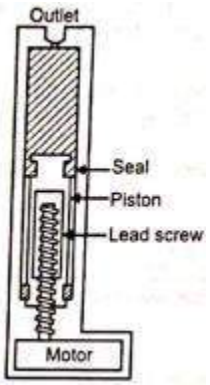

Fig. Syringe Pumps

4.2.2. Reciprocating- piston Pump

A reciprocating pump is one of the most commonly used designs in modern High-Performance Liquid Chromatography (HPLC). Its operation is similar to that of a constant displacement pump. The pump head consists of check valves and a seal-piston assembly. The check valves control the flow of solvents from the reservoir into the pump chamber and then onto the column. The mechanism involves two main strokes: the fill stroke and the delivery stroke. During the fill stroke, the solvent is drawn into the liquid chamber from the solvent reservoir. In the delivery stroke, the piston moves into the chamber, compressing the solvent. As a result, the inlet check valve closes, and when the pressure in the pump head exceeds that in the column, the outlet check valve opens, allowing the mobile phase to flow toward the column.

The advantages of reciprocating pumps include a continuous solvent flow, no limitations on the reservoir size or operating time, and easy and quick solvent changes, which are especially beneficial during gradient elution. These pumps are essential for equipment used in automated operations. A diagram of the reciprocating pump is provided in Fig.

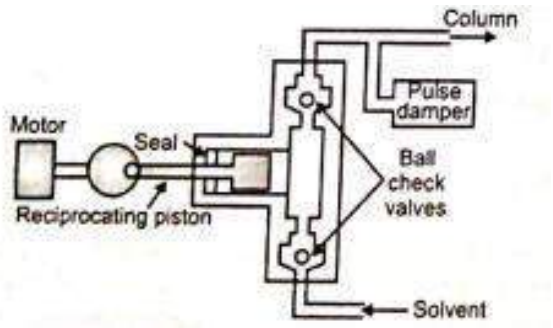

Fig. Reciprocating Piston Pump

4.2.3. Constant Pressure Pumps:

In these pumps, high-pressure gas is introduced into a large piston, which then drives the solvent from the pump chamber to the column. The volume of the solvent chamber is approximately 70 mL (as shown in Fig. 15.9). The pressure exerted on the solvent is proportional to the ratio of the areas of the two pistons, typically between 30:1 and 50:1. As a result, a low-pressure gas source of 1 atm can generate liquid pressures ranging from 1 to 400 atm. To minimize the interference of dissolved gas in the solvent, an intermediate solvent is often used. A valve facilitates the rapid refill of the solvent chamber. This system ensures continuous and pulsation-free pumping, enabling high flow rates, which makes it ideal for preparative applications. It is commonly used for packing columns, though it is less suited for gradient elution due to its limitations in flexibility.

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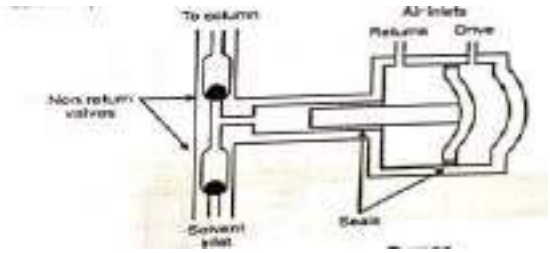


Fig. Constant Pressure Pumps

4.3. Sample Injection System:

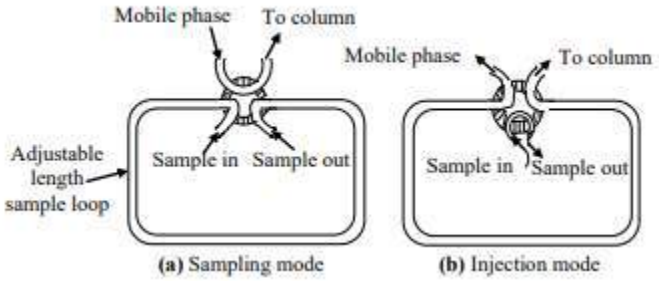
Three primary modes of sample injection are commonly utilized in High-Performance Liquid Chromatography (HPLC):

1. Septum Injectors: In this system, the sample is introduced into the HPLC system through a high-pressure syringe that punctures a self-sealing septum made of elastomer. A significant disadvantage of this method is that the mobile phase comes into direct contact with the septum, leading to a leaching effect. This can result in the appearance of ghost or pseudo peaks in the chromatogram.
2. Stop-Flow, Septum-Less Injection: This method addresses many of the issues associated with septum injectors. The flow of the mobile phase through the column is temporarily halted, and when the column reaches ambient pressure, the top of the column is opened. The sample is then introduced at the top of the column packing. This system is more reliable and still relatively inexpensive compared to other methods.
3. Micro-Volume Sampling Valves: In modern, high-precision HPLC systems, micro-volume sampling valves are used. These valves enable highly reproducible and automated sample injections into pressurized columns with minimal disruption to the mobile phase flow. The operation of these valves is typically described through two modes of sample loop operation:

Sampling Mode
Injection Mode

In the sampling mode, the sample is introduced into an external loop of the micro-volume sampling valve at atmospheric pressure. During the injection mode, the valve rotates, and the sample is injected into the mobile phase. The sample volumes typically range from 2 to 100 µL, although the volume can be adjusted by changing the sample loop or by using variable-volume sampling valves.

This method is particularly advantageous for applications requiring high precision and reproducibility, and it has become standard in modern, automated HPLC systems.



4. 4.Columns

The column is the heart of the chromatograph, providing the means for separating a mixture into components. The selectivity, capacity, and efficiency of the column are all affected by the nature of the packing material or the materials of construction.

- **Column Types in HPLC**

Guard Columns

A guard column is a short column placed between the injector and the analytical column. Although the packing material in both guard columns and analytical columns is similar, the guard column has a larger particle size, which helps reduce the pressure drop.

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The benefits of guard columns include
1. They trap foreign particles and contaminants from the solvents, thereby extending the life of the analytical column.
2. In liquid-liquid chromatography, they help prevent the loss of stationary phase from the analytical column by ensuring the mobile phase is saturated with the stationary phase.

While guard columns and retention gaps are similar in structure (typically 1–10 meters of deactivated fused silica tubing), they serve different functions. Both are connected to the front of the column, but the tubing in a guard column does not contain a stationary phase, and its surface is deactivated to reduce interaction with the solute. A union connects the guard column to the analytical column. The diameter of the guard column or retention gap is typically the same as that of the column, though a larger diameter may be used if necessary.

Guard columns are especially useful for samples that may contain non-volatile residues, which could otherwise contaminate the column. These residues are deposited in the guard column, reducing their interaction with the sample since the guard column does not contain a stationary phase. This prevents contamination of the stationary phase and helps maintain good peak shapes. However, guard columns may require periodic trimming or replacement due to residue buildup. Guard columns are typically 5–10 meters long, which allows for easy trimming before replacement. If peak shape deteriorates, it may indicate the need for trimming or changing the guard column.

- **Retention Gaps**

Retention gaps improve peak shapes for specific samples, columns, and GC conditions. Usually, 3–5 meters of tubing is sufficient to provide the benefits of a retention gap. Retention gaps are particularly useful for large-volume injections (>2 µL) and situations where there is a mismatch in polarity between the solvent and the stationary phase, as seen in splitless, megabore direct, or on-column injections. These conditions can sometimes cause distorted peak shapes.

Polarity mismatches occur when the sample solvent and the column stationary phase have different polarities, leading to issues, especially for peaks near the solvent front or when solutes have similar polarity to the solvent. The benefits of a retention gap are best realized when a guard column is also used in combination with it.

Fig. Retention Gap Or Guard Coulmn

4.4.2 Column Thermostats

Chromatographic procedures can be performed at room temperature without the need for precise control over the column temperature. However, better chromatographic results are achieved when the column temperature is maintained within a few tenths of a degree Celsius. To ensure stable and accurate temperature regulation, water jackets are often installed around the columns. Modern commercial instruments are equipped with heaters that can regulate the column temperature to within a few tenths of a degree, typically ranging from ambient temperature up to 150°C.

5. Detectors

In HPLC, a detector is placed at the end of the system.
Its job is to analyze the solution that comes out of the column.
The concentration of each component in the mixture is directly related to the electronic signal it produces.

- **Features of Detectors Used in HPLC:**

a) The detector should respond to all components in the mixture.
b) The response should be directly proportional to the analyte concentration.
c) The response should not be affected by changes in temperature.
d) The detector should be unaffected by the composition of the eluent (gradient).

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e) It should be able to detect even very low concentrations.
f) The peaks should remain sharp, not broaden.
g) The signal should be stable and reproducible.
h) The detector should be non-destructive.

- **Classification of Detectors**

1. Bulk Property Detectors:
   - Electrical Conductivity HPLC Detector
   - Refractive Index HPLC Detectors
   - Electrochemical HPLC Detectors
   - Light Scattering HPLC Detectors
2. Solute Property Detectors
   - UV/Visible Detectors
   - Fixed Wavelegth Detectors
   - Diode Array Detectors
   - Fluorescence HPLC Detectors

Bulk Property Detectors
Bulk property detectors measure changes in both the solute and the mobile phase together. These detectors often show fluctuations in readings, even with small changes in the mobile phase composition. Examples include refractive index and conductivity detectors. Despite being applicable to many situations, they are used less frequently due to their lower sensitivity and limited range. These detectors are generally referred to as non-selective because they respond to the overall properties of the analyte.

Solute Property Detectors
Solute property detectors, also known as selective detectors, respond to specific physical or chemical properties of the analyte, and ideally, their response is independent of the mobile phase. While it is not entirely possible to achieve complete independence from the mobile phase, the ability of these detectors to discriminate the signal is usually enough to work effectively even when the solvent composition changes, such as in gradient elution.

5.1 Other Popular Detectors Used in HPLC
a) Transport Detectors
Transport detectors use a carrier, such as a metal chain, wire, or disc, which continuously moves through the column, carrying the analyte out of the mobile phase. The solute sticks to the surface of the carrier as a thin film, while the mobile phase evaporates. Two types of transport detectors commonly used in HPLC systems are moving wire and moving chain detectors.

b) Chiral Detectors
Some compounds, especially drugs, can exist as enantiomers, which may have different biological effects. Chiral detectors are designed to detect these different forms of compounds. These detectors are used for optically active substances like amino acids, terpenes, sugars, and other chiral compounds. Techniques like Polarimetry, Optical Rotatory Dispersion (ORD), and Circular Dichroism (CD) are commonly used for chiral detection. ORD detectors work by detecting differences in the refractive index, while CD detectors distinguish enantiomers by measuring the absorption differences of right- and left-handed circularly polarized light.

c) Corona Discharge Detectors
Corona Discharge Detectors (often referred to as Corona Charged Aerosol Detectors, or CAD) are a newer, unique detection method. In this technique, the HPLC eluent is first nebulized using nitrogen (or air) gas to create droplets, which are then dried to remove the mobile phase, leaving behind analyte particles. The principle behind corona discharge detection is the transfer of charge from the analyte particles to a secondary nitrogen (or air) stream. This positively charged stream generates a high voltage in a platinum corona wire, causing diffusion of the particles. The analyte particles are then collected and measured by a sensitive electrometer, which produces a signal directly proportional to the amount of analyte present.

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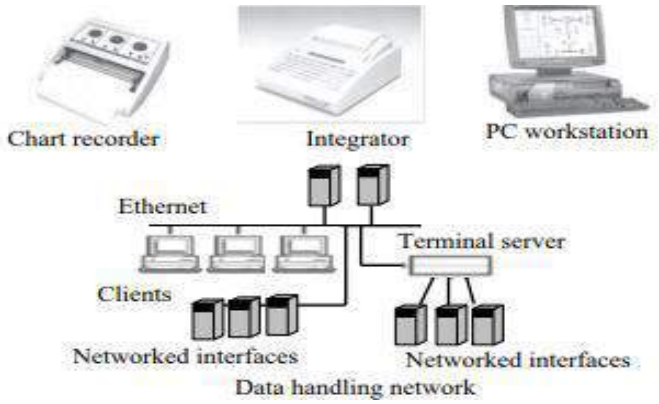
6. Data Handling System

In HPLC, there has been significant progress in data handling systems, evolving from basic devices like strip chart recorders and electric integrators to more advanced setups such as PC-based workstations and modern client-server network systems (the most recent development). Automation and complexity have also improved over time, keeping pace with technological advancements.



7.Advantages And Disadvantages Of HPLC

7.1 Advantages

HPLC has the following advantages:

1) It is a simple, rapid, and reproducible technique.
2) It is highly sensitive.
3) It shows a better performance.
4) It is a rapid process and is less time consuming.
5) Its resolution and separation capacity is high.
6) It is accurate and precise.
7) It utilises a chemically inert mobile and stationary phases.
8) It needs a small amount of mobile phase for developing chamber.
9) It involves early recovery of separated components.
10) It enables easy visualisation of separated components.
11) It shows a good reproducibility and repeatability.
12) It is useful in qualitative and quantitative analysis.
13) It is used for analytical and preparative purposes.
14) It is used for validation and quality control studies of product.

7.2 Disadvantages

The disadvantages of HPLC focus on the detection systems available, and include:

1) The most commonly used detectors in HPLC are UV spectrometers; however, the compound to be analysed should have a UV absorbing chromophore.
2) Variable wavelength UV spectrometers offer versatility but some steroids and other drugs must be derivatized before UV detection.
3) Another slight disadvantage is that the chemically bonded stationary phases applicable in drug analysis should be used within 3 -7 pH range to ensure long term stability.

8.Applications of HPLC

1. Pharmaceutical Industry: HPLC plays a crucial role in the pharmaceutical sector, particularly in Research & Development (R&D), Quality Control (QC), and Formulation & Development (F&D). It is employed for analyzing samples throughout the entire production process, from raw material analysis to final product testing.
   For instance, reverse-phase HPLC is used to analyze polar compounds like polyphenols, steroids, and vitamins, while normal-phase HPLC is suited for non-polar compounds.

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HPLC is primarily used for drug assays, where the chromatographic method is optimized by adjusting factors such as mobile phase composition, pH, flow rate, and column temperature. The method is then validated to ensure its suitability. Additionally, HPLC facilitates multi-component analysis efficiently.

2. Stability Studies: HPLC is widely applied in stability testing of pharmaceutical products. It allows for the comparison of the stability of products with reference standards. Furthermore, the specificity of the analytical method is assessed through degradation studies, including acid, base, oxidation, and photodegradation.
3. Bioanalysis: HPLC is invaluable in bioanalytical studies, particularly for determining drug concentrations in biological samples like blood, plasma, urine, serum, and feces. This makes it essential in pharmacokinetic and bioequivalence studies.
4. Natural Product Analysis: HPLC is essential for the standardization of herbal extracts based on key marker compounds. For example, curcuminoids in turmeric extract and withanolides in Ashwagandha extract can be quantified using HPLC. It is also widely used to standardize polyherbal formulations.
5. Food Analysis: HPLC plays a significant role in analyzing food products, such as testing honey for methylglyoxal content, examining food formulations, and analyzing dairy products. Sugar analysis in food can be carried out using HPLC with a refractive index detector. Additionally, HPLC is used to assess the nutritional content of nutraceuticals, including flavonoids, amino acids, and polyphenols. The choice of column depends on the specific nature of the sample.
6. Drug Interaction Studies: HPLC is valuable in studying drug-drug and herb-drug interactions. By comparing the pharmacokinetic profiles of individual drugs and combinations of herb-drug or drug-drug mixtures in biological samples, HPLC helps predict potential interactions.
7. Preparative Analysis: Preparative HPLC is employed to isolate individual components from a mixture. It is particularly useful for isolating phytoconstituents from herbal fractions following column chromatography.
8. Forensic Sciences: In forensic analysis, HPLC is widely used to identify and quantify substances in biological matrices like blood, plasma, serum, and urine. For example, the presence of morphine can be detected, and in cases of suspected poisoning, HPLC can help identify toxic substances.
9. Cosmetics: HPLC is an important tool in the cosmetics industry for analyzing various cosmetic products, particularly herbal-based ones. Both qualitative and quantitative analyses are carried out using HPLC to determine the active ingredients in these products.

9. CONCLUSION

The conclusion of an HPLC (High-Performance Liquid Chromatography) demonstration typically summarizes the key outcomes and observations from the experiment. It might include the following points:

1. Separation Efficiency: The HPLC successfully separated the components of the sample based on differences in their affinity for the stationary and mobile phases, as evidenced by distinct peaks in the chromatogram.
2. Retention Time: Each compound showed a characteristic retention time, which allows for identification and quantification of the components in the sample.
3. Application: The demonstration highlighted the versatility of HPLC in analyzing complex mixtures, with applications in fields like pharmaceuticals, environmental testing, and food analysis.
4. Instrument Functionality: The HPLC system performed as expected, with the detector providing accurate and reliable readings, and the solvent delivery system maintaining a consistent flow rate.
5. Analysis of Results: The integration of the chromatogram peaks allowed for qualitative and quantitative analysis of the sample, demonstrating the power of HPLC for detailed chemical analysis.

In conclusion, the demonstration provided a clear understanding of HPLC's principles, operation, and its ability to efficiently analyze complex mixtures with high precision and accuracy.

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CASE STUDY OF HEART FAILURE

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ABSTRACT
A case study highlights a 55-year-old man admitted for chest pain, sweating, and breathlessness. He has a history of diabetes, hypertension, and hyperthyroidism. Examinations and tests revealed signs of heart issues, and he was given medications to manage his condition, with specific drugs prescribed upon discharge to continue treatment at home.

Heart disease has become more prevalent as people focus on work and wealth, often at the expense of their health. This lifestyle leads to poor diets, inactivity, and high stress, increasing the risk of conditions like diabetes, high blood pressure, and eventually heart disease. Regular medical check-ups are vital to monitor heart health, as heart disease affects not just the heart but also other organs.
KEYWORDS: *Heart attack, CHF, Heart failure*

INTRODUCTION

Heart disease has become increasingly common today. To live a luxurious life, many people work nonstop to earn more money, often neglecting their health. This leads to unhealthy lifestyle changes, including poor diets, lack of exercise, and high stress levels, which in turn cause conditions like diabetes, high blood pressure, and other diseases at younger ages. Neglecting health increases the risk of heart disease. Since the heart is a vital organ, any issues with it can also affect other major organs, making regular check-ups and doctor's advice crucial for good health and preventing heart problems.

A lack of physical activity is a significant contributor to conditions like prediabetes and heart disease. Many inactive people develop excess body fat, especially abdominal fat, which increases the risk of prediabetes and heart failure.
Staying physically active and managing weight are essential for maintaining heart health and avoiding these health issues

Heart failure, or congestive heart failure, happens when the heart can't pump enough blood to meet the body's needs. This can occur if the heart doesn't fill up with enough blood or if it's too weak to pump effectively. "Heart failure" doesn't mean the heart has stopped working, but it is a serious condition that requires medical attention.

In India, approximately 8–10 million people are affected by heart failure, making it a significant public health issue. This high prevalence is driven by increasing rates of lifestyle-related conditions such as hypertension, diabetes, and obesity, along with a lack of physical activity among many adults

Cardiovascular diseases (CVDs), which include heart failure, account for around 26% of all deaths in India, with CVDs being the leading cause of mortality in the country.
The World Heart Federation and WHO have highlighted the urgent need for preventive measures and better healthcare access to manage these diseases effectively.

Heart failure can develop either suddenly (acute heart failure) or gradually over time as the heart weakens (chronic heart failure). It can impact either the left or right side of the heart, or even both, and each side may be affected by different causes. Common causes of heart failure include other health conditions that damage the heart, such as coronary artery disease, high blood pressure, heart inflammation, cardiomyopathy, or irregular heart rhythms.

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Heart failure may not cause symptoms immediately, but over time, it often leads to fatigue, shortness of breath, and fluid buildup in areas like the legs, abdomen, or neck. It can also harm other organs, like the liver and kidneys, and can lead to additional issues, including pulmonary hypertension, heart valve disease, or even sudden cardiac arrest.

Doctors diagnose heart failure through your medical history, a physical exam, and imaging or blood tests. While heart failure is serious and has no cure, lifestyle changes, medications, certain medical devices, and procedures can help many people manage symptoms and improve their quality of life.

Congestive Heart Failure

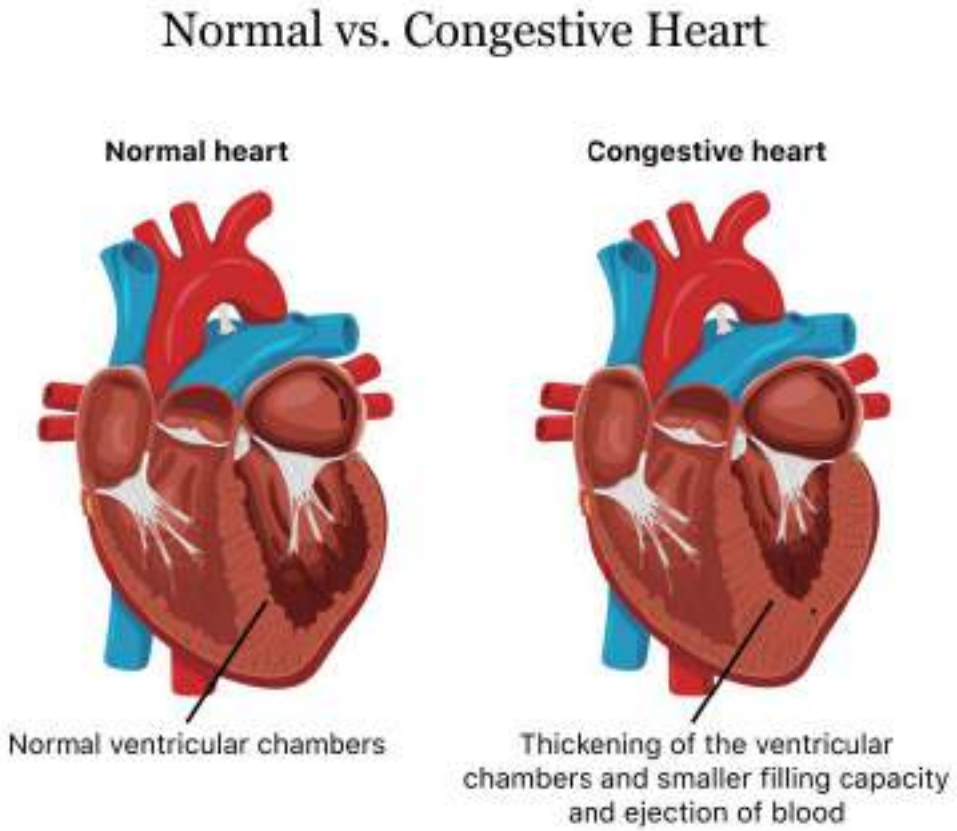

Figure 1 : Shows Differences Between Normal Heart And Congestive Heart

Congestive heart failure, also called heart failure, is a chronic condition where the heart struggles to pump enough blood to meet the body's needs. Despite the name, heart failure doesn't mean the heart has stopped working completely. Instead, it indicates the heart is weakened and can't effectively circulate blood, causing blood and fluid to back up in other parts of the body like the lungs, legs, and feet.

Typically, heart failure can develop due to existing medical conditions that damage the heart, such as coronary artery disease or high blood pressure. Symptoms may start gradually, with patients feeling fatigue, shortness of breath, or noticing fluid buildup in areas like the legs. Because of the heart's reduced function, other organs, like the liver and kidneys, may also be affected.

Congestive heart failure (CHF) is classified into different types based on which part of the heart is affected and how it affects heart function.

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Here are the main types :

1. **Left-Sided Heart Failure**:
   This is the most common type and occurs when the left ventricle, responsible for pumping oxygenated blood to the body, weakens. Left-sided heart failure is further divided into:

- **Heart Failure with Reduced Ejection Fraction (HFrEF)**
  Also known as systolic heart failure, this type happens when the left ventricle can't contract effectively, reducing the amount of blood pumped with each heartbeat.

- **Heart Failure with Preserved Ejection Fraction (HFpEF)**
  Also known as diastolic heart failure, this type occurs when the left ventricle becomes stiff and doesn't fill properly with blood between heartbeats.

2. **Right-Sided Heart Failure**
   This type occurs when the right side of the heart struggles to pump blood to the lungs. It often results from left-sided heart failure because increased pressure from the left side strains the right side, leading to fluid buildup in areas like the legs, abdomen, and liver.

3. **Biventricular Heart Failure**
   This type involves both the left and right sides of the heart and is typically a progression of chronic heart failure. It results in widespread fluid retention and reduced blood flow to various organs.

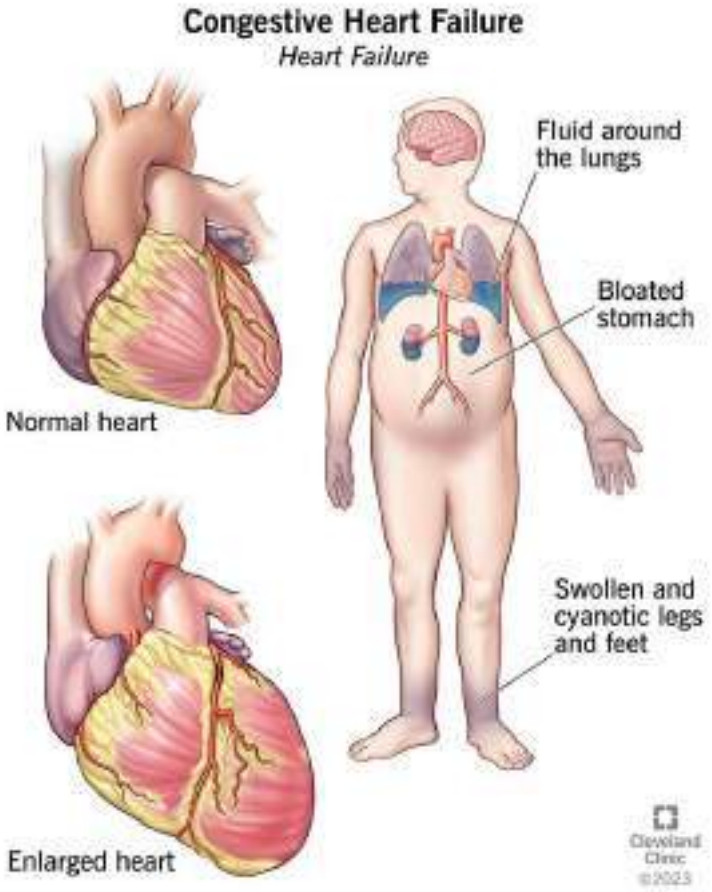

Figure 2: Shows The signs and symptoms of Heart Failure in body by affecting body parts.

Each type of heart failure may have different causes, symptoms, and treatment options. Managing CHF often requires a tailored approach based on the type and severity, as well as lifestyle changes and medications to improve heart function and quality of life.

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Symptoms of Heart Failure

Heart failure symptoms are usually caused by fluid buildup and poor blood circulation. Common symptoms include:

1.Shortness of Breath (Dyspnea)

This often happens during physical activity or when lying down. Fluid can build up in the lungs, making breathing difficult.

2.Fatigue and Weakness

Happen because reduced blood flow to muscles and tissues lowers energy levels and makes it harder to exercise.

3.Swelling (Edema)

This usually occurs in the legs, ankles, and feet due to fluid buildup caused by the heart's weaker pumping ability.

4.Persistent Cough or wheezing

This often produces white or pink-tinged mucus and is caused by fluid buildup in the lungs.

5.Increased need to urinate at night

Called nocturia, this happens when the body tries to remove extra fluid during rest.

6.Rapid or irregular heartbeat (palpitations):

The heart might beat faster to make up for reduced blood flow.

7.Reduced exercise tolerance and chest pain:

Decreased heart function can make physical activity difficult and may cause chest pain, especially in some types of heart failure.

Causes of Heart Failure

Heart failure is often caused by other long-term health conditions and lifestyle factors, including:

1. **Coronary artery disease (CAD)**
   When the coronary arteries narrow, blood flow to the heart decreases, which can lead to heart failure over time.

2. **High blood pressure (hypertension)**
   High blood pressure over time increases the heart's workload, which can eventually weaken and damage the heart muscle.

3. **Heart attack (myocardial infarction)**
   A heart attack damages a portion of the heart muscle, which can reduce its ability to pump blood effectively.

4. **Diabetes**
   It is linked to a higher risk of heart failure due to damage to blood vessels and metabolic strain.

5. **Cardiomyopathy**:
   A disease of the heart muscle caused by genetic factors, alcohol abuse, infections, or other factors that can weaken the heart.

6. **Valvular heart disease**:
   If not treated, faulty heart valves can increase the heart's workload and lead to heart failure.

7. **Excessive alcohol or drug use**:
   Heart muscle damage (cardiomyopathy) from long-term alcohol or drug use can increase the risk of heart failure.

A Case Report

A 62 Year Male Was Admitted In MIT Hospital Under Dr. Tukaram Aute Sir With C/O Acute Onset Of Chest Pain, Profuse Sweating, Breathlessness, Restlessness, Chronic Smoker NO H/O-DM/HTN/COPD Now Patient Is Admitted For CAG .

Table 1.Previous History Of Patient

Sr No.	Name Of Disease
1	Diabetes Mellitus
2	HyperTension
3	Hyperthyroidism

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Table 2. Present Condition of Patients

Sr No.	Symptoms
1	Breathlessness
2	Sweating
3	Chest Pain/Discomfort

Table 3. Personnel Lifestyle

Sr No.	Lifestyle
1	Alcohol
2	Smoking
3	Tobacco
4	Physically Active

Table 4. PrimaryExamination

Sr No.	Examinations
1	Stable
2	Oriented
3	Consciousness
4	Afibrile

Table 5. Systemic Examination

Sr No.	Examinations	Results
1	Cardio Vascular System	S1 S2 +
2	Respiratory System	Clear
3	Central Nervous System	Concious Oriented
4	Per Abdomen	Soft & NT

Examination on Admission
Vital Signs
Normal Range >

Temperature (°C)	Pulse Rate	Respiratory Rate	O Saturation	Blood Pressure
36-37	60-100	16-20	>96%	120/80

Patient Vital Signs >

Temperature (°C)	Heart Rate	Respiratory Rate	O Saturation	Blood Pressure
36.44	78/Min	19/Min	>67%	98/60

CBC – Haematology Profile
Normal Range >

WBC 10^9/uL	RBC 10^12/uL	Haemoglobin Gm/dl
4-10*10^9/uL	4,5-5,5*10^12/L	12-16

Patient's Ranges >

WBC 10^9/uL	RBC 10^12/uL	Haemoglobin Gm/dl
4	4.63	8.6

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Electrolytes
Normal Range >

Albumin	Potassium	Sodium	Chloride
3.5-5.2	3.5-5.3	135-153	0.7-1.2

Patients Range >

Albumin	Potassium	Sodium	Chloride
4.75	4.0	140	1.1

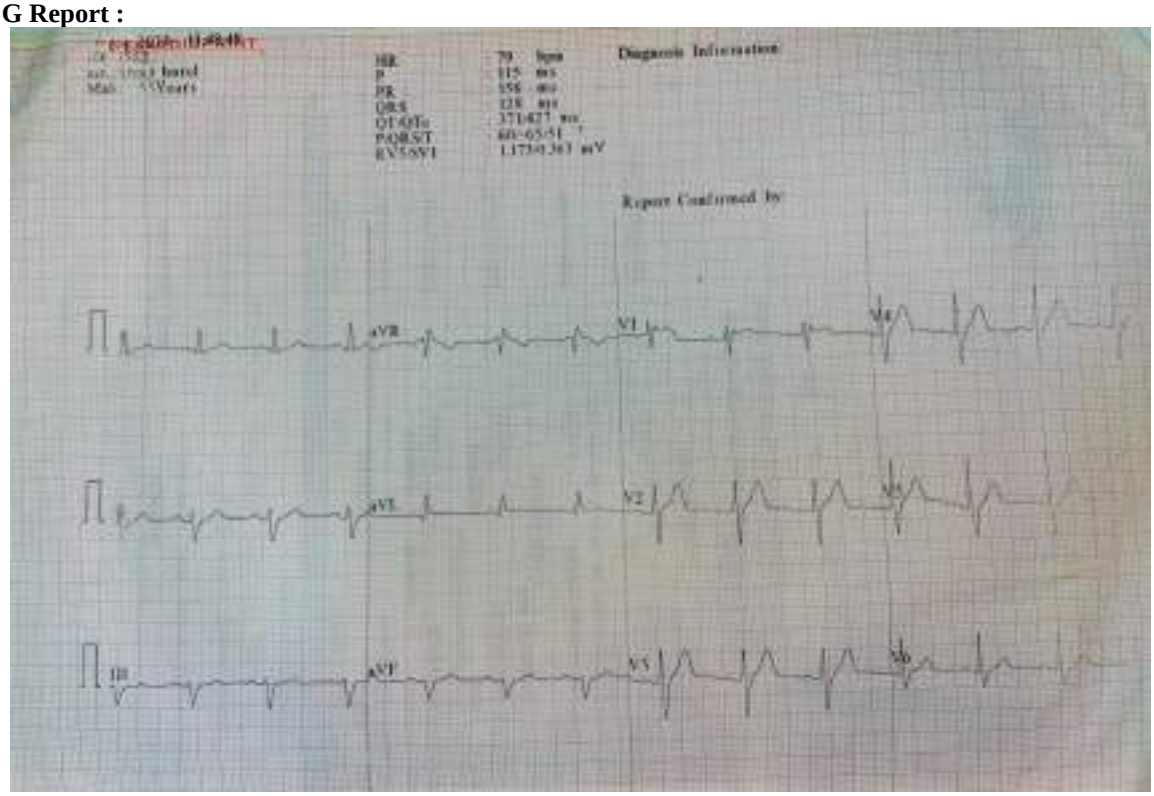
Troponin –

Name	Ng/ml
Troponin-1 (quantitative)	<0.01ng/ml

KFT- Kidney Function Test -

Name	mg/dl
Creatinine	1.33mg/gl
Urea	19.53mg/dl

ECG Report :



CPK-MB (Serum) –

Name	IU/L
CPK-MB	93.63IU/L

Treatment Given –

- NJ HEPARIN 5000 IU
- TAB AOMLOG 5 MG
- INJ TAXIM 1 GM IV
- INJ ECOSPRIN 7.5 MG
- TAB TONACT 40 MG
- TAB PAN 40 MG

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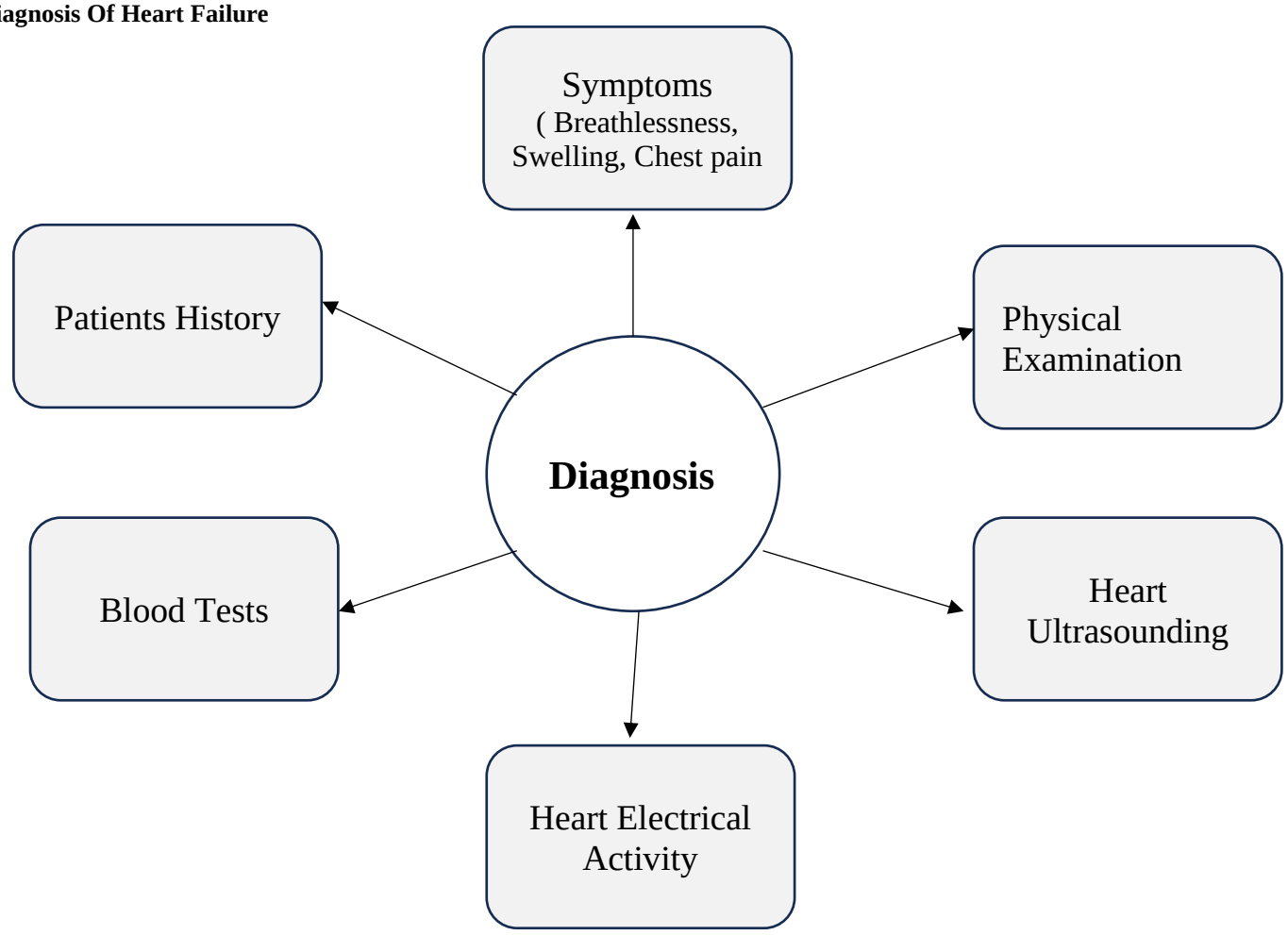
- TAB NIKORAN 5 MG
- TAB ZAPIZ 0.5 MG
- TAB TAZIOC 40 MG
- TAB IRONEMIC PLUS
- TAB FOLVET 0.5 MG
- TAB MET-XL 25 MG
- SYP DUPHELAC 15 ML
- SYP DEXORANGE 10 M

Drug Treatment On Discharge –

- TAB ECOSPRIN 75 MG
- TAB BRILLINTA 90 MG
- TAB TONACT 40 MG
- TAB PAN 40 MG
- TAB NIKORAN 5 MG
- TAB MET-XL 25
- TAB TELMA 40 MG
- SYP DEXORANGE 10 ML

Diagnosis Of Heart Failure



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Diagnosis of Heart Failure in Simple Terms

1.Medical History and Physical Exam

Doctors ask about symptoms like breathlessness or fatigue and check for risk factors, including high blood pressure or diabetes. They may also examine for fluid buildup in areas like the legs or lungs, which can signal heart failure.

2.Blood Tests

Blood tests measure substances like BNP or NT-proBNP, which tend to be higher when the heart is under strain. Other tests check kidney and liver function and electrolyte levels, as these organs can also be affected by heart failure.

3.Electrocardiogram (ECG)

An ECG records the heart's electrical activity, helping detect issues like irregular heart rhythms, previous heart attacks, or conduction problems that may contribute to heart failure.

4.Chest X-Ray

A chest X-ray helps detect fluid buildup in the lungs, an enlarged heart, or other signs associated with heart failure.

5.Echocardiogram

This ultrasound test provides images of the heart's structure and measures the heart's ejection fraction (EF), showing how effectively it pumps blood. A low EF indicates systolic heart failure, while normal EF with symptoms might mean diastolic heart failure.

6.Stress Test

A stress test measures how the heart functions under physical exertion, which can help detect coronary artery disease, a possible cause of heart failure.

7.Cardiac MRI or CT Scan

MRI or CT scans give detailed images of the heart and can reveal structural issues, scarring, or muscle damage that may be causing or worsening heart failure.

8.Cardiac Catheterization (Coronary Angiography)

A catheter is used to examine blood flow in the heart's arteries, helping identify any blockages or narrowings that could lead to heart failure.

8.Nuclear Heart Scan

In this test, a small amount of radioactive material is used to create images of blood flow in the heart, helping to spot areas with poor blood flow that might affect heart function.

Congestive Heart Failure (CHF) Treatment Approaches

1.Lifestyle Changes

• **Diet:** Reducing salt intake helps control fluid buildup, which is crucial for managing CHF. The American Heart Association advises consuming less than 2,300 mg of sodium per day, ideally under 1,500 mg for heart failure patients.

• **Exercise:** Moderate exercise can strengthen the heart, improve circulation, reduce symptoms. However, it should be done under medical supervision to avoid over Excertion

• **Fluid Management**: Limiting daily fluid intake may help reduce swelling and prevent fluid buildup, especially in advanced CHF cases.

• **Quitting Smoking and Limiting Alcohol:** Smoking damages the heart and blood vessels, while excessive alcohol can weaken heart muscles, worsening CHF symptoms.

2.Medications

• **ACE Inhibitors/ARBs:** Medications like lisinopril and losartan lower blood pressure, improve blood flow, and reduce the heart's workload. They are often prescribed to increase survival rates in CHF.

•**Beta-Blockers:** Drugs like carvedilol and metoprolol lower heart rate and blood pressure, improving heart function.

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•Diuretics: Diuretics like furosemide help remove extra fluid from the body, reducing swelling and fluid buildup in the lungs.

• Aldosterone Antagonists: Medications like spironolactone control fluid retention and are sometimes used alongside other drugs in heart failure.

• Digoxin: This medication strengthens heart contractions and can help control symptoms in severe heart failure.

• Vasodilators: Hydralazine and isosorbide dinitrate widen blood vessels, helping blood flow more easily and reducing strain on the heart.

3.Medical Devices

• Implantable Cardioverter Defibrillator (ICD): An ICD monitors and corrects dangerous heart rhythms by delivering electrical shocks, which can prevent sudden cardiac arrest in high-risk CHF patients.

• Cardiac Resynchronization Therapy (CRT): CRT devices coordinate the left and right ventricles' rhythms, improving heart function in some CHF patients.

• Ventricular Assist Devices (VADs): VADs help pump blood for patients with severe CHF and are sometimes used as a bridge to heart transplant.

4.Surgical Options

• Coronary Artery Bypass Grafting (CABG): CABG surgery bypasses blocked arteries, restoring blood flow to the heart and helping relieve CHF symptoms.

• Heart Valve Surgery: Repairing or replacing damaged heart valves can improve heart function in CHF patients with valvular disease.

• Heart Transplant: For end-stage CHF, a heart transplant may be an option if other treatments are ineffective.

5.Monitoring and Follow-Up

• Regular follow-ups are important for monitoring heart health, adjusting medications, and managing symptoms. Remote monitoring tools, like wearable devices, can detect early signs of worsening conditions, allowing for prompt treatment.

CONCLUSION

This case study of a 55-year-old man highlights how complex and serious congestive heart failure (CHF) can be. The patient, a long-time smoker, came in with chest pain, breathlessness, and sweating. His medical history, including hypertension, diabetes, smoking, and alcohol use, added to his risk for heart disease. Tests showed cardiovascular strain, and his treatment involved medications to support heart function, control fluid buildup, and reduce other risk factors.

This case shows how important lifestyle changes, timely medical care, and regular check-ups are for managing heart failure. CHF management requires a team approach, combining lifestyle adjustments, medications, and sometimes surgery or devices. With effective treatment, CHF patients can have a better quality of life, experience fewer symptoms, and potentially live longer. This case underscores the value of early detection and comprehensive care in managing heart failure.

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TO REVIEW ON STUDY AND TREATMENT OF GLUCOMA

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ABSTRACT

Glaucoma, a progressive optic neuropathy characterized by retinal ganglion cell degeneration and visual field loss, is the leading cause of irreversible blindness worldwide.A leading causes of irreversible blindness.glucoma is a group of eye conditions the progressively damge the optic nerves leading irreversible vision loss a and blindness.glucoma is characterized by increasing introcular pressure(iop) optic nerve damge and visual field loss.primary open angle glucoma (poag)is chronic disease characterized by elveted intravascular and visual field loss.

A chronic progressive eye disease caused by damage to the optic nerve which leads to visuals field loss glucoma is a heterogeneous group disease characterized by capping of the optic nerve to bead and visual field damage .A gernal understand of die pathophysiology the gole treatment with drop larer therapy or surgery is to slow visual field loss by lowering introcular pressure.they are the optic nerve atrophy peripheral visual field loss.their are several type of test and type and glucoma and treatment of present type of glucoma are open angle glucoma closure glucoma congenital glucoma childhood glucoma and secondary glucoma present

INTRODUCTION

Glaucoma is the leading cause of irreversible blindness world-wide and is the second most common cause of bilateral blindness after cataract. Glaucoma represents a group of diseases defined by a characteristic optic neuropathy and is associated with the development of distinctive patterns of visual dysfunction.

The optic neuropathy is characterized by excavation, deepening, and undermining of the neural and connective tissue elements of the optic nerve head. Visual field defects typically begin in the midperipheral field and eventually involve the central field.

Although elevated intraocular pressure (IOP) is a major risk factor, its presence or absence does not have a role in the definition of the disease. It is, however, the only modifiable risk factor, and lowering the IOP is the only proven intervention for the preservation of vision in glaucoma.

In individuals who are susceptible to glaucoma "normal" IOP may be defined as a pressure that does not lead to optic nerve damage.

Unfortunately, precise numerical values are not clear because individuals show susceptibility to optic nerve damage at different pressure levels.

The Early Manifest Glaucoma Trial identified predictive baseline factors of progression in glaucomatous patients.

Besides higher IOP at baseline, other factors included exfoliation syndrome, bilaterality, worse baseline visual field mean deviation, older age, and disc hemorrhages at follow- up visits. These findings indicate that IOP control alone is not enough to stop glaucoma progression in certain eyes and non- IOP related risk factors may contribute to neuronal loss in glaucoma.

The cardinal event In glaucoma is injury to the axons of retinal ganglion cells (RGCs) that results in characteristic optic nerve head cupping. 184 RGC death in glaucoma may be mediated by direct insults to RGCs, such as oxidative stress and neurotrophic factor deprivation, and by indirect pro inflammatory effects caused by other retinal cells, such as microglia and astrocytes.

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OBJECTIVE

1.Glaucoma patient can live full lives.
2.The ultimate goal of glaucoma therapy is maintain vision.
3.Detecting changes in the disease progress.
4.Avoiding future vision loss are the goal of this study of glaucoma apotentially blinding condition.

PLAN OF WORK

1. Section of topic.
2. Study of literature review.
3. Study of history of glaucoma.
4. Study of pathophysiology of glaucoma.
5. Study of sign and symptom of glaucoma.
6. To determine diagnosis and treatment of glaucoma.

HISTORY OF GLAUCOMA

Glaucoma has been known in medicine since Antiquity. Hippokrates described "glaykoseis" as blindness which occurs in the elderly. The English ophthalmologist Banister was the first to establish the connection between increased tension of the eyeball and glaucoma.

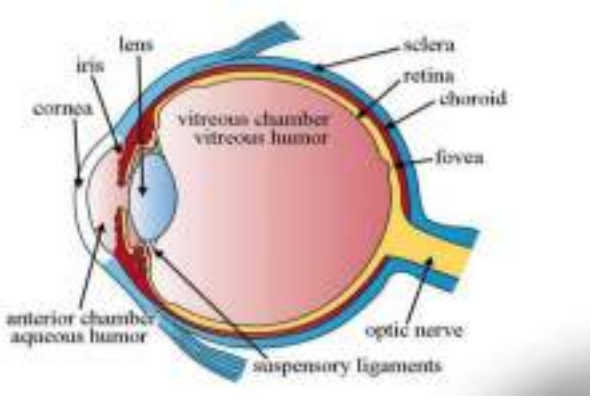
The important invention of the ophthalmoscope by von Helmholtz (1850) made it possible to diagnose glaucomatous changes in the fundus. in 1862, Donders discovered that high intraocular pressure caused blindness and called the disease "Glaukoma simplex." Further progress in the diagnosis of glaucoma was made by the invention of the tonometer and the perimeter, and the use of cocain. The first effective surgical treatment of glaucoma, an iridectomy, was carried out by von Graefe in 1856.

PATHOPHYSIOLOGY

Elevated intraocular pressure and low perfusion pressure increase the gradient across the lamina cribrosa and cause papillary hypoperfusion, leading to structural changes and remodeling of the lamina cribrosa and to impaired axonal transport in the optic nerve fibers.

The retinal ganglion cells are neurons of the central nervous system that receive signals from the photoreceptors, process them, and transmit them in axons through the optic nerve to further centers in the brain. These axons run from the ganglion cell nuclei in the retina to the

optic disc, and then together with the retinal vessels through the lamina cribrosa, a sieve-like structure composed of collagen. Behind the lamina cribrosa, the axons, surrounded by a myelin sheath, continue as the optic nerve. Elevated intraocular pressure, low perfusion pressure, and/or low cerebrospinal fluid pressure increase the gradient across the lamina cribrosa and cause papillary hypoperfusion, leading to structural changes and remodeling of the lamina cribrosa and to impaired axonal transport in the optic nerve fibers.



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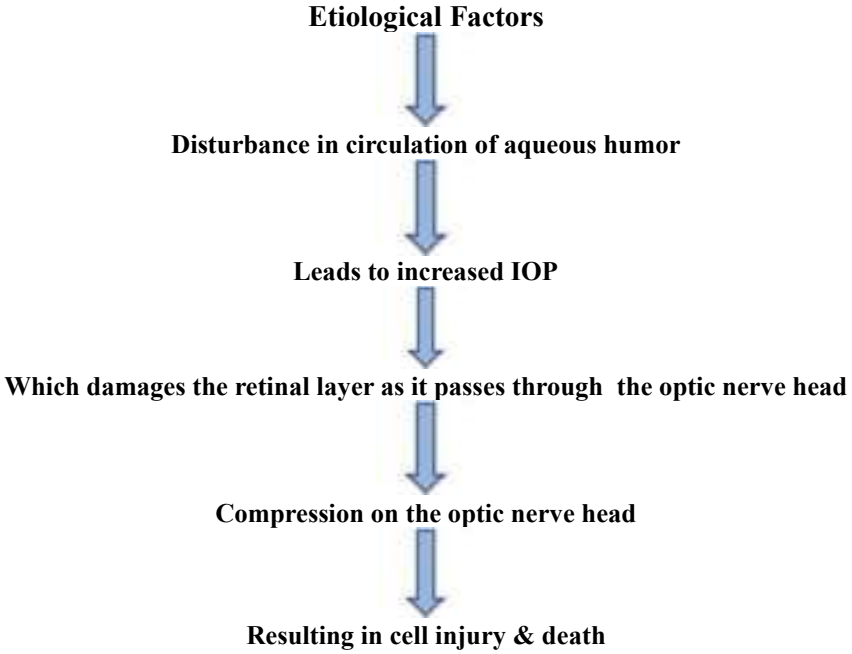
PATHOPHYSIOLOGY



SYMPTOMS

- The symptoms of glaucoma depend on the type and stage of your condition.
- Open-angle glaucoma
- No symptoms in early stages Gradually, patchy blind spots in your side vision. Side vision also is known as peripheral vision. In later stages, difficulty seeing things in your central vision.
- Glaucoma in children
- A dull or cloudy eye [infants] Increased blinking [infants]
- Acute angle closure Glaucoma
- Severe headache
- Nausea
- Vomiting Blurred
- Vision
- Halos or Colored rings Around lights eye redness
- Normal-tension glaucoma
- No symptoms in early stages gradually, blurred vision.
- In later stages loss of side vision tears without crying [infants] blurred vision. Nearsightedness that gets worse headache.
- Pigmentary glaucoma
- Halos around lights Blurred vision with exercise Gradual loss of side vision.

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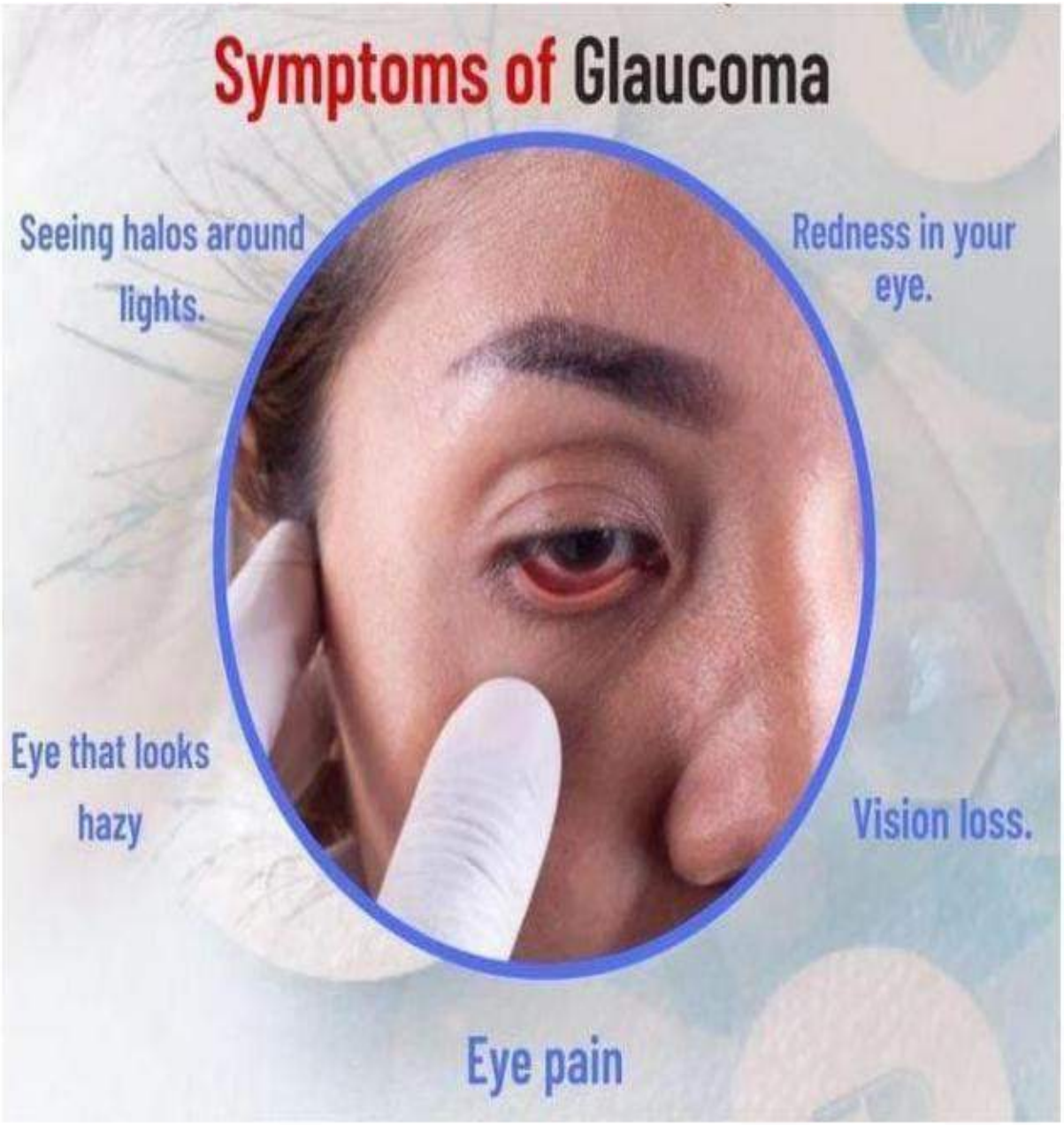

- **CAUSES**

• Open-Angle Glaucoma

This is the most common form of glaucoma. The drainage angle formed by the iris and cornea remains open. But other parts of the drainage system don't drain properly. This may lead to a slow, gradual increase in eye pressure.

• Angle Closure Glaucoma

This form of glaucoma occurs when the iris bulges. The bulging iris partially or completely blocks the drainage angle. As a result, fluid can't circulate through the eye and pressure increases. Angle-closure glaucoma may occur suddenly or gradually.

• Normal-Tension Glaucoma

No one knows the exact reason why the optic nerve becomes damaged when eye pressure is normal. The optic nerve may be sensitive or experience less blood flow. This limited blood flow may be caused by the buildup of fatty deposits in the arteries or other conditions that damage circulation. The buildup of fatty deposits in the arteries also is known as atherosclerosis.

• Glaucoma In Children

A child may be born with glaucoma or develop it in the first few years of life. Blocked drainage, injury or an underlying medical condition may cause optic nerve damage.

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PREVENTION

1. These steps may help detect and manage glaucoma in its early stages. That may help to prevent vision loss or slow its progress.
2. Get regular eye examinations. Regular comprehensive eye exams can help detect glaucoma in its early stages, before significant damage occurs.
3. As a general rule, the American Academy of Ophthalmology recommends a comprehensive eye exam every 5 to 10 years if you're under 40 years old; every 2 to 4 years if you're 40 to 54 years old; every 1 to 3 years if you're 55 to 64 years old; and every 1 to 2 years if you're older than 65.
4. If you're at risk of glaucoma, you'll need more frequent screening. Ask your health care provider to recommend the right screening schedule for you.
5. Know your family's eye health history. Glaucoma tends to run in families. If you're at increased risk, you may need more frequent screening.
6. Wear eye protection. Serious eye injuries can lead to glaucoma. Wear eye protection when using power tools or playing sports.
7. Take prescribed eye drops regularly. Glaucoma eye drops can significantly reduce the risk that high eye pressure will progress to glaucoma. Use eye drops as prescribed by your health care provider even if you have no symptoms.

DIAGNOSIS

1. Glaucoma is usually picked up during a routine eye test, often before it causes any noticeable symptoms. Other tests are usually needed afterwards to diagnose and monitor the condition.
2. It's important to have regular eye tests so problems such as glaucoma can be diagnosed and treated as early as possible. Early treatment can help stop your vision becoming severely affected.
3. You can get an eye test at a local opticians, and the tests are carried out by an optometrist. Find an optician near you. Some people can receive free eye tests on the NHS. Find out if you're entitled to free NHS eye tests.
4. Tests to diagnose and monitor glaucoma

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5. There are different tests that can be carried out by an optometrist if they suspect you have glaucoma after a routine eye test.

1. Eye Pressure Test

An eye pressure test (tonometry) uses an instrument called a tonometer to measure the pressure inside your eye.
The optometrist will put a small amount of painkilling medicine (anaesthetic) and dye into the front of your eye. They will then shine a light into your eye and gently touch the surface of it surface of it with the tonometer.
Some optometrists use a different instrument, which uses a puff of air and doesn't touch the eye, to check pressure.

2.Gonioscopy

Gonioscopy is an examination to look at the front part your eye the fluid-filled space between the coloured part (iris) and the clear window of the front of the eye (cornea). This is where the fluid should drain out of your eye.

3. **Visual field test**

A visual field test (sometimes called perimetry) checks for missing areas of vision. You may be shown a sequence of light spots and asked to press a button to indicate which ones you can see. Some dots will appear at the edges of your vision (your peripheral vision), which is often the first area to be affected by Glaucoma

4. **Optic nerve assessment**

The optic nerve, which connects your eye to your brain, can become damaged in glaucoma, so an assessment may be carried out to see if it's healthy.

TREATMENT

The damage caused by glaucoma can't be reversed. But treatment and regular checkups can help slow or prevent vision loss, especially if you catch the disease in its early stages.
Glaucoma is treated by lowering intraocular pressure. Treatment options include prescription eye drops, oral medicines, laser treatment, surgery or a combination of approaches.

• Eyedrops

Glaucoma treatment often starts with prescription eye drops. Some may decrease eye pressure by improving how fluid drains from your eye. Others decrease the amount of fluid your eye makes. Depending on how low your eye pressure needs to be, you may be prescribed more than one eye drop.

- **Oral medications**

Eye drops alone may not bring your eye pressure down to the desired level. So your eye doctor may also prescribe oral medicine. This medicine is usually a carbonic anhydrase inhibitor. Possible side effects include frequent urination, tingling in the fingers and toes, depression, stomach upset, and kidney stones.

- **Surgery and other therapies**

Other treatment options include laser therapy and surgery. The following techniques may help to drain fluid within the eye and lower eye pressure.

- **Laser therapy**

Laser trabeculoplasty (truh-BEK-u-low-plas -tee) is an option if you can't tolerate eye drops. It also may be used if medicine hasn't slowed the progression of your disease.

- **Filtering surgery**

This is a surgical procedure called a trabeculectomy (truh bek-u- LEK-tuh-me). The eye surgeon creates an opening in the white of the eye, which also is known as the sclera. The surgery creates another space for fluid to leave the eye.

- **Drainage tubes.**

In this procedure, the eye surgeon inserts a small tube in your eye to drain excess fluid to lower eye pressure.

- **Minimally invasive glaucoma surgery (MIGS).**

Your eye doctor may suggest a MIGS procedure to lower your eye pressure. These procedures generally require less immediate postoperative care and have less risk than trabeculectomy or using a drainage device.

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CONCLUSION

Glaucoma is a common eye disease that is usually associated with an elevated intraocular pressure. Treatment options for patients with glaucoma include medications, laser therapy, and incisional surgery. The risks and benefits of each type of treatment must be carefully considered to maximize the treatment's benefits while minimizing adverse effects.

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A DETAIL REVIEW ON "BEAUTY OF BANYAN BONSAI TREE"

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ABSTRACT

The Banyan bonsai (Ficus benghalensis) is a miniature tree known for its iconic aerial roots, thick trunk, and broad leaves. It captures the grandeur of a full-sized Banyan tree in a compact form, symbolizing strength, longevity, and interconnectedness. This bonsai is highly adaptable, thriving in bright, indirect sunlight and requiring consistent moisture and humidity. It offers both aesthetic appeal and health benefits, such as air purification and stress relief. While relatively easy to care for, the Banyan bonsai requires careful management of its roots and leaves. Its cultural significance and resilience make it a popular choice among bonsai enthusiasts. The Banyan bonsai, derived from the *Ficus benghalensis* species, is a popular and striking bonsai tree known for its thick trunk, sprawling branches, and signature aerial roots that grow down from the branches and anchor into the soil. This miniature version of the large Banyan tree represents strength, stability, and longevity, making it a symbol of endurance in bonsai art. With its tropical origins, the Banyan bonsai thrives in warm, humid environments and offers both aesthetic beauty and therapeutic benefits.*

KEYWORDS: *Banyan bonsai, Ficus benghalensis, Miniature tree, Consistent moisture, Humidity.*

1.INTRODUCTION OF BANYAN BONSAI

The Banyan bonsai (Ficus benghalensis), a miniature version of the sprawling Banyan tree, is one of the most iconic and revered trees in the bonsai world. Known for its majestic aerial roots, sturdy trunk, and expansive canopy, the Banyan bonsai captures the essence of a full-grown Banyan tree in a compact, meticulously cultivated form. Originating from tropical regions, primarily India, the Banyan tree holds significant cultural and spiritual value and is deeply associated with longevity, strength, and shelter.

1.2Biological Classification

- Kingdom: Plantae
- Clade: Angiosperms
- Clade: Eudicots
- Clade: Rosids
- Order: Rosales
- Family: Moraceae
- Genus: Ficus
- Species: F. Benghalensis

1.3Historical and Cultural Significance

The Banyan tree has been historically significant in several cultures, especially in South Asia. In Hinduism, it is considered sacred and represents immortality and protection. In India, Banyan trees often serve as gathering places for spiritual discussions and community activities, symbolizing wisdom, life, and eternal connection. The transformation of the Banyan tree into bonsai allows enthusiasts to bring this rich symbolism and cultural reverence into their homes.

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1.4Aesthetics and Structure

The visual appeal of the Banyan bonsai lies in its striking architecture:Aerial Roots: The most defining feature of a Banyan bonsai, these roots grow down from the branches toward the ground, forming a web-like structure. When properly nurtured, these roots give the bonsai a dramatic, ancient look, emphasizing its natural beauty and intricate design.Sturdy Trunk:

The Banyan bonsai boasts a thick, robust trunk that contributes to its overall sense of stability and strength. The trunk's smooth, grayish bark enhances its elegant appearance.Canopy and Foliage: The foliage of the Banyan bonsai is broad and lush, with glossy green leaves that can be pruned to maintain their size and shape. This dense canopy adds to the tree's impressive and balanced form.

1.5Bonsai Techniques and Adaptability

The Banyan bonsai is particularly adaptable, making it suitable for bonsai cultivation even for beginners. It can be grown both indoors and outdoors, provided it receives the right care:Light and Temperature: As a tropical species, the Banyan bonsai thrives in bright, indirect sunlight. It can tolerate direct sunlight for a few hours but prefers warmer temperatures ranging between 65°F to 75°F (18°C to 24°C). It is sensitive to cold and frost, so indoor cultivation or protection during winter months is necessary.Water and Humidity: Maintaining consistent moisture levels is crucial for Banyan bonsai. The tree thrives in high humidity, so regular misting is recommended, especially if kept indoors. Over-watering or waterlogging should be avoided to prevent root rot.Pruning and Styling: Pruning is essential to control the growth of the leaves and branches, maintaining the tree's desired shape.

The aerial roots require careful management, as they can grow rapidly and overwhelm the tree's structure if not controlled. Techniques like defoliation are used to reduce leaf size and encourage finer branch development.

2.STYLES OF BONSAI

Bonsai trees are cultivated in various styles, each inspired by natural forms and aimed at capturing the essence of a full-sized tree in miniature. These styles emphasize balance, proportion, and aesthetics, showcasing different shapes, orientations, and structures of the tree. Below are some of the most common and classic bonsai styles:

2.1Formal Upright (Chokkan)

Description: This style mimics a tree growing straight and upright with a perfectly vertical trunk. The branches are evenly spaced and taper from the thick base of the trunk to a pointed apex, creating a balanced, pyramid-like form.Characteristics:Straight, upright trunk.Branches become progressively shorter toward the top.Perfectly symmetrical and balanced.

2.2Informal Upright (Moyogi)

Description: In this style, the trunk is still upright but bends or curves as it ascends. The branches and foliage follow the curves, creating a more natural and less formal appearance.Characteristics:Curved or slanted trunk.Branches emerge from the outer curves of the trunk.More natural and less rigid form compared to Chokkan.

2.3Root-Over-Rock Style (Sekijoju):

This style mimics the banyan's natural tendency to grow over rocks in the wild, with roots wrapping around a stone and growing into the soil below. The aerial roots help secure the tree onto the rock, creating a dramatic visual effect.

2.4Multi-Trunk Style (Kabudachi):

This style reflects the banyan's growth habit of producing multiple trunks from a single root system. It can give the appearance of a small forest, with trunks spreading out and interweaving as they grow upward.

2.5Bonsai Classification

This classification is this on size, as shown in table 1. Each size has its own aesthetic appeal and level of maintenance, with smaller bonsai generally being more demanding due to their precision care requirements.

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Table 1: Classification of bonsai based on size

Common name	Size	Dimensions
Miniature Bonsai Trees		
Kenshitsubo	Poppy sized eye	1–3 in
Shito	Fingertip sized	2–4 in
Shohin	Palm Sized	2–6 in
Mame	One handed	5-8 in
Komono	One handed	6-10 in
Medium Sized Bonsai		
Chiu	Two-handed	16–36 in
Chumono	Two-handed	16–36 in
Katade-mochi	One-handed	10–18 in
Large bonsai Trees		
Imperial bonsai	Eight-handed	60–80 in
Omono	Six-handed	40–60 in
Dai	Four-handed	30–48 in
Omono	Four-handed	30–48 in

1)Formal Upright

2) Informal Upright

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3. Root over the Rock/soil

4. Multi-Trunk

3.GROWING A BANYAN BONSAI

Requires patience and attention to detail, as this tropical tree (Ficus benghalensis) can develop into a striking miniature version of its full-sized counterpart. Here's a detailed guide on how to grow a Banyan bonsai:

3.1Choosing a Banyan Tree for Bonsai

Seedlings or Cuttings: You can start a Banyan bonsai either from seeds or cuttings. Cuttings are often preferred as they root quickly and allow for faster growth.

Young Tree or Pre-Bonsai: You can also purchase a young Banyan tree or pre-bonsai that's already partially developed, which allows you to start shaping the tree right away.

3.2Ideal Growing Conditions

Temperature: Banyan trees are tropical, so they thrive in warm conditions. They prefer temperatures between 65°F to 75°F (18°C to 24°C) but can tolerate slightly higher temperatures. They cannot withstand frost and need to be kept indoors during cold weather.

Humidity: High humidity is ideal for Banyan bonsai, as they are native to humid environments. Mist the leaves regularly to keep the humidity high, especially if you're growing the tree indoors.

Light:Banyan bonsai needs bright, indirect light for at least 4-6 hours a day. It can tolerate partial sunlight, but avoid harsh midday sun, which can scorch the leaves. If growing indoors, place the bonsai near a bright window or use grow lights if necessary.

3.3Planting a Banyan Bonsai

Container Selection:Choose a shallow bonsai pot with drainage holes. The shallow depth helps control the tree's growth, while good drainage prevents waterlogging, which can lead to root rot.

-Soil Mix: A well-draining bonsai soil mix is essential. You can use a mix that includes akadama, pumice, and lava rock or a mixture of peat, sand, and perlite. This ensures proper drainage while still retaining enough moisture for the Banyan's roots.

-Planting Process:If starting from a cutting, plant the cutting in the bonsai pot using the prepared soil mix. Water the soil thoroughly after planting.

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3.4 Watering

Regular Watering:The Banyan bonsai prefers moist soil, so water it consistently, allowing the top layer of soil to dry out slightly before watering again. However, don't let the soil completely dry out. Humidity Trays: You can place a humidity tray filled with water beneath the bonsai pot to create a more humid environment, which the tree will appreciate, especially indoors.

3.5 Fertilization

Fertilizer Schedule:Feed your Banyan bonsai with a balanced fertilizer (like a 10-10-10 NPK ratio) during the growing season, which is from spring to early fall. Fertilize every two weeks during this time.

Winter Feeding: In the winter, reduce feeding to once a month or stop altogether, as the tree's growth slows down in cooler conditions.

3.6Pruning and Shaping

Pruning Branches: Regular pruning helps maintain the size and shape of the bonsai. Remove any overly long branches, and trim back new growth to encourage denser foliage. Prune to create a balance between the tree's canopy and its root system.

Leaf Pruning (Defoliation): You can practice defoliation, removing some leaves to encourage smaller leaves and finer branch development. This is usually done in summer and helps maintain the tree's miniature scale.

Shaping with Wiring: Wiring can be used to shape the branches and trunk. Banyan bonsai has flexible branches when young, making it easy to shape. Be careful when applying wire, and check it regularly to avoid damaging the bark as the tree grows.

3.7 Aerial Roots

Encouraging Aerial Roots: One of the Banyan bonsai's most distinctive features is its aerial roots, which grow from the branches and descend to the soil. To encourage the growth of aerial roots, increase humidity by misting the branches frequently or using a plastic covering to retain moisture.

Managing Aerial Roots: As the roots grow, they can be directed to the soil or trimmed if they become too numerous. Aerial roots add to the ancient and dramatic appearance of the Banyan bonsai.

3.8 Repotting

-When to Repot: Repot the Banyan bonsai every 2-3 years to refresh the soil and prevent rootbound conditions. Spring is the best time to repot, just before the growing season begins.

How to Repot: When repotting, trim back about one-third of the roots. Use fresh bonsai soil to promote healthy root growth. After repotting, water thoroughly and keep the tree in a shaded area for a week or two to recover.

3.9Propagation

From Cuttings: Banyan trees are easy to propagate from cuttings. Take a cutting from a healthy branch, about 4-6 inches long. Remove the lower leaves and plant the cutting in moist soil. Keep it in a warm, humid environment until it develops roots.

From Seeds: You can also grow a Banyan bonsai from seeds, but this takes more time. Sow seeds in well-draining soil and keep them moist. Germination can take a few weeks, after which the seedlings can be transferred to individual pots for development.

3.10Pest and Disease Management

Pest Prevention:Banyan bonsai can attract pests like aphids, spider mites, and mealybugs. Regularly inspect the leaves and branches. Treat infestations with neem oil, horticultural soap, or insecticidal sprays.

Disease Prevention: Overwatering can lead to root rot, a common issue with Banyan bonsai. Make sure the soil drains well, and avoid letting the tree sit in standing water. Fungal infections like leaf spot can also occur in high-humidity environments, so ensure proper air circulation and treat with fungicides if needed.

3.11Winter Care

Indoor Care: In colder regions, bring the Banyan bonsai indoors during winter. Keep it in a warm room with plenty of light and maintain humidity with regular misting or using a humidifier.

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Reducing Water and Fertilizer: During winter, the tree's growth slows down, so reduce watering slightly and stop fertilizing until spring.

4.Classification of Banyan Bonsai

The classification of Banyan bonsai based on size aligns with standard bonsai size categories. These classifications are universal across bonsai species and depend on the tree's height and the number of hands needed to move it. Below are the size categories relevant to Banyan bonsai:

1.Mame (Miniature Bonsai)
Size: Up to 15 cm (6 inches) in height.
Description: Small and delicate, often displayed on tables or shelves. Requires intricate care and pruning due to its small size.
Handling: Can be lifted with two fingers.

2. Shohin
Size: 15–25 cm (6–10 inches) in height.
Description: Small but slightly larger than Mame, easier to care for while retaining portability.
Handling: Easily lifted with one hand.

3. Chuhin (Medium Bonsai)
Size: 25–60 cm (10–24 inches) in height.
Description: Most common size for Banyan bonsai, offering a good balance between manageability and visual impact.
Handling: Typically lifted with two hands.

4. Omono/Dai (Large Bonsai)
Size: 60–120 cm (24–48 inches) in height.
Description: Larger Banyan bonsai with an impressive presence, ideal for spacious displays.
Handling: Requires two to four hands to move.

5. Hachi-Uye (Extra-Large Bonsai)
Size: Over 120 cm (48 inches) in height.
Description: Rare for Banyan bonsai but possible for exhibition pieces. Mimics the grandeur of a natural Banyan tree on a reduced scale.
Handling: Needs multiple people or special equipment to move.
This size-based classification helps enthusiasts choose a bonsai size that suits their display preferences and maintenance capabilities.

5.Tool's use for Banyan bonsai

Maintaining and styling a banyan bonsai requires a variety of specialized tools to ensure proper care and aesthetic shaping. Here's a guide to the most essential tools and their uses:

- **Basic Tools**

1. Pruning Shears or Scissors
Used for trimming branches, leaves, and roots.
Essential for maintaining the canopy shape and encouraging healthy growth.
2. Concave Cutters
Ideal for cutting branches close to the trunk, leaving a clean wound that heals seamlessly.
3. Root Cutters:
Specialized for trimming thick roots during repotting without damaging the root system.

- **Shaping Tools**

1. Bonsai Wire (Aluminum or Copper)
Used to shape branches and guide their growth direction.
Soft aluminum is preferred for beginners, while copper provides stronger support for mature branches.
2. Wire Cutters
Designed to cut bonsai wire without damaging branches or bark.

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3. Branch Benders
Useful for reshaping thicker branches that are too rigid for wire alone.

- **Repotting Tools**

1.Root Rake or Hook
Helps untangle and comb out roots during repotting for better soil aeration and space.

2.Soil Scoop
Assists in adding or removing soil neatly during repotting.

3.Mesh Screens
Placed at the bottom of the pot to prevent soil loss while ensuring proper drainage.

4.Chopsticks
Used to work soil around the roots and eliminate air pockets.

- **Aerial Root Management**

1.Misting Bottle
Keeps humidity high, encouraging the development of aerial roots.

2.Tweezers
Helps clean up moss, dead leaves, or debris around the roots and trunk.

- General Maintenance Tools

1.Watering Can with Fine Spout:
Provides a gentle, even watering without disturbing the soil or aerial roots.
2.Spray Bottle:
Keeps the foliage clean and enhances humidity levels around the bonsai.
3.Cleaning Brushes:
Used to clean the trunk and roots, enhancing the tree's natural texture and appearance.

- **Optional but Useful**

1.Turntable
Makes styling and repotting easier by allowing 360° access to the bonsai.
2.Knob Cutters
Ideal for removing large or knobby growths from the trunk or branches.
Using these tools ensures precise care and allows you to style your banyan bonsai beautifully while promoting its long-term health.

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COMPLETE STUDY OF CISSUS QUABDRAGYLARIS FOR BONE HEALING

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ABSTRACT

Cissus quadrangularis, a medicinal plant belonging to the family Vitaceae, has been used traditionally for its therapeutic properties in various cultures, particularly in Africa, India, and Southeast Asia. Known for its anti-inflammatory, analgesic, antioxidant, and antimicrobial activities, C. quadrangularis is widely employed in treating fractures, joint disorders, and bone health-related issues. It contains bioactive compounds, such as flavonoids, alkaloids, and phenolic acids, which contribute to its wide range of pharmacological effects. Studies suggest that C. quadrangularis may enhance bone healing, promote collagen synthesis, and reduce pain associated with bone fractures. In addition, it is being investigated for its potential in managing metabolic disorders like obesity and diabetes due to its ability to regulate blood glucose and lipid profiles. Despite its promising benefits, further clinical studies are needed to validate its efficacy and safety for therapeutic use.

INTRODUCTION

Cissus quadrangularis, commonly known as "Veldt Grape" or "Adamant Creeper," is a perennial plant belonging to the Vitaceae family. Native to tropical and subtropical regions of Africa and Asia, it has gained attention for its medicinal properties and is widely used in traditional medicine. This plant features a fleshy, succulent stem that is often angular in shape, giving it a distinctive appearance. Its stems and leaves are typically used in the preparation of various herbal remedies.

In traditional medicine systems like Ayurveda and Traditional African Medicine, Cissus quadrangularis has been utilized for its wide array of therapeutic benefits, particularly for its anti-inflammatory, analgesic, and antioxidant properties. It has been studied for its potential in supporting bone health, improving joint function, and aiding in the healing of fractures, among other uses. Additionally, it is often used for managing weight, controlling blood sugar, and promoting overall vitality.

Phytochemical Constituents and Mechanisms of Action

Cissus quadrangularis contains a rich array of bioactive compounds, including flavonoids, alkaloids, triterpenoids, and phenolic acids. These compounds contribute to its medicinal properties, which include promoting collagen synthesis, enhancing bone mineral density, reducing inflammation, and supporting wound healing. Some studies suggest that its compounds may also play a role in reducing oxidative stress, improving metabolic function, and supporting gastrointestinal health.

Biological Source

Cissus Quadrangularis

1. Family: Vitaceae (the grape family)
2. Biological Source: The biological source of Cissus quadrangularis is the aerial parts of the plant, particularly the stem. It is a succulent, perennial herb with a distinctive four-angled (quadrangular) stem.
3. Chemical Constituents: Cissus quadrangularis is rich in various bioactive compounds, which contribute to its medicinal properties. Some of the key chemical constituents include:

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Flavonoids: These include compounds like quercetin, kaempferol, and other glycosides, which have antioxidant and anti-inflammatory effects.

Alkaloids: Cissus quadrangularis contains alkaloids, which may contribute to its analgesic (pain-relieving) properties.

Phenolic Acids: These include chlorogenic acid, caffeic acid, and ferulic acid, which have antioxidant and anti-inflammatory properties.

Triterpenoids: Compounds like oleanolic acid and ursolic acid, which are known for their anti-inflammatory and hepatoprotective effects.

Steroids: Cissus quadrangularis contains sterols, such as β-sitosterol, which may contribute to its anti-inflammatory and anti-cancer properties.

Flavonol Glycosides: These compounds are important for the antioxidant activity of Cissus quadrangularis.

Vitamins and Minerals: Cissus quadrangularis also contains important nutrients such as vitamin C, carotenoids, and calcium, which support bone health and healing processes.

Resins and Tannins: These have astringent properties and contribute to the plant's antimicrobial and wound-healing effects.

These active compounds work synergistically to provide Cissus quadrangularis with its reputed benefits, including promoting bone health, aiding in wound healing, reducing inflammation, and improving metabolic functions.

Material and Methods of Cissus Quadrangularis

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The following is a detailed example of materials and methods typically used in scientific studies involving Cissus quadrangularis, such as studies on its phytochemical properties, pharmacological effects (e.g., anti-inflammatory, bone healing), and other therapeutic potential.

1.Collection of Plant Material

Plant Part Used: The stems of Cissus quadrangularis are most commonly used for extraction in medicinal studies, as they contain the highest concentration of bioactive compounds.

Collection: Fresh or dried aerial parts (stems, leaves) of Cissus quadrangularis are collected from local herb gardens, commercial suppliers, or wild habitats in tropical and subtropical regions.

2. Preparation of Plant Extracts

The preparation of extracts is essential for isolating the active compounds of Cissus quadrangularis.

Drying: The collected plant material (stems) is washed to remove dirt and then dried in the shade for several days.

Grinding: The dried stems are ground into a fine powder using a mechanical grinder or mortar and pestle.

Solvent Extraction

Ethanolic Extraction: A known method to extract a wide variety of bioactive compounds. The powdered plant material is macerated in ethanol (95%) for 48-72 hours at room temperature, with occasional shaking. Afterward, the mixture is filtered, and the solvent is evaporated under reduced pressure to yield the ethanolic extract.

Aqueous Extraction: Fresh plant material may be boiled in water to prepare an aqueous extract, which is often used for traditional medicinal purposes.

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3. Phytochemical Screening

Phytochemical screening is conducted to identify and analyze the presence of bioactive compounds in the extracts.

Alkaloids: Dragendorff's reagent or Mayer's reagent is used to test for the presence of alkaloids.

Flavonoids: Shinoda's test or the alkaline reagent test detects the presence of flavonoids.

Triterpenoids and Steroids: Liebermann-Burchard test is used to detect triterpenoids and steroids.

Saponins: Foam test to detect the presence of saponins.

Tannins: Ferric chloride test is used to detect tannins.

4. Analytical Techniques

-To confirm and quantify the chemical composition of Cissus quadrangularis extracts, the following methods may be used:

Thin Layer Chromatography (TLC): TLC is used to separate and identify different compounds in the plant extract. A solvent system is chosen based on the nature of the compounds (e.g., polar or non-polar).

High-Performance Liquid Chromatography (HPLC): For the quantitative analysis of specific compounds, such as flavonoids (e.g., quercetin, kaempferol) or phenolic acids.

Gas Chromatography-Mass Spectrometry (GC-MS): Used for identifying volatile organic compounds in the extracts.

Fourier Transform Infrared Spectroscopy (FTIR): Used to identify functional groups in the plant extract based on their vibration frequencies.

5. Pharmacological Evaluation

Pharmacological activity is evaluated through a series of in vitro and in vivo tests, depending on the specific therapeutic effects under investigation (e.g., anti-inflammatory, antioxidant, bone healing, etc.).

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Anti-inflammatory Activity
In vitro:
Enzyme inhibition assays like COX-1 and COX-2 inhibition.
Measurement of nitric oxide production in macrophage cell lines .
In vivo:
Carrageenan-induced paw edema model in rats: The anti-inflammatory effect is tested by measuring paw volume at different time intervals after injection of carrageenan and treatment with Cissus quadrangularis extraction.

Bone Healing and Osteogenic Activity
In vivo (Bone Healing Model):
The bone healing potential is tested using an animal fracture model (e.g., rats). A fracture is induced (e.g., mid-shaft femur fracture), and Cissus quadrangularis extract is applied topically or administered orally.

Parameters such as healing time, fracture callus formation, and bone mineral density are measured using radiographs or histological analysis.

Histopathology
After a certain period, animals are euthanized, and bone samples are collected for histopathological examination, where the new bone formation and the quality of healing are assessed under a microscope.

6. Antioxidant Activity
Antioxidant activity is tested to evaluate the potential of Cissus quadrangularis in scavenging free radicals.

In vitro assays:
DPPH (2,2-Diphenyl-1-picrylhydrazyl) Assay: A common method to measure the free radical scavenging activity of the extract.

ABTS (2,2'-Azino-bis(3-ethylbenzothiazoline-6-sulfonic acid)) Assay: Another test to assess the antioxidant potential by measuring the reduction of ABTS radical cations.

In vivo assays: Measurement of oxidative stress markers in rats (e.g., malondialdehyde, superoxide dismutase, catalas.

7. Statistical Analysis
After collecting data from various experiments, statistical analysis is performed to determine the significance of the findings.
Software: SPSS, GraphPad Prism, or similar software is used for statistical analysis.
Analysis Methods: Analysis of variance (ANOVA) followed by post-hoc tests (e.g., Tukey's test) is commonly used to compare different treatment groups. Results are typically presented as mean ± standard deviation (SD), and significance is set at $p < 0.05$

Advantage of Cissus Quabdragylaris
Cissus quadrangularis, also known as “Veldt grape” or “bone setter,” is a plant commonly used in traditional medicine for its potential health benefits. Some of its reported advantages include:

1. Bone Health & Joint Support: It is most well-known for promoting bone healing and reducing joint pain. It may help in treating fractures and improving bone mineral density, making it beneficial for conditions like osteoporosis or arthritis.
2. Anti-inflammatory Properties: The plant contains compounds that may help reduce inflammation in the body, which can aid in managing conditions like arthritis or general inflammation.
3. Weight Management: Some studies suggest that Cissus quadrangularis might help in weight management by supporting fat metabolism and improving overall body composition.
4. Antioxidant Effects: The plant is rich in antioxidants, which help combat oxidative stress and protect cells from damage caused by free radicals.
5. Digestive Health: It has been used traditionally to support digestive health, including reducing symptoms of indigestion and improving gut health.
6. Blood Sugar Regulation: Preliminary research suggests that Cissus quadrangularis might help regulate blood sugar levels, potentially supporting individuals with type 2 diabetes.

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7. Liver Health: There is some evidence to suggest that Cissus quadrangularis may have protective effects on the liver, helping to detoxify and reduce liver damage.

Evaluation test for Cissus Quabdragylaris

Cissus quadrangularis is a plant commonly used in traditional medicine for its purported benefits in bone health, weight management, and as an anti-inflammatory. It is important to evaluate Cissus quadrangularis from multiple angles, such as its pharmacological properties, clinical applications, and potential side effects. Below is a general framework for evaluating Cissus quadrangularis, along with references from scientific literature:

- Pharmacological Properties

Active Compounds: Cissus quadrangularis contains bioactive compounds such as flavonoids, alkaloids, phenolic acids, and triterpenoids. These compounds are believed to contribute to its medicinal properties.

Anti-inflammatory Activity: Cissus quadrangularis has been shown to have anti-inflammatory effects in various studies. Its ability to reduce markers of inflammation could be beneficial for conditions like arthritis.

Bone Health: The plant is often used for its purported ability to promote bone healing, particularly in fractures. Studies suggest that Cissus quadrangularis may enhance the formation of bone matrix and improve calcium metabolism.

- Clinical Applications

Bone Fractures: Clinical studies have reported that Cissus quadrangularis may accelerate healing in bone fractures and improve the recovery process. This effect is thought to be related to its ability to stimulate collagen synthesis and increase osteoblast activity.

Obesity and Weight Management: Cissus quadrangularis is sometimes used for weight loss. Research suggests that it may help in weight reduction by increasing metabolic rate and reducing appetite.

Osteoarthritis: Some studies have found that it may be effective in reducing the symptoms of osteoarthritis by decreasing joint pain and improving mobility.

- Toxicity and Side Effects

Safety Profile: Cissus quadrangularis is generally considered safe when used as directed, but overuse may lead to mild side effects like gastrointestinal disturbances or allergic reactions. Long-term safety data is still limited.

Interactions: There is limited information on potential drug interactions, but individuals taking medications for diabetes or hypertension should use caution, as Cissus quadrangularis might influence blood sugar levels or blood pressure.

- Formulations and Dosage

Dosage Forms: Cissus quadrangularis is available in various forms, including powder, capsules, tablets, and extracts.

Recommended Dosage: In clinical studies, dosages have ranged from 300 mg to 1,200 mg daily, depending on the form and specific health condition. It is always important to follow recommended guidelines or consult a healthcare professional before using it as a supplement

- Conclusion

Cissus quadrangularis holds promise for several therapeutic applications, particularly in bone health and weight management. However, more large-scale clinical trials are needed to confirm its efficacy and safety, as well as to establish standardized dosages and treatment regimens.

CONCLUSIONS

Cissus quadrangularis, a plant commonly used in traditional medicine, has attracted attention for its potential therapeutic properties, especially in the fields of bone health, weight management, and antioxidant activity. Studies suggest that the plant's bioactive compounds may promote the healing of fractures, reduce inflammation, and improve joint health. Additionally, its potential to support weight loss

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through various mechanisms, including appetite regulation and fat metabolism, has been explored. Cissus quadrangularis also exhibits antioxidant and anti-inflammatory properties that could offer benefits for conditions like arthritis.

Conclusion: Cissus quadrangularis appears to hold promise in various therapeutic areas, particularly for musculoskeletal health and weight management. However, while preliminary studies are promising, further clinical trials are necessary to establish optimal dosages, confirm long-term efficacy, and fully understand its mechanisms of action.

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HERBAL MEDICINES: ACROSS SECTIONAL STUDY TO INVESTIGATE THE PREVALENCE AND PREDICTORS OF USE AMONG INDIAN CITIZENS AND THEIR THERAPEUTIC EFFECTIVENESS DURING THE COVID-19 PANDEMIC

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ABSTRACT
Herbal drugs are widely utilized in many nations, and they include leaves, fruits, barks, seeds, stems, flowers, roots, rhizomes, and bulbs. Many small and major illnesses can be prevented and treated with herbal remedies. This study aims to assess the prevalence and correlates of usage of herbal medications among Indian citizens through a cross-sectional analysis. The relevant data was gathered from 246 persons between March 11, 2022 and March 24, 2022, using a Google form. People most frequently utilized ginger, turmeric, tulsi , cloves, cinnamon, Giloy , and black pepper as natural remedies. Around 98% of participants stated that herbal medications were superior to commercially accessible allopathic drugs. Drugs made from herbal medicinal plants had reduced toxicity and better therapeutic effects during the COVID-19 pandemic. During the COVID-19 pandemic period, a survey of herbal medicinal plants of Indian origin was conducted. According to the survey's findings, the majority of Indian Ayurvedic practitioners reported that these medications had better therapeutic efficacy, minimal toxicity, and no negative side effects. These herbal medicinal plant parts, which are of Indian origin, have anti-oxidant, detoxifying, and respiratory-supporting properties.

KEYWORDS : *Turmeric, Clove, Survey, Anti Oxidant, Anti inflammatory, Therapeutic effectiveness & Toxicity.*

INTRODUCTION

A new coronavirus disease called COVID-19, commonly known as SARS-CoV-2, has been causing an acute respiratory sickness outbreak worldwide since December 2019. The World Health Organization declared a pandemic on March 11, 2020, due to the rapid spread of COVID-19. This pandemic was able to show a larger amount of deaths . Because of the wide range of symptoms, there are currently no particular treatment medications for this illness. Historically, herbal therapy has been a significant factor in the management of infectious disorders. The notion that herbal medicine has a positive impact on the treatment and prevention of epidemic diseases has been bolstered by the noteworthy outcomes of clinical evidence from several research on the use of herbal medicine in the treatment of SARS coronavirus (SARS-Co V) has produced noteworthy findings and bolstered the notion that herbal therapy might help cure and prevent pandemic diseases. Herbal treatment in conjunction with Western medicine may help SARS-Co V patients with their symptoms and quality of life, according to a Cochrane systematic review. Herbal medicine may also lower the likelihood of H1N1 influenza infection, according to a recent meta-analysis .Herbal therapy is regarded as one of the alternate methods for treating COVID-19 because it is based on prior experience. To date, there is a large body of clinical evidence demonstrating the benefits of using herbal therapy in the treatment of COVID-19. Several systematic reviews of evidence from case reports, case series, and observational studies were also undertaken to investigate the efficacy of herbal medicine in COVID-19 treatment. However, reviews of randomized control trials (RCTs) provide the highest degree of evidence in the hierarchy of systematic reviews.. Therefore, using only currently available RCTs, our goal in this study was to assess the efficacy and side effects of herbal medications in the treatment of COVID-19.

IMPORTANCE OF HERBS WITH THEIR THERAPEUTIC EFFECTIVENESS :

1. TURMERIC

It is useful in inhibiting the growth of germs, harmful microbes and bacteria. Turmeric is widely used as home remedy to heal cut and wound. Traditionally, it is used as anti-inflammatory. Turmeric and its most active compound, curcuminoids have many scientifically proven health benefits, such as the potential to improve cardiac activity and useful in the treatment of Alzheimer's disease and cancer. Turmeric (Curcuma longa) and its component, curcumin, have long been used for their therapeutic benefits. Turmeric and curcumin's anti-inflammatory, antinociceptive, and antioxidant properties may be responsible for the majority of their therapeutic effects. The current review summarizes the preventative and therapeutic potentials of turmeric and its key constituent, curcumin, on inflammatory illnesses and pain, as well as patents linked to their analgesic and anti-inflammatory properties, to emphasize their significance on human health. Turmeric has a variety of therapeutic applications, including treating Alzheimer's disease. Curcuminoids, a compound composed of curcumin, dimethoxy curcumin, and bisdemethoxycurcumin, are essential components of turmeric. Curcumin is often regarded as the most essential component of the curcuminoid combination, contributing to the pharmacological profile of the parent curcuminoid mixture or turmeric. A thorough review of the literature demonstrates that

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the other two components of the curcuminoid mixture also play an important role in the efficacy of curcuminoids in AD. As a result, this review emphasizes that each component of the curcuminoid mixture has a separate function in making the curcuminoid mixture effective in AD, and so the curcuminoid mixture better represents turmeric in terms of medicinal usefulness than curcumin alone. Alzheimer's disease is the most frequent type of dementia. There is little choice in modern therapies, and the drugs that are accessible have limited success, as well as numerous side effects, and are expensive. As a result, better and more effective therapy approaches for Alzheimer's disease are being investigated in search of safer therapeutic targets. Turmeric has various therapeutic purposes, including treatment for Alzheimer's disease.

Fig (1.1) TURMERIC

2. TULSI

Tulsi has excellent medicinal properties. Tulsi has also been demonstrated in studies to be useful at treating diabetes by lowering blood glucose levels. The same study found that Tulsi significantly reduced overall cholesterol levels. Another study found that Tulsi's favorable effect on blood glucose levels stems from its antioxidant qualities. The Rama Tulsi is an effective treatment for severe acute respiratory syndrome. The juice of its leaves provides relief from colds, fevers, bronchitis, and coughs. Tulsi oil is sometimes used as an eardrop. Tulsi can help cure malaria. It is highly useful against indigestion, headaches, hysteria, sleeplessness, and cholera. Every day, millions of individuals take fresh Tulsi leaves. For generations, Tulsi (the queen of herbs) . In this study, we attempted to summarize the various ethnomedicinal uses, phytochemicals, and pharmacological applications of various Ocimum species that have long been used in traditional medicine for a variety of therapeutic applications, including antibacterial, antioxidant, anti-inflammatory, wound healing, and other medicinal properties. Medicinal plants used to treat various maladies and diseases are the most abundant biological reservoirs of phytochemicals. Ocimum species differ in terIms of morphology, pharmacology, and natural bioactive chemicals

Fig (1.2)TULSI

3.GINGER

The ginger plant is a herbaceous flowering plant from the Zingiberaceae family. Zingiber officinale Roscoe is the scientific name for the perennial plant, which consists of a pseudo-stem, yellow flowers, and tuberous rhizomes, generally known as ginger root or ginger. The rhizomes of ginger plants are the most sought-after component due to their aromatic odor and spicy taste. Ginger is consequently a significant culinary component. Originally from Asia, the most popular traditional usage of ginger was as a flavoring

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agent in its different forms, which might include fresh, dried, pickled, powdered, and preserved; and, more interestingly, as a tonic root to treat many maladies for its medicinal properties.

Heart health is mostly linked to the crude extract and its associated strong active ingredients. Ginger's cardiotonic, anti-hypertensive, anti-hyper lipidemia, and anti-platelet properties all contribute to its cardioprotective benefits. Additionally explained are the molecular mechanisms and signal ing pathways involved in ginger's cardioprotective properties. Despite recent advances in the treatment of cardiovascular problems, CVDs continue to pose a medical challenge. Many traditional medications are used to protect the heart, but they have a number of negative effects. Given the rich phytochemistry and fewer adverse effects of herbal medicines, researchers have focused on developing novel herbal pharmaceuticals with cardioprotective properties. Ginger is a widely used and well-known functional food and condiment with numerous bioactivities, such as anti-inflammatory, antioxidant, and antibacterial characteristics, that aid in the treatment of a variety of illnesses.

Fig (1.3) GINGER

4. CLOVE

It helps with coughs and colds. It is useful for nausea. It reduces mouth ulcers. It promotes blood flow. Clove oil derived from clove buds serves as a local anesthetic . It promotes digestion and alleviates tension. Cloves are used for a variety of purposes, including culinary and medicinal. Clove is a versatile kitchen spice that can be used to season onions, tomatoes, salads, herbal teas, and soups. It adds taste to a variety of products, including meat, cookies, gum, spices, fruits, pickles, chocolates, soft drinks, puddings, sandwiches, pastries, and candy. Volatile oil is used to add fragrance to perfumes, soaps, toothpastes, and medications. In Indonesia, a particular cigarette known as "Kretek" is made by mixing clove with tobacco in a 1:2 ratio. Clove has antibacterial properties and is used in mouthwashes, dental creams, throat sprays, and toothpastes to fight germs.

Fig (1.4) CLOVE

5. NEEM

Leprosy, eye conditions, intestinal worms, stomach distress, appetite loss, heart and blood vessel illnesses, fever, diabetes, and liver issues are all treated with neem leaves. Azadiracta indica (Neem) is mostly utilized in complementary and alternative medicine, which includes homeopathy, ayurveda, and unani medicine. According to the unani system, it works well to improve the liver, enrich blood, and strengthen teeth and gums. Because it works as an anti-malarial, anti-fungal, anti-microbial, and anti-parasitic in a variety of animal species, it is well-known for its numerous health advantages. Consuming foods and herbs high in polyphenols and flavonoids can slow the progression of a number of chronic illnesses, such as diabetes, cancer, and cardiovascular diseases Anticancer Effect Neem, a versatile medicinal plant, has been used for centuries to give various health advantages. Cancer is the uncontrolled proliferation of cells that disrupts the body's natural activities. Cancer can be healed using neem leaf extract. A study used MNNG to develop mouth and stomach cancer in rats. Arivazhagan et al. (1999) found that administering neem leaf extract decreased tumor cell mitotic activity.

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Fig (1.5) NEEM

6. GARLIC

Another extensively researched garlic preparation is aged garlic extract. Sliced garlic that has been preserved in 15-20% ethanol for more than 1.5 years is referred to as aged garlic extract. This entire process is expected to result in a major loss of allicin and enhanced activity of certain newer molecules, such as S- allyl cysteine, sallyl mer capto cysteine , allixin, N-0 -(Ideoxy-D-fructose-1-yl)-L-arginine, and selenium, which are stable and considerably antioxidant. Garlic oil is primarily manufactured for medicinal purposes through the steam distillation technique. Steam-distilled garlic oil contains diallyl, allyl methyl, and dimethyl mono to hexa sulfides . Botanically, Allium sativum belongs to the Lillaceae family, which includes onions, chives, and shallots. Garlic and its preparations are well-known for their ability to prevent and treat cardiovascular problems. Research suggests that garlic consumption can lower blood pressure, prevent atherosclerosis, lower serum cholesterol and triglycerides, inhibit platelet aggregation, and increase fibrinolytic activity . Both experimental and clinical investigations on several garlic formulations show that they have beneficial cardiovascular benefits.

Fig (1.6) GARLIC

MATERIALS & METHODS

Herb Collection

The fresh garlic (Allium sativum) and clove (Syzygium aromaticum) utilized in this study were gathered from the neighborhood market and identified and verified by a botanist. After being twice cleaned with distilled water, the fresh herbs were chopped, let to air dry, and then ground into a powder using a pestle and mortar.

Aqueous Extract

Conical flasks were filled with five grams (5gm) of the powdered herbs and twenty milli liters of distilled water. A wooden cork was placed over the flasks, and the contents were well combined. Overnight, the flasks were kept in a shaker set to 100 rpm. After passing the mixtures through a muslin cloth and centrifuging them for five minutes at 2000 rpm, the supernatant was poured into a sterile falcon tube and refrigerated at 4°C.

Ethanolic Extract

To make the ethanolic extract, 20mL of 95% ethanol and 5g of powdered herbs were combined in a flask and corked. A similar process was used for the mixing, 24-hour shaking, and muslin cloth filtration. After five minutes of centrifugation at 2000 rpm, the supernatant was decanted. After discarding the particle, the supernatant was filtered and then concentrated using a rotary evaporator. After that, the extract was kept in a refrigerator at 4°C in a sterile falcon tube until it was needed again.

Extract Sterility Test

All extracts' sterility was assessed using nutrient agar. Nutrient agar plates were inoculated with 1 ml of each extract, and the plates were then incubated for 24 hours at 37°C. The contamination was checked by looking for bacterial growth. The extracts were sterile since there was no growth in the plates.

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Antimicrobial Susceptibility Testing

All of the bacterial isolates used in this investigation, including three gram negative (E. coli, Pseudomonas aeruginosa, Klebsiella pneumoniae) and two gram positive (Methicillin-resistant Staph aureus, Streptococcus spp.), were described in accordance with Singh et al. (2015).

Antimicrobial susceptibility testing was conducted using the agar well diffusion method in accordance with the standards set out by the Clinical and Laboratory Standard Institute (CLSI). Bacterial suspensions were made using a 0.5 McFarland comparison. Criteria and injected onto Oxoid Mueller-Hinton agar plates. Steel borer (12mm) was used to make wells on agar plate. The wells were filled with 0.1mL, 0.5mL and 1.0mL of each extract. Ciprofloxacin (10 µ g) was used as the positive control, while the central well served as the negative control.

Each dilution's sample was examined three times. Following a 24-hour incubation period at 37ºC, ZOI (Zone of Inhibition) measurements were made (Mukhtar and Ghori, 2012). The diameter of ZOI determines the extracts' antibacterial activity; a larger ZOI indicates a high level of activity, whereas a smaller or absent ZOI indicates no activity.

Clove and garlic extract minimum inhibitory concentration (MIC)

A modified version of the previously published broth dilution method by Eloff (1998) was used to determine the minimum inhibitory concentration (MIC) of clove and garlic. 50 u L of nutritional broth was added to each of the 12 wells on the microtitration plate. Next, 50 u L of extract was added from the first well to the tenth well using a two-fold serial dilution. After that, 20 u L of bacterial suspension (0.5 McFarland) was added to the 12th well. The 11th and 12th (nutrient broth+ extract) wells served as the positive and negative controls, respectively, and were cultured for 24 hours at 37ºC. The growth on nutrient agar plates was used to determine the results.

RESULTS

With the exception of K. pneumoniae, which it demonstrated mild antibacterial activity against (7.30±0.5mm, 8.70±0.5mm, and 9.00±1mm) at 01 mL, 0.5 mL, and 1.0 mL of 50 µg/mL, respectively, the ethanolic extract of garlic exhibited no antibacterial activity against any of the bacterial isolates, as illustrated in Fig. 1. According to the findings, garlic's aqueous extract exhibited no antibacterial action against any of the bacterial isolates at any concentration. The zone of inhibition produced by Table 1 lists the aqueous and ethanolic extracts of garlic.

According to the current investigation, clove ethanolic extracts had better antibacterial activity than aqueous extracts. Clove extracts shown antibacterial action against all bacterial species, with the maximum activity against MRSA (12±0.5 mm and 20±1 mm) and K. pneumoniae (12±0.5 mm, 18±1 mm, and 26±0.5 mm). As shown in Figures 2 and 3, the aqueous extract exhibited little bactericidal impact against MRSA and P. aeruginosa but superior antibacterial activity against K. pneumoniae (10±0.5 mm and 16±0.5 mm). Table 2 lists the zone of inhibition generated by clove aqueous and ethanolic extracts.

Table 1 lists the antimicrobial properties of ethanolic and aqueous extracts of garlic (Allium sativum) and cloves (Syzygium aromaticum).
The organism Zone of Inhibition and Concentration of Garlic Aqueous Extract 50µg/mL
The organism Concentration of garlic ethanolic extract and inhibition zone: 50 µg/mL
Control positive (Ciprofloxacin)
5 µg of 0.1Ml, 0.5Ml, 1.0Ml, 0.1Ml, 0.5Ml, 1.0ML
MRSA Resilient, resilient, resilient MRSA Resistant Resistant 23 mm of resistance
P. aeruginosa Resilient, resilient, resilient P. aeruginosa Resistant Resistant 20 mm of resistance
K. pneumoniae Resistant Resistant Defiant K. pneumoniae 8.70±0.5 mm 9.00±1 mm 20 mm 7.30±0.5 mm
S. pyogenes Resilient, resilient, resilient S. pyogenes Resistant Resistant 20 mm of resistance
E. Coli Resilient, resilient, resilient E. Coli Twenty millimeters of resistance

Table 2: Inhibition zones generated by clove aqueous and ethanolic extracts
The organism Zone of Inhibition and Clove Aqueous Extract Concentration (50µg/mL)
The organism Concentration of zone of inhibition and clove ethanolic extract (50µg/mL)
Control positive (Ciprofloxacin)
Five µg of 0.1 mL, 0.5 mL, and 1.0 mL
MRSA Resilient, resilient, resilient MRSA 12±0.5 mm, 20±1 mm, and 23 mm resistant
P. aeruginosa Resilient, resilient, resilient P. aeruginosa Defiant 20 mm, 10±1 mm resistant
K. pneumoniae 10±0.5 mm to 16±0.5 mm resistant K. pneumoniae 18±1 mm, 26±0.5 mm, 20 mm, and 12±0.5 mm
S. pyogenes Resistance S. pyogenes Resistant 11±0.5 mm 8±1 mm, 14±1 mm, and 20 mm resistant
Resistant E. Coli Resistant 8±1 mm E. Coli Ten to twenty millimeters of resistance

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OBJECTIVES

1) Providing current data on herbal drug trends among Indian citizens is the primary goal of this study.

2) To compile further data regarding the quality, safety, and effectiveness of conventional medications.

3) To raise the general public's level of knowledge and interest in therapeutic herbs.

4) To raise knowledge about the use of herbal medications as home cures.

5) To raise public understanding about herbal drugs' safety.

RESULT & CONCLUSION

The application of herbal remedies was the main emphasis of the project. In order to assess the prevalence and predictors of herbal medications among Indian citizens during the COVID-19 pandemic, this survey aims to conduct a cross-sectional investigation. The study showed a sectional analytical report regarding herbal medicinal plants and their therapeutic effectiveness during COVID-19 pandemic. The study and the approved above data shows and percentage of herbal remedies and their effects with minimal side effects and overcounting action against covid 19. Also about the various properties of the herbal medicines like anti microbial activity, anti oxidant, anti inflammatory action, with boosting immunity of body towards covid 19. Also some herbal medicines were used by Doctors which was very helpful to create awareness regarding the therapeutic effectiveness of herbal medicines during covid 19 pandemic. The above study shows a clear beneficial results towards use of herbal medicinal plants and herbal medicines during covid 19 outbreak. The below graphical diagrammatical data shows a clear vision regarding the use of herbal medicines during covid 19. Hence the cure rate of people in young age during covid 19 was a large use of herbal remedies on homemade basis. (It was about 56% cure rate estimated).

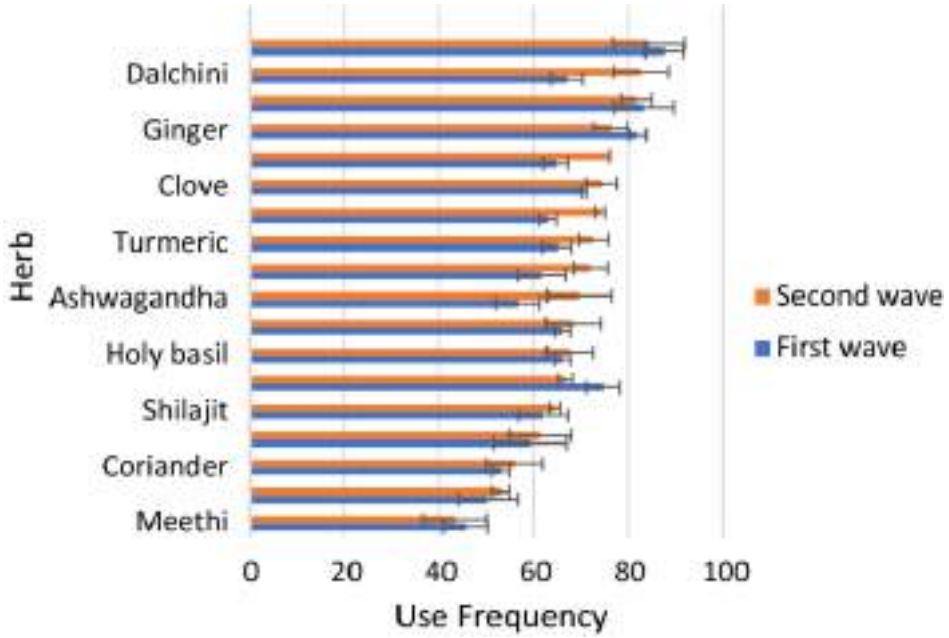

Fig (1.7) Analyzing the use of Medicinal Herbs During Covid 19

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ANALYZING SALES TRENDS OF MARKETED PREPARATIONS IN DENTAL PRODUCTS FOR REGION OF JALNA (MAHARASHTRA)

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ABSTRACT

The dental products market has seen substantial growth over the years, influenced by factors such as rising awareness of oral health, increasing disposable incomes, and advancements in dental care technologies. This review paper aims to analyze the sales trends of marketed preparations in the dental products sector within the region of Jalna, Maharashtra. The study explores various categories of dental products, including oral hygiene items like toothpaste, mouthwashes, dental floss, and therapeutic dental products, such as fillings, crowns, and orthodontic materials. It delves into the distribution channels, retail patterns, and consumer preferences specific to the region, considering socio-economic factors that impact purchasing behavior. Additionally, the paper examines seasonal variations, the influence of local cultural practices, and the role of marketing strategies in shaping sales. Data sources such as regional sales reports, market surveys, and consumer feedback will be reviewed to provide insights into the growth trajectory of the dental product market in Jalna. This paper also aims to highlight the challenges faced by stakeholders in the industry, including regulatory constraints, competition from unorganized sectors, and the impact of emerging online retail trends. The findings will serve as a valuable resource for manufacturers, distributors, and policymakers seeking to understand and capitalize on the evolving dental products market in the region.

KEYWORDS : *Analyzing Sales Trends, Marketed Preparations, Dental Products, Regional Sales Analysis, Market Analysis, Dental Market Trends, Consumer Behavior, Pharmaceutical Sales, Dental Preparations, Healthcare Products, Geographical Market Study, Product Performance.*

1. INTRODUCTION

The introduction of your review paper provides essential context for the study, highlighting the importance of analyzing sales trends in dental products within the region of Jalna, Maharashtra. This section sets the foundation for the review, giving readers an understanding of why this topic is relevant and timely.

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Background of the Dental Products Market

Fig:1. Dental Product Market.

The global dental products market has experienced significant growth over the last few decades. As oral health awareness has increased worldwide, the demand for dental care products has surged, leading to advancements in both the products available and the ways in which they are marketed. The market for dental products includes a wide range of items such as toothbrushes, toothpastes, mouthwashes, dental floss, therapeutic dental products, implants, and orthodontic materials. These products serve to prevent oral diseases, improve hygiene, and offer restorative solutions.

The dental Industry is also heavily influenced by continuous innovation in product formulations, packaging, and marketing strategies. Emerging trends include the demand for eco-friendly, natural, and innovative oral care products. As a result, companies in this sector are focusing not only on product efficacy but also on sustainability and consumer health-consciousness.

In India, the dental products market has been growing rapidly due to a combination of rising disposable incomes, an increase in dental awareness, and a burgeoning middle-class population. However, regional variations in product demand, purchasing behavior, and access to products exist, creating a need for localized market analyses.

2. IMPORTANCE OF DENTAL HEALTH: GROWING AWARENESS AND IMPACT

Dental health plays a critical role in overall well-being. Poor oral hygiene can lead to a range of health issues, including tooth decay, gum disease, and in severe cases, systemic diseases like heart disease and diabetes. Furthermore, dental health is closely linked to an individual's self-esteem, with the appearance of teeth influencing one's confidence and social interactions.

In India, a rising awareness about the importance of oral hygiene has significantly contributed to the growth of the dental products market. Government campaigns, educational programs, and increased media coverage have raised awareness about preventive dental care. According to surveys, a larger portion of the population is now prioritizing daily oral hygiene and regular dental visits, especially in urban and semi-urban areas.

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In the context of Maharashtra, including regions like Jalna, there has been a noticeable shift toward more people adopting preventive dental care practices. As a result, products such as fluoride toothpaste, mouthwashes, and teeth-whitening products are in high demand, contributing to the market's expansion. Additionally, the rise in middle-income consumers, a higher number of dental clinics, and better access to products have spurred the growth of the region's dental market.

Focus on Jalna (Maharashtra)

Jalna is a city located in the state of Maharashtra, an important region in Western India. Jalna, although smaller compared to major urban centers like Mumbai or Pune, represents a growing and evolving market for dental products. As urbanization increases, consumer behavior in rural and semi-urban areas is shifting, with more people becoming aware of the importance of dental care. The demand for dental products has been on the rise in Jalna, particularly among middle-class families who are becoming more health-conscious and are increasingly able to afford dental treatments and care products.

The region's dental market differs from more urbanized areas due to factors like Income disparities, educational levels, and cultural preferences. Rural and semi-urban markets in Maharashtra may face challenges such as limited access to a wide variety of dental care products, but they also present opportunities for market expansion due to untapped demand. Understanding how these regional factors influence the sales trends of dental products in Jalna can provide valuable insights for manufacturers and distributors looking to enter or grow in this market.

3. RESEARCH OBJECTIVES

The main objective of this review paper is to analyze the sales trends of marketed preparations in the dental product sector for the region of Jalna, Maharashtra. The paper will focus on understanding the following key areas:

1. Market Trends and Growth: Analyzing the historical sales trends of dental products in the region, including the growth rate, fluctuations in demand, and identifying products that have seen significant adoption in recent years.
2. Product Categories: Examining the types of dental products that are most popular in Jalna, such as oral hygiene products (toothpaste, toothbrushes, mouthwashes), therapeutic dental items (fillings, crowns, implants), and the growing market for teeth-whitening and orthodontic products.
3. Consumer Behavior: Investigating consumer preferences, including brand choices, price sensitivity, and the role of dental clinics and pharmacies in influencing buying decisions. Understanding how local socio-economic factors impact purchasing behavior is a critical aspect of this analysis.
4. Distribution Channels: Studying the distribution networks in Jalna, including local pharmacies, dental clinics, and online retail channels, to identify the most common ways consumers access dental products.
5. Challenges and Opportunities: Identifying barriers to market growth, such as limited awareness, counterfeit products, regulatory challenges, and distribution issues. At the same time, the paper will explore opportunities for market expansion, including the increasing popularity of e-commerce platforms and the growing demand for advanced dental care products.
6. Regional Factors Impacting Sales: Understanding the cultural and socio-economic factors in Jalna that influence the types of dental products purchased, such as the effect of local festivals, community health initiatives, and government policies on consumer behavior and product demand.

Overview of Dental Products

Dental products are essential items used to maintain oral hygiene, prevent dental diseases, and enhance the aesthetics of teeth. These products include daily care items such as toothpaste, toothbrushes, and mouthwashes, as well as specialized products like orthodontic devices, fillings, and dental implants. The dental products market is expanding due to increased awareness about oral health and growing consumer demand for both preventive and restorative dental solutions.

4. CATEGORIES OF DENTAL PRODUCTS

1. Oral Hygiene Products: Includes toothpaste, toothbrushes (manual and electric), mouthwashes, dental floss, and tongue scrapers used for everyday dental care.
2. Therapeutic Products: Includes fillings, crowns, dental implants, orthodontic devices, and gum care products designed to treat or prevent specific dental issues.
3. Preventive Products: Products like fluoride treatments, dental sealants, and diagnostic tools used to prevent dental problems before they arise.

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4. Cosmetic Products: Products aimed at improving the aesthetic appearance of teeth, such as teeth whitening products, veneers, and cosmetic fillings.

Market Segmentation

1. By Product Type: Oral hygiene products dominate the market, followed by therapeutic and cosmetic dental products.
2. By Distribution Channel: Products are sold through pharmacies, supermarkets, dental clinics, hospitals, and online platforms.
3. By Consumer Demographics: The market is segmented based on age groups (children, adults, seniors), income levels, and health-conscious consumers.
4. By Geography: Urban markets tend to have higher demand for advanced dental products, while rural areas focus on basic oral care solutions. Regional preferences and local economic conditions also influence purchasing behavior.

Regional Market Dynamics in Jalna

The dental products market in Jalna is shaped by several regional factors, including socio-economic conditions, consumer preferences, and distribution networks. Understanding these dynamics is essential for analyzing sales trends and identifying opportunities for market growth.

Socio-Economic Factors Affecting Dental Product Sales in Jalna

Jalna's socio-economic structure plays a significant role in shaping consumer demand for dental products. With a growing middle class and increasing health awareness, more consumers in Jalna are investing in dental care. Higher disposable incomes allow for greater spending on preventive and cosmetic dental products. However, affordability remains a key factor, with price-sensitive segments preferring budget-friendly options. Rural areas may see more demand for basic hygiene products, while urban areas witness a rise in demand for advanced dental care solutions.

Geographical Influences

Jalna, being a semi-urban region, experiences a mix of urban and rural influences on consumer behavior. Urban areas see higher adoption of advanced dental products, while rural areas often focus on basic oral hygiene items due to lower awareness and access. Accessibility to retail outlets, including local pharmacies, impacts product availability, with rural areas facing challenges in accessing a wide range of dental products.

Consumer Behavior

Consumer behavior in Jalna is influenced by increased health consciousness, social media trends, and awareness campaigns. As dental hygiene becomes a priority, consumers are more inclined to purchase branded and quality oral care products. However, price sensitivity and traditional preferences also play a role in product selection, with consumers often opting for established, familiar brands.

Role of Local Pharmacies and Dental Clinics

Local pharmacies and dental clinics in Jalna serve as important distribution channels for dental products. Pharmacies offer basic hygiene products like toothpaste and mouthwashes, while dental clinics often sell specialized items such as fillings, orthodontic appliances, and other therapeutic products. Dental professionals significantly influence consumer purchases, particularly in terms of recommended treatments and products.

Seasonal Variations in Sales

Sales of dental products in Jalna are subject to seasonal fluctuations. For example, demand for oral care products may rise during festivals, when people tend to focus on health and wellness. Additionally, dental product sales may spike during health campaigns or awareness months. There may also be fluctuations due to climatic conditions, with higher sales in the summer when consumers are more likely to seek oral care for issues like bad breath or dehydration.

5. SALES TRENDS AND MARKET GROWTH

Historical Sales Trends

Recent years have shown a steady growth in sales of dental products in the region of Jalna. With increasing awareness about oral health, products like toothpaste, toothbrushes, and mouthwashes have seen consistent demand. A shift from basic to more advanced dental care solutions is noticeable, particularly in urban areas where disposable income has risen. Seasonal sales, such as during health campaigns and festivals, also contribute to spikes in demand.

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Growth Trajectory
The dental products market in Jalna appears to be expanding, albeit at a moderate pace. Increased consumer awareness and rising middle-class incomes are driving growth, though it is slower compared to larger urban centers. The market is likely to continue growing, especially as access to modern dental care improves in semi-urban and rural regions.

Brand Performance
Popular brands like Colgate, Sensodyne, and Oral-B dominate the market, holding a significant market share. Emerging local brands have started gaining traction due to competitive pricing and region-specific products. Brand loyalty remains strong in the region, though new entrants are challenging established players with innovative products and localized marketing.

Impact of Pricing and Discounts
Pricing plays a key role in consumer purchasing decisions, particularly in a price-sensitive market like Jalna. Discounts, bundled offers, and seasonal promotions significantly impact sales volume, with consumers often waiting for promotions to purchase more expensive items like electric toothbrushes or premium toothpaste.

Online vs. Offline Sales
The rise of online retail platforms is changing the dynamics of dental product sales in Jalna. While traditional brick-and-mortar stores, such as pharmacies and supermarkets, remain the primary sales channels, e-commerce platforms are growing in popularity due to convenience, competitive pricing, and home delivery options. Online sales of dental products are expected to continue increasing, particularly in the wake of the COVID-19 pandemic.

6. FACTORS INFLUENCING SALES TRENDS

Consumer Awareness and Education
Increasing awareness about the importance of dental hygiene, driven by health education campaigns, has led to higher consumption of dental care products. As consumers become more informed, there is a growing demand for products targeting specific issues like teeth whitening, sensitivity, and gum care.

Marketing Strategies
Aggressive marketing, including TV advertisements, celebrity endorsements, and social media promotions, has a significant impact on sales. Brands are investing in digital marketing to reach a wider audience, particularly targeting younger, tech-savvy consumers in Jalna.

Government and Health Initiatives
Government initiatives, such as dental health awareness campaigns and programs promoting regular dental check-ups, have influenced sales of preventive dental care products. Regulatory measures also ensure product safety, fostering consumer confidence in established brands.

Healthcare Professional Recommendations
Dentists and healthcare professionals in Jalna have a strong influence on consumer choices, particularly for therapeutic and advanced dental products. Products recommended by dental professionals are more likely to be trusted and purchased by consumers.

Competition from Local, Regional, and National Players
The market in Jalna is highly competitive, with both national brands and local players vying for market share. Local products, which are often more affordable, compete with national brands, impacting the pricing strategies of larger companies. Smaller, regional brands also try to offer products suited to local tastes and needs.

Technological Advancements in Dental Products
Innovations such as electric toothbrushes, smart dental devices, and eco-friendly products are gaining traction in the market. Consumers in Jalna are increasingly seeking advanced products that offer greater convenience, improved results, and better sustainability.

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7. CHALLENGES IN THE DENTAL PRODUCT MARKET

Regulatory Challenges

The legal framework surrounding dental products in Maharashtra can affect market entry and product availability. Stringent regulations on product quality, safety, and labeling ensure consumer protection but may create hurdles for smaller companies and new brands.

Unorganized Sector

The presence of unbranded or lesser-known products in the market, often sold in local markets or directly by vendors, poses a challenge to the growth of organized dental brands. These products may be sold at lower prices, attracting price-sensitive consumers.

Counterfeit Products

Counterfeit dental products are a growing concern in the market, as they undermine consumer trust in legitimate brands. These products can compromise consumer health and affect sales of genuine products.

Logistical and Distribution Challenges

The distribution of dental products in rural areas of Jalna faces logistical challenges due to limited access to retail outlets, poor transportation infrastructure, and less market penetration by large retail chains.

8. EMERGING TRENDS IN THE DENTAL MARKET

Fig:2. Emerging trends in the Dental Market

Natural and Organic Dental Products

There is a growing demand for natural and organic dental products, such as herbal toothpastes and eco-friendly oral care items. Consumers are increasingly interested in products that are free from harmful chemicals and align with their health-conscious lifestyles.

Sustainability in Dental Products

Sustainability is becoming a key factor in product development. Manufacturers are focusing on eco-friendly packaging, biodegradable products, and reducing the environmental impact of their production processes.

Innovative Product Formulations

Consumers are looking for multi-functional products, such as whitening toothpastes that also help with gum health, or sensitivity-reducing toothpaste with natural ingredients. These innovations cater to growing consumer demand for more efficient and effective solutions.

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Digital Marketing and E-commerce
The shift toward online shopping has intensified the role of digital marketing and e-commerce in the dental product market. Brands are leveraging platforms like Amazon and Flipkart, as well as their own websites, to reach a larger audience.

9. IMPACT OF COVID-19 ON SALES TRENDS

Pandemic Influence on Dental Habits
During the COVID-19 pandemic, consumers reduced visits to dental clinics, leading to an increase in the demand for home oral care products such as toothpaste, mouthwashes, and at-home teeth whitening kits. The shift to online shopping also accelerated during this period.

Effect on Product Demand
The pandemic caused a spike in demand for home-use dental products, such as toothpastes and electric toothbrushes, while reducing the demand for professional dental services and products. With dental clinics closed or offering limited services, consumers focused on maintaining oral hygiene at home.

Post-pandemic Recovery
As dental clinics reopened and consumer confidence returned, the market began recovering. People are now more aware of their oral health than ever, which continues to drive demand for both preventive and therapeutic dental products.

10. FUTURE OUTLOOK AND OPPORTUNITIES

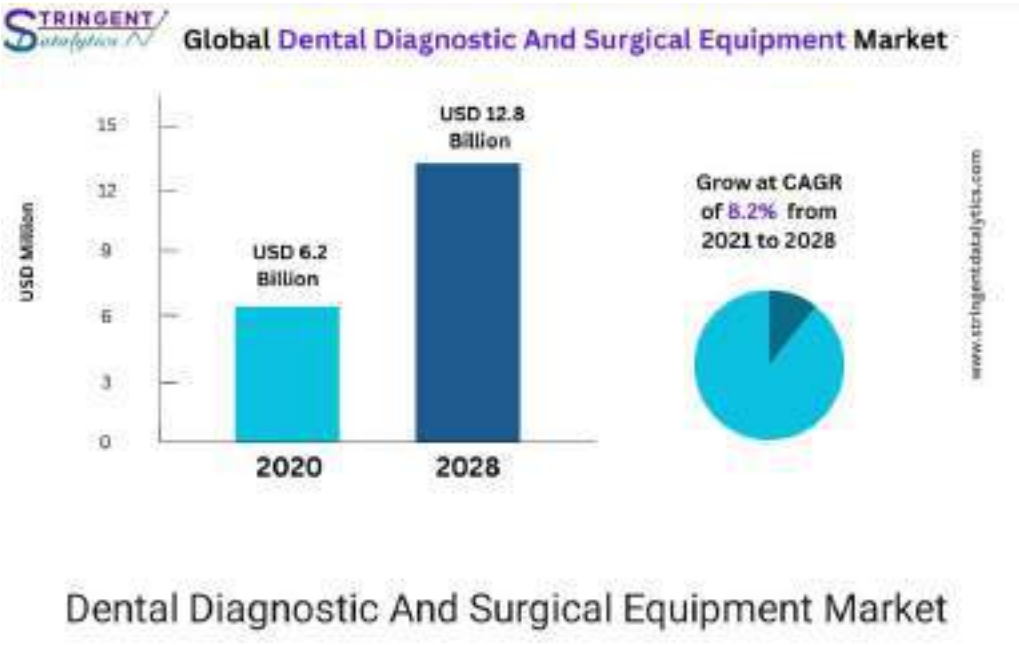

Fig:3. Future Outlook and opportunities.

Market Forecasts
The dental products market in Jalna is expected to grow over the next 5-10 years, driven by increased health awareness, rising disposable incomes, and greater access to dental care. The shift toward preventive care and premium dental products is likely to continue.

Opportunities for Growth
There are significant growth opportunities in rural and semi-urban areas of Jalna, where dental care awareness is still emerging. Expanding the availability of affordable, high-quality dental products in these areas can drive market growth.

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Potential Market Entry Strategies

New brands can enter the Jalna market by focusing on affordability, leveraging local distribution networks, and introducing innovative, health-conscious products that cater to the region's evolving consumer preferences.

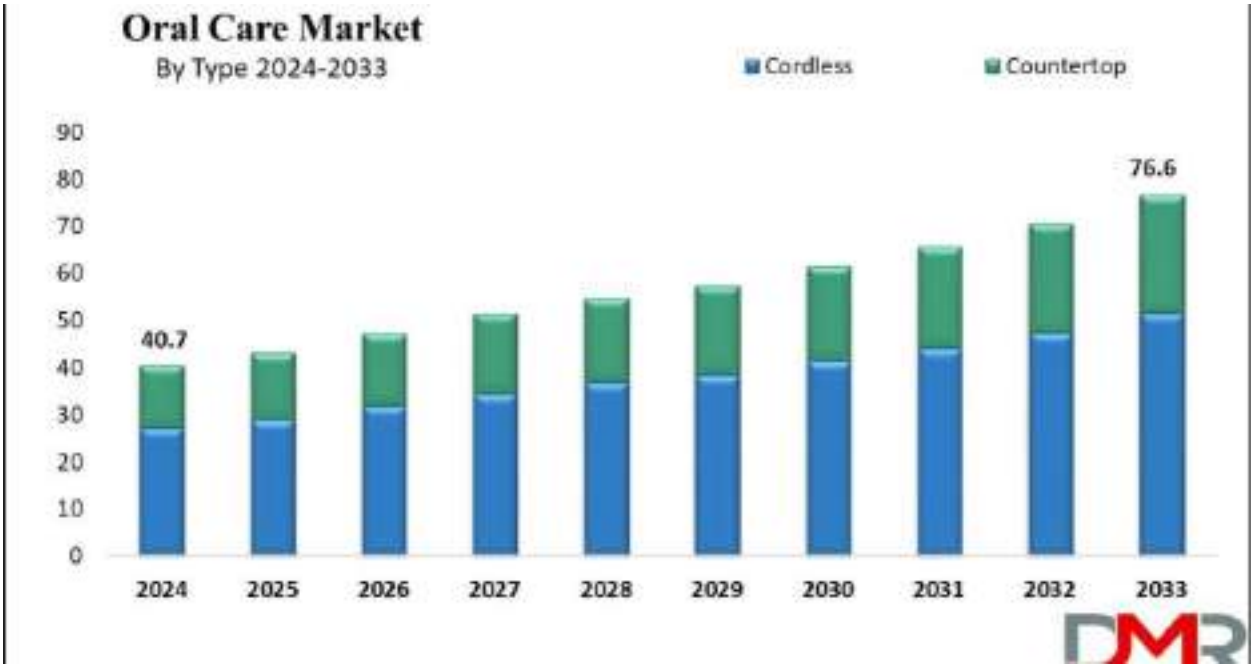

Fig:4. Oral Care Market

11. CONCLUSION

This review of sales trends in dental products in Jalna highlights the dynamic nature of the market. Factors such as socio-economic conditions, consumer awareness, marketing strategies, and emerging trends are all contributing to the region's growth in the dental product sector. Despite challenges like counterfeit products and logistical hurdles, there are significant opportunities for new brands and innovations to thrive in the region. As the market continues to expand, stakeholders should focus on addressing consumer needs, especially in rural and semi-urban areas, to capitalize on the growth potential.

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CHALLENGES IN SAFEGUARDING THE CYBERSECURITY MEASURES AMONG HIGHER EDUCATION INSTITUTIONS IN THE NATIONAL CAPITAL REGION

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ABSTRACT
Higher Education Institutions are using various Management Information Systems as their main repository of the vast data that schools acquire from their stakeholders. On this dependency on technology the paradox of its misuse of platforms entailed breach on sensitive information, operational protocols, and even communication. Hence, creating a much demand for its heightened focus on safeguarding the institution's digital environments, through dynamic security measures and creating a much more technologically advanced landscape. As the call for safeguarding the digital environment, among Higher Education Institutions have resulted in strengthening their protection, however, even how much commercially offered software and systems are made available cyberthreats are still common to the said industry. Hence, the study purports to see the challenges in safeguarding the cybersecurity measurements being implemented by the HEIs in the National Capital Region that may stop or prevent cyberthreats and attacks as well as checking on the resiliency and awareness of its employees as they are the first line of defense. Using a descriptive-correlational approach, the data serves as the anchor-points of the proposed countermeasures that the cybersecurity framework has to offer.

KEYWORDS: *Cybersecurity, Cyberthreat, Cyber Attack, Higher Education Institutions, National Capital Region*

INTRODUCTION

In the contemporary landscape of Higher Education Institutions throughout the world, the effective functioning of Management Information Systems (MIS) as a repository of vast data is integral to their operations. The reliance on digital platforms for managing sensitive information, operational processes, and communication demands a heightened focus on safeguarding their digital environments with the security measures they implement in a dynamic and technologically advanced landscape. Connections with other institutions internationally opened the issues on the protection of critical data, confidentiality of client information, and the overall integrity of their information systems which has become the paramount consideration in the age of artificial intelligence.

In the event that cybersecurity is critical, global collaboration becomes essential for effective incident response. Since academic institutions are centers of learning, knowledge and generation of noble information, cybersecurity measures developed by the employees of schools are highly responsive to cybersecurity issues and cyberattacks, but only for the meantime. This is because of the dynamic and evolving landscape of cyberspace. Globalization aids in the creation of protocols in coordinating with relevant authorities across borders to mitigate the impact of cybersecurity breach and cyberattacks that target sensitive information, including personal data as part of their operations. As such, international data protection laws have been forged to mitigate the effects of cyberattacks, such as the European Union's General Data Protection Regulation (GDPR).

The academic landscape is a complex structure where some key aspects, challenges and problems related to cybersecurity in the context of higher education on the international level need sustainability and resiliency. The promotion of cybersecurity awareness remains inadequate since the incidents are mostly linked with human error. The problems encountered by schools throughout the world are not uniform since they vary as to the degree or gravity, frequency and effects. There are no uniform security measures implemented globally because of jurisdictional concerns and legal compliance in each political unit. On a wider perspective, it is considered as an advantage for cybercriminals when different countries do not treat the acts leading to cybercrimes similarly.

International Background

The worldwide panorama of protecting the digital environments with cybersecurity measures implemented by Higher Education Institutions with their Management Information Systems (MIS) is defined by the intricate interactions between global cybersecurity threats, legal frameworks, and technology developments. Just like any other organization holding a great volume of information or data,

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HEIs are subject to a wide range of cyberthreats that cut across national borders since they operate internationally.
The nature of cyber threats is transnational and continually evolving along with the dynamics of the society. Threat actors, including state-sponsored entities, cybercriminal organizations, and hacktivists, operate on a global scale. Safeguarding digital environments with security measures must therefore address a broad spectrum of potential threats. Various international standards and frameworks provide guidance for cybersecurity best practices such as, but not limited to the ISO/IEC 27001 for information security management and NIST Cybersecurity Framework. HEIs may adopt these standards to enhance their digital security posture and demonstrate compliance on a global scale.

The international landscape of safeguarding digital environments of schools in their Management Information Systems (MIS) is characterized by a complex interplay of global cybersecurity challenges, regulatory frameworks, and technological advancements. As Higher Education Institutions (HEIs) operate across borders and engage in cross-jurisdictional activities due to their foreign linkages, they are exposed to a myriad of cyber threats that transcend national boundaries. Understanding the international background of safeguarding digital environments is crucial for these agencies to effectively navigate the evolving landscape of cybersecurity.

National Background
In the Philippines, safeguarding digital environments within the Management Information Systems (MIS) of HEIs is of utmost importance since these are centers of learning, honing of knowledge and skills and centers for research and development that are vital in societal development. The amount of data they possess may be useful for cybercriminals in perpetrating cyber offenses, such as scamming, phishing and remote or online access to an individual's accounts. Although much emphasis is given to business organizations, financial institutions or banks in particular due to the monetary gains of cybercriminals, academic institutions also suffer the impacts of cyberattacks and breach to their digital environment security, whether monetary or not. The country's dynamic cybersecurity landscape, regulatory framework, and technological advancements shape the approach to securing the digital assets of every institution or organization.

On the national cybersecurity policy, the Philippines had been actively working on enhancing its national cybersecurity policies, in which institutions or organizations are expected to align their digital security measures or practices with the country's cybersecurity frameworks and guidelines issued by government agencies, like the Department of Information and Communications Technology (DICT). The Data Privacy Act of 2012 (Republic Act No. 10173) imposes obligations towards organizations that handle personal information. Hence, HEIs must comply with the said law by implementing data protection measures, and secure the confidentiality of client and employee data stored in their MIS. Despite the severity of the penalty, cybersecurity issues remain active and even reached its height during the pandemic

The National Privacy Commission is the regulatory body responsible for enforcing the Data Privacy Act including NPC regulations, advisories, and guidelines that may impact the digital security practices of HEIs and other institutions. Government-led initiatives and partnerships aimed at enhancing national cybersecurity where every organization must actively participate.

Collaborative efforts with government agencies can include information sharing, capacity-building programs, and joint cybersecurity exercises that may be useful to every HEIs security measures.

Local Background
The security landscape of Higher Education Institutions (HEIs) in the NCR, are oftentimes infiltrated with cyber-attacks and maligned with the poor firewall, security measures implemented or cybersecurity in the academe. This often invites hackers preying on the weak cyber defenses of institutions which were established by poor, incompetent and fly-by-night security providers, still in the trial stage, or free services with less security features. As a result, the integrity of the data being handled and secured by the institution ends up infiltrated and used for other unauthorized and illegal purposes. This is the very threat in the digital environment.

Cybersecurity implemented in different HEIs are all effective, as long as they are properly maintained by employees with full knowledge of security awareness and best practices combating cyberthreats. Measuring the level of effectiveness of cybersecurity is subjective to the HEIs, depending on various circumstances, such as the amount of data stored in their MIS, the operating capacity of the institution and the prevalence of online transactions as a business practice adopted. The dynamic and evolving landscape of cybersecurity shifts the effectiveness of cybersecurity measures.

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Since there is no guarantee when cyberattacks occur, HEIs must be ready at any time to patch any vulnerability that they notice, before hackers take advantage of the weakness in the security measures. Any form of breach in the security measures exposes the held data to cyberattacks, and the said data may be used to perpetrate any form of cybercrime where hackers may greatly benefit. Problems of some institutions to come up with a strong cybersecurity are linked with their available resources and financial capability. At the end, their cybersecurity implemented is weak and vulnerable to cyberattacks. Others also end up with outdated software and vulnerable legacy systems.

The implementation of cybersecurity measures by the HEIs to protect their data necessitates the capacitation of their employees on cybersecurity awareness and adherence to security policies that are critical. Problems are encountered by HEIs in implementing their cybersecurity when limited personnel or less-qualified employees are hired to monitor the cybersecurity performance. This is the main reason why problems are encountered at the implementation stage, and such problems are mitigated when employees are capacitated in cybersecurity issues. Vulnerabilities and weaknesses can be detected and addressed by qualified employees before hackers exploit them through an effective intrusion detection and prevention system. Solutions or countermeasures to the encountered problems come with the cybersecurity resilience framework or model.

METHODOLOGY

Research Design

This study used a descriptive-correlational research design utilizing quantitative data under the quantitative research methods. Through the research design used, the research investigations seek to demonstrate the link between several variables and give statistical representations. The design was suitable as the researcher gathered information relevant to a participant's behavior or attitude in order to perform the assessments needed in the study.

The variables were measured as they happen, such as the profile of the Higher Education Institutions (HEIs) in terms of years of operation (year established up to present), current number of employees, capability for online transactions, average number of students in the last five years, existing number of linkages with local/national institutions (academic, non-academic, community-based, NGOs, and the like), existing number of linkages with foreign institutions (academic, non-academic, community-based, NGOs, and the like), digitized records system and types of cybersecurity measures implemented; effectiveness of the cybersecurity measures implemented in terms of cybersecurity structure, anti-virus and anti-malware software, data encryption, access controls, security structure, and network monitoring tool; level of awareness of the employees of the Higher Education Institutions (HEIs) on cybersecurity in terms of the types of cybersecurity or domains, common cybersecurity threats, common and dangerous cybersecurity myths, key cybersecurity technologies and best practices, Management Information System, and related solutions; and challenges encountered in implementing the cybersecurity measures.

The results of the evaluation of the effectiveness of security measures implemented, awareness of the respondents on cybersecurity and challenges encountered were correlated with the profile of the HEIs. Likewise, the profiles were also used as predictors of effectiveness, awareness and challenges encountered in the implementation of cybersecurity measures. The results were used as the basis of a proposed Resilient Cybersecurity Model, a framework of enhanced cybersecurity measures for HEIs use.

Research Method

This study utilized quantitative research through survey methods or use of a researcher-made questionnaire. Research methods refer to the systematic approaches and techniques employed to gather, analyze, interpret, and draw conclusions from data in a structured and rigorous manner. The researcher adequately constructed a survey questionnaire-checklist sufficient to gather the needed data to complete the study.

Through survey technique, the researcher used the research instrument that was validated by experts and later on assessed with reliability statistics to assure the internal consistency of the items. Once reliable, the data were gathered through the research instrument that was floated or sent to the respondents both via online or through Google Forms and face-to-face administration of the instrument after the researcher made appointments to the qualified respondent in each HEI of NCR. The final data were simplified in a matrix for systematic data analysis using the appropriate statistical tools, and facilitated by the use of IBM SPSS v.29 software as to the computations.

Population of the Study

The respondents of this study were the representatives from different Higher Education Institutions (HEIs) of the National Capital Region (NCR). Each HEI included in this study was represented by one (1) employee whose qualifications must conform to the order identified by the researcher: must be the head, director, supervisor, a key employee, or any authorized representative of the HEI's

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Management Information System (MIS) or equivalent office. In the absence of MIS, the dean, program chair/head of the College of Information Technology or Studies, Computer Science, Computer Management, Computer Engineering, or any professor or instructor in the same field, or any authorized employee by the HEI.

Locale of the Study

The research focused on the Higher Education Institutions (HEIs) operating in the National Capital Region, based on the list of recognized HEIs by the Commission on Higher Education (CHED). With the dynamic landscape of educational technology, HEIs throughout the country have leveled up their online environment in response to progress and globalization. All academic institutions have been forced to innovate and embrace technology in education since the pandemic in 2020. Those who failed to embrace technology were forced to close and shut down their operations.

Scope and Limitation of the Study

This study was emphasized on the results of the evaluation of the security measures implemented by selected Higher Education Institutions (HEIs) within the National Capital Region as means to protect their possessed digital and online information, ensure confidentiality and integrity of data in their respective Management Information System (MIS). The results were the basis of the proposed Resilient Cybersecurity Model, a framework of enhanced cybersecurity measures for the HEIs.

The independent variables used were the profile of the HEIs and their existing or implemented cybersecurity measures. The dependent variables were the assessment or evaluation of the cybersecurity measures of the HEIs as to the effectiveness of the cybersecurity measures, awareness of the employees of HEIs on cybersecurity, and challenges encountered in implementing their own cybersecurity measures. Correlation and regression analysis revealed the predictors and the cause-and-effect relationship of variables.

Limitations include the level and status of implementation of cybersecurity measures in different HEIs relative to their financial resources, revenues derived in their operations, facilities, equipment, physical structures, and online capabilities. The results of the assessment or evaluation may be subjective for each HEI as to the effectiveness of their cybersecurity measures being implemented. The challenges encountered in each HEI may be viewed differently by other HEIs depending on their capabilities. Further, the size of the HEIs (number of students), facilities for online transactions, engagement and utilization of the Internet, online capabilities and technological inclination also set limitations to this study since there is no minimum requirement or standard for HEIs in their online or technology usage.

On the part of the researcher, limitations existed as regards the time and situation when the instrument was administered or floated, and the availability of the respondents that was far more challenging than the gathering of data.

Data Gathering Tool/s

The researcher used a self-constructed or researcher-made research instrument in gathering the data. The instrument was divided into four parts. The first part inquired on the profile of the respondents that the statement of the problem provided, and a checklist was designed by the researcher to facilitate accurate response from the participants. Other information or data about the HEIs were also accessible in their official website. The second part measured the effectiveness of the cybersecurity measures of the HEIs implemented in the digital environment of their MIS in terms of cybersecurity structure, anti-virus and anti-malware software, data encryption, access controls, security structure and network monitoring tool. The third part measured the awareness of the employees of HEIs on cybersecurity in terms of types of cybersecurity or domains, common cybersecurity threats, common and dangerous cybersecurity myths, key cybersecurity technologies and best practices, Management Information System (MIS) and related solutions. The fourth part assessed the challenges encountered in the implementation of cybersecurity measures by

Higher Education Institutions (HEIs).

The research instrument was crafted and conceptualized by the researcher based on the information provided at the IBM website, literature review and existing studies, law, policies and other pertinent sources with legal implications. Although self-constructed, the instrument contained guided and carefully chosen information that satisfied the criteria and contents needed for the study. Chapter 2 contained the related literature and studies used by the researcher as a springboard to complete the research instrument.

The instrument or tool of this research was subject to different scrutiny. The initial draft of the researcher was checked and edited by an external consultant of research as preparatory in the initial draft. When finalized, the researcher sent the instrument to three experts for purposes of validation by experts in the field of cybersecurity, academe and practitioners in the information and communications technology. The assessment of validity were based on the Face Validity which proved that the items in the measurement or instrument

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linguistically and analytically look like what was supposed to be measured based on the assessment in each item by the selected experts or validators; Content Validity which ensured that the items of the instrument were relevant and representative of the target construct using the Content Validity Ratio (CVR) or Lawshe's Method, where the CVR depends on the number of validators who assessed the instrument; and the Criterion-based Validity which ensured that the outcomes of the study were measured by the items of the instrument. Their certification and validation assessments were appended for reference purposes.

Data Gathering Procedure

The procedure in data gathering commenced from the time the research instrument was fully assessed of its validity and reliability. From thereon onwards, the researcher sent communication letters or notices, both printed in black and white and email to all the 328 HEIs of NCR, since others might not participate in the study. The HEIs that gave their consent on the study, or replied with the communication sent to them were either sent with a questionnaire in Google forms, or visited by the researcher for personal administration of the research instrument. Hence, the survey instrument was floated or administered to the respondents both in person and through online means.

To ensure the integrity of the data, the researcher ensured that before the respondents answered the questionnaire, they understood the purpose and objectives of the study. Further, the consent of the respondents was given freely before they began answering. Ample time was given to the respondents in completing their responses. Once done, the researcher retrieved the instrument personally, and for the online responses, the respondents must submit the completed survey forms to complete the process, and the data were extracted by the researcher from the Google documents.

The complete data of the study were simplified in a matrix, where all the data from the sample respondents need to be placed. Incomplete data or responses coming from any respondent were disregarded since they affected the integrity of the whole study or the missing data were substantial. The responses made through online means were gathered by downloading the responses and extracting them carefully to be included in the paper-based results, in the matrix earlier prepared to maintain the integrity and accuracy of the data. The researcher gathered the data from the respondents within a 25-day period. Thereafter, the simplified data were exported to the IBM SPSS v.29 software for treatment, computations and analysis that aided the researcher in interpreting the results and made inferences.

Treatment of the Data

The following statistical tools were used in the analysis of data and interpretation of the results:

Frequency Count and Percentage is used in the descriptive measurement of data in the profile of the respondents such as education, eligibility, appointment; position, years in industry and seminar attended.

Pearson Product Moment of Correlation (Pearson r) was used in determining the significant relationship between interval or ratio data or variables such as the profile of HEIs (years of operation, number of employees, average number of students in the last five years, existing number of linkages with local/national institutions and existing number of linkages with foreign institutions) and the effectiveness of cybersecurity measures implemented and awareness of the employees on cybersecurity.

RESULTS AND DISCUSSION

It can be gleaned below the summary of findings of the research:

Most of the respondents came from private schools/universities and most of the schools existed for more than 20 years in ***terms of operations****. For the* **Current Number of Local Employees,** *most of the HEIs have 201-300 employees.* **On the Average Number of Students for the last five years,** *majority of the HEIs had 15,001-20,000 students in the last five years.* **For Capability for Online Transactions,** *majority of the HEIs are capable in online transactions.* **For Digitized Records System,** *majority of the HEIs are digitized in records system.* **In line with the Number of Existing Linkages with Local/National Institutions,** *all HEIs have local linkages* **same with the Number of Existing Linkages with Foreign Institutions,** *all HEIs have foreign linkages.*

The HEIs have all of the types of cybersecurity measures implemented when it comes to **Types of Cybersecurity Measures Implemented and** *all of the HEIs have a stiff cybersecurity measures.*

On the Effectiveness of Cybersecurity Measures Implemented, *it can be concluded that most of the respondents strongly agreed on the imposed cyber security of the HEIs while* **On the Effectiveness of Cybersecurity Measures Implemented (Anti-Virus and Anti-Malware Software) ,** *the HEIs the anti-virus and anti-malware software of the HEIs protect the institutions.*

On the Effectiveness of Cybersecurity Measures Implemented (Data Encryption) *the HEIs have a safe and sound standards of security with regards to data encryption.* **On the Effectiveness of Cybersecurity Measures Implemented (Access Controls**

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Indicators) , *the HEIs' portals and data can be accessed only by the authorized stakeholders of the HEIs.* **On the Effectiveness of Cybersecurity Measures Implemented(Security Structure Indicators),** *there is a need for thorough information dissemination to the employees of the HEIs in line with the cybersecurity structure of the HEIs.* **On the Effectiveness of Cybersecurity Measures Implemented (Network Monitoring Tool Indicators),** *there is a need for thorough information dissemination to the employees of the HEIs in line with the cybersecurity structure of the HEIs.*

On the Awareness of HEI Employees on Cybersecurity (Types of Cybersecurity or Domains Indicators), *the employees of the HEIs are aware of the cybersecurity measures of their respective institution.* **On the Awareness of HEI Employees on Cybersecurity (Common Cybersecurity Threats indicators Indicators),** *the employees of the HEIs are aware of the effects on the services and operations of the HEIs once a glitch in the system will take place.* **On the Awareness of HEI Employees on Cybersecurity (Myths or Misconceptions Indicators),** *the employees of the HEIs are aware of the effects on the services and operations of the HEIs once a glitch in the system will take place.*

On the Awareness of HEI Employees on Cybersecurity (Key Cybersecurity Technologies & Best Practices), *the employees of the HEIs are somewhat agreed on the awareness about the daily monitoring of the glitches in the HEIs.*

On the Awareness of HEI Employees on Cybersecurity Management Information System (MIS) Indicators, *the employees of HEIs are strongly agreed on the awareness regarding the existence and functions of the MIS.*

On the Awareness of HEI Employees on Cybersecurity Related Solutions indicators , *HEIs employees had somewhat agreed on the features of the cybersecurity of their company/institutions.*

On the Challenges Encountered in Cybersecurity Implementation, *the HEIs have ways and means to address the challenges of the cybersecurity implementation.*

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FORMULATION AND EVALUATION OF HERBAL HAIR SERUM

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ABSTRACT
Hair Serum was formulated by using Aloevera, fenugreek seed water, rice water, coconut oil, Almond oil, rose water. The cosmetics are very helpful and it is less sensitive to any side Effects. All ingredients are easily available in market this serum not only controls frizz, Enhance smoothness, reduces tangles, promotes shine, enhances straightness and protects Against damage. Healthy looking hair is a sign of good health, beauty and hair care practices Which moulds one's personality. Human hair follicle cycle consists of 4 main phases anagen,Catagen, telogen and exogen. Hair gets its pigment from Melanin stored in hair follicle cells. Follicle can lose their ability to produce melanin as age which result in growth of grey or white Hair damage follicle can also stop producing hair which can lead to certain condition such as Alopecia which can cause follicle to stop producing hair altogether.Coconut oil may have several benefits for our hair and scalp, it may help to moisturise and seal Hair. This can help to prevent dry, flaky scalp and dandruff. Almond oil moisturises your scalp And strengthens hair follicles. To know the different parameter regarding this prepared hair Serum I have performed some evaluation parameters i.e. physical appearance, homogeneity Test, pH test, viscosity, spread ability etc.Stability testing for prepared formulation was performed by storing it at different temperature Condition for time period of one week to know the parameter like colour, odour, pH and Smoothness of hair serum.

KEYWORDS: *Human hair , Hair strength , Hair nutrition , Alovera*

1.Introduction

Hair serum is a liquid treatment formula. A smooth layer of serum reflects the sunshine, Which is how serum gives your hair a shiny, not greasy, finish. It's a common Misconception that hair serum will be set naturally fine hair. Instead, it all depends on Which serum you utilize and in what quantity. Hair serum a squadron of fans Who claim that it has revolutionized the look of their hair, while some people aren't quite Sure where and the way it fits into their hair care routines. We take a better look at what Exactly hair serum is, how it works, whether it's right for you and, if so, a way to get the. Most out of it. Hair serum plays a significant role in the protection and nourishment of the Hair. Hair serums do have volatile oil extracts in them. That's why it helps to keep the hair Smooth and healthy. Not only does it nourish the hair but it also provides strength and Shine. Using the shampoo and conditioner isn't enough to ensure maximum protection. Hair Serum plays a significant role because it can keep the hair secure from environmental Pollution. This is the reason why applying hair serum is very important to guard the hair Completely and supply them with strength. Scroll below to understand the advantages of Hair serum. There are a variety of advantages to using hair serums. These not only provide An outstanding look to the but also make the hair healthy and glossy.

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Sr no	**Ingredients**
1	Alovera Gel
2	Rice Water
3	Rose Water
4	Vitamin E
5	Coconut Oil
6	Almond Oil
7	Carbopole 934
8	Methyl Parabean

2.MATERIALS (INGREDIENTS) USED LN FORMULATION

2.1 Alovera Gel

Fig. Alovera gel

Scientific Name – Aloebarbadensismilleer
Synonym – Aloe vera , aloe , burn plant, lily of oil
Family – Liliaceae
Biological source – Aloe is the dried juice collected by incision .
Chemical const – Emodin , Aloesin

2 .2 Rice Water

Fig. Rice Water

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Botanical Name – Oryza Sativa
Biological Source – Embryo and Endosperm
Family: Gramineae / Poaceae

2.3 Coconut Oil

Fig. Coconut Oil

Kingdom: Plantae
Order: Arecales
Family: Arecaceae
Genus: Cucos
Species: C. Nucifera
Synonims: Coconut oil, coconut butter, copra oil.

3. MATERIAL AND METHOD

3.1 Materials

All fresh herbs aloevera, fenugreek seeds, oils were collected from Maharashtra, India, and
Authenticated by gmcp, methyl paraben, Carbopol 934 and Carbopol 940 available was gmcp Laboratories.

Ingredients

- Aloevera gel
- Fenugreek seeds extract
- Rice water extract
- Rose water
- Oils
- Vitamin-E

Chemicals

- Methyl paraben
- Carbopol 934

Carbopol 934

934 polymer is a white powder, crosslinked polyacrylic acid polymer. It is an extremely
Efficient rheology modifier capable of providing high viscosity and forms sparkling clear gels
Or hydro-alcoholic gels and creams. Its short flow, non-drip properties are ideal for applications

Such as clear gels, hydroalcoholic gels, serum and creams

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Fig. Carbopol

Methyl Paraben

Methylparaben is an anti-fungal agent often used in a variety of cosmetics and personal-care Products. It is also used as a food preservative.

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3.2Formulation of Herbal Hair Serum

• Formula

Sr.No	Ingredients	Quantity Taken(60ml)
1.	Aloevera Gel	30gm
2.	Rice WATER	5ml
3.	Coconut OIL	3ml
4.	Almond OIL	4ml
5.	Rose WATER	5ml
6.	Vitamin-E	1ml
7.	Carbopole 934	5ml
8.	Methyl PARABEN	2ml

METHOD OF PREPARATION

- Cleaned all the glassware and dried them properly as per SOP.
- Measured the accurate quantity of Aloevera gel, rice water, fenugreek seeds water and mix Well transfer it in beaker.
- In another beaker take some amount of and water Carbopol 934 (1 % w/w) and purified Water were taken in a beaker and Stirred by mechanical stirrer at 400 to 650 rpm.
- Now mix accurate amount of almond oil and coconut oil in above carbopole mixture.
- Given quantity distilled water was taken and add required quantity of methyl paraben were Dissolved by heating on water bath, Cool the solution.
- Mixed the above both solution properly and stirred continuosly by mechanical stirrer at 400 to 650 rpm. As well as mixed required quantity of rose water and vitamin-E .
- After properly mixed solution and transferred solution in container and added Preservatives as methyl parabens .
- Then formed a Herbal Hair Serum

3.3 Here are 8 Common hair problems and the best ways to overcome them:

• Dandruff
• Hair loss
• Dry Hair
• Spit Ends
• Oily / Greasy Hair

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• Frizzy Hair
• Dull Hair
• Heat Damaged

3.4 Hair Serums For Different Hair Types

- For Dry Hair
- For Curly Hair
- For Coloured, Chemically Treated Hair
- For Split-End Hair

Excessively dry hair needs extra care and nutrition. The good news is that now there are Serums available that can be applied overnight and kept that can revitalize your hair while You get your beauty sleep. Make sure though that these serums are cream-based and not Oil-based so that that they don't weigh down your hair instead of moisturizing it.

Uses of Hair Serum

1. Adds shines
2. Helps Nourish Dry Hair
3. Softens Yours Strands
4. 4.Protects Against Humidity
5. 5.Helps with Damages.

Causes of Damage Hair

- Deficiencies
- Heat Damage
- Lack Of Deep Conditioning
- Nutritional Excessive Shampooing
- Swimming Without a Cap
- Sun Damage
- Excessive Using Hot Water

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4. STRUCTURE OF HAIR

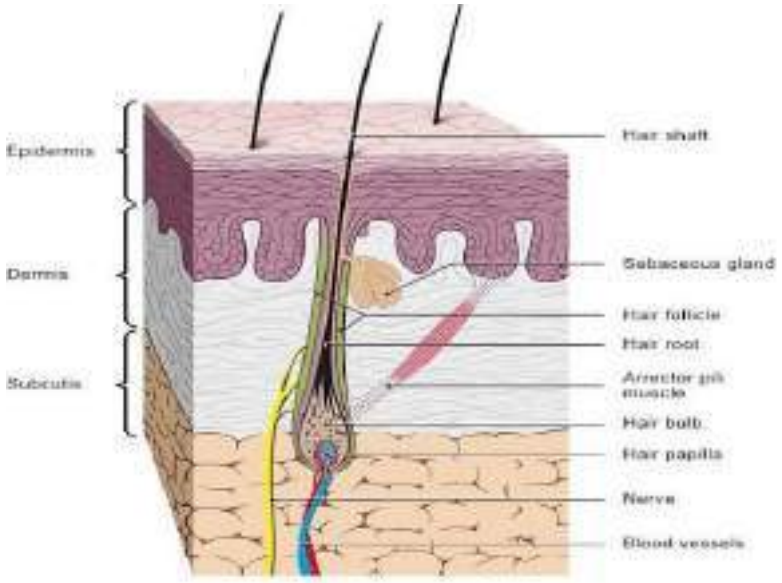

Fig. Hair Folicle

1. Each hair has a hair shaft and a hair root. The shaft is the visible part of hair that sticks Out of the skin. The hair roots are in the skin and extend down to the deeper layers of skin. It is surrounded by the hair follicle (a sheath of skin and connective tissue), which is also Connected to a sebaceous gland
2. Each hair follicle is attached to a tiny muscle (arrector pili) that can make the hair stand up. Many nerves sense hair movement and are sensitive to even the slightest draft.
3. At the base of the hair, the hair root widens to a round hair bulb. The hair papilla, which Supplies the hair root with blood, is found inside the bottom of the hair bulb. New hair cells Are constantly being in the hair bulb, close to the papilla.
4. New cells are constantly forming in the hair bulb. These cells stick together and harden. The full strand of hair develops from this group of hardened hair cells. Because new Hardened cells keep on attaching to the hair from below, it is gradually pushed up out of the Skin. In this way, a single hair on your head grows at a rate of about 1 cm per month.
5. The colour of the hair is determined by the amount of melanin in the hardened cells. This Can vary a lot from person to person, and it changes over the course of a lifetime. The Amount of melanin typically decreases as people get older, and more air gets trapped inside The hair – it then loses its colour and turns white. Depending on someone's original haircolour and the number of white hairs that grow, the hair on their head then turns gray or White

Nutrients Important For Hair Health

Betacarotene	Biotin	VitaminB1	Vitamin B2
VitaminB5 (pantothenic acid)	Vitamin B6	Vitamin B12	Vitamin D
Vitamin E	inositol	Folic acid	Calcium
Zinc	Iron	L-Methionine	L – Cysteine
L Lysine	L-Taurine	Selenium	Polyunsaturated fattyacids

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5.HAIR FOLLICLE CYCLE

Ingredients & Roles

1.Aloe Vera: Moisturizes and soothes the scalp, promotes hair growth, and provides hydration.
2.Rice Water: Strengthens hair, improves shine, and helps in hair growth due to the presence of inositol.
3.Coconut Oil: Nourishes hair, penetrates the hair shaft, and reduces protein loss, promoting softness.
4.Rose Water: Balances the scalp's pH, reduces inflammation, and adds a pleasant fragrance.
5.Vitamin E: Acts as an antioxidant, protects hair from environmental damage, and nourishes the scalp.
6.Carbopol 934: A gelling agent used to increase the viscosity and create a smooth gel texture.
7.Methyl Paraben: A preservative used to prevent microbial growth and increase shelf life.

Uses : The herbal hair syrup formulated with aloe vera, rice water, coconut oil, rose water, vitamin E, carbopol 934, and methyl paraben has several beneficial uses for hair and scalp health. Here are the key uses:

1.Hair Growth Stimulation

• Aloe vera and rice water are known for promoting hair growth by improving scalp circulation and providing essential nutrients to the hair follicles.

2.Deep Conditioning and Hydration

• Coconut oil and aloe vera moisturize and deeply condition the hair, leaving it soft and manageable. They also help to reduce hair dryness and prevent split ends.

3.Strengthening Hair

• Rice water is rich in amino acids, vitamins, and minerals that help strengthen the hair shaft, reducing breakage and improving overall hair strength.

4.Scalp Soothing and Nourishment

• Rose water and aloe vera help soothe the scalp, reducing irritation, inflammation, and itchiness. This is particularly helpful for those with sensitive scalps or conditions like dandruff.

5.Protection from Damage

• Vitamin E provides antioxidant protection, which shields the hair and scalp from damage caused by free radicals, environmental pollutants, and UV exposure.

6.Improving Hair Texture

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• The combined hydrating and conditioning properties of coconut oil and aloe vera enhance the smoothness of the hair, making it easier to detangle and style. This leads to softer, shinier, and more manageable hair.
7.Reducing Frizz
• Aloe vera and coconut oil help control frizz by sealing moisture into the hair strands and smoothing the cuticle layer, preventing flyaways.
8.Scalp pH Balance
• Rose water helps maintain the scalp's natural pH balance, which is important for preventing excessive oiliness or dryness and for keeping the scalp healthy.
9.Preservation and Long-Lasting Effect
• The inclusion of methyl paraben ensures that the syrup remains safe and effective for a longer period without the risk of microbial contamination.
10.Pre-Wash Treatment
11.It can be used as a pre-wash treatment to provide deep nourishment. Apply to the scalp and hair, leave it on for 20-30 minutes, and then wash it off. This helps in repairing and protecting hair before shampooing.
• This formulation serves as a multipurpose product that can be used as a hair mask, conditioner, or leave-in treatment, depending on the user's needs.

6. APPLICATION OF HERBAL SYRUM

The application of a herbal hair serum is simple and can greatly benefit hair and scalp health. Here's how to use it effectively:
1. For Dry or Frizzy Hair (Leave-In Serum)
Step 1: Take a small amount of serum (1-2 pumps or a few drops) on your palms.
Step 2: Rub your hands together and apply it evenly to your hair, focusing on the mid-lengths and ends where frizz and dryness are more common.
Step 3: Gently comb through your hair with your fingers or a wide-tooth comb to distribute the serum evenly.
Step 4: Style as desired. You can apply the serum to either damp or dry hair.
Benefits: It smooths frizz, adds shine, and moisturizes dry ends without making the hair greasy.
2. As a Scalp Treatment
Step 1: Take a few drops of the serum and apply it directly to your scalp using your fingertips.
Step 2: Gently massage the serum into your scalp using circular motions for 2-3 minutes. This improves blood circulation and helps absorb the nutrients from the serum.
Step 3: Leave it on overnight or for at least 30 minutes before washing it out with a mild shampoo.
Benefits: This nourishes the scalp, prevents dandruff, and promotes healthy hair growth.
3. Pre-Wash Treatment
Step 1: Apply the serum generously to your hair and scalp, covering it from roots to ends.
Step 2: Leave it on for 30 minutes to an hour before washing it off with shampoo.
Step 3: Rinse thoroughly with water.
Benefits: Works as a deep conditioning treatment, repairing dry and damaged hair, and protecting it from harsh shampoos.
4. Heat Protection Before Styling
Step 1: Before blow-drying or using heat tools (like flat irons or curling wands), apply a small amount of the serum to damp hair.
Step 2: Distribute the serum evenly through the hair, focusing on the ends.
Step 3: Style as usual with heat tools.
Benefits: It forms a protective barrier against heat damage while keeping the hair smooth and shiny.
5. Post-Styling Shine
Step 1: After styling, apply a small amount of serum to your hands.
Step 2: Lightly smooth the serum over the surface of your hair, focusing on flyaways or frizzy areas.
Benefits: Adds shine and smoothness to styled hair without weighing it down.
General Tips:
Use sparingly: Herbal serums are often concentrated, so start with a small amount and add more if needed.
Avoid the roots for daily use: When applying as a leave-in serum, avoid using it too close to the scalp to prevent greasiness unless treating specific scalp concerns.
Suitable for all hair types: Adapt the quantity used based on your hair type—use less for fine hair and more for thick or curly hair.
The serum can be used daily or as needed based on your hair's condition and styling requirements.

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7. MECHANISMS OF ACTION

The mechanisms of action of a herbal hair serum are based on the bioactive properties of its ingredients. Here's how the components typically work to enhance hair health:

• Aloe Vera

Moisturization and Scalp Healing: Aloe vera contains proteolytic enzymes that repair dead skin cells on the scalp. It deeply hydrates the hair shaft and scalp, improving elasticity and reducing dryness. Its anti-inflammatory and antifungal properties help soothe and heal the scalp, reducing dandruff and irritation.

Hair Growth Stimulation: Aloe vera contains vitamins A, C, and E, which support cell turnover, promoting healthier, stronger hair growth.

• Rice Water

• Strengthening Hair: Rice water is rich in inositol, a carbohydrate that helps repair and protect damaged hair by coating the hair shaft. Inositol penetrates the hair, making it stronger and more resilient to damage.

Improved Hair Elasticity: The amino acids in rice water improve hair elasticity and reduce breakage, leading to longer, healthier hair.

Scalp Health: Rice water has anti-inflammatory properties, which help in soothing the scalp and reducing irritation.

• Coconut Oil

Penetration and Nourishment: Coconut oil has a unique ability to penetrate the hair shaft deeply due to its low molecular weight and straight chain structure, nourishing the hair from within. It prevents protein loss, which is crucial for maintaining the strength of the hair.

Moisture Retention: It creates a protective layer over the hair, sealing in moisture and preventing water loss. This reduces frizz and improves hair texture.

Antimicrobial Action: Coconut oil has antifungal and antibacterial properties that help protect the scalp from infections, reducing dandruff and scalp issues.

• Rose Water

pH Balancing: Rose water helps balance the scalp's pH, which is crucial for maintaining a healthy scalp environment. A balanced pH reduces excessive oil production or dryness, both of which can lead to hair problems.

Anti-inflammatory Properties: Rose water's anti-inflammatory action soothes irritated or inflamed scalps, helping with conditions like dandruff and itchiness.

Hair Strengthening: The natural flavonoids and antioxidants in rose water help strengthen hair follicles, reducing hair fall.

• Vitamin E

Antioxidant Protection: Vitamin E is a powerful antioxidant that protects hair cells from oxidative stress caused by UV rays, pollution, and free radicals. This reduces damage to the hair shaft and scalp.

Improved Circulation: Vitamin E helps improve blood circulation to the scalp, which enhances nutrient and oxygen delivery to hair follicles, promoting healthy hair growth.

Moisturizing: It acts as a natural conditioner, preventing moisture loss and leaving the hair softer and shinier.

• Carbopol 934 (Gelling Agent)

Consistency and Stability: Carbopol helps maintain the serum's gel-like consistency, making it easy to apply and ensuring even distribution of the active ingredients. It doesn't interact with the herbal components, allowing them to retain their efficacy.

Controlled Release: As a thickener, it may help in slow release of the active ingredients, allowing for prolonged contact with the hair and scalp.

• Methyl Paraben (Preservative)

Antimicrobial Action: Methyl paraben prevents the growth of bacteria, yeast, and molds in the serum, ensuring the product remains safe and effective over time. While it doesn't directly affect the hair, it ensures the serum remains uncontaminated, preventing scalp infections from microbial growth.

Combined Mechanisms of Action:

Hydration and Moisture Retention: Aloe vera, coconut oil, and vitamin E deeply hydrate the scalp and hair while locking in moisture, preventing dryness, frizz, and split ends.

Strengthening and Repair: Rice water, aloe vera, and vitamin E work together to strengthen hair strands by promoting protein retention, repairing damage, and improving elasticity, which helps reduce breakage.

Scalp Health: The anti-inflammatory and antimicrobial properties of aloe vera

Almond oil is widely used in hair care due to its rich content of vitamins, fatty acids, and antioxidants. Here's a detailed explanation of the mechanisms of action of almond oil for hair health

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• Deep Moisturization

Rich in Oleic Acid (Omega-9 Fatty Acid): Almond oil contains a high concentration of oleic acid, which is an emollient that penetrates deeply into the hair shaft, providing intense moisturization. It helps seal the cuticle, preventing moisture loss and keeping hair hydrated, soft, and shiny.

Sealing Effect: As a carrier oil, almond oil creates a protective layer on the hair surface, locking in moisture and preventing dehydration, which is especially beneficial for dry, frizzy, or damaged hair.

• Nourishing and Strengthening

Vitamin E: Almond oil is rich in vitamin E, a potent antioxidant that protects hair cells from oxidative stress caused by free radicals, UV rays, and environmental pollutants. This protection helps reduce damage and maintains the strength and elasticity of the hair.

Biotin (Vitamin B7): Almond oil contains small amounts of biotin, which helps strengthen the keratin structure in the hair, reducing breakage and split ends, and promoting thicker, healthier hair growth.

• Promoting Hair Growth

Magnesium and Zinc Content: Almond oil contains essential minerals like magnesium and zinc, which play a key role in supporting hair growth. Magnesium helps regulate blood circulation to the scalp, promoting better nutrient delivery to the hair follicles. Zinc deficiency is often linked to hair thinning and loss, and the presence of zinc in almond oil helps maintain healthy hair follicles.

Scalp Nourishment: Regular scalp massage with almond oil stimulates blood flow, enhancing the delivery of oxygen and nutrients to hair follicles, which can lead to increased hair growth.

• Repairing and Preventing Hair Damage

Linoleic Acid (Omega-6 Fatty Acid): Almond oil contains linoleic acid, which is important for maintaining the integrity of the hair's lipid barrier. This helps repair damaged cuticles and improves the overall structure of the hair, making it smoother and less prone to breakage.

Protein Preservation: Almond oil helps prevent protein loss from the hair shaft, particularly when the hair is exposed to damaging factors such as heat styling, sun exposure, or harsh chemicals. By preserving the protein content of the hair, almond oil maintains hair strength and elasticity.

• Reducing Scalp Inflammation and Irritation

Anti-Inflammatory Action: Almond oil has mild anti-inflammatory properties, which help soothe irritated, itchy, or inflamed scalps. This is particularly beneficial for people suffering from scalp conditions like seborrheic dermatitis, psoriasis, or dandruff.

Fatty Acids: The oleic and linoleic acids in almond oil help moisturize and nourish the scalp, preventing dryness, flakiness, and the formation of dandruff.

• Detangling and Frizz Control

Smoothing the Hair Cuticle: The emollient properties of almond oil smooth the hair cuticle, reducing tangling and preventing knots. This makes it easier to comb and style the hair, while also controlling frizz and flyaways.

Softening Effect: Almond oil coats the hair and reduces roughness, making it softer, shinier, and more manageable. It helps reduce the static that often causes frizzy hair, especially in humid environments.

• UV Protection

Natural Sun Protection: Almond oil contains small amounts of squalene and fatty acids, which offer a natural barrier against UV damage. Although it doesn't replace sunscreen, almond oil helps shield the hair and scalp from sun-induced damage, which can cause dryness, color fading, and loss of elasticity.

• Split End Prevention

Cuticle Sealing: By smoothing and sealing the hair cuticle, almond oil prevents the hair from splitting at the ends. It forms a protective layer around each strand, reducing the likelihood of breakage or split ends caused by environmental factors or styling damage.

Combined Benefits:

Almond oil works by nourishing the hair and scalp with essential vitamins, fatty acids, and antioxidants.

It strengthens hair, improves elasticity, and prevents damage by protecting against environmental stressors, moisture loss, and breakage.

The moisturizing and emollient properties of almond oil result in smoother, softer hair with reduced frizz and tangles, while promoting overall scalp health.

In summary, almond oil acts as a moisturizer, strengthener, repair agent, and scalp nourisher, making it an effective remedy for dry, damaged, or frizzy hair.

8. MARKETED PREPARATION OF HERBAL SYRUM

There are several marketed preparations of herbal hair syrups that combine natural ingredients to nourish the scalp and promote hair health. These formulations typically include herbal extracts, oils, and vitamins to address common hair problems such as hair fall, dandruff, dryness, and lack of shine. Below are a few examples of well-known herbal hair syrup products that are widely available in the market:

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• **Sesa Ayurvedic Hair Vitalizer**
Key Ingredients: Bhringraj, Amla, Brahmi, Hibiscus, Neem, and Milk Proteins.
Benefits: Strengthens hair roots, promotes hair growth, reduces dandruff, and prevents premature greying.
Application: Spray or apply directly to the scalp and gently massage for absorption.
• **Khadi Natural Herbal Hair Growth Serum**
Key Ingredients: Aloe Vera, Basil, Green Tea, Rosemary, and Ginseng.
Benefits: Stimulates hair growth, controls dandruff, and improves hair thickness and texture.
Application: Applied directly to the scalp, usually as a leave-in treatment after washing.
• **Livon Hair Gain Tonic**
Key Ingredients: Aloe Vera, Ginseng, and Biotin.
Benefits: Reduces hair fall, stimulates hair growth, and strengthens hair follicles.
Application: Applied to the scalp and massaged daily to prevent hair fall and improve density.
• **Indulekha Bringha Hair Oil**
Key Ingredients: Bringharaj, Aloe Vera, Coconut Oil, Amla, and Rosemary.
Benefits: Promotes new hair growth, strengthens the roots, prevents hair thinning and hair fall.
Application: Applied directly to the scalp through a special comb applicator and massaged in for better penetration.
• **Trichup Herbal Hair Serum**
Key Ingredients: Aloe Vera, Vitamin E, Amla, and Bhringraj.
Benefits: Smoothens hair, controls frizz, adds shine, and reduces hair fall.
Application: Applied to damp hair, focusing on the lengths and ends, to control frizz and add shine.
• **Biotique Bio Mountain Ebony Vitalizing Hair Serum**
Key Ingredients: Mountain Ebony, Neem, Bhringraj, Amla, and Peppermint Oil.
Benefits: Promotes hair growth, reduces dandruff, prevents hair thinning, and stimulates scalp circulation.
Application: Applied to the scalp and massaged gently. No need to rinse out.
• **Himalaya Herbals Anti-Hair Fall Hair Oil**
Key Ingredients: Bhringraj, Amla, Fenugreek, and Aloe Vera.
Benefits: Strengthens hair roots, promotes hair growth, and reduces hair fall.
Application: Massaged into the scalp before or after washing hair.
• **Kesh King Ayurvedic Hair Oil**
Key Ingredients: Bhringraj, Amla, Brahmi, and Aloe Vera.
Benefits: Reduces hair fall, stimulates hair growth, and prevents dandruff.
Application: Applied to the scalp and left overnight or for a few hours before washing.
Common Features in Marketed Herbal Hair Syrups:
Natural Ingredients: Most products are formulated with herbal extracts like Bhringraj, Aloe Vera, Amla, Neem, and other well-known Ayurvedic or herbal components that are beneficial for hair health.
Moisturization and Conditioning: Many products include ingredients like coconut oil, aloe vera, and vitamin E for hydration and softness.
Hair Fall and Growth Support: Products focus on reducing hair fall and stimulating new hair growth by strengthening hair roots and nourishing hair follicles.
Easy Application: Most are designed as leave-in treatments or oils to be massaged into the scalp for better absorption and results.
These preparations are designed for individuals looking for natural or herbal alternatives to commercial hair care products that often contain synthetic chemicals.

9.DIFFERENCE BETWEEN NATURAL AND SYNTHETIC

The primary difference between natural hair serums and synthetic hair serums lies in their ingredients, mechanisms of action, and long-term effects on hair health. Here's a detailed comparison:
• **Ingredients**
Natural Hair Serums:
Composed of natural ingredients such as plant extracts, essential oils, and herbal components like aloe vera, coconut oil, argan oil, and vitamin E.
Free from artificial chemicals, preservatives, and synthetic fragrances. They may include naturally derived preservatives like vitamin E or rosemary extract.
Examples of key ingredients: jojoba oil, almond oil, bhringraj, amla, green tea extract, rose water.
Synthetic Hair Serums:

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Formulated with silicones, synthetic polymers, and various chemicals that help coat the hair to make it appear smooth and shiny.
Often contain artificial preservatives like parabens, sulfates, and fragrance for a longer shelf life and scent enhancement.
Examples of synthetic ingredients: dimethicone, cyclopentasiloxane, polyquaternium, mineral oils.

10.MECHANISM OF ACTION

10.1 Natural Hair Serums:

Work by nourishing and moisturizing the hair from within. They penetrate the hair shaft and scalp to provide essential vitamins, fatty acids, and antioxidants.
Encourage long-term hair health by strengthening hair strands, improving scalp circulation, and repairing damaged cuticles.
They typically focus on enhancing hair texture naturally, promoting growth, and improving overall hair health without relying on artificial coatings.

10.2 Synthetic Hair Serums:

Function primarily by coating the hair shaft with a thin layer of silicone or other synthetic compounds, which creates a temporary smoothness and shine.
They mask hair damage by smoothing the cuticle layer and reducing frizz but don't provide deep nourishment. Instead, they offer instant cosmetic improvements.
Their effect wears off after washing, and they may lead to product buildup over time, potentially causing hair to feel greasy or weighed down.

10.3 Benefits

Natural Hair Serums:
Promote long-term hair health by delivering nutrients, antioxidants, and natural oils that strengthen hair and protect it from damage.
Free from harsh chemicals, making them suitable for individuals with sensitive scalps or those prone to allergic reactions.
Support hair growth, reduce breakage, and improve scalp health over time.
Less likely to cause product buildup or clog hair follicles.

Synthetic Hair Serums:
Provide instant results like smoothness, shine, and frizz control due to the silicone coating.
Effective for creating a polished look and protecting the hair from heat styling damage in the short term.
Often designed for specific hair types, such as smoothing serums for straight hair or curl-defining serums for curly hair.

• Long-Term Effects

Natural Hair Serums: • Improve the health of both the hair and scalp over time by delivering real nourishment.
• Can stimulate healthy hair growth, repair damaged hair, and enhance the overall strength and resilience of hair.
• Gentle on the scalp, unlikely to cause irritation, and safe for prolonged use without adverse effects like buildup.

Synthetic Hair Serums:
•Prolonged use can lead to product buildup, as silicones and polymers may not fully wash out of the hair with regular shampoos. This can make hair feel heavy, dull, and greasy over time.
Can block moisture from entering the hair shaft, potentially leading.

11. EVALUATION OF HERBAL HAIR SERUM

11.1 Physical Evaluation:

• **Color:** Pale green color.
• **Odor:** Pleasant.
• **Texture:**Smooth.
• **State:**Semi-solid.

Irritancy: Mark the area (1cm) on left hand dorsal surface. Applied on that area
And time was noted. Then checked irritancy.
Wash Ability:A small amount of serum was applied on hand and wash withTapped water.
pH Test : The pH meter was calibrated using pH 4 and pH 7 buffer solutions. Then, the electrode was soaked in the hair serum and left until the pH normalized after a few minutes.
Viscosity: viscosity of serum was measured by Brooke field viscometer at a Temperature of 25˚C
Homogeneity Test:A clean and dry object glass was smeared with the hair Serum, and a cover glass was sealed. The appearance under the light of some coarse Particle/homogeneity was investigated. Herbal hair serum was tested by visual Examination for homogeneity and tested for some lumps, flocculates, or aggregates.

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Spread ability: Spread ability was measured by a parallel plate process typically Used to assess and measure the spread ability of semi-solid preparations. One gram Hair serum was pressed between two horizontal plates of dimension 20× 20 cm, the Upper of which weighed 125 g. The spread diameter was measured after 1 min.

Spread ability was calculated using the following formula:

$$S = M \times L / T$$

Where:
S= Spread ability,
M= Weight in the pan (tied to the upper slide),
L= Length moved by the glass slide, and
T = Time (in sec) taken to separate the slides completely.

Stability
The herbal hair serum was kept for three months at two separate temperatures of 4 ± 2 °C and 30 ± 2 °C, with 65 RH. Compared with the original pH and density, the pH And density of the herbal hair serum were determined after three months

11.2 PHYSIOCHEMICAL EVALUATION OF FORMULATION

Sr.no.	PhysiochemicalParameters	Observations
1.	Colour	Pale green colour
2.	Odour	Pleasent
3.	Consistency	Smooth
4.	State	Semi-solid
5.	PH	6.7
6.	Spreadibility	6g.cm/s(good and uniform)
7.	Solubililty	Soluble in many(polar) oils; Also soluble in alcohol
8.	Washibility	Good
9.	No-irritancy	Non-irritant

12. RESULT AND DISCUSSION

Hair serum was prepared and evaluated by above mentioned methods

12.1 **Physical Appearance :-**It was observed that the colour of all the herbal hair serum was pale green with a translucent look, which on the operation was founded to be smooth

12.2 **Homogeneity :-**By visual examination of the looks and presence of any lumps, flocculates, or summations, the produced herbal hair serum was checked for unity. The unity of set serum has been shown to be fine.

12.3 **pH Determination:-**The pH of the entire herbal hair serum was 6.8, which was sufficient for **Stability Studies:-**The herbal hair serum was stable during the exploration time, as these the hair, suggesting that the herbal hair serum was suitable for the hair. serums showed no physical insecurity, and there was no conspicuous difference within the pH ahead and after the study

12.4 **Skin irritation test :-**after we apply on skin no any variety of redness occur .

12.5 **Sensitivity test :-** apply on skin and observed after 10 min no any rashes or itching Occurred.

Conclusion
This research provides guideline on the employment of herbal ingredients on the preparation of Herbal toilet article having minimal or no side effects. All the parameters showed that they'ret Within the boundaries and since all the ingredients added have many advantages, this oil will help In maintaining good growth of hair, turning grey hair to black, protects from dandruff and leads to Lustrous looking hair.

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A CLINICAL STUDY OF KELOID THROUGH AGNIKARMA

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ABSTRACT

Keloids are abnormal scars that cause significant emotional and physical distress in patients. Keloid formation is theorized to occur as a result of an imbalance between an increased synthesis of collagen and extracellular matrix and decreased degradation of these products. Inflammatory mediators— namely, transforming growth factor beta have been proposed to influence the dysregulation of collagen remodeling in the scar healing process. Though limited, current knowledge of keloid pathophysiology has guided clinicians to explore novel therapies for keloid prevention and treatment. In addition to conducting research refining the use of common therapies, such as steroids and radiation, clinicians have evaluated the potential of anti-inflammatory and chemotherapeutic molecules to suppress keloid recurrence. Management includes agnikarma procedure which is one of the oldest healing system in alternative medicine dating back thousands of years to ancient India. Among its numerous therapeutic methods, Agnikarma stands out as a distinct and effective technique. Agnikarma is derived from the Sanskrit words "agni" meaning fire and "karma" meaning action. As per Acharya Sushrut basically anginkarm is used in two manner i.e. one for रोग उन्मूलन (diseases cure) and other for pain management.

A 28years old male presented with keloid scar on shoulder and complaints with itching. Ayurvedic examination and diagnostic procedures led to the decision to administer Agnikarm therapy through Louha Shalaka. This therapy demonstrated significant improvement in symptoms and healing procedures over three sessions conducted at 15-day intervals. It works by stimulating the body's natural healing mechanisms and promoting the circulation of vital energy.

KEY WORDS : *Agnikarma, Keloid, management, healing*

INTRODUCTION

Keloids, also called keloid scars, are a type of scar tissue that usually grows at the site of an injury. They can also result from infection, inflammation, surgery, blisters, acne, and body piercings. It is not clear why keloids form, but they are harmless — they do not turn into cancer. They eventually stop growing and do not change after that point.

Most types of skin injury can contribute to keloid scarring, including:

- Acne Scars
- Burns
- Chickenpox Scars
- Ear Piercing
- Scratches
- Surgical Incision Sites
- Vaccination Sites

Keloids can occur anywhere — but, they are less common on the eyelids, genitals, soles of the feet, or palms of the hands.
They frequently develop on the following parts of the body.

- Ears
- Neck
- Shoulders
- Chest
- Back

Keloids can continue to grow for months or even years. They eventually stop growing but they do not disappear without treatment.

CASE REPORT

A 28years old male named Biswa Ranjan residing at Satapada, Dist – Puri , Odisha presented at the Out patient Department of Shalya Tantra at Gopabandhu Ayurveda Mahavidyalaya, Puri with complaints of mild itching and swelling on his left shoulder persisting for 6 months. He has no history of any injury.

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The patient underwent a thorough assessment incorporating both Ayurvedic and modern diagnostic principles to as certain the underlying pathology. Essential investigations were performed to corroborate the clinical findings and guide the treatment approach. Based on the diagnosis, it was decided to initiate therapeutic intervention employing Agnikarma therapy through the method by using Louha shalaka.

Agnikarma is a superior para surgical procedure & the procedure aims at management of various afflictions by inflicting burns on the tissue surface directly by using different materials known as Dahanopakrama.

Agnikarma, a form of cauterization therapy, applied by the part preparation & by local anesthesia. This patient is followed by 3 sessions, after the Agnikarma thepary. After this therapy using of Satadhouta Ghrita for healing the wound.

Agnikarma is a procedure in which there is the application of heat in the affected part. The therapeutic use of agni is described as Agnikarma in Sushrut Sahmita Sutra Sthana Chapter 12. There is no chance of recurrence of disease which is treated with agnikarma.

It is also included in Anushastra. Anusashtra means Parasurgical Procedure.

Agnikarma can be co- related to Thermal Cauterization.

MATERIAL AND METHODOLOGY

Spirit, Cotton, Xylocaine Injection ,Panchadhauta Shalaka,Gas stove, Aloe vera, Satadhouta Ghrita, Gauze Piece

METHODS OF PURVA KARMA

Before Agnikarma informed written consent were taken.
CBC, BT, CT, HbsAg, HIV, Blood sugaretc routine blood investigation done before procedure. On right lateral position the shoulder of the left hand was fixed & sterilization was done by spirit cotton. Next was application of local anesthesia.

PRADHANA KARMA

After the part preparation was done, the red hot panchadhauta shalaka was applied on the affected area. Firstly, agnikarma on keloid was by Bindu with the tip of Shalaka. Every Shalaka was applied within the area of keloid for 10-15 seconds. During entire procedure, a kumari swaras was applied after application of red hot Shalaka to get relief from Daha (burning sensation).

PASCHAT KARMA

After completion of procedure, Dagdha vrana was covered with Satadhauta Ghrita. The patient was advised to apply this Ghrita daily after the dressing. The entire procedure was followed up 3 times at the interval of 15 days.

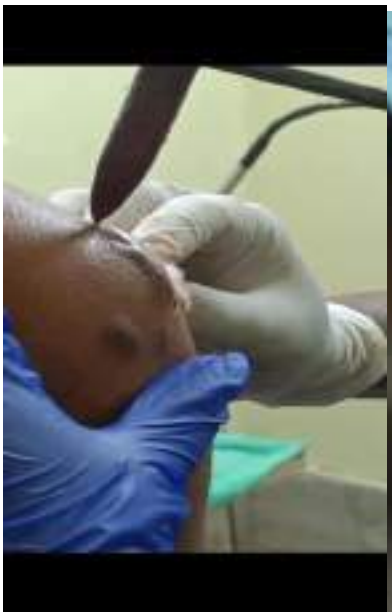

Figure 1 Day 1

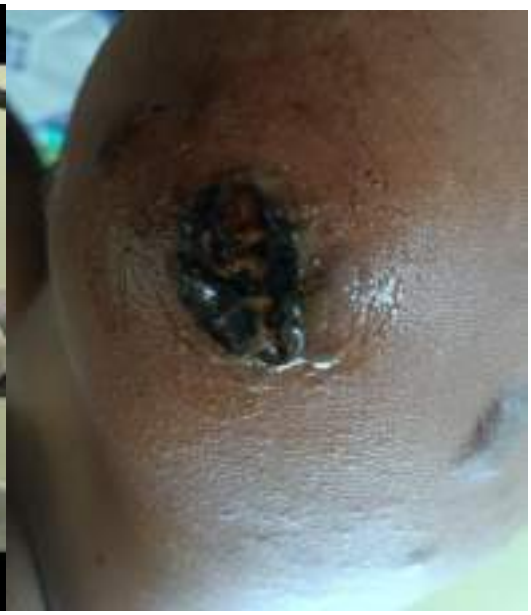

Figure 2 Day 1

Figure 1- Before Treatment

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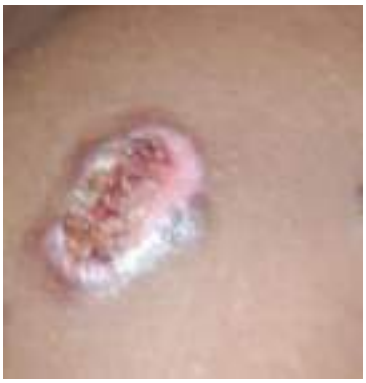
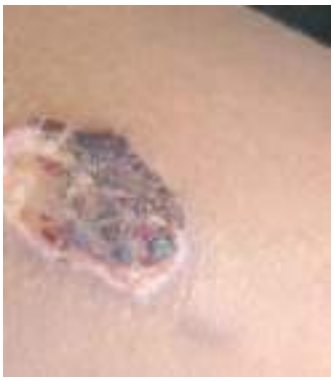
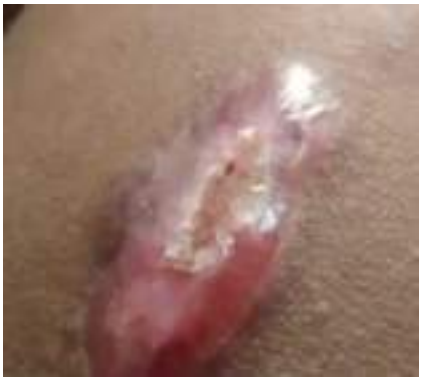
Figure 2- After Treatment


Day 15


Day 30


Day 45

OBSERVATIONS

Session 1: Initial improvement was seen in terms of reduced itching and mild flattening of the keloid. The patient reported less pain.

Session 3: Significant reduction in the size and thickness of the keloid. The keloid was softening, and the itching had completely subsidedThe keloid had flattened substantially, with no pain or itching. The cosmetic appearance had improved, and the patient reported satisfaction with the outcome.

Follow-Up
At a follow-up 1 months after the last Agnikarma session, the keloid showed no signs of recurrence. The skin over the treated area was flat with minimal scarring. The patient remained symptom-free, with no discomfort or itching.

DISCUSSION

Agnikarma is described in Ayurveda as a therapeutic procedure that not only resolves abnormal tissue growth but also prevents recurrence. The heat applied through Agnikarma helps in breaking down excess collagen, reduces local inflammation, and promotes the formation of healthy tissue. Moreover, Ayurvedic texts mention that conditions treated by Agnikarma have a lower chance of recurrence compared to other treatment modalities.

In this case, Agnikarma proved effective in managing keloid with no recurrence in a 1month follow-up period. The patient tolerated the procedure well, with minimal discomfort and a positive outcome in both functional and cosmetic terms.

CONCLUSION

Agnikarma is an effective and safe modality for the management of keloids. It offers a promising alternative to conventional treatments, particularly for patients who have not responded to other interventions or have experienced recurrences. Further research with larger sample sizes and longer follow-up periods is recommended to establish the long-term efficacy of Agnikarma in keloid management.

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ATTITUDE OF HIGHER SECONDARY STUDENTS TOWARDS PRIVATE TUITION

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ABSTRACT
The aims of education encompass holistic child development, fostering confidence and enthusiasm through timely advice, motivation, and support from parents, guardians, teachers, and members of society. In today's competitive era, younger generations are striving for success in various fields, particularly in education. Private tutoring has become a globally pervasive phenomenon. This study aims to measure students' attitudes toward private tuition. The objectives of the study are to determine whether there are any gender differences in higher secondary students' attitudes toward private tuition and to examine variations in attitudes based on locality. Additionally, the study seeks to explore the relationship between attitudes toward private tuition and academic achievement, considering both gender and locality. A total of 198 higher secondary students participated in the study, serving as the sample. A descriptive survey method, following a quantitative approach, was employed. The sample was selected using the purposive sampling technique. A self-developed questionnaire was used to measure the attitudes of higher secondary students toward private tuition. The results were analyzed using Means, Standard Deviation, t-tests, and correlation. The outcomes of the study demonstrate that higher secondary students generally hold positive attitudes toward private tuition, with significant differences observed in relation to class, gender, and locality. It can be inferred from the research that the primary reasons for the growing prevalence of private tuition are the lack of proper study environments and the inadequacy of school teachers.
KEYWORD: *Attitude, Private Tuition, Higher Secondary Students.*

INTRODUCTION
The overall development of the student is the primary aim and objective of education. Present-day education is versatile and dynamic. If we review the concept of education in ancient times, it is evident that education has evolved and now emphasizes child-centered learning. A psychological review of the learning process shows that every student has a unique personality, and accordingly, their learning abilities differ. Not all students have the same learning style, and since each student acquires knowledge differently, it is often challenging to cater to individual needs within an institutional education setting. As a result, students frequently rely on private tuition to meet their specific learning needs. In other parts of the world, this is referred to as shadow education. The impact of private tuition or shadow education can be observed in various countries. According to the ASER-2021 report, the number of students taking private tuition in India, including states like West Bengal, is increasing day by day. Private tuition has become a global trend, operating alongside formal school education. It keeps children engaged, provides flexible time for doubt-solving, improves academic performance, and prepares students for exams and professional courses. Private tuition benefits students by helping them achieve high exam scores and addressing educational gaps, particularly for first-generation learners. The rising demand for private tuition complements both public and private schooling systems, driven by factors such as the prestige of certain schools, ineffective teaching methods, large class sizes, strikes, and a lack of individual attention. However, private tutoring does not always guarantee improved academic achievement. The National Curriculum Framework of 2005 adopted a constructivist perspective on education, aiming to develop learners who actively construct their own knowledge. The growing concern about fee-based private education, or private tutoring, warrants further investigation. This study explores the phenomenon, causes, effectiveness, and challenges of private tutoring, particularly for children or adolescents, as funded by households or parents.

REVIEW OF RELATED LITERATURE
Adhikari (2022) conducted a study on the Perception of Teachers and Students towards Shadow Education. This study aimed to investigate teachers' and students' perceptions of shadow education practices and trends using narrative inquiry as a qualitative approach. The study found that students and teachers prefer private tutoring over formal classes, as it is more interactive and student-centric. The study highlights the importance of involving learners, teachers, and authorities in shadow education for effective formal schooling.

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Mondal and Barman (2020) investigated a study on the Attitude of Secondary School Teachers and Students toward Private Tuition in the District of Hooghly. The study aimed to compare students with and without private tuition attitudes towards it. Using a descriptive survey method and purposive sampling, it was found that private tuition is an attractive medium for students, enhancing self-confidence and achieving good results.

Omoke, Nyakundi & Getange (2020) studied the Influence of Private Tuition on Students' Academic Performance in Public Secondary Schools in Gucha South Sub County, Kisii County, Kenya. The study investigates the cost implications of private tuition on public secondary school performance in Gucha South sub-county, Kisii County. It reveals that parents still provide extra school lessons, despite government policy, and that parents of higher socioeconomic status prefer private classes due to time constraints and fear of certain subjects.

Kotaky (2018) researched Private Tuition at The Secondary Level in Assam: An Analytical Study of the Attitude and Achievement of the Students. The study aimed to assess Secondary school students' attitudes towards private tuition using a descriptive survey method and Quota sampling technique. The study shows private tuition is popular among secondary school students in Assam, mainly in General Mathematics, English, and Science. Reasons include academic pressure, personal, family, and peer pressure. Mixed opinions exist among Headmasters, Principals, schoolteachers, and parents.

Singh and Bai (2018) researched A Study on secondary-level students' Attitudes Towards Private Tuition in West Tripura District. The study's objectives were to examine the nature of private tuition at the secondary level. The descriptive method was used in this study. The study reveals that private tuition is a significant secondary education issue affecting quality. 85% of tutors are school teachers, with urban students receiving less private tuition than rural ones. Girls receive equal resources, with a 1.6% difference. Nearly 90% of students seek private tuition in one or two subjects.

Sripriya & Ramesh (2017) conducted a study on the Attitude Towards Private Tuition Among Selected 10th Standard and 12th Standard Students. The objectives of the study were to find out the attitude of selected 10th-standard and 12th-standard students toward private tuition. The study uses stratified random sampling to analyze student attitudes toward private tuition. Results show female, Class 12 and government students have more favorable attitudes, with no influence from school location, tuition center area, or tuition time.

Sharma & Kalia (2015) researched on the study of the attitude of students towards private tuition at the senior secondary level. The study aimed to identify significant differences in attitudes towards private tuition among boys and girls, as well as between sciences and art students at the senior secondary level. This study used a descriptive survey method and random sampling for data collection, finding that students often prioritize tuition over classroom teaching, suggesting efficient classroom teaching to avoid external assistance.

Suleman & Hussain (2014) performed a study on the Effects of Private Tuition on the Academic Achievement of Secondary School Students in the Subject of Mathematics in Kohat Division in Pakistan. The study investigated the impact of private tuition on the academic achievement of 50 secondary school Mathematics students using experimental methods and statistical tools. The study found that private tuition significantly enhances secondary school students' mathematics academic achievement, recommending parents to arrange such tuition for their children.

Sujatha (2014) studied Private tuition in India: trends and issues. The study's objectives are to examine the nature, extent, and trends of private tutoring in secondary education in India and discuss reasons and some policy issues. The study surveyed 4,031 Grade IX–X students from 49 schools in Kerala, Maharashtra, Andhra Pradesh, and Uttar Pradesh, India, on private tuition. Students seek tuition for academic, personal, and social reasons. Private unaided schools had the highest percentage of students seeking tuition, with 65.72% attending. Gender disparity in private tuition was found, with boys attending more than girls, with only 39.58% of girls and 54.86% of boys.

Alotaibi (2014) conducted a study on the Causes of Private Tutoring in English: Perspectives of Saudi Secondary School Students and Their Parents. The study aimed to explore the opinions of secondary school students and their parents regarding the reasons behind private English tutoring, through interviews with two groups. The study found that students' group interviews revealed difficulties with English, weak teacher performance, and high exam scores. Parents' interviews revealed factors like lack of follow-up, social pressure, and heavy teaching loads. The Ministry of Education and other educational institutions should minimize these causes to prevent negative consequences.

Zhan et al. (2013) conducted a study on the effectiveness of private tutoring: students' perceptions in comparison with mainstream schooling in Hong Kong. The study investigates Hong Kong students' perceptions of private tutoring's effectiveness compared to

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mainstream schooling, employing mixed methods of quantitative survey and qualitative interview. The study found that lecture-type tutoring, particularly video recording, improved students' examination grades, confidence, revision skills, and learning strategies. However, only 17.2% of students reported not receiving tutoring due to existing academic performance or financial constraints, while 23.7% felt tutoring was burdensome due to parental choice.

THE RATIONALE OF THE STUDY

In the 21st century, education is crucial for excelling in any field. However, the quality of education is declining day by day, hence students are being directed towards private tuition for quality education. This has both positive and negative effects on students' performance. Research is needed to understand students' attitudes toward private tuition/coaching classes, as many studies have explored this topic.

STATEMENT OF THE PROBLEM

Private tuition is an important issue these days. The purpose of tutoring is to support students to learn from outside of the classroom. Both parents and students see private lessons as a significant part of the education process and believe that tutoring plays an important and successful role in children's education. The researcher, therefore, tries to explore how private tuition is considered in the education process. The researcher conducts the study entitled **"Attitude of Higher Secondary Students Towards Private Tuition"**

OBJECTIVES OF THE STUDY

1. To find out the difference between 11th and 12th standard students' attitudes toward private tuition.
2. To find out the difference between boys and girls higher secondary students' attitudes toward private tuition.
3. To find out the difference between science and arts higher secondary students' attitudes toward private tuition.
4. To find out the difference between urban and rural higher secondary students' attitudes toward private tuition.
5. To find out the relationship between attitudes and academic achievement of higher secondary students towards private tuition based on gender and locality.

HYPOTHESIS OF THE STUDY

H_{01}: There is no significant difference between the attitudes of 11th and 12th-standard students toward private tuition.
H_{02}: There is no significant difference between the attitudes of boys and girls higher secondary students toward private tuition.
H_{03}: There is no significant difference between the attitudes of science and arts higher secondary students toward private tuition.
H_{04}: There is no significant difference between the attitudes of rural and urban higher secondary students toward private tuition.
H_{05}: There is no significant difference between the attitudes of urban boys and rural girls' higher secondary students toward private tuition.
H_{06}: There is no significant difference between the attitudes of urban girls and rural boys higher secondary level students toward private tuition.
H_{07}: There is no significant relationship between attitudes and academic achievement of higher secondary students towards private tuition.
H_{08}: There is no significant relationship between attitudes and academic achievement of higher secondary boy students towards private tuition.
H_{09}: There is no significant relationship between attitudes and academic achievement of higher secondary girl students towards private tuition.
H_{010}: There is no significant relationship between attitudes and academic achievement of higher secondary rural students towards private tuition.
H_{011}: There is no significant relationship between attitudes and academic achievement of higher secondary urban students towards private tuition.

METHODOLOGY OF THE STUDY

Method

The descriptive survey method has been used in this investigation to determine whether there is a significant difference in students' attitudes toward private tuition.

Population and Sample

The researcher considered as the population of this study the pupils of higher secondary school students of North Bengal were also considered as the population of this study. The researcher collected data from two districts in North Bengal by using a questionnaire. The researcher collected 198 samples.

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Tool Used

For data collection, the researchers used a self-made questionnaire. The questionnaire consisted of 47 items. The 47 items contained both Positive and Negative questions. Respondents were asked to rate each statement on a five-point Likert scale. The self-made questionnaire on private tuition was validated by the experts.

Statistical Techniques Used

The Mean, Standard deviation, 't' test, and correlation were used to determine the significance of the difference between the groups.

DATA ANALYSIS AND INTERPRETATION

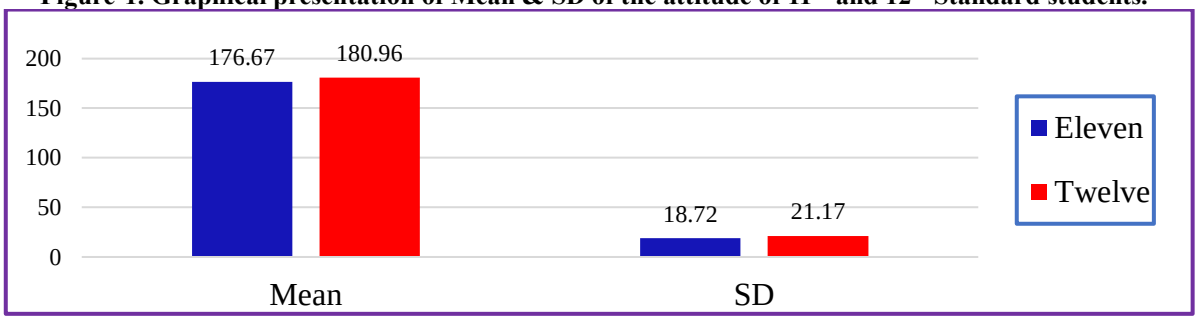
Hypothesis-1.

H_{01}: There is no significant difference between the attitudes of 11th and 12th standard students toward private tuition.

Table-1

Variable	Group	N	Mean	SD	df	't' value	Level of significance
Standard	11th Class	102	176.67	18.72	196	1.51	Not Significant at 0.05 level
	12th Class	96	180.96	21.17			

Figure-1. Graphical presentation of Mean & SD of the attitude of 11th and 12th Standard students.



The corresponding null hypothesis was accepted as the value appeared to be not significant. So, the researcher concluded that there was no significant difference in private tuition scores between the 11th and 12th-standard students toward private tuition.

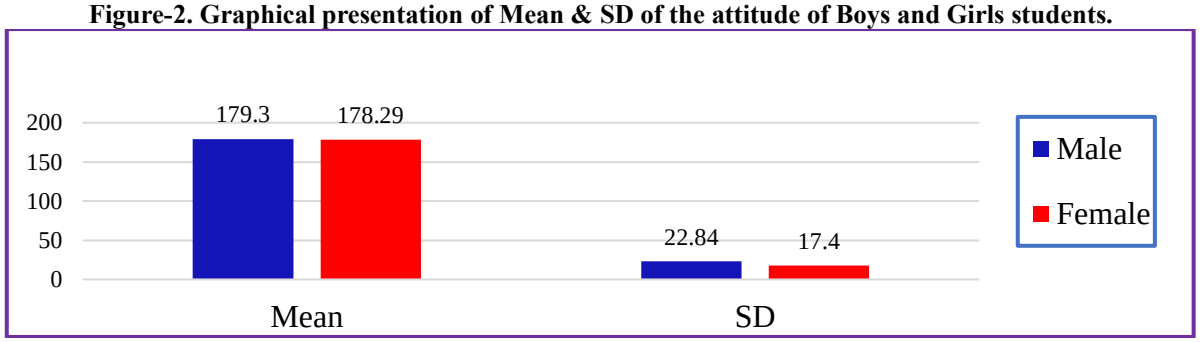
Hypothesis-2.

H_{02}: There is no significant difference between the attitudes of boys and girls higher secondary level students toward private tuition.

Table-2

Variable	Group	N	Mean	SD	df	't' value	Level of significance
Gender	Boys	90	179.30	22.84	196	0.35	Not Significant at 0.05 level
	Girls	108	178.29	17.40			

Figure-2. Graphical presentation of Mean & SD of the attitude of Boys and Girls students.



The corresponding null hypothesis was accepted as the value appeared to be not significant. So, the researcher concluded that there was no significant difference in private tuition scores between the higher secondary boy and girl students.

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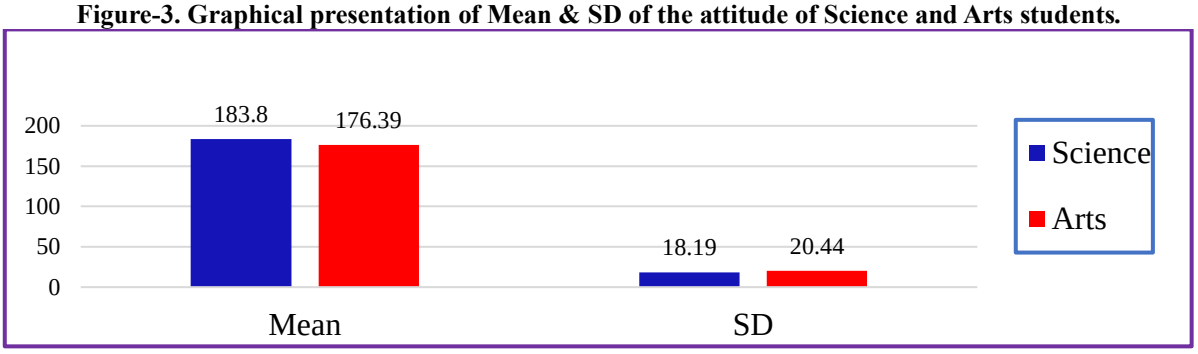
Hypothesis-3.

H_{03}: There is no significant difference between the attitudes of science and arts higher secondary level students toward private tuition.

Table-3

Variable	Group	N	Mean	SD	df	't' value	Level of significance
Strems	Science	63	183.80	18.19	196	2.46*	Significant at 0.05 level
	Arts	135	176.39	20.44			

Figure-3. Graphical presentation of Mean & SD of the attitude of Science and Arts students.



The value is significant. The corresponding null hypothesis is rejected. So, the researcher concluded that there is a significant difference in Private Tuition scores between Higher Secondary Science and Arts students.

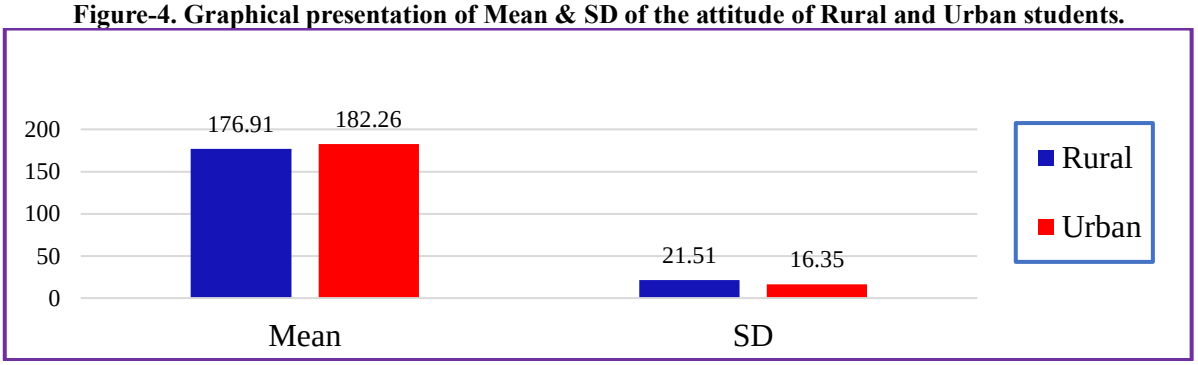
Hypothesis-4.

H_{04}: There is no significant difference between the attitudes of rural and urban higher secondary level students toward private tuition.

Table-4

Variable	Group	N	Mean	SD	df	t value	Level of significance
Location	Rural	130	176.91	21.51	196	1.80	Not Significant at 0.05 level
	Urban	68	182.26	16.35			

Figure-4. Graphical presentation of Mean & SD of the attitude of Rural and Urban students.



The corresponding null hypothesis was accepted as the value appeared to be not significant. So, the researcher concluded that there was no significant difference in private tuition scores between the higher secondary rural and urban students.

Hypothesis-5.

H_{05}: There is no significant difference between the attitudes of urban boys and rural girls higher secondary level students toward private tuition.

Table-5

Variable	Group	N	Mean	SD	df	't' value	Level of significance
Location	Urban Boys	37	182.92	15.48	112	1.77	Not Significant at 0.05 level
	Rural Girls	77	177	17.28			

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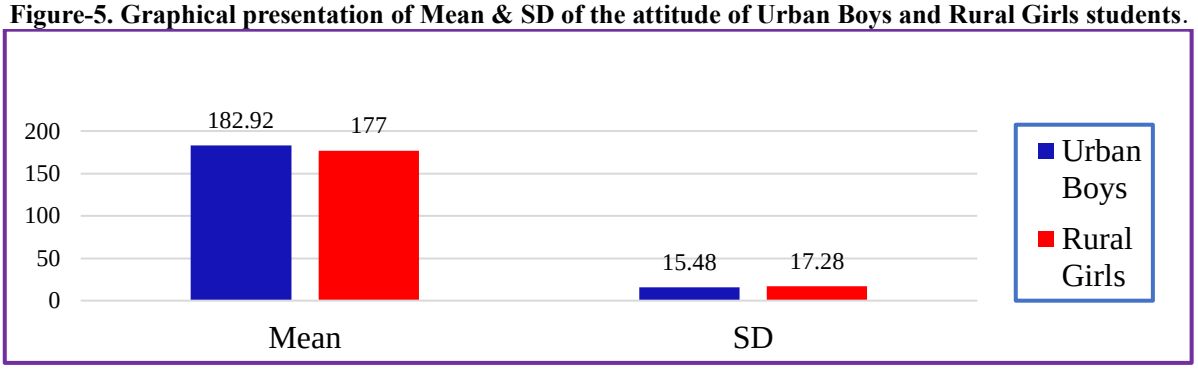
Figure-5. Graphical presentation of Mean & SD of the attitude of Urban Boys and Rural Girls students.



The corresponding null hypothesis was accepted as the value appeared to be not significant. So, the researcher concluded that there was no significant difference in private tuition scores between the higher secondary urban boys and rural girls students.

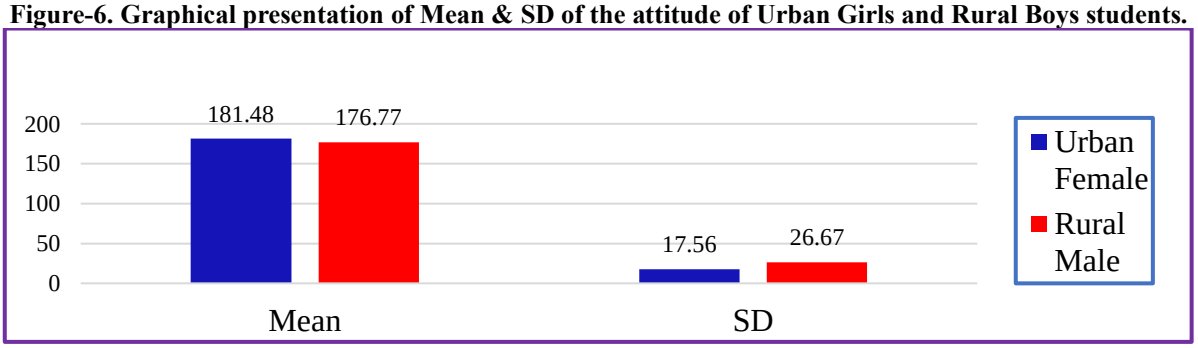
Hypothesis-6.

H_{06}: There is no significant difference between the attitudes of urban girls and rural boys' higher secondary level students toward private tuition.

Table-6

Variable	Group	N	Mean	SD	df	't' value	Level of significance
Location	Urban Girls	31	181.48	17.56	82	0.88	Not Significant at 0.05 level
	Rural Boys	53	176.77	26.67			

Figure-6. Graphical presentation of Mean & SD of the attitude of Urban Girls and Rural Boys students.



The corresponding null hypothesis was accepted as the value appeared to be not significant. So, the researcher concluded that there was no significant difference in private tuition scores between the higher secondary urban girls and rural boys' students.

- **Relationship between Higher Secondary student's attitude and academic achievement**

Hypothesis-7.

H_{07}: There is no significant relationship between attitudes and academic achievement of higher secondary students towards private tuition.

Variables	No. of sample	Pearson 'r'	df	p-value	Level of significance
Attitudes and Academic Achievement of Higher Secondary Students	198	0.1931	196	0.006431	Significant at 0.05 level

The value is significant. The corresponding null hypothesis is rejected. Therefore, the researcher concluded that there is a significant relationship between Attitudes and academic achievement scores of the higher secondary students.

Hypothesis-8.

H_{08}: There is no significant relationship between attitudes and academic achievement of higher secondary boy students towards private tuition.

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Variables	No. of sample	Pearson 'r'	df	p-value	Level of significance
Attitudes and Academic Achievement of Higher Secondary Boys Students	90	0.3113	88	0.002818	Significant at 0.05 level

The value is significant. The corresponding null hypothesis is rejected. Therefore, the researcher concluded that there is a significant relationship between Attitudes and academic achievement scores of higher secondary Boys students.

Hypothesis-9.

H_{09}: There is no significant relationship between attitudes and academic achievement of higher secondary girl students towards private tuition.

Variables	No. of sample	Pearson 'r'	df	p-value	Level of significance
Attitudes and Academic Achievement of Higher Secondary Girls Students	108	0.06592	106	0.4979	Not Significant at 0.05 level

The value is not significant. The associated null hypothesis is accepted. Therefore, the researcher concluded that there is no significant relationship between Attitudes and academic achievement scores of the higher secondary Girls students.

Hypothesis-10.

H_{010}: There is no significant relationship between attitudes and academic achievement of higher secondary rural students towards private tuition.

Variables	No. of sample	Pearson 'r'	df	p-value	Level of significance
Attitudes and Academic Achievement of Higher Secondary Rural Students	130	0.2416	128	0.005614	Significant at 0.05 level

The value is significant. The associated null hypothesis is disproved. Thus, the researcher concluded that there is a strong correlation between the higher secondary rural students' academic achievement scores and their attitudes.

Hypothesis-11.

H_{011}: There is no significant relationship between attitudes and academic achievement of higher secondary urban students towards private tuition.

Variables	No. of sample	Pearson 'r'	df	p value	Level of significance
Attitudes and Academic Achievement of Higher Secondary Urban Students	68	-0.02453	66	0.8426	Not Significant at 0.05 level

The value is not significant. The associated null hypothesis is accepted. Thus, the researcher concluded that there is no meaningful correlation between the higher secondary urban students' academic achievement scores and their attitudes.

DISCUSSION

From the above findings and discussion, it can be said that higher secondary students' attitude towards Private Tuition is independent regarding gender, class, Strems, and residence. Both boys and girls, rural and urban, eleven and twelve, science and arts higher secondary students have high attitudes towards Private Tuition. The present study revealed that Twelve class students have comparatively higher attitudes than Eleven students toward Private Tuition, and science students have more attitudes towards Private Tuition than arts students. Higher secondary school students spend more money on private tuition than any other class, while science students spend the most on private tuition (Laskar, 2016). Logically, science students have high positive attitudes towards private tuition where they spend more money on tuition. The study also revealed that urban students have a higher attitude toward rural students, and male students have a slightly higher attitude toward Private Tuition than female students. Moreover, it was found that urban male students have more attitude toward rural female students, and urban female students have more attitude towards rural male students towards private tuition. The study found that most secondary school students in Assam have a favorable attitude toward private tuition, (Kotaky, 2018).

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Also, there is a significant relationship between attitude towards private tuition and the academic achievement of higher secondary boys and rural students.

CONCLUSION

Currently, the main reason for the increasing demand for tutors is the inadequacy of teachers for the growing number of students in schools and colleges. Even if a student has difficulty understanding a teacher's reading, he must read with that teacher. But if a home teacher is not according to the student's mind, then he can be changed to another teacher. The tutor teaches according to the student's preferences and needs. As a result, students' interest in studies increases. So nowadays students prefer private tutors more than school teachers. Parents also support private tuition keeping in mind the quality of student achievement.

So, it can be said from the research that the main reason why private tuition is currently increasing to such an extent is the lack of proper study environments in schools. In addition, teachers provide private tuition which results in parents giving private tuition to their children.

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DECODING PHARMACEUTICAL MARKETING AND SALES: ROLES, STRATEGIES, AND INNOVATIONS IN EMERGING MARKETS

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ABSTRACT

The dynamic landscape of pharmaceutical marketing and sales necessitates a thorough understanding of market dynamics, consumer behavior, and competitive forces, particularly in emerging markets. This review paper, titled "Decoding Pharmaceutical Marketing and Sales: Roles, Strategies, and Innovations in Emerging Markets," explores critical components of the marketing and sales ecosystem, emphasizing the role of research and strategic decision-making.

The paper begins by examining marketing research as a foundation for developing effective strategies. It delves into the study of macro-environmental factors, including economic, political, social, and technological influences, to provide a holistic view of the market environment. Consumer research is highlighted as a key element in understanding the preferences, behaviors, and unmet needs of target audiences. Additionally, competitor research is analyzed to identify market gaps and craft strategies to gain a competitive edge.

Price research is discussed in detail, focusing on its importance in ensuring affordability while maintaining profitability in diverse markets. The paper also emphasizes the significance of research into distribution and sales channels to optimize product availability and accessibility. By integrating these aspects, the review provides a comprehensive framework for navigating the complexities of pharmaceutical marketing and sales, offering valuable insights and actionable strategies for professionals and stakeholders in emerging markets.

KEYWORDS: *Pharmaceutical marketing, Marketing research, Macro-environment analysis, Consumer behavior, Competitor analysis, Price research, Distribution channels, Sales strategies, Emerging markets, Pharmaceutical industry innovations.*

INTRODUCTION

The pharmaceutical industry, as a cornerstone of modern healthcare, relies heavily on marketing and sales to bridge the gap between innovative products and the healthcare professionals and patients who need them. As the industry continues to expand into emerging markets, it is essential to decode the complex mechanisms underlying pharmaceutical marketing and sales. This review paper, titled "Decoding Pharmaceutical Marketing and Sales: Roles, Strategies, and Innovations in Emerging Markets," offers a detailed exploration of the fundamental concepts, roles, and processes that drive success in this field, with a particular focus on emerging markets.

A basic understanding of pharmaceutical marketing and sales Is imperative for professionals seeking to navigate this dynamic domain. This includes familiarization with key terminologies and frameworks that underpin industry practices. From market segmentation to product lifecycle management, these foundational concepts set the stage for effective decision-making and strategy formulation.

The role of pharmacists in pharmaceutical sales and marketing is increasingly recognized as critical. Pharmacists, with their in-depth knowledge of drugs, formulations, and patient needs, serve as valuable contributors to product promotion and customer education. Their role extends beyond dispensing medications to advising healthcare professionals, conducting training sessions, and ensuring ethical marketing practices.

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Understanding the professional terminology used in the pharmaceutical industry is another vital aspect. Terms such as "market access," "pharmacovigilance," and "key opinion leaders (KOLs)" are not only industry-specific but also instrumental in shaping communication and collaboration across stakeholders.

The pharmaceutical sales hierarchy provides a structured approach to market penetration, with defined roles ranging from sales representatives to district and regional managers. An in-depth understanding of this hierarchy is crucial for aligning sales strategies with organizational goals and ensuring optimal performance across levels.

Detailed Information for Each Point

1. Marketing Research

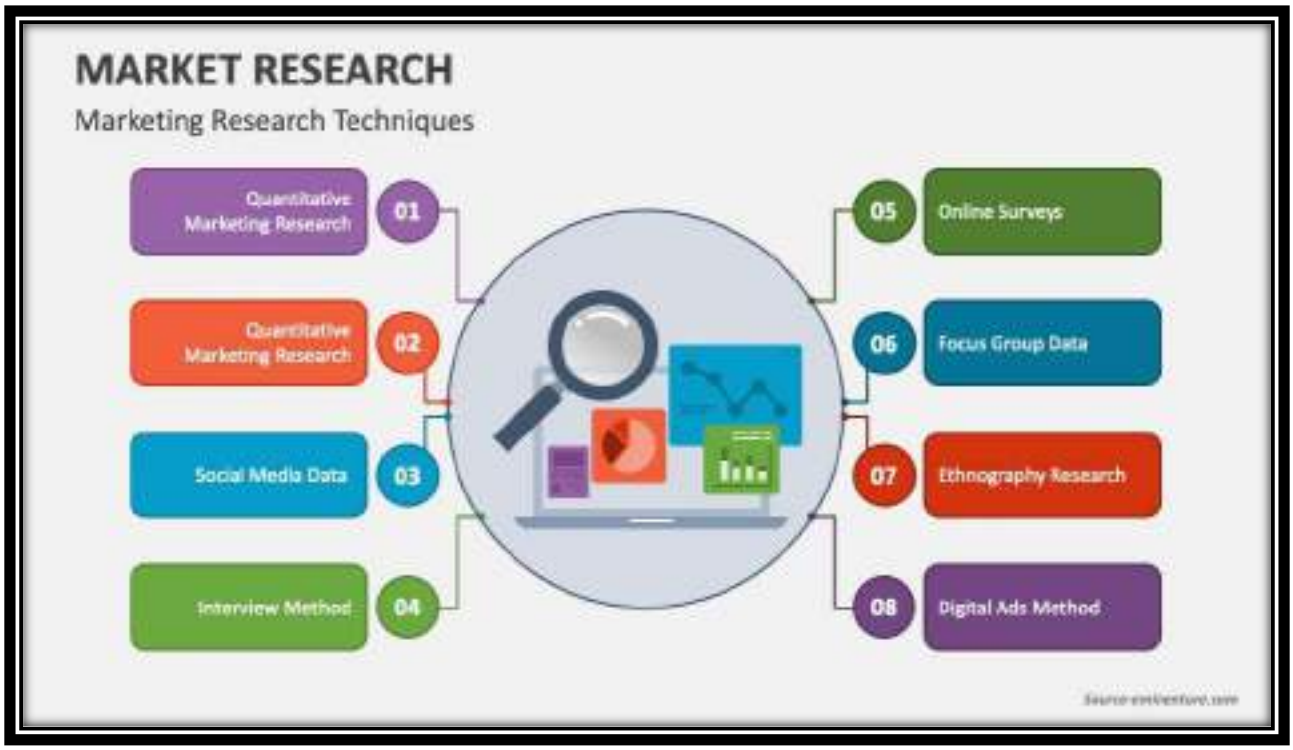

Fig:1. Marketing Research

Marketing research serves as the foundation for successful pharmaceutical marketing and sales strategies. It involves systematically gathering, analyzing, and interpreting data to make informed decisions. In the pharmaceutical industry, marketing research focuses on:

Market Needs Analysis: Identifying unmet medical needs and opportunities for new products.

Product Positioning: Determining how to differentiate a product within a competitive landscape.

Regulatory Trends: Assessing compliance requirements across different regions.

Stakeholder Insights: Understanding the perspectives of healthcare providers, patients, and policymakers.

Emerging markets require localized research approaches due to unique demographic, cultural, and regulatory factors, making marketing research critical to tailoring strategies.

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Fig:2. Market Research

2. Studying Macro Environment Factors

Fig:3.Macro Environment

The pharmaceutical industry operates within a complex macro-environment shaped by external factors, often summarized as PESTLE (Political, Economic, Social, Technological, Legal, and Environmental).

Political Factors: Government policies, healthcare regulations, and international trade agreements. For example, national health programs in emerging markets influence drug accessibility and affordability.

Economic Factors: GDP growth, healthcare budgets, and income levels affect market demand and pricing strategies.

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Social Factors: Cultural attitudes toward healthcare, patient education, and population health trends.

Technological Factors: Advancements in drug development, digital marketing, and telemedicine.

Legal Factors: Compliance with local and international laws, intellectual property protection, and marketing ethics.

Environmental Factors: Sustainability initiatives, such as eco-friendly packaging and waste management.

Studying these factors helps pharmaceutical companies anticipate risks, adapt strategies, and seize opportunities in emerging markets.

3. Research of Consumers

Fig:4. Consumer Behavior Research

Consumer research in pharmaceuticals involves understanding the needs, preferences, and behaviors of key stakeholders, including:

Patients: Identifying patient demographics, treatment preferences, and barriers to medication adherence.

Healthcare Providers: Gaining insights into prescribing patterns, treatment guidelines, and brand loyalty.

Pharmacists: Evaluating their role as influencers in product selection and patient education.

In emerging markets, consumer research must consider variations in healthcare access, affordability, and cultural perceptions, helping companies design products and marketing campaigns that resonate with local populations.

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4. Research of Competitors

Fig:5. Competitive Research

Competitor research provides insights into the strategies and performance of rival pharmaceutical companies. Key aspects include:

Product Portfolio Analysis: Understanding the range, quality, and innovation of competitors' offerings.

Market Share Assessment: Evaluating competitors' dominance in specific therapeutic areas or regions.

Pricing Strategies: Analyzing pricing models and discounts offered by competitors.

Promotional Activities: Reviewing marketing campaigns, sales tactics, and digital outreach efforts.

Partnerships and Alliances: Identifying strategic collaborations that enhance market presence.

In emerging markets, local competitors often dominate due to their understanding of the market. Researching these players helps multinational companies adapt and position themselves effectively.

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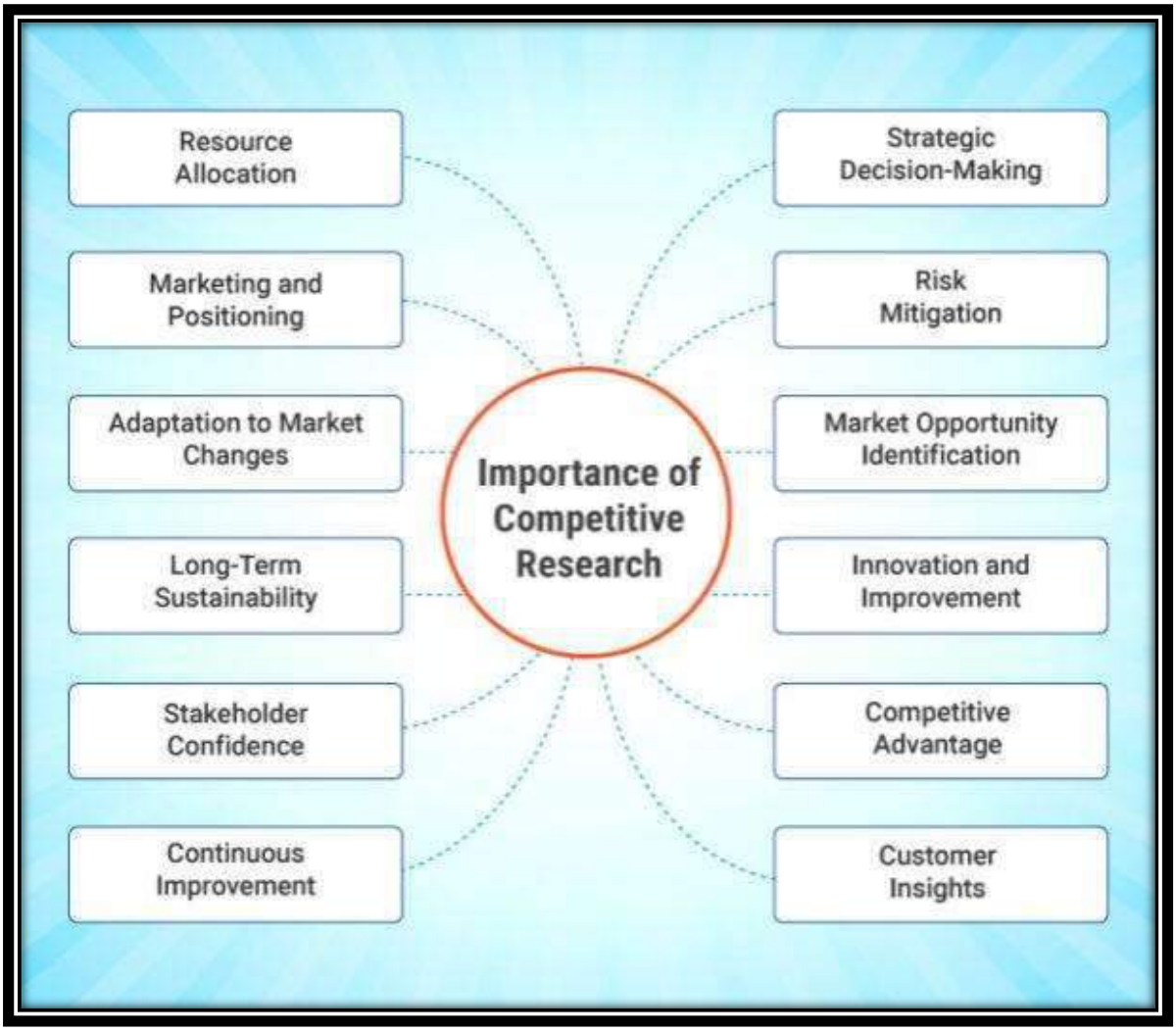

Fig:6. Importance of competitive Research

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5. Price Research

Fig:7.Price Research

Pricing is a critical factor in pharmaceutical marketing, especially in emerging markets where affordability is a major concern. Price research focuses on:

Cost Analysis: Evaluating the cost of production, distribution, and marketing.

Market-Based Pricing: Setting prices based on what customers are willing to pay.

Competitor Pricing: Benchmarking against rivals to ensure competitiveness.

Value-Based Pricing: Justifying prices based on the clinical benefits and cost savings offered by the product.

Regulatory Impact: Understanding government pricing controls, such as price caps and reimbursements.

Effective price research helps companies strike a balance between profitability and accessibility, which is particularly important in price-sensitive emerging markets.

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6. Research of Distribution and Sales

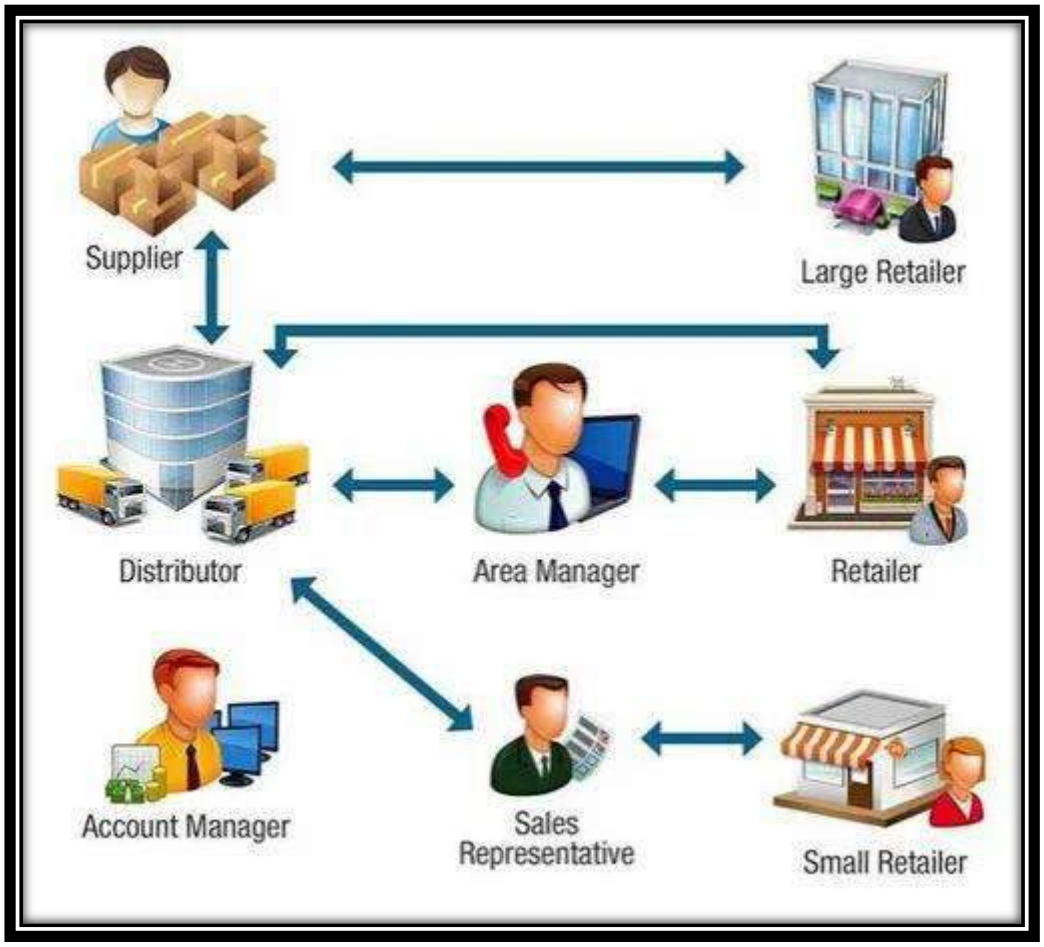

Fig:7. Research of Distribution and sales

Distribution and sales research ensures that pharmaceutical products are efficiently delivered to end-users. Key areas of focus include:

Supply Chain Analysis: Evaluating the logistics network, from manufacturing to final delivery.

Distribution Channels: Identifying the best mix of wholesalers, pharmacies, and online platforms.

Retail Trends: Assessing the role of independent pharmacies, hospital pharmacies, and chain stores.

Sales Force Effectiveness: Measuring the performance and training needs of sales representatives.

Geographic Reach: Analyzing coverage in rural and urban areas, especially in regions with limited infrastructure.

For emerging markets, distribution research must address challenges such as poor infrastructure, geographic diversity, and regulatory barriers, ensuring products are available and accessible to target audiences.

By integrating insights from these research areas, this paper provides a comprehensive roadmap for understanding and optimizing pharmaceutical marketing and sales, with a particular emphasis on the unique challenges and opportunities in emerging markets.

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Future Prospects in Pharmaceutical Marketing and Sales

1. Marketing Research

Future Prospects

AI-Driven Insights: The integration of artificial intelligence (AI) in marketing research will enable faster and more accurate analysis of large datasets, providing deeper insights into market trends and customer behaviors.

Predictive Analytics: Advanced tools will help forecast future demand for products, allowing companies to anticipate market needs proactively.

Personalized Marketing: Research will shift toward understanding individual preferences, paving the way for targeted and personalized marketing strategies.

Real-Time Data Analysis: Enhanced digital tools will enable real-time tracking of market dynamics, helping companies adapt strategies quickly in response to changing conditions.

Expansion into Untapped Markets: Research will increasingly focus on identifying and entering underserved areas within emerging markets, fostering new growth opportunities.

2. Studying Macro Environment Factors

Future Prospects

Dynamic Scenario Planning: Advanced modeling techniques will allow companies to better predict and adapt to changes in political, economic, and regulatory environments.

Focus on Sustainability: Environmental concerns will drive companies to develop eco-friendly practices, influencing strategies for product packaging and distribution.

Global-Local Synergies: Companies will invest in understanding how global trends intersect with local market realities, enabling them to balance standardized approaches with localized adaptations.

Digital Transformation: The rapid adoption of technology in healthcare will necessitate deeper analysis of technological advancements, such as telemedicine and digital health tools.

3. Research of Consumers

Future Prospects

Consumer-Centric Innovation: Increasing emphasis on patient-centric care will drive research into understanding specific needs, leading to customized product development.

Digital Health Behavior: Understanding how patients and healthcare providers use digital platforms for health information and treatment decisions will shape marketing strategies.

Improved Access and Affordability: Research will focus on addressing barriers to healthcare access in emerging markets, ensuring products meet local affordability standards.

Behavioral Science Applications: Insights from psychology and behavioral science will be integrated into consumer research to better understand decision-making processes.

Patient Advocacy and Engagement: Companies will invest in research to engage with patient advocacy groups, fostering trust and improving product adoption.

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4. Research of Competitors

Future Prospects

Competitive Intelligence Platforms: The use of AI-driven tools for competitor monitoring will provide real-time updates on rival activities and market positioning.

Collaborative Ecosystems: Research will explore opportunities for strategic partnerships and collaborations, particularly with local players in emerging markets.

Disruptive Innovation Analysis: A focus on identifying disruptive technologies and business models will help companies stay ahead of competition.

Open-Source Intelligence: Increasing use of publicly available data for competitor analysis will enhance transparency and reduce dependency on traditional methods.

Focus on Start-Ups: Emerging competitors, including digital health start-ups, will become key research targets due to their innovative approaches.

5. Price Research

Future Prospects

Dynamic Pricing Models: The adoption of flexible pricing strategies based on real-time market conditions and consumer demand will become more prevalent.

Value-Based Pricing: Companies will focus on demonstrating the clinical and economic value of their products to justify premium pricing in cost-sensitive markets.

Price Transparency: Growing demand for transparency in pricing will require companies to clearly communicate the cost-benefit of their products.

Collaborative Pricing Approaches: Partnerships with governments and non-governmental organizations will drive innovative pricing models to improve affordability in emerging markets.

Digital Pricing Tools: Advanced software solutions will streamline pricing decisions, enabling faster adjustments to competitive and regulatory changes.

6. Research of Distribution and Sales

Future Prospects

Digital Supply Chains: Enhanced digital tools, such as blockchain and IoT, will revolutionize supply chain management, ensuring greater efficiency and transparency.

E-Commerce Expansion: Online sales platforms will gain prominence in pharmaceutical distribution, especially in urban areas of emerging markets.

Last-Mile Delivery Solutions: Companies will invest in innovative delivery mechanisms to reach remote and underserved regions.

Sales Automation: The use of AI and machine learning in sales processes will improve targeting, customer relationship management, and efficiency.

Sustainability in Distribution: Companies will adopt eco-friendly practices in logistics, such as using electric vehicles and reducing packaging waste.

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The Role of Pharmacists in Sales and Marketing

The role of pharmacists in the sales and marketing of pharmaceutical products is multifaceted, encompassing a range of responsibilities that influence both product promotion and patient care. Pharmacists are uniquely positioned in the healthcare ecosystem, bridging the gap between pharmaceutical manufacturers, healthcare providers, and patients. In emerging markets, this role becomes even more significant due to the evolving healthcare landscape, regulatory challenges, and the need for improved access to medications. This section will explore the various aspects of a pharmacist's involvement in pharmaceutical sales and marketing, including their influence on product selection, promotion, and education, as well as their impact on the overall success of pharmaceutical products in the market.

1. Pharmacists as Key Influencers in Pharmaceutical Sales

Pharmacists are often the first point of contact for patients seeking advice about medications, making them vital contributors to the sales process. Their role in sales and marketing includes:

Product Recommendation and Education: Pharmacists help patients understand the therapeutic benefits, potential side effects, and proper usage of medications. They provide essential information on drug interactions, dosages, and proper storage, directly influencing patient adherence and product success.

Building Patient Trust: As healthcare professionals trusted by patients, pharmacists play a critical role in shaping patient perceptions of pharmaceutical brands. Their endorsements or recommendations can significantly influence patient purchasing decisions.

Advising on Over-the-Counter (OTC) Products: Pharmacists often serve as advisors for OTC medications, guiding patients toward effective and safe self-care products, which plays an important role in the sales of such products.

Education for Healthcare Providers: Pharmacists also engage with doctors and other healthcare professionals, providing them with updated information about new drugs, formulations, and delivery methods. This helps influence prescribing behaviors and aligns marketing efforts with medical guidelines.

2. Pharmacists in Marketing and Promotion

Pharmacists are directly involved in the promotion of pharmaceutical products, acting as key players in strategies aimed at educating both healthcare providers and patients. Their marketing functions are aligned with the broader sales strategies of pharmaceutical companies and include:

Product Awareness Campaigns: Pharmacists can be actively involved in educational campaigns, whether through direct communication with patients, participation in healthcare seminars, or providing promotional materials such as brochures, leaflets, and product samples.

Involvement in Marketing Collateral Creation: Pharmacists often collaborate with marketing teams to ensure the technical accuracy and clinical relevance of marketing materials, particularly for new product launches or when introducing new indications.

Training Sales Representatives: Pharmacists play a role in training pharmaceutical sales representatives, ensuring that they have a deep understanding of the clinical benefits, risks, and appropriate use of pharmaceutical products. This helps ensure that marketing and sales representatives deliver accurate, evidence-based information to healthcare providers.

Brand Advocacy: In many cases, pharmacists become brand advocates for certain pharmaceutical products. Their professional recommendation can elevate a product’s reputation, especially when the product fulfills a significant clinical need or provides an innovative solution for patient care.

3. Pharmacists as Educators and Trainers in Emerging Markets

In emerging markets, where healthcare infrastructure and access to information may be limited, pharmacists assume a more prominent role in training and educating various stakeholders. Their role as educators extends to:

Patient Education: Pharmacists provide counseling on the correct use of medications, the importance of adherence to prescribed regimens, and the potential side effects. In emerging markets where literacy rates may be lower, this becomes even more crucial in promoting the proper use of medications and preventing misuse.

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Healthcare Provider Training: Pharmacists train healthcare providers, including doctors and nurses, on the latest drugs and treatment regimens, fostering a more informed and collaborative healthcare environment. They are often called upon by pharmaceutical companies to conduct Continuing Medical Education (CME) sessions.

Training on Medical Devices: In markets where medical devices are becoming more prevalent, pharmacists also take on the responsibility of educating both healthcare professionals and patients on the proper use of these products, ensuring their safe and effective application.

4. Pharmacists and Regulatory Compliance

In pharmaceutical sales and marketing, compliance with local and international regulatory frameworks is essential. Pharmacists help ensure that marketing efforts and sales activities adhere to these standards. Key roles include:

Ensuring Ethical Marketing Practices: Pharmacists are well-versed in the ethical considerations related to pharmaceutical marketing. Their involvement in sales ensures that marketing strategies respect professional ethics, prevent over-promotion, and avoid misleading claims.

Navigating Regulatory Guidelines: Pharmacists are knowledgeable about the regulatory landscape in their respective regions, including the registration of pharmaceutical products, labeling requirements, and restrictions on product claims. In emerging markets, where regulatory frameworks may still be developing, pharmacists play a critical role in ensuring compliance and helping companies navigate complex local regulations.

Safety and Pharmacovigilance: Pharmacists help monitor and report adverse drug reactions (ADRs) and other safety concerns, ensuring that pharmaceutical companies comply with regulatory requirements for post-market surveillance. This contributes to the integrity of marketing efforts by promoting safe and responsible use of medications.

5. Influence of Pharmacists in Pricing Strategies

Pharmacists can also play an indirect yet influential role in shaping the pricing strategies of pharmaceutical products, particularly in emerging markets:

Negotiating Prices with Healthcare Institutions: Pharmacists working within healthcare institutions, such as hospitals and clinics, often influence bulk purchasing decisions. Their expertise in the therapeutic value of medications can help institutions choose cost-effective yet clinically effective options, thereby affecting the overall pricing strategy.

Assessing Product Affordability: In emerging markets, pharmacists have a unique understanding of local pricing sensitivities and economic conditions. They can provide feedback to pharmaceutical companies about what patients are willing and able to pay for certain products, helping to shape more affordable pricing strategies.

Government and Policy Influence: Pharmacists often engage in policy discussions surrounding the regulation of pharmaceutical prices. They can advocate for reasonable pricing structures that balance the interests of both the pharmaceutical industry and the patients who require access to medications.

6. The Evolving Role of Pharmacists in Digital Marketing

The rise of digital marketing in the pharmaceutical industry presents new opportunities for pharmacists to engage with patients and healthcare professionals:

Telemedicine and Online Consultations: Pharmacists play a role in supporting telemedicine platforms by providing remote consultations and guidance to patients, particularly in underserved areas. This expands their involvement in pharmaceutical marketing by reaching a broader audience.

Online Training and Webinars: Pharmacists are increasingly involved in delivering online education programs and webinars to healthcare professionals, educating them about new drug products, medical devices, and therapeutic strategies.

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Digital Tools for Adherence: Pharmacists are integrating digital tools into their practices, such as mobile apps for medication reminders, which are being used in marketing campaigns to increase patient adherence and improve health outcomes.

Marketing and Product Development for Formulations and Medical Devices in Emerging Markets

Pharmaceutical marketing and product development are critical components of the healthcare industry, especially in emerging markets where there are unique challenges and opportunities. The development of both pharmaceutical formulations (drugs) and medical devices requires a strategic approach that aligns with the needs of local populations, regulatory frameworks, and market conditions. This section will delve into the complexities of marketing and product development in the pharmaceutical and medical device sectors, specifically focusing on how these processes are adapted and executed in emerging markets.

1. The Product Development Process for Pharmaceuticals and Medical Devices

The development of pharmaceutical formulations and medical devices follows a rigorous process that spans from initial research and development (R&D) to commercialization. However, the complexity of these processes can vary, particularly when targeting emerging markets, which often have different healthcare needs, regulatory hurdles, and economic considerations.

Pharmaceutical Product Development

1. Preclinical and Clinical Development:

Formulation Research: Pharmaceutical development begins with the research and formulation of new drugs, which involves the identification of active pharmaceutical ingredients (APIs), excipients, and the ideal delivery system. In emerging markets, where diseases and treatment regimens may vary significantly, these formulations need to be tailored to the local health challenges, such as infectious diseases or chronic conditions prevalent in the region.

Clinical Trials: Clinical trials are crucial for testing the safety, efficacy, and pharmacokinetics of new drugs. Emerging markets present an opportunity to conduct clinical trials with diverse populations, but they also pose challenges related to ethical guidelines, regulatory approval, and recruitment of trial participants. Global pharmaceutical companies must navigate different regulatory systems and ensure compliance with international standards, such as the Good Clinical Practice (GCP) guidelines.

2. Regulatory Approval and Market Entry:

Registration with Regulatory Authorities: After successful clinical trials, the next step is to submit the product for approval by local regulatory agencies (e.g., the FDA in the U.S., EMA in Europe, or local bodies like the Central Drugs Standard Control Organization (CDSCO) in India). In emerging markets, the regulatory environment can be fragmented, making it crucial for pharmaceutical companies to adapt their strategies to local conditions. Navigating the varying approval processes, import restrictions, and clinical trial requirements is often more complex and time-consuming.

Market Authorization: Once regulatory approval is granted, pharmaceutical companies need to obtain marketing authorization, which includes proper labeling, packaging, and documentation. Many emerging markets have strict guidelines for product claims, marketing materials, and labeling, necessitating a localized approach to packaging and promotional efforts.

Medical Device Development

1. Concept and Design

Needs Assessment: The development of medical devices requires a deep understanding of local healthcare needs. In emerging markets, where there is a growing burden of chronic diseases, the demand for affordable diagnostic tools, medical implants, and therapeutic devices is increasing. Companies must design devices that are not only effective but also affordable, durable, and user-friendly, considering the socioeconomic conditions in these regions.

Prototype Development: After identifying the medical need, product prototypes are developed and tested for functionality, safety, and efficacy. The testing phase is critical, especially in regions where healthcare infrastructure may not be as advanced. Devices must be designed to function well in resource-limited settings.

2. Regulatory Compliance

International Standards and Local Regulations: Medical devices are subject to stringent regulatory requirements, including safety standards and certifications. In emerging markets, regulatory bodies often adopt international standards such as ISO 13485 for quality

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management and CE marking for European Union compliance. However, many local markets also have their own sets of rules and regulations that must be adhered to in order to gain market access.

3. Marketing Strategy for Formulations and Medical Devices in Emerging Markets

Effective marketing strategies are essential to ensure that newly developed pharmaceutical products and medical devices reach their target audiences. The strategies must be adapted to local market conditions, healthcare needs, cultural nuances, and economic realities.

Targeting the Right Market Segment

1. Identifying Market Needs

Pharmaceutical products and medical devices must be designed with the local patient population in mind. Emerging markets often present distinct health challenges, such as higher incidences of infectious diseases, malnutrition, and chronic illnesses like hypertension or diabetes. Understanding the epidemiological profile of a region helps companies develop products tailored to these needs.

Medical devices, in particular, must be developed with an eye on affordability and ease of use in lower-resource settings. For example, diagnostic tools and point-of-care devices must be portable, easy to operate, and capable of working in environments with limited infrastructure (e.g., unreliable electricity).

2. Pricing Strategy

Affordable Pricing Models: Pricing remains one of the biggest challenges in emerging markets, as patients often have limited access to healthcare services. Pharmaceutical companies often adopt tiered pricing strategies, offering different price points depending on the country's economic status or patient segment. For instance, generic drugs are a common solution for reducing treatment costs in these regions.

Government and Private Partnerships: In many emerging markets, pharmaceutical companies partner with governments, non-governmental organizations (NGOs), and private healthcare providers to ensure broader access to medications and devices at affordable prices.

3. Distribution Channels

In emerging markets, building an effective distribution network is key to ensuring that products reach the end-user. Distribution channels must be customized to meet the logistical challenges of each region. Pharmaceuticals and medical devices need to be distributed through a mix of retail pharmacies, hospitals, clinics, and even mobile healthcare units in rural areas.

E-commerce and digital health platforms are gaining traction in some emerging markets, offering new ways to distribute pharmaceutical products and medical devices, especially for OTC products.

Promotion and Education

1. Promotional Strategies

Pharmaceutical companies and medical device manufacturers often rely on a mix of traditional and digital marketing techniques. In emerging markets, sales representatives are essential for educating healthcare professionals and pharmacies about the benefits and proper usage of products.

Medical seminars, conferences, and webinars have become increasingly important in educating healthcare providers and decision-makers about the latest developments in pharmaceutical products and medical devices.

2. Healthcare Professional Engagement

Engaging with Healthcare Providers: Physicians, pharmacists, and nurses play an integral role in the success of a pharmaceutical product or medical device. Companies often organize educational events, provide product samples, and offer training to healthcare professionals to build trust and increase the adoption of their products.

Patient Awareness: Educating patients directly through campaigns and consultations can lead to better product uptake, particularly when patients are encouraged to take charge of their health and adhere to treatment regimens.

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3. Building Trust in Emerging Markets

Brand Reputation: Brand recognition and trust-building are crucial in markets where consumers may have limited information about foreign pharmaceutical products or medical devices. Establishing a strong reputation for safety, efficacy, and affordability is critical to building customer loyalty in these markets.

Patient Advocacy and Community Engagement: Advocacy campaigns and community-based education programs can help raise awareness about specific health conditions and the treatment options available, which, in turn, drive the adoption of new products.

4. Innovations in Pharmaceutical Marketing and Product Development for Emerging Markets

The rapid evolution of healthcare technologies and digital marketing methods is transforming how pharmaceutical products and medical devices are developed and marketed in emerging markets.

Innovative Product Development Approaches

1. Point-of-Care Diagnostics: The demand for affordable and accurate diagnostic devices is rising in emerging markets. Point-of-care diagnostics are transforming healthcare delivery by enabling faster and more cost-effective testing, especially in rural and underserved areas. Companies developing such devices must focus on simplicity, durability, and accuracy.
2. Mobile Health (mHealth): With increasing smartphone penetration in emerging markets, mHealth solutions are gaining traction. Pharmaceutical companies are incorporating mobile health applications and digital platforms for patient monitoring, treatment reminders, and education.
3. Telemedicine Integration: The integration of telemedicine with pharmaceutical and medical device marketing strategies provides an opportunity to reach remote and underserved populations. Telemedicine allows healthcare providers to consult with patients remotely, and pharmaceutical companies can capitalize on this trend by offering products that facilitate remote care.

Emerging Market-Specific Strategies

1. Localization of Products: Companies must adapt their products to meet the needs of local populations. For example, in markets with a high prevalence of tropical diseases, pharmaceutical products must be tailored to address these conditions. Similarly, medical devices may need to be adjusted to suit local health practices or environmental conditions.
2. Public-Private Partnerships: Many pharmaceutical companies engage in public-private partnerships to improve healthcare access. These partnerships may focus on making essential medicines more affordable, especially in the context of the growing non-communicable diseases (NCDs) burden in emerging markets.

CONCLUSION AND RESULTS

This review highlights the critical role of pharmaceutical marketing and sales in emerging markets, emphasizing the need for tailored strategies that address the unique healthcare challenges and regulatory landscapes of these regions. Key findings include:

1. Pharmacists' Influence: Pharmacists are vital in driving product adoption, educating healthcare providers, and ensuring patient compliance, making them central figures in pharmaceutical marketing and sales.

2. Regulatory Compliance: Navigating complex and varied regulations across emerging markets is crucial for successful product launch and market penetration.

3. Market Tailoring: Customized marketing strategies that align with local health needs, cultural contexts, and economic conditions lead to better product uptake and patient engagement.

4. Digital Transformation: The integration of digital tools, such as mHealth apps and telemedicine, is revolutionizing marketing and patient engagement in underserved areas.

5. Innovative Product Development: Affordable and accessible drug formulations, such as generics and biosimilars, and medical devices tailored for resource-limited settings are key to meeting local demand.

6. Distribution and Sales: Overcoming logistical challenges and developing flexible distribution models are essential for ensuring product availability in remote or underserved regions.

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7. Pricing Strategies: Tiered pricing models and partnerships with governments and NGOs are necessary to address affordability issues and expand access to essential medications.

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A REVIEW ON STUDY OF HERBAL DRUGS MONOGRAPHS

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ABSTRACT

A pharmacopoeia is an official book used by the government to prescribe good medicine. Examples of Indian, British and Japanese medicines. Pharmacopoeias and herbal monographs and medical summaries are examples of descriptive and topographical texts on botanicals that describe the arrangement of plants. The monograph includes information on active pharmaceutical ingredients (APIs) and tests for contamination, identification, solubility, appearance, and more. . . Includes uses, ingredients, side effects, dosage, dosage, side effects of herbs.- Herbal medicines are an important part of the official health system in India through Ayurveda, Siddha. Unani, homeopathic yoga and naturopathy. According to the Indian Medicines Act, there is no separate section for herbal medicines and dietary supplements. Indian medicinal plants are a great source for preventing / delaying various diseases. Therefore, this paper reviews the history and status of herbal medicine standards and provides information on herbal medicine through the literature.

KEYWORD:-*Pharmacopoeia , Botenical species , Herbal drug , Ayurveda , Siddha , Unani ,Monograph.*

INTRODUCTION

Many types of plants are used as herbal medicine. Plant parts, including non-wood plants and fruits, needles, stems, seeds, leaves, flowers, stems, roots, etc. Only non-woody plants such as trees and shrubs are considered plants. These plants are used in food, medicine, perfumes, and even some research. Today, herbal medicines are used in different ways. Due to many reasons including high cost of medicine, side effects/harmful effects of synthetic drugs, lack of drugs, population growth, changes in herbal use,. In diseases, medicine is used to treat many human diseases. Indian forests are home to a variety of medicinal plants, many of which are harvested for raw materials to make medicines and perfumes. creams, including a variety of products. Provides scientific information, botanical properties, uses, dosage, side effects, contraindications of medicinal plants. The monograph helps us to learn the current and standard status of herbal medicines such as synonyms, plant species, source, chemical family, medicinal uses as well as medical effects, side effects, etc. (2)Each and every Text contains useful information Based on research and overview research on herbal medicine and brief information on herbal medicines and dietary supplements(3) The purpose of this overview article on herbal medicine monograph is to provide enough information to stimulate researchers. passion and also looking to the future.

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- **Format for Individual Herbal Monograph**

HERBAL MONOGRAPH CONTENT
TITLE
SYNONYM
VERNICULAR NAME
IDENTIFICATION PLANT MORPHOLOGY • Microscopy • Chemical testing • Nyias txheej chromatography • High performance liquid chromatography
PURITY TEST • Foreign matter • Ash content • Loss on drying • Extraction cost
SAFETY ASSESSMENT • Heavy Metals • Microbiological Limit
CHEMICAL COMPOSITION
MEDICINAL USE • Uses identified in folk medicine and unsupported from experiments or clinical studies • Supports Biology and Pharmacology Efficacy, clinical It is taught with experimental data obtained from research.
SAFETY INFORMATION • Scientific Research (Toxicology Research) • Other (Complaints, Precautions, Warnings, Warnings, Warnings)
DOSAGE
STORAGE
REFERENCE

Fig.1: Herbal Monograph Content

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✦ALOE VERA

•Botanical species:-Aloe barbadensis
•Family: Aloeaceae
•Medicinal parts: Leaves.
Areas of use:
•Purpose: As a local protection for wounds, burns, sunburns, and minor punctures.
•Major: Throat at times.
•Minor: Cancer, psoriasis, genital herpes, radiation dermatitis, type 2 diabetes, HIV, ulcerative colitis, irritable bowel, lung cancer prevention.
•Caution: Thyrotoxicosis, heart disease, electrolyte imbalance, diabetes or hypoglycaemia. Avoid excessive and long-term use (more than 2 weeks), because potassium can be lost and may change the electrophysiology of the heart.
•Indications: allergy to aloe or nausea, vomiting, signs and symptoms of gastrointestinal obstruction, gastric obstruction, appendicitis, abdominal pain of unknown origin, children under 12 years of age, pregnancy and breastfeeding, chronic constipation, kidney disease, hemorrhoids, irritable bowel syndrome.
•Side effects: muscle stiffness, diarrhea, dependence or worsening of constipation, red urine. Hypersensitivity and contact dermatitis to aloe.
•Drug interaction: antidiabetic treatment, laxatives, cardiac glycosides, antiarrhythmics. Thiazide diuretics, corticosteroids, licorice root can worsen potassium loss.

✦CINCHONA

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•Botanical species: Cinchona pubescens
•Family: Rubiaceae
•Medicinal parts: dry bark of 6-8 year old trees.
•Symptoms: Main: loss of appetite.
•Major: complaints of lack of appetite, bloating and feeling of fullness.
•Other causes: febrile illness, malaria. ", flu, muscle pain, muscle pain, stomach disease, cancer.
•Caution: Do not exceed the recommended dose because it contains quinine alkaloids, which are toxic in large doses.
•Indications: pregnancy, allergies, stomach ulcers or intestinal ulcers
•Side effects: allergic reactions (skin allergy, fever),increased risk of bleeding.
•Drug interactions: digoxin, anticoagulants, flecainide.
•Dosage: total daily dose: 1 to 3 medicinal grams. Daily dose of liquid extract: 0.6 to 3 grams of cinchona liquid extract. The standard unit dose of the extract is 0.2 grams. The liquid extract dose is 0.5 to 1 gram..

✦CARDAMOM

•Botanical species: - Elettaria cardamomum
•Family:-Zingiberaceae
•Medicinal part: Oil extracted from seeds and fruits and seeds harvested shortly after ripening.
•User Method: -
•Severe: morning sickness, vomiting and diarrhea, loss of appetite, Romhold disease.
•Minor: high blood pressure, cancer.
•Other uses: mouth warmer.
•Contraindications: the presence of gallstones.
•Side view: stone.
•Drug interaction: Not known.
•Dosage: The average daily dose is 1.5 grams of the substance. When using the tincture, the dosage range is 1-2 grams. Candaway™ (Lamberts) See Cinnamon.

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✦BRAHMI

•Botanical species:- Bacopa monnieri
•Family:Scrophulariaceae
•Indications:- Improve learning, mental performance, memory, cognition. neuroprotection against Alzheimer's disease; Great memories. Stomach ulcer, bronchitis and asthma, epilepsy at high doses, irritable bowel syndrome
•Medicinal parts: The aerial parts are mainly leaves and stems.
•Minor: hypothyroidism, heart disease.
•Warning: Hyperthyroidism.
•Side effects: Not known with therapeutic doses.
•Drug interactions:- Cholinergic drugs including perphenazine,prochloroprazine, thioridazine.
•Dosage: dry aerial parts of the plant: 5-10 grams per day. Liquid extract (1:2) or equivalent oral dose: 5-13 ml per day in divided doses. Mentally stimulating effects: 300 mg per day 5
Brain tablets (HealthAid). 150 mg Brahmi extract (20:1) (equivalent to 3000 mg powder), 60 mg Ginkgo biloba extract (50:1) (equivalent to 3000 mg powder) (equivalent to at least 24% ginkgoflavone glycosides and 6 % triterpene glycosides) (1) equal to 120 mg gotu kola powder), 67 mg vitamin E, 60 mg vitamin C, 50 mg L-tyrosine, 50 mg L-phenylalanine, 50 mg L-methionine, 50 mg L-arginine, 50 mg includes alpha-lipoic acid 25 mg phosphatidylcholine, 25 mg phosphatidylserine, 20 mg Co-Q10, 20 mg acetyl-L-carnitine, 20 mg L-glutathione, 20 mg, L-18 mg niacin, 15 mg incl 1.4 mg tannic acid , 3.2 mg riboflavin , 400 mcg folic acid, 200 mcg selenium, 50 mcg vitamin B12.
•Local suppliers: Galea and Galea.

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✦DANDELION

•Biological species :-Taraxacum officinale
•Family: Asteraceae/Compositae
•Medicinal parts: Dried leaves and roots.
•Drug interactions: anticoagulants, antiplatelet agents, thrombolytic agents, low molecular weight heparins, fluoroquinolones, potassium.
•Uses:Meaning: water retention due to many reasons, liver failure.
•Important: digestive disorders, urinary disorders, liver and liver disorders, loss of appetite.
•Other causes: diabetes, rheumatic diseases, urticaria, eczema[3]
•Contraindications: obstruction of the bile duct, empyema of the gallbladder, ileus.
•Side effects: pain of superacidic stomach, allergic reactions.
•Dosage: Tincture: 10-15 drops three times a day. A fresh cup of tea can be drunk in the morning and in the evening.2-Day Detox Plan (HealthAid) See Milk ThistleShape Up Organic (Arkopharma) S

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✦ALFALFA

•Botanical species:- Medicago sativa
•Family: Fabaceae
•Medicinal Parts: Whole flowering plant, germinating seeds.
•Indications:-Hypercholesterolemia; used as a source of nutrients including vitamins.
•Major: Diabetes".; malfunctioning of the thyroid gland.
•Minor: Kidney, bladder & prostate disorders; asthma; arthritis.
•Cautions: Undergoing HRT, taking birth control medications", diabetes".
•Contraindications: History of SLE,children under 181, pregnant or breast-feeding 12
•Side-effects: Photosensitivity", mild GI symptoms (stomach discomfort, diarrhea, flatulence),hypoglycemia, muscle pain, fatigue, abnormal blood cell count.
•Drug interactions: HRT, anti- oestrogen therapy, contraceptive pill, anticoagulants.
•Dose: 5-10g dried herb three times daily; 5-10ml liquid extract (1:1 in 25% alcohol) three times daily. Healthy Mega (HealthAid) see Buckwheat.Alfalfa (Arkopharma).Tablets; Medicago sativa powder 435mg. Local Distributor: Pharmacos Ltd. Alfalfa 500mg (Power Health)
Tablets; Alfalfa powder 500mg. Local Distributor: Galea & Galea
Eye Vir (HealthAid) see Eyebright Formula VM-75 (Solgar) see Buckwheat Slim-Rite (HealthAid) Tablets; Alfalfa leaf powder 200mg. buckthorn extract 75mg, cascara sagrada extract 50mg, birch extract 40mg, taurine 40mg, dandelion extract 20mg, uva ursi extract 20mg, bladderwrack extract 17mg, barberry root powder 10mg, ginger root powder 5mg, chicory powder 3mg. parsley seed powder 2mg, nasturtium extract 2mg, juniper berry powder 2mg, curcuma root powder 250mcg.
Local Distributor: Galea & Galea

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✦Clove

•Botanical species :-Syzygium aromaticum

•Family: Myrtaceae
•Medicinal parts: dried flower buds, leaves, stems
•Purpose: toothache, pain and inflammation of the mouth and throat mucosa, for oral hygiene.
•Major: Stomach ulcers, bloating, cramps, bloating, nausea, headache, chills
•Minor: Cough, treatment of minor wounds, ulcers, acne and other inflammatory (local) diseases", chronic inflammation, herpes simplextype of virus
•Other: neuralgia, bronchitis, whooping cough" .
•Warning: No knowledge
•Contraindications: impaired liver function, patients taking paracetamol or anticoagulants. : Anticoagulants, platelet inhibitors, thrombolytic agents, low molecular weight heparins
•Inside: three times a day: dry buds, or 120-300 mg as an infusion of 2 cloves in cup of warm water, 20 drops of clove. oil, 0.05- 0.1 ml (2-4 drops)".In mouthwash it is like 1-5% essential oil.
Coloclear Extra (High Nature) See Flaxseed Erbalax Forte Compress (Erba Vita) See SennaJointace Gel (Vitabiotics) See GingerJointace Patch (Vitabiotics) See Ginger\ n Natural Herbal Inhaler Oil (Numark) See EucalyptusNeuralta Migraine (Alta Care) See PeppermintTeenstick (Arkopharma)Roll-on ; Essential oils of clove, geranium, palmarosa, tea tree, ylang.
Local distributor: Pharmacos Ltd..

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✦CINNAMON

•Botanical species:-Cinnamomum verum
•Family: Lauraceae
•Medicinal Parts: Oil extracted from bark, bark of younger branches, leaf oil. •Indications: Digestive disorders •such as nausea, flatulence, dyspepsia & GI colic; loss of appetite.
•Major: Diarrhoea in children, common cold, influenza, winter chills, poor circulation".
•Minor: Type 2 diabetes, gestational diabetes, Helicobacter pylori infection.
•Others: Cancer
•Contraindications: Pregnancy
(except in amounts normally used in foods), allergy to cinnamon or Peru balsam, in cases of fever of unknown origin, active stomach or duodenal ulcers.
•Side-effects: Allergic skin and mucosal reactions may occur in sensitive individuals, arising mainly from cinnamaldehyde (the major component of the essential oil).
•Drug interactions: Hypoglycaemic agents.
•Dose: Three times daily: dried bark, 0.5-1 gm as an infusion; liquid extract (1:1 in 70% alcohol), 0.5-1 ml; tincture, 2-4 ml.
- Shape Up Ultimate (Arkopharma) see Fenugreek
Altasterol Stimulant (Alta Care)
Candaway™ (Lamberts) Capsules, Cinnamon bark 3750mg
(provided by 750mg of a 5:1 extract), olive leaf 800mg (provided by 200mg of a 4:1 extract), fennel seed 400mg (provided by 100mg of a 4:1 extract), cardamom oil 100mg.
•Local Distributor: Health Plus

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✦GINGER

•Botanical species:- Zingiber officinale
•Family: Zingiberaceae
• Medicinal Parts: Rhizome.
•Indications: Sore throat, upper respiratory tract infections, motion sickness, morning sickness in pregnancy, postoperative nausea, chemotherapy-induced nausea.
•Major: Dyspeptic complaints, osteoarthritis, rheumatoid arthritis, migraine, anorexias.
•Minor: Colds, shortness of breath.
•Others: Primary dysmenorrhoea 176, mastitis (externally).
•Cautions: Gastric ulcers or reflux, gallstones, children under 6 years, pregnancy. Suspend use of high dose supplements (>10g) 1 week before major surgery.
•Side-effects: Gastric irritation, heartburn, bloating, contact dermatitis with topical use.
•Drug interactions: Anticoagulants (warfarin), antiplatelets, thrombolytic agents, nifedipines.
•Dose:-
Ginger (Arkopharma) Capsules; Ginger root powder 365mg. Local Distributor: Pharmacos Ltd.
Ginger (Lamberts) Capsules; Ginger root 14,400mg (provided by 120mg of a 120:1 extract). Local Distributor: Health Plus
Ginger (Quest)
Tablets; Ginger root extract 250mg, providing gingerols & essential oils. Local Distributor: Pharma MT Ltd.
Ginger Root (HealthAid)
Liquid; Ginger root 1:3 (equiv. of 330mg of ginger root herb in 1ml).
Liquid extract (1:2): 0.7-2.0 ml/day. Dried root: 1-3 gm daily in divided doses or 1-2 gm taken as a single dose for nausea and vomiting.
Ginger Root Extract (HealthAid)
Tablets; Standardised ginger root extract (4:1) 138mg (standardised to contain at least 5% ginerols extract) equiv. to 550mg of ginger root powder.
• Local Distributor: Galea & Galea.

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✦FENNEL

•Botanical species:-Foeniculum vulgare
•Family: Umbelliferae
•Medicinal Parts: Seeds, oil extracted from ripe fruit and dried ripe fruit.
•Indications:-Internal
Dyspeptic complaints including flatulence, infantile colic, eructation, sluggish digestion, appetite suppressant, feeling of fullness
External:-Principal: Idiopathic hirsutism conjunctivitis, blepharitis (as an eye wash), sore throat, pharyngitis (as a gargle) .
•Major: Cough, bronchitis, catarrh of the upper respiratory tract
•Minor: Anorexia, amenorrhoea, dysmenorrhoea, to stimulate milk flow in nursing mothers'".
•Contraindications: Hypersensitivity
to other plants of the Umbelliferae family, pregnancy, pediatrics
•Side-effects: Cross sensitivity among patients with celery allergy, allergic reactions of the skin and respiratory tract.
•Drug interactions: Ciprofloxacin.
•Dose: Daily dose: 5-7 gm drug; 10-20 gm fennel syrup or fennel honey,or 5-7.5 gm of compound fennel tincture". 2-Day DetoxPlan (HealthAid) see Milk Thistle Performance Detox (Arkopharma) see Green Tea . Shape Up Day & Night (Arkopharma) see Green Tea

CONCLUSION

The current monograph investigation came to the conclusion that the monograph is available in many pharmacopoeias. It contains comprehensive standard information on many herbal plant species and attributes.In the past, the plant was seen as a symbol of rebirth and new life. This herb poses no health hazards when consumed in large quantities. Almost all herbs are rich in nutrients and health benefits. The leaves and roots of the plant are used primarily because the entire plant is edible. In the religious world, chervil is regarded as the plant of immortality and is used as an incense or elixir to speak with the spirits of the dead or the human soul (as a guide for fresh souls to find peace and tranquility). is a part of amulets that is also said to have a magical function.

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RESULT

Herbal remedies are primarily used to treat chronic illnesses rather than life-threatening ones and to promote wellness. However, when Western medicine fails to treat a condition, the use of traditional medicines increases. The production, identification, use, and side effects of the drug are all covered by the herbal drug monograph.

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A REVIEW ON DOCUMENTATION IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

In the pharmaceutical industry, documentation is critical for ensuring product quality, regulatory compliance, and operational efficiency. This process involves the creation, management, and storage of various documents, such as Standard Operating Procedures (SOPs), batch records, validation protocols, and reports. Pharmaceutical documentation serves as the foundation for traceability and transparency across all phases of drug development, manufacturing, and distribution. Effective documentation practices help prevent errors, facilitate audits, and ensure adherence to Good Manufacturing Practices (GMP). Regulatory authorities such as the FDA and EMA require accurate and up-to-date documentation to evaluate compliance with safety and quality standards. The industry relies on a structured approach to documentation, incorporating both manual and electronic systems, to manage the vast amount of data and ensure the integrity of the information recorded. This abstract discusses the importance of proper documentation management and the challenges faced by the industry in maintaining accuracy, consistency, and compliance.

KEYWORDS: *Documentation in pharmaceutical industry, Good documentation practices (GDP), Quality control Documentation in pharmaceutical industry*

1.INTRODUCTION

Effective documentation of these elements ensures regulatory adherence, smooth audits, and the safeguarding of product quality. The transition from manual to electronic systems, while improving data management, brings challenges in maintaining accuracy, security, and real-time updates. This abstract explores the integral components of documentation in the pharmaceutical industry, focusing on DMF, CTD/eCTD, BMR, MFR, audit plans, and reports, and their importance in maintaining a high standard of compliance and operational excellence.

Documentation plays a pivotal role in the pharmaceutical industry to ensure product quality, regulatory compliance, and operational efficiency. Key documents include Drug Master Files (DMFs), which provide confidential information about the manufacturing process and facilities, and are critical for regulatory approval. The industry also follows structured audit plans and reports to ensure adherence to Good Manufacturing Practices (GMP), allowing for regular assessments of compliance with both internal standards and regulatory requirements.

1.1 History of documentation In the pharmaceutical industry:

The history of documentation In the pharmaceutical industry is deeply intertwined with the development of the industry itself, particularly in terms of regulations, quality control, and the need for safety and efficacy in medicines. Below is an overview of the evolution of pharmaceutical documentation:

1.1.1 Early Practices (Pre-19th Century)

• Ancient Civilizations: Pharmaceutical documentation began with ancient medical texts such as the Ebers Papyrus (1500 BCE, Egypt), which recorded medicinal recipes. Similarly, Indian Ayurveda texts and Chinese Materia Medica contained medicinal records.
• Middle Ages and Renaissance: European apothecaries and pharmacists kept detailed handwritten records of medicinal preparations to ensure consistency. Herbal books (herbals) were widely used.

1.1.2 Industrial Revolution and 19th Century

• 1800s: The advent of large-scale drug manufacturing highlighted the need for standardized processes and record-keeping.

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• 1848: The United States passed the Drug Importation Act, marking an early regulatory requirement for drug purity, indirectly emphasizing the importance of documentation.
• Pharmacopoeias: National pharmacopoeias (e.g., the British Pharmacopoeia, 1864) formalized standards for drug composition, requiring detailed documentation of formulations.

1.1.3 20th Century: Birth of Modern Pharmaceutical Documentation

• 1906: The U.S. Pure Food and Drug Act required manufacturers to ensure accurate labeling, necessitating batch records and documentation of ingredients.
• 1938: The U.S. Food, Drug, and Cosmetic Act (FDCA) was enacted following the 1937 Elixir Sulfanilamide tragedy. It required safety data to be submitted to the FDA, introducing systematic clinical trial documentation.
• 1940s-1950s: World War II and the post-war boom in antibiotics (e.g., penicillin) led to the need for quality assurance documentation in mass production.
• 1970s-1990s: Global Harmonization and Electronic Records
• 1976: The Medical Device Amendments extended documentation requirements to medical devices.
• 1980s: Computerized systems began to replace paper documentation, leading to the introduction of electronic records in pharmaceutical manufacturing and clinical trials.
• 1995: The establishment of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) led to harmonized documentation standards across regions.
ICH Guidelines: Key guidelines include ICH E6 (Good Clinical Practice) and ICH Q7 (GMP for APIs).
• 1997: The FDA introduced the 21 CFR Part 11 regulation, setting standards for electronic records and signatures.

1.1.4 21st Century: Digital Transformation and Advanced Standards

• 2000s: The pharmaceutical industry saw widespread adoption of electronic document management systems (EDMS) and enterprise resource planning (ERP) tools to manage documentation more efficiently.
• 2010s: Regulatory agencies increasingly emphasized data integrity, requiring detailed documentation of raw data, metadata, and audit trails.
• 2020s: Emerging technologies such as blockchain, artificial intelligence, and electronic batch records (EBR) are revolutionizing documentation, ensuring real-time tracking, transparency, and compliance.

1.2 Key Milestones in Pharmaceutical Documentation

• 1848: U.S. Drug Importation Act
• 1906: U.S. Pure Food and Drug Act
• 1938: Food, Drug, and Cosmetic Act
• 1963: GMP regulations introduced
• 1995: ICH established
•1997: FDA 21 CFR Part 11 implemented
The evolution of pharmaceutical documentation reflects a continuous effort to ensure drug safety, efficacy, and quality through meticulous record-keeping and compliance with global standards.

2.RETENTION AND RETRIEVING OF RECORDS

Retention and retrieval of documentation are critical processes in ensuring information is properly stored, organized, and accessible when needed.

2.1 RETENTION

INTRODUCTION
Records are information (stored in any form or medium) that are an important Part of the functioning of an organization and are an essential aspect in fulfilling Its legal obligations. It is therefore imperative to give due care to the maintenance Of this vital resource.

2.1.2 DEFINITION

The Biopharmaceutical Development Program(BDP) Records Retention Standard operating Procedure (SOP) defines the period of time during which records are maintained And specifies the disposition of records.

2.1.3 OBJECTIVE

Over time, offices generate numerous records, including files, registers, and dossiers. Ensuring the relevance and quick retrieval of these records is crucial. This Record Retention and Disposal Manual aims to provide guidelines for the Personnel Department to retain official records in compliance with applicable laws and to dispose of redundant records at the appropriate time. By following these guidelines, operations can become more efficient, and valuable office space can be freed up for better utilization.

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2.1.4 RETENTION PERIOD

Records must be retained according to operational, legal, regulatory, and fiscal requirements. The BDP maintains records for at least ten years, unless otherwise specified in writing for certain documents or categories of documents.

2.1.5 RECORDS RETENTION POLICY & SCHEDULE(MANAGE THE ORGANISATION)

Global policy references for record management, detailing various record categories, their descriptions, examples, and retention periods as per the proposed India SOP. Below is a consolidated overview:

1. Accounting Records (GRS042)

Documentation of payment and receipt transactions, such as account reconciliation files, bank statements, and purchase orders.
Retention Period: Minimum 8 years.

2. Audit Records and Audit Schedules (GRS043, GRS077)

Records related to compliance examinations, audit schedules, findings, and recommendations for internal and external suppliers or contractors.
Retention Period: 7 years after the audit is closed.

3.Benefits Programme Records (GRS044)

Covers documentation for benefit programs, including pension funds, retirement savings, and health insurance plans.
Retention Period: 12 years after the program ends.

Likewise the retention of records are done

Global policy Ref. #	Record Category	Description	Examples	Retention Period as per Proposed India SOP
GRS042	Accounting Records	Documentation detailing payment / receipt transactions within the Company or between the Company and others.	Account Analysis: Account Reconciliation Files: Accounts Payable Batch Files: Accounts Receivable Files: Balance Sheets Bank Statements Cash Receipts Cheque Registers Cheque Requests Credit Cardholder Files Credit Case Files Education Reimbursement Forms Expense Reports Invoices Monthly Account Control Reports Purchase Orders Purchase Requisitions Travel & Entertainment Files Voided Cheques	For not less than 8 years immediately preceding current year
GRS043,GRS 077	Audit Records, Audit Schedules	a) Documentation relating to the examination of compliance with internal and external controls, policies and procedures, laws and regulations, by the Company and its external suppliers and contractors; and improved process recommendations. b) Audit schedules for internal (Company) and external suppliers and contractors.	a) Action Plan & Resolution Records: Audit Findings: Audit Plans: Audit Reports: Audit Schedules Audit Timetables Compliance Overview Documents Self-Assessments of Compliance required by the Company and its Regulators b) Audit Plans: Audit Timetables	7 Years after Audit is Closed
GRS044	Benefits Programme Records	Documentation detailing the Company's various benefit programmes including pension fund membership, retirement savings plans, health and life insurance plans.	Benefit Plan Documents: Cash Balance Plan Documents: Employee Assistance Programme Files: Matching Gift Programme Files: Pension Files Retirement Savings Plan Files	12 Years after Life of Programme
GRS045	Business Continuity Planning Records	Documentation detailing plans and preparations necessary to minimise loss and maximise the continuity of critical business functions in the event of an unforeseen business interruption.	Business Impact Analysis Documents: Contingency Resource Information: Disaster Recovery Plans: Emergency Response Plans: Findings Reports Mock Disaster Project Files	Until Superseded by New Version
GRS046	Communication Records – External	Communication materials prepared by or for the Company for external use with investors, stock analysts, corporate regulators and the general public.	Briefing Books: Company Promotional Information: Executive Biographies : Government Relations Files: Investor Relations Files Lobbying Records Press Releases / Kits Product Information Public Relations Records Request / Reply Letters Speeches – External Submissions to Corporate Regulators	5 Years
GRS047	Communication Records – Internal	Internal Company communication materials that are widely distributed throughout the organisation or within large business areas.	Bulletins / Announcements: Company Newsletter / Publications: Employee Communications	3 Years
GRS048	Compensation Programme Records	Documentation detailing terms and conditions of the Company's various compensation programmes.	Bonus Programme Records: Compensation Surveys: Salary Range History Records Sales Incentive Programme Records Special Incentive Programme Records Stock Option Programme	10 Years after Superseded by New Programme

Fig.GlaxoSmithKline Pharmaceuticals Limited,Records Retention Policy & ScheduleTable of documents Retention

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2.2 RETRIEVAL MAINTAINING

2.2.1 DEFINITION

The process of locating and accessing specific information or data from a system, database, or set of records. This can involve searching through various formats, such as text, images, or databases, to find relevant content or resources needed for reference or use.

Retrieving in documentation involves the systematic process of finding and accessing specific information stored in various types of documents, such as manuals,reports,databases, or digital archives.

2.2.2 DATA RETRIEVAL PROCESS

Identification: Determining what information is needed.
Locating: Finding the documents that contain the required information.
Extraction: Accessing and pulling the relevant content from those documents.

2.2.3 CHALLENGES

Volume of Information: Large datasets can make retrieval time-consuming.
Quality of Metadata: Poorly tagged documents can hinder effective searching.

2.2.4 APPLICATIONS

Legal and Compliance: Retrieving documents for audits or investigations.
Business Operations: Accessing policies, procedures, or records for decision-making

3. STANDARD OPERATING PROCEDURE (SOP)

A Standard Operating Procedure (SOP) is a set of written instructions that outline routine or repetitive tasks followed by an organization. SOPs play a key role in ensuring the success of a quality system, as they provide essential information for individuals to perform tasks correctly. Furthermore, they promote consistency in the quality and integrity of products or end-results.
The term “SOP” is sometimes used interchangeably with terms like protocols, instructions, and worksheets. The definition of SOPs can vary depending on the area in which they are applied.

3.1 OBJECTIVES

The task involves developing explanatory texts for a pharmacy curriculum and reference textbook, as well as creating model standard operating procedures (SOPs) for key quality and operational activities in the pharmaceutical file

3.2 PURPOSE

Standard Operating Procedures (SOPs) define the recurring work processes within an organization. They are designed to ensure that activities are performed consistently and in compliance with both technical and quality system requirements. Additionally, SOPs support data quality by documenting the proper methods to be followed.

Standard operating procedures (SOPs) outline fundamental programmatic and technical actions, such as analytical processes and procedures for maintaining, calibrating, and using equipment. They are designed to be specific to the organization or facility conducting the activities, helping to maintain quality control and quality assurance processes while ensuring compliance with governmental regulation

3.3 BENEFITS OF SOP

1.To ensure that processes continue uninterrupted and are completed on a Described Schedule. Ensure against process shut-downs caused by equipment failure or other Facility damage.
2.To ensure that approved procedures are followed in compliance with company and Government regulations. Well-written SOPs help ensure that government regulations Are satisfied. They also demonstrate a company good-faith intention to operate properly.
3. To serve as a checklist for auditors. Auditing job performance is a process similar to Observation mentioned in the previous item only it usually involves record keeping. SOPs should serve as a strong basis when detailed audit checklists are developed. [DMPI]

3.4 METHOD

3.4.1 Design

Follow the general directions of SOP F08-1 ‘Capsules, design composition´ if it concerns a new Preparation. The solvent method is preferably used for mixtures with very unfavourable mixing ratios(< 5 mg active substance). The method needs careful testing and validation.

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Choice of a suitable organic solvent. In a suitable organic solvent the drug should dissolve easily. The solvent must …

Active substance and dose	Solvent and amount	Deposition and ratio	Diluent	Reference
.....	.....	.....	.....	.....

Determination of amount of diluent
[……]
Dissolving the active substance
[……]
Filling of the capsules
[……]
In process controls
[……]
Control checks
[……]
References
[……]

4. MASTER FORMULA RECORD AND BATCH FORMULA RECORD

4.1 MASTER FORMULA RECORD

A document or set of documents specifying the starting materials and their quantities, along with the packaging materials, the processing instructions (including in-process controls), and a description of the procedure and precautions required to produce a specified quantity of a finished product.

4.1.1 The master Formula shall include

1. The name of the product together with product reference code relating to its Specifications.
2. The patent or proprietary name of the product along with the generic name, a Description of the dosage form, strength, composition of the product and batch Size
3. Name, Quantity, and Reference Number of Starting Materials
4. List all starting materials to be used, including their names, quantities, and reference numbers Include any substances that may disappear during processing.
5. Detailed Stepwise Processing Instructions Provide step-by-step instructions for processing Include the time required for each step.

4.1.2 Example

Master Formula Record (MFR) used in pharmaceutical manufacturing for the compression process of XYZ Tablets (Calcium Carbonate and Zinc Sulfate). It outlines the standard operating parameters and in-process checks for a batch size of 1,00,000 tablet

This record ensures that the manufacturing process follows strict quality controls, and every critical parameter is monitored periodically during tablet production. It helps maintain consistency, ensures regulatory compliance, and ensures the quality of the final product.

Key Elements
. Product Details:Name: XYZ Tablets
Compression Parameters:Temperature and Humidity:

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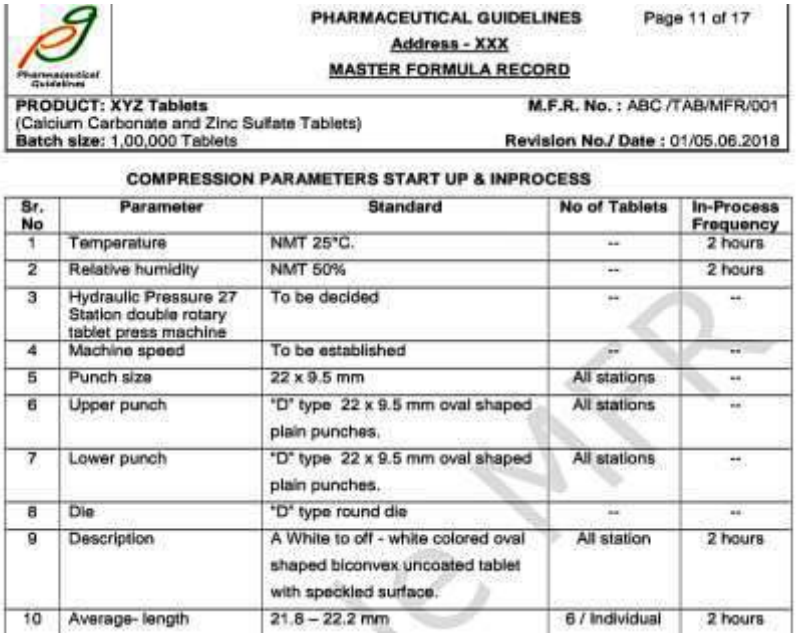

PHARMACEUTICAL GUIDELINES Page 11 of 17
Address - XXX
MASTER FORMULA RECORD

PRODUCT: XYZ Tablets M.F.R. No. : ABC /TAB/MFR/001
(Calcium Carbonate and Zinc Sulfate Tablets)
Batch size: 1,00,000 Tablets Revision No./ Date : 01/05.06.2018

COMPRESSION PARAMETERS START UP & INPROCESS

Sr. No	Parameter	Standard	No of Tablets	In-Process Frequency
1	Temperature	NMT 25°C.	--	2 hours
2	Relative humidity	NMT 50%	--	2 hours
3	Hydraulic Pressure 27 Station double rotary tablet press machine	To be decided	--	--
4	Machine speed	To be established	--	--
5	Punch size	22 x 9.5 mm	All stations	--
6	Upper punch	"D" type 22 x 9.5 mm oval shaped plain punches.	All stations	--
7	Lower punch	"D" type 22 x 9.5 mm oval shaped plain punches.	All stations	--
8	Die	"D" type round die	--	--
9	Description	A White to off - white colored oval shaped biconvex uncoated tablet with speckled surface.	All station	2 hours
10	Average- length	21.8 – 22.2 mm	6 / Individual	2 hours

Fig.Master formula record of xyz tablet

4.2 BATCH FORMULA RECORD (BFR): DETAILED OVERVIEW

A Batch Formula Record (BFR) is a standardized document used in pharmaceutical, biotech, and food industries to outline detailed instructions and procedures for producin specific batch of a product. It is a vital part of Good Manufacturing Practices (GMP) and ensures consistency, quality, and compliance.

4.2.3 PURPOSE OF A BATCH FORMULA RECORD

- To provide step-by-step guidance for manufacturing a product batch.
- To ensure that every batch meets the quality standards and regulatory requirements.
- To document all processes and materials for traceability.
- Ensures that every batch of a product is manufactured using the same formula and process.

4.2.3 Benefits

Meets regulatory requirements set by agencies like the FDA, EMA, or other local authorities.
Demonstrates adherence to Good Manufacturing Practices (GMP) or ISO standards.
Provides a detailed record of all raw materials, quantities, and steps taken during production.

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COMPANY NAME	BATCH MANUFACTURING RECORD			Page: 1 of 8
Department : Production	Title : Tongkat Ali Tablet			Batch Record : BMR-001
	Name	Signature	Date	Revision No. : 0
Prepared by :	Production Manager			
Approved by :	QA Manager			Effective Date : 1 January 2016

1. Product Details	
Description	Tongkat Ali 250mg Tablet Colour: Pale Shape: Round/ Biconvex
Batch Quantity	Batch size: 50 kg Approx No. tablets: _____
Packaging	Bottle of 60's
Storage Conditions	Ambient - conditions. store in tight container protected from light and moisture

2. Production Batch Record Issuance		
Issued By – Issuer has reviewed the Batch Record to ensure that the copy is a complete, accurate copy of the Master Batch Record.		
(Print) Issued By – Quality Assurance	Signature	Date
Issued To – Production has reviewed the Batch Record to ensure that the copy is a complete and correct. Production is responsible for the Batch Record following issuance.		
(Print) Issued By – Quality Assurance	Signature	Date

Fig. Batch Formula Record Table

4.2.4 KEY COMPONENTS OF A BATCH FORMULA RECORD

General Information

- Product Name: Full name of the product being manufactured.
- Product Code: Unique identifier for the product.
- Batch Number: Unique number assigned to the batch for traceability.
- Batch Size: Quantity to be manufactured, often specified in units, liters, or kilograms.
- Dosage Form: Tablet, capsule, syrup, cream, etc.

5. AUDIT PLANNING AND REPORT

5.1 Audit

An audit, in simple terms, can be described as the inspection of a process or system to ensure it meets the requirements for its intended use. According to the International Organization for Standardization (ISO), an audit is defined as a "systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the verification criteria are met."

In the pharmaceutical industry, audits are virtual means for Assessing compliance with the established objectives defined in the Quality system and thus paving the way for the continuous Improvement program by providing feedback to management .

5.2 GOALS OF AN AUDIT

The goal of this process is to evaluate existing activities and documentation to determine whether they meet established standards. An audit assesses the strengths and weaknesses of quality control and quality assurance processes. The results help improve these processes and create a better system for the benefit of the company. In the pharmaceutical industry, every product manufactured has specific characteristics that must be quantified or qualified through laboratory tests. Quality control and quality assurance serve as essential control and balance systems to ensure compliance and reliability.

5.3 AUDIT PLANNING PROCEDURES

To conduct an audit effectively and efficiently, the work must be properly planned and controlled. Audit planning involves formulating a general strategy that sets the direction of the audit, outlines its expected scope and conduct, and provides guidance for developing the audit program. The nature and extent of planning will vary based on factors such as the size and complexity of

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the enterprise, the commercial environment in which it operates, the methods used for processing transactions, and its reporting requirement.

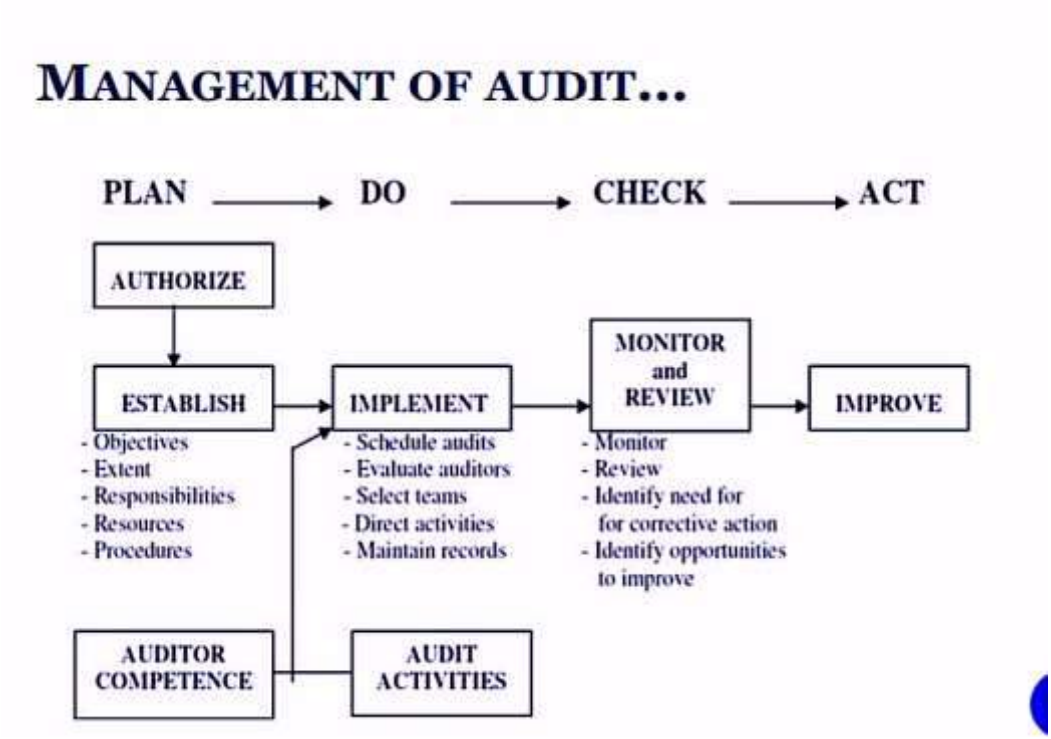

Fig.Management of Audit chart

5.4 AUDIT REPORT

The audit report is a key outcome of an audit, presenting the results of the auditor's investigation. It provides accurate and clear data, along with recommendations that outline corrective actions necessary for improvement.

Nonconformities identified through audits can be classified into two types: major and minor, based on the severity of the infraction and the corrective actions required. A minor non-conformance indicates a system weakness that does not significantly impact the company's operations or quality control. It can typically be resolved quickly and with minimal effort.

Quality Management Audit Report Template

It is a form designed to document and standardize the process of conducting a quality management audit. Here's a breakdown of the sections in the template:

1. Header Information:Report Name: Title of the audit report.
2. Audit Summary: A concise summary of the audit findings.
3. Audit Objective: States the purpose or goal of the audit.
4. Audit Participants: Names of individuals involved in the audit process.
5. Checklist(s)/Guideline(s) Used: References to the checklists or standards followed during the audit.

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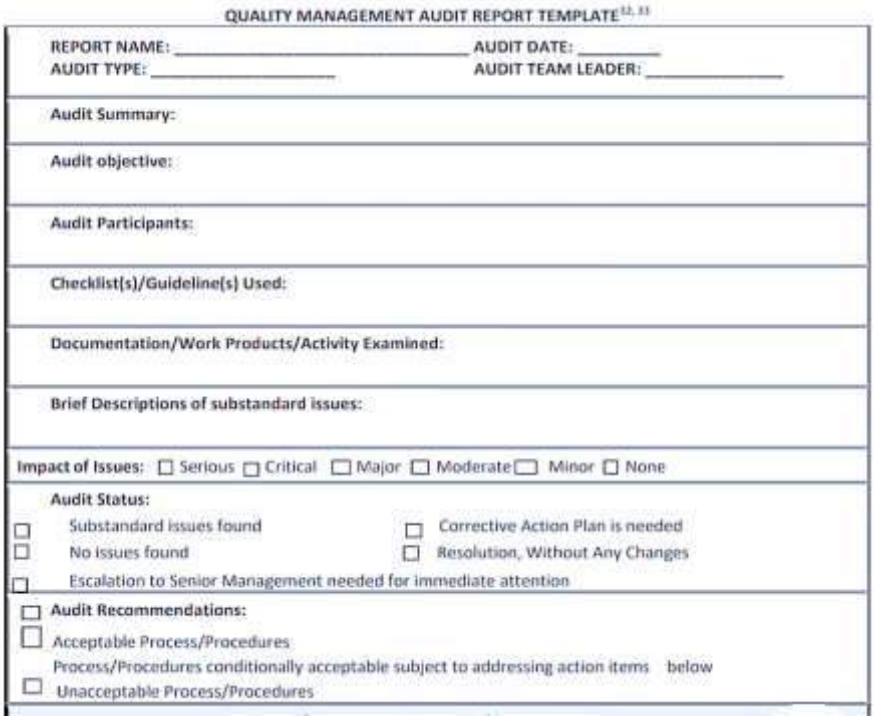

QUALITY MANAGEMENT AUDIT REPORT TEMPLATE[12, 13]

REPORT NAME: _____ AUDIT DATE: _____
AUDIT TYPE: _____ AUDIT TEAM LEADER: _____

Audit Summary:

Audit objective:

Audit Participants:

Checklist(s)/Guideline(s) Used:

Documentation/Work Products/Activity Examined:

Brief Descriptions of substandard issues:

Impact of Issues: ☐ Serious ☐ Critical ☐ Major ☐ Moderate ☐ Minor ☐ None

Audit Status:

☐ Substandard issues found ☐ Corrective Action Plan is needed
☐ No issues found ☐ Resolution, Without Any Changes
☐ Escalation to Senior Management needed for immediate attention

☐ Audit Recommendations:

☐ Acceptable Process/Procedures
Process/Procedures conditionally acceptable subject to addressing action items below
☐ Unacceptable Process/Procedures

Fig. Quality Management Audit Reports Template

This template is typically used in quality management systems to ensure consistency, identify areas for improvement, and document compliance or non-compliance with standards.

6. SUBMISSIONS DOCUMENTS TO DRUG MASTER FILES(DMF)

6.1 Drug Master File (DMF)

A Drug Master File (DMF) is a voluntary submission to the Food and Drug Administration (FDA) that provides confidential, detailed information about facilities, processes, or articles involved in the manufacturing, processing, packaging, and storage of human drugs. While not required by law or FDA regulation, a DMF may be submitted at the discretion of the holder. The information contained in a DMF can support various regulatory submissions, including an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or amendments and supplements to any of these.

6.1.1 TYPES OF DRUG MASTER FILES

There are five types of DMF's:

- I Plant information (It has been discontinued)
- II Drug substance, drug product, intermediates and material used in Their manufacture
- III Packaging
- IV Excipients
- V FDA Accepted Reference Information (Not much in use)

By fulfilling these roles, DMFs contribute significantly to the pharmaceutical industry by ensuring drug quality, safety, and efficacy while protecting proprietary information.

6.1.2 SUBMISSIONS TO DRUG MASTER FILES(STEPS)

1.A DMF submission should include a transmittal letter, administrative information about the submission, and the specific details to be included in the DMF as outlined in this section.
2.The DMF must be in the English language. Whenever a submission contains information in another language, an accurate certified English translation must also be included.
3.Each page of each copy of the DMF should be dated and consecutively numbered. An updated table of contents should be included with each submission.

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4.This flowchart outlines the regulatory requirements for Drug Master Files (DMFs) across different markets, focusing on regulated and emerging markets. Here's the explanation:

6.1.3 DRUG MASTER FILE (DMF) REGULATORY REQUIREMENTS:

The chart begins with the general regulatory requirements for DMFs, which are detailed documents submitted to regulatory authorities to provide confidential information about manufacturing, processing, packaging, and storage of drugs.

• DMF related Regulated Market (USA):

For regulated markets like the USA, the DMF requirements are based on ICH-CTD (International Council for Harmonisation - Common Technical Document) guidelines.ICH-CTD serves as a harmonized framework for the preparation and submission of regulatory dossiers.

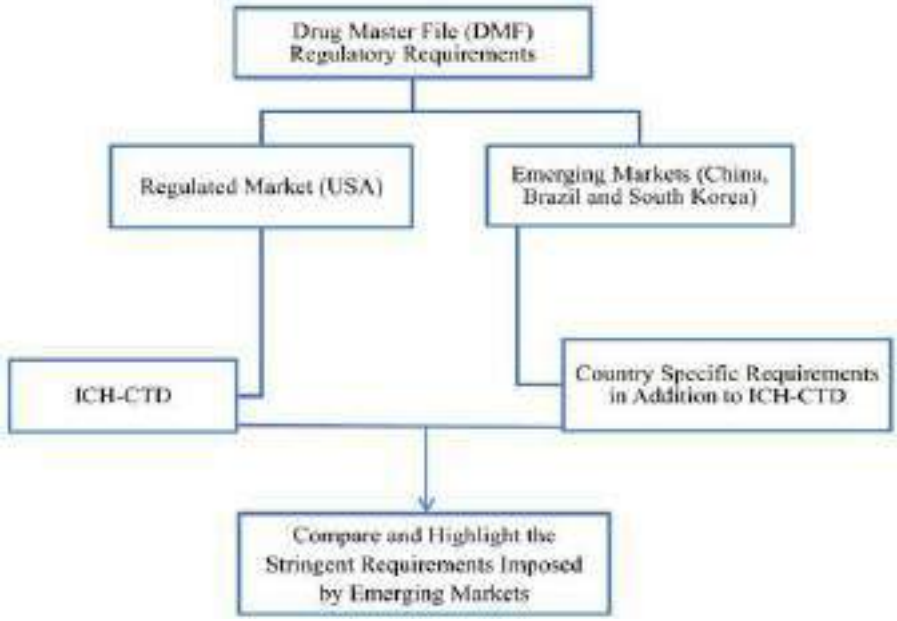

Fig. Drug Master File (Dmf) Regulatory Requirements

• Emerging Markets (China, Brazil, South Korea)

Emerging markets may follow ICH-CTD guidelines but often impose additional country-specific requirements. These unique regulations may reflect local standards, procedures, or legal frameworks, making compliance more challenging.

• Comparison and Highlighting of Stringent Requirements:

The chart emphasizes the importance of comparing the regulatory landscapes of emerging markets with the USA.It specifically focuses on identifying and highlighting stricter or more complex requirements imposed by emerging markets compared to those in regulated markets.

In summary, the flowchart provides a high-level comparison between the regulatory requirements in the USA (a regulated market) and emerging markets, with an emphasis on identifying the additional, more stringent requirements in the latter.

6.1.4 ROLE OF DMF

1.Confidentiality Protection:

A DMF allows manufacturers to maintain the confidentiality of their proprietary information (e.g., formulation, manufacturing process) while sharing necessary technical details with regulatory authorities.

2.Streamlining Regulatory Approvals:

DMFs support the regulatory review process by providing detailed information about specific components (e.g., active pharmaceutical ingredients (APIs), excipients, or packaging materials) to ensure compliance with quality and safety standards.

3.Facilitating Collaboration:

Contract manufacturers, suppliers, and pharmaceutical companies can use DMFs to share critical data without disclosing proprietary details to their partners, thus enabling smoother collaborations

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4.Ensuring Compliance:
By submitting a DMF, manufacturers demonstrate compliance with current Good Manufacturing Practices (cGMPs) and regulatory requirements, supporting the approval process for associated drug products.

5.Reducing Duplication of Effort:
A single DMF can be referenced in multiple applications by different pharmaceutical companies, reducing the need for redundant submissions and reviews.

6.2 COMMON TECHNICAL DOCUMENT (CTD)
The Common Technical Document (CTD) is a key project of the International Council for Harmonisation (ICH) designed to streamline the drug registration process by avoiding duplication and the need for translation into regional languages. Using this format, applicants can submit a single application simultaneously to multiple countries for the registration of their drug product. The CTD is an internationally accepted format for preparing applications for novel medications intended for submission to regional regulatory authorities in participating countries.

6.2.1 The Common Technical Document is organized into Five modules
- Module 1-Administrative and prescribing information
- Module 2-Overview and summary of modules 3 to 5
- Module 3- Quality (pharmaceutical documentation)
- Module 4-Non clinical document safety (toxicology studies)
- Module 5-Clinical document efficacy (Clinical studies)

6.2.2 CTD TRIANGLE
The CTD triangle refers to the structure of the Common Technical Document (CTD), a standardized format for submitting information to regulatory authorities for drug approval. It was established by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) to streamline and harmonize submissions across regions like the U.S., Europe, and Japan.

CTD TRIANGLE

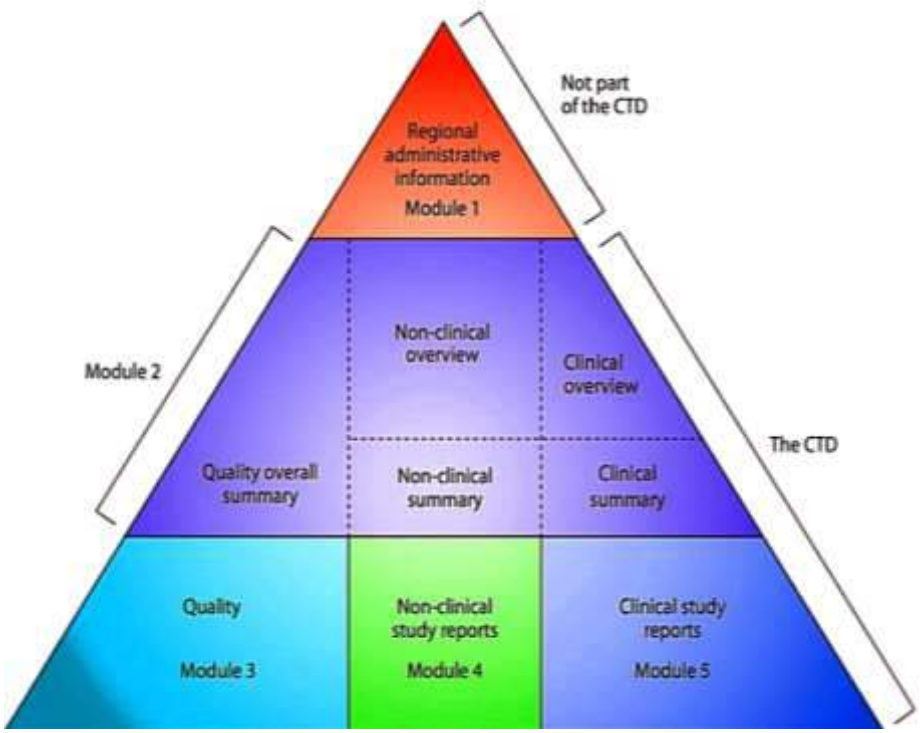

Fig. common technical Documentation Triangle including 5 module

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6.2.3 CTD TRIANGLE: KEY COMPONENTS

The CTD is represented as a triangle to highlight its hierarchical structure, divided into five modules:

1. Module 1: Regional Administrative Information
2. Module 2: Common Technical Document Summaries
3. Module 3: Quality
4. Module 4: Nonclinical Study Reports
5. Module 5: Clinical Study Reports

6.2.4 Significance of the Triangle

• The base represents detailed data (Modules 3, 4, 5), which supports the submission.
• The middle (Module 2) summarizes and organizes the data for easier review.
• The top (Module 1) ensures region-specific compliance for submission.

This structured approach facilitates global regulatory harmonization, reduces duplication, and improves the efficiency of drug review processes.

6.3 eCTD

The eCTD is the standard format for submitting applications, amendments, supplements, and reports to FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

6.3.1 Submissions Using the eCTD Specifications Guidance for Industry

• Under section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), sponsors and applicants must submit specified submission types to the Food and Drug Administration (FDA) electronically and in the format specified by the Agency. This requirement applies at least 24 months after the issuance of a final guidance document in which the FDA has defined the electronic format.
• This guidance document, along with the technical specification documents it incorporates by reference, outlines how sponsors and applicants must organize the content of their electronic submissions for all submission types under section 745A(a) of the FD&C Act. Additionally, more detailed technical instructions are provided in a separate eCTD technical conformance guide.
• In Japan And Canada DMF submissions in eCTD format are still not possible. In Europe and the USA, eCTD Is considered the preferred submission format. Furthermore, the EDQM offers alternative ways To submit DMFs in electronic format (NeeS, or single pdf for the whole submission), while this is Not foreseen for FDA and EMA
• When it Comes to eCTD submission, there continues to be Differences among different countrie and even ICH regions. For example, the FDA began Accepting eCTD submissions in 2003; Japan began accepting in 2004, yet the EU Heads of Medicines Agencies committed themselves, in 2005, to be ready for eCTD submissions by 2010.

6.3.2 Benefits of eCTD

• Efficiency: Faster submission preparation and review process.
• Standardization: Provides a uniform structure for submissions across regions.
• Lifecycle Tracking: Simplifies version control and document updates.
• Accessibility: Electronic format allows easy access, storage, and retrieval.

6.3.3 Challenges in Implementing eCTD

• Complexity: Requires training and expertise in XML and submission software.
• High Initial Costs: Investing in eCTD preparation tools and resources.
• Regulatory Variations: Module 1 is region-specific, requiring customization

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6.3.2 eCTD STRUCTURE FOLDER

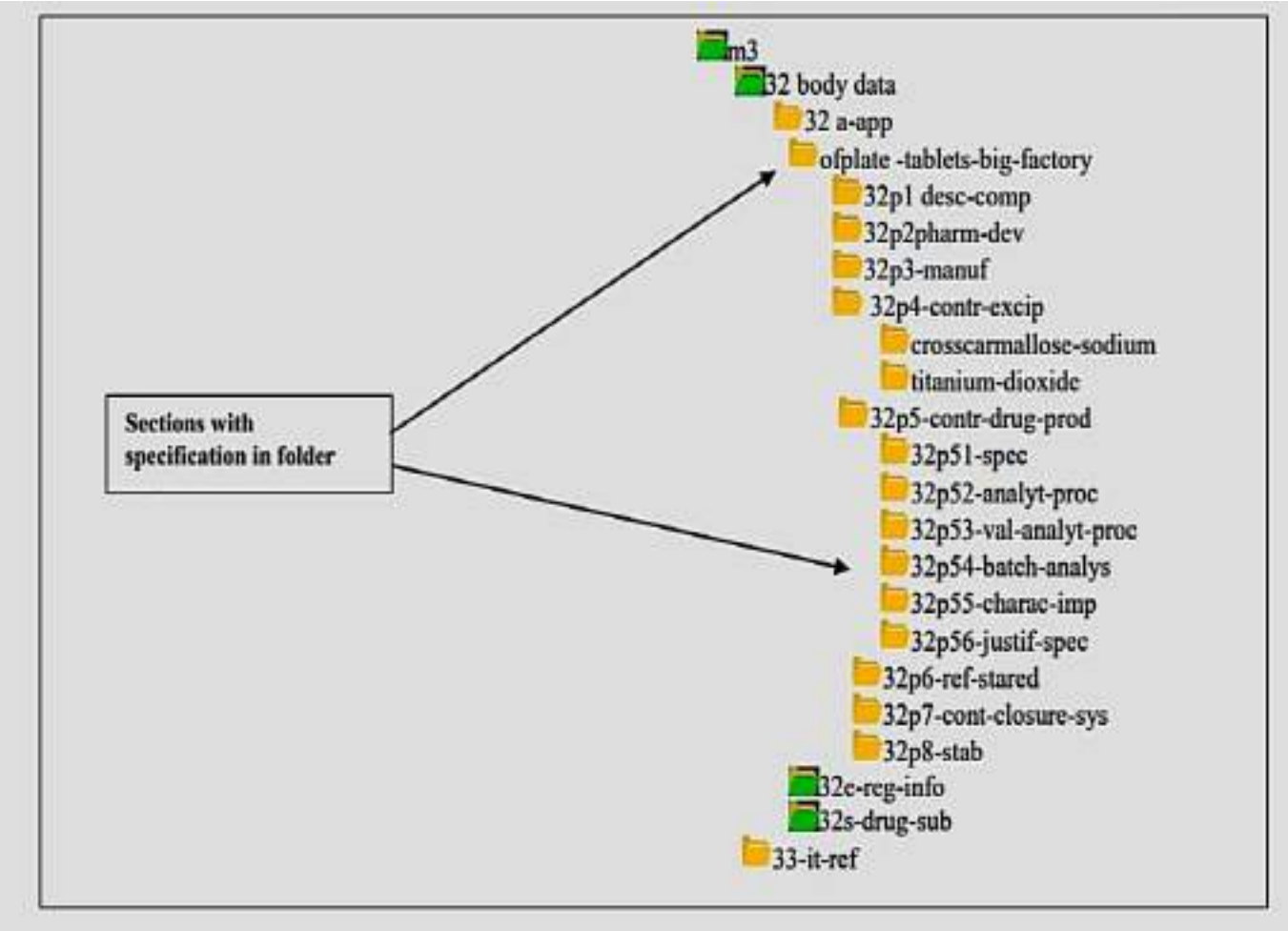

Fig.eCTD STRUCTURE FOLDER

7. REGULATED AND NON-REGULATED MARKETS

The pharmaceutical industry is among the most highly regulated industries, with the primary aim of protecting public health and well-being. The stringent drug approval system is designed to ensure that medicinal products are manufactured to meet acceptable standards of quality and efficacy. By law, all new drugs must be proven safe and effective before they can be approved for marketing. A regulated market refers to the provision of services overseen by a government-approved body.

7.1 REGULATED MARKET

A regulated market is governed by stringent rules and regulations enforced by governmental or international bodies. These regulations ensure the quality, safety, and efficacy of pharmaceutical products

A regulated market in the pharmaceutical industry refers to a region where stringent laws and guidelines govern the development, production, approval, marketing, and distribution of pharmaceutical products. These markets are overseen by regulatory authorities such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), or Japan's Pharmaceuticals and Medical Devices Agency (PMDA). The primary goal of regulation is to ensure drug quality, safety, and efficacy through rigorous standards like Good Manufacturing Practices (GMP), clinical trial approvals, and post-market surveillance (pharmacovigilance). Regulated markets typically require extensive documentation, clinical evidence, and compliance with international standards before a product can be approved for sale. While these regulations significantly increase development costs and time-to-market for pharmaceutical companies, they also provide high levels of consumer trust, minimized risks of counterfeit drugs, and a structured framework for innovation and competition.

7.1.1 Key characteristics include

• Regulatory Bodies: Agencies like the FDA (USA), EMA (Europe), and MHRA (UK) oversee these markets.

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• Stringent Standards: Compliance with Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), and Good Clinical Practices (GCP).
• High Costs and Time: Drug approval involves extensive clinical trials and documentation.
• Examples: USA, European Union, Canada, Japan, and Australia.

7.1.2 Countries and regulatory Authorities Considered in this review

Country	Regulatory authority	Website
Australia (17)	Therapeutic Goods Administration (TGA)	http://www.tga.gov.au/
Brazil (18)	National Health Surveillance Agency (ANVISA)	http://www.anvisa.gov.br/
Canada (19)	Health Canada	http://www.hc-sc.gc.ca/
China (20)	National Institute for the Control of Pharmaceutical and Biological Products	http://www.nicpbp.org.cn/cmsweb/
Europe (5)	European Medicines Agency (EMA)	http://www.ema.europa.eu/
India (21)	Central Drugs Standard Control Organization (CDSCO)	http://cdsco.nic.in/
Japan, (6,22–24)	Pharmaceuticals and Medical Devices Agency (PMDA)	http://www.pmda.go.jp/
Mexico (25)	Ministry of Health	http://www.salud.gob.mx/
Russia (5)	Ministry of Health	http://government.ru/
Thailand (26)	Ministry of Public Health	http://eng.moph.go.th/
Turkey (27)	Ministry of Health	http://www.saglik.gov.tr/
South Africa (28)	Medicines Control Council (MCC)	http://www.mccza.com/
South Korea (29)	Ministry of Food and Drug Safety (MFDS)	http://www.mfds.go.kr/
United States (4,14)	US Food and Drug Administration (FDA)	http://www.fda.gov/

Fig.Countries and regulatory Authorities Considered in this review

7.2 NON-REGULATED MARKET

A non-regulated market operates with relatively less stringent regulatory requirements. Oversight may be limited, and standards vary widely between countries.

A non-regulated market in the pharmaceutical industry refers to regions or markets where pharmaceutical production, distribution, and sales are subject to minimal or no oversight by governmental or regulatory agencies. Unlike regulated markets, which are governed by stringent standards for drug approval, manufacturing practices, and marketing (e.g., the U.S. FDA, EMA in Europe, or PMDA in Japan), non-regulated markets often lack uniform enforcement of such standards.

7.2.1 Key Characteristics Include

• **Minimal Regulations:** Lower requirements for clinical trials, quality control, and documentation.
• **Cost-Effective:** Easier and faster market entry due to less regulatory burden.
• **Market Diversity:** Standards differ significantly across regions.
• **Examples:** Many African, Asian, and Latin American countries fall under this category.

7.2.2 Here's a Table Comparing Regulated and non-regulated markets in the pharmaceutical industry:

S.NO	DIMENSIONS	REGULATED MARKETS	EMERGING MARKETS
1	Level of economic development	High	Medium/low
2	State of economy (and society)	Developed/stable	Transitional/ unstable (economic/ political reforms)
2.1	Macroeconomic frame work	Developed/stable	Undeveloped / being created
2.2	Market institutions	Developed	Undeveloped (being built)
2.3	Market conditions	Stable	unstable

Fig. **Regulated Vs Non Regulated Market Comparison**

7.2.3 RISKS AND CHALLENGES OF NON REGULATED MARKET

1. Patient Safety: Lack of regulation can lead to adverse health outcomes due to unsafe or ineffective drugs.
2. Market Dynamics: The proliferation of low-cost, low-quality drugs can undermine the value of genuine pharmaceutical innovation.

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3. Reputational Risks: Pharmaceutical companies operating in these markets may face ethical scrutiny if they are perceived as exploiting weaker regulations.

7.2.4 Generic Drugs Approved in the USA in the year 2017

Approval process for generic drugs in the United States is overseen by the U.S. Food and Drug Administration (FDA). This process ensures that generic drugs meet rigorous standards for safety, efficacy, and quality, while offering a cost-effective alternative to brand-name drugs.

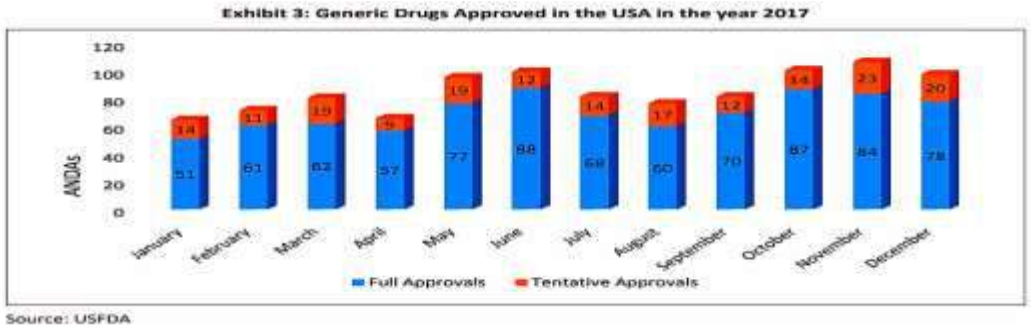

Fig.Generic Drugs Approved in the USA in the year 2017

• ROLE OF PHARMACEUTICAL COMPANIES

Pharmaceutical companies operating in or exporting to non-regulated markets must balance profitability with corporate social responsibility, ensuring they do not contribute to public health crises by prioritizing profits over safety and quality

8. CONCLUSION

In the pharmaceutical industry, robust documentation practices are essential for ensuring product quality, regulatory compliance, and operational efficiency. Proper retention and retrieval systems safeguard historical records, enabling quick access during audits, inspections, and reviews. Documents such as Standard Operating Procedures (SOPs), Manufacturing Formula Records (MFRs), and Batch Manufacturing Records (BMRs) ensure consistency, traceability, and adherence to Good Manufacturing Practices (GMP). Comprehensive audit documentation and reports demonstrate transparency and support continuous improvement. Regulatory submissions are streamlined through standardized formats like the Common Technical Document (CTD) and Electronic Common Technical Document (eCTD), while Drug Master Files (DMFs) provide detailed information for regulatory approval. Together, these practices uphold patient safety, facilitate regulatory approvals, and build trust among stakeholders, forming the foundation of a compliant and efficient pharmaceutical system.

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REVIEW ON INTERACTION OF NANOPARTICLES/NANODRUG WITH IMMUNE SYSTEM

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Author[1], Guide[2], Principal[3]

ABSTRACT

The immune system protects the body by detecting and eliminating foreign invaders, as well as identifying and rejecting ancient cells and aberrant endogenous organisms. Proteins that have misfolded or been degraded are considered cellular trash. As a result, the susceptible system may detect chemical and biological features with a spatial resolution of several nano meters. Molecular patterns found in a wide range of illnesses, such as viral and bacterial proteins and nucleic acid sequences. The susceptible system can either rejoice or pass nanoparticles undetected. Once honored, they can evoke a seditious or anti-inflammatory response. When nanoparticles enter the body, they virtually always interact with cells. The interactions between nanoparticles and immune cells may have a negative impact, increasing susceptibility to infectious infections, autoimmune disorders, and cancer. The nanoparticles Interact with various types of Immune cells such as Interaction of nanoparticles with monocytes/ macrophages, interaction of nanoparticles with Lymphocytes.

KEYWORDS: *Immune System-immune cells, immune toxicity, Nanoparticles no particles.*

1.INTRODUCTION

Immune system is defined as a system which includes the cells, tissues, organs, and the substances they make that helps the body fight infections and other diseases. Nanoparticles are defined as small particles with size range is between 1 and 100 nm. The immune system consists of Immune cells, Immune organs, Immune molecules. Currently, Nanoparticles formulation mainly affects the immune system through specific interaction with various types of Immune cells and molecules. Nanoparticles can be designed on the basis of the targeting cellular and molecular components based on their own characteristics and give accurate modulating function.

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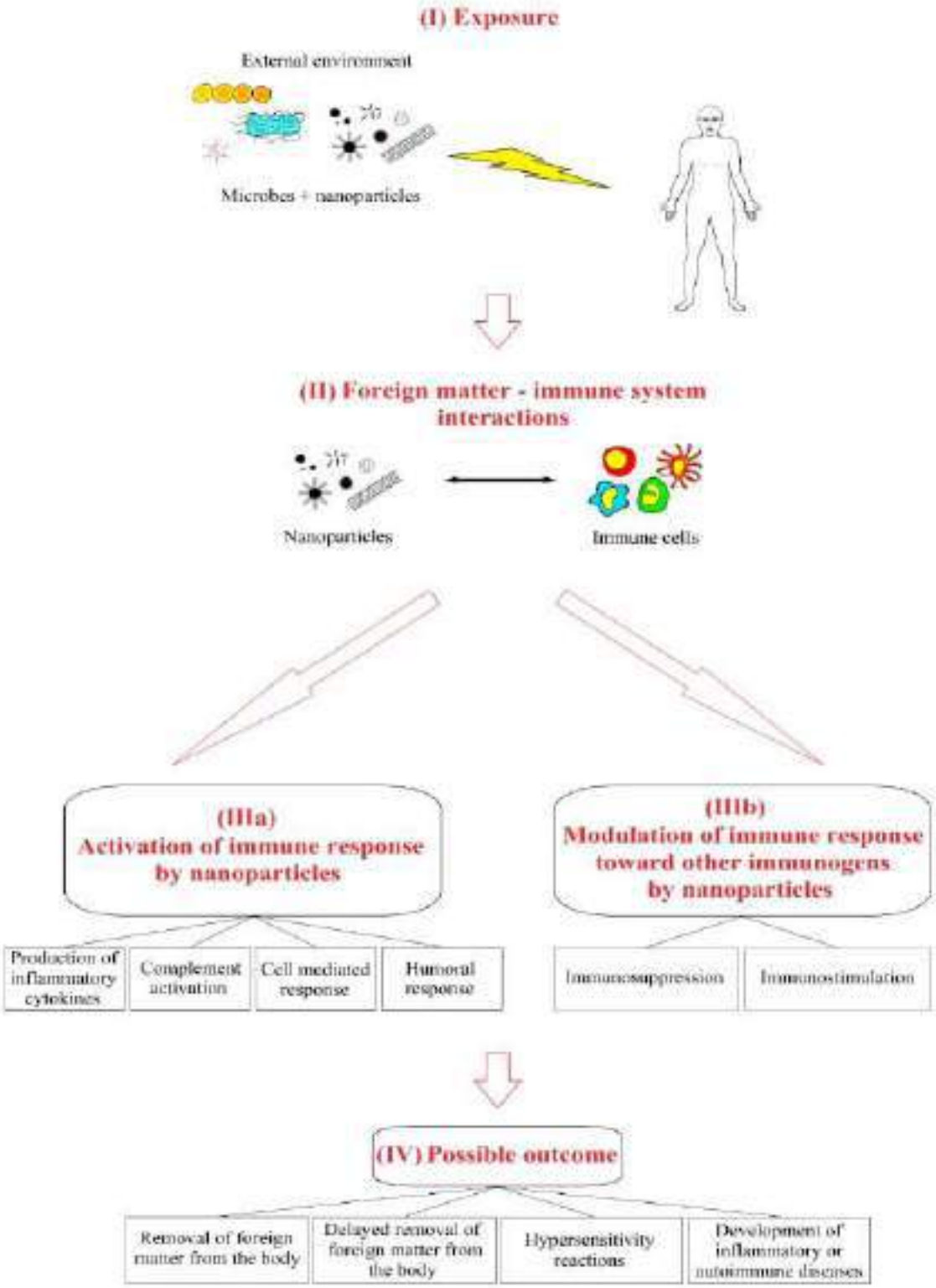

Fig. No.1. Fig. shows how nanoparticles interact with the immune system and give various effects.(1)

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2. The interaction of nanoparticles with the Immune system: The nanoparticles interact with various types of immune cells, such as followings;

1. The interaction of nanoparticles with macrophages.

2.The interaction of nanoparticles with lymphocytes.

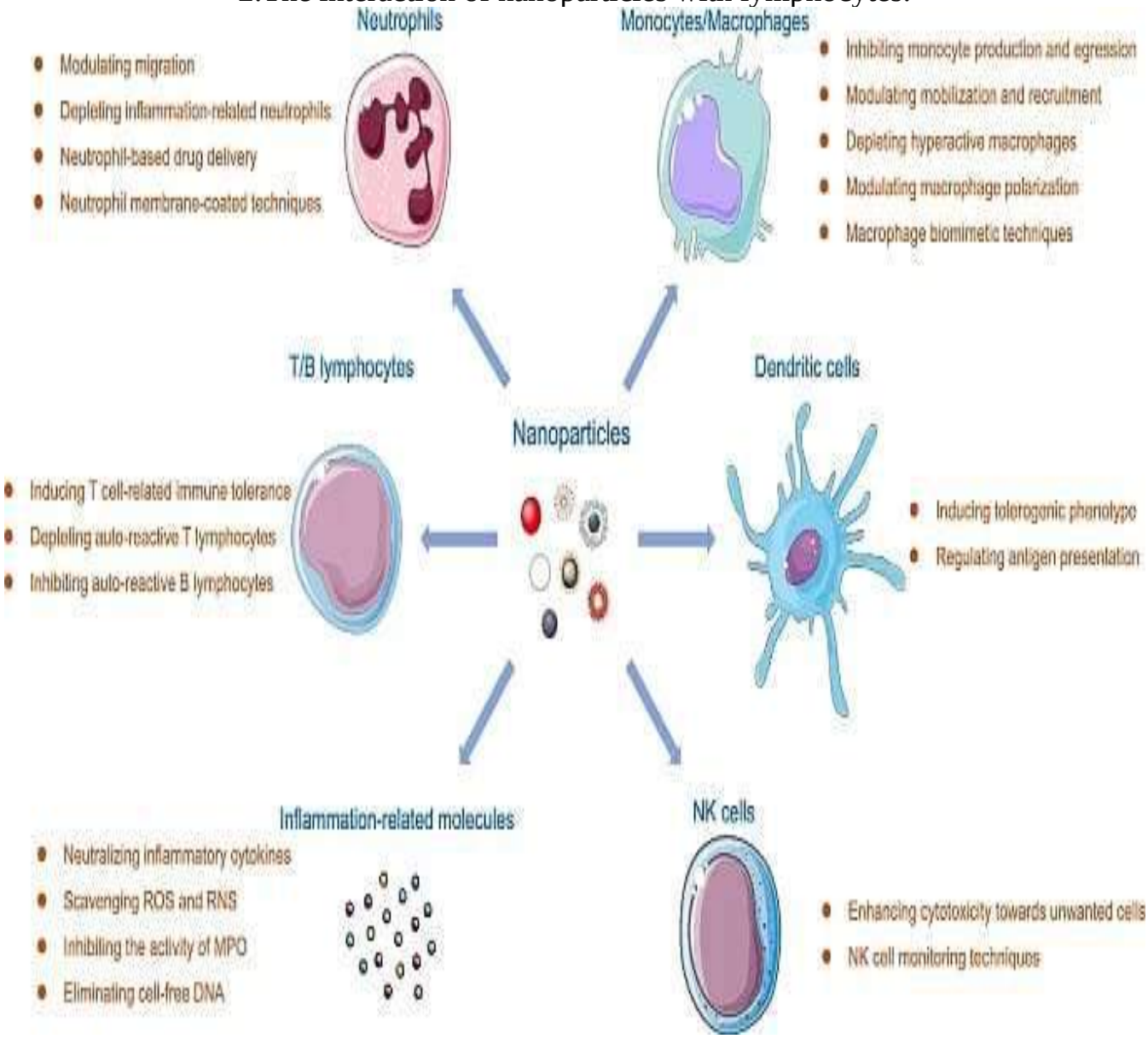

Fig.No.2. Nanoparticle interact with different cells of immune system.(2)

2.1Interaction of nanoparticles with macrophages:

In the innate immune system, macrophages are important cellular components. The functions of macrophages are to degrade and ingest foreign substances and dead cells, tumour cells. **(**3**)**. Macrophages are classified on the basis of their activation and function characteristics - M1 (classically activated) and M2 (alternatively activated). (4). Currently, macrophages play an important role in multiple pathogenic processes. Various nanoparticle formulations interact with these cellular components. Nanoparticles target specific macrophages and achieve their functions. (5).Nanoparticles require designing various ligands on their surface, such as monoclonal antibodies, oligomers, peptides, etc. Then they are binding to certain receptors of macrophages and over express on the surface of macrophages. Resulting, it gives modulating bone marrow activation, monocyte mobilization, and polarization modulation. (6).

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Inhibiting monocyte production and regression in bone marrow

Bone marrow activation is one of the important characters in inflammatory diseases. (7). In inflammatory conditions, increases level of inflammatory cytokines, toll-like receptor agonist and noradrenaline which shows effect the proliferation of hematopoietic stem cells, resulting to large production of inflammatory monocytes, and then which will accumulate in the inflammatory lesions. (8). The bone marrow environment, the interaction of chemokine C-C motif ligand 2 and C-C motif receptor 2, which leads to increased blood vessel permeability, will increase the motivation/egression of inflammatory monocytes. The nanoparticles can be designed to target different levels of inflammatory monocyte production and egress, and diagnosis and treatment of inflammatory diseases. (9).

2.2Interaction of Nanoparticles with Lymphocytes

Lymphocytes is obtained from hematopoietic stem cells (HSCs) present in bone marrow. HSCs firstly differentiate into common myeloid progenitor (CMP) and common lymphoid progenitor (CLP) cells. Granulocytes, macrophages, and erythrocytes are the origins of CMP cells. T and B lymphocytes are the main component and major effector of the adaptive immune system. (10). Lymphocytes play an important role in adaptive immunity. Various nanoparticles platforms have been developed to modulate the target of cellular components. Thus, the resulting management of inflammatory diseases. The mechanisms include T cell-related immune tolerance. (11).

Induce T-cell related immune tolerance

It is a key role in the pathogenesis of variety of inflammatory diseases. The primary goal for the treatment of such conditions involves the reestablishment of immune tolerance. Relevant antigen delivery is considered as a reliable method to produce immune tolerance. Nanoparticles consist of encapsulated antigen [PLG(Ag)] to treat Th2-mediated allergic airway inflammation. (12).

CONCLUSION

Studies show that nanoparticles interact with different components of the immune system. The fast development of nanotechnology has given us a new tool for the nodulation of immune responses. Nanoparticles show great potential to target and give various effects. Nanoparticles are able to target pathogenic substances of different types of diseases, such as inflammatory diseases. The nanoparticles give immunosuppression and immunostimulant.

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PHARMACEUTICAL APPLICATIONS OF PLANT-BASED DERIVATIVES IN SUNSCREEN: A SUSTAINABLE APPROACH TO SKIN PROTECTION

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ABSTRACT
The Sun, while essential for life, can cause significant harm through prolonged exposure, particularly due to UV radiation. This can lead to various skin problems, including accelerated aging, hyperpigmentation, loss of elasticity, and even skin cancer. This paper provides an overview of different types of sunscreens, their history and classifications as per their mechanism of action.
Protecting the skin from sun damage is vital, and sunscreen is one of the most effective prevention methods. With the growing influence of social media highlighting its importance, most people now recognize the need for daily sunscreen use. Available worldwide, sunscreens offer a wide variety of formulations to suit individual needs. The following section will explore potential phytoconstituents that can be incorporated into sunscreen products as an alternative to synthetic filters.
KEYWORDS: *Sunscreen, UV A, UV B, UV C, skin cancer, Sun Protection Factor, Physical sunscreen, Chemical sunscreen, Systemic sunscreen, Sustainable, Plant-based derivatives, Ozone layer, Lignin, Rosmarinic Acid, Eucheuma cottonii, Hylocereus polyrhizus, L-Ergothioneine, Moringa oleifera, Padina australis, Pterocarpus marsupium, Rutin succinate, Salicornia europaea, Sargassum glaucescens, Scytonemin, Sorbates, Strychnos af. darienensis, Fucoxanthin*

1) INTRODUCTION

Sunscreens, also known as sunblocks or sun protectors, are designed to shield our skin from UV radiation. There are three main types: ultraviolet A (UVA) at 350 nm, ultraviolet B (UVB) at 300 nm, and ultraviolet C (UVC) at 250 nm. [25] Exposure to these rays can cause skin burns, premature aging, discoloration, and even tumor formation over time.

2) HISTORY

The first sunscreen was formulated by 2 German scientists Hausser and Vahel in 1928 and contained the main active ingredients such as benzyl salicylate and benzyl cinnamate. [16] In later years sunscreen was formulated by an Australian chemist H.A. Milton Blake (1932) with the UV filters as "salol" (phenyl salicylate) having a concentration of 10%. Its UV protection capacity was later tested by the University of Adelaide and was manufactured and sold commercially by Blake company - Hamilton Laboratories.

3) SUN PROTECTION FACTOR

Sunscreens feature a sun protection factor (SPF) rating, which indicates their effectiveness against sunburn. For instance, SPF 15 means only 1/15th of solar radiation reaches the skin. A minimum SPF of 30 is recommended for effective protection, and sunscreen should be applied at a rate of 2 mg per square centimeter of skin.

While SPF indicates protection against UVB rays, it doesn't guarantee the same for UVA rays. Therefore, choose a broad-spectrum sunscreen to ensure adequate protection against both types of UV radiation.

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4) CLASSIFICATION OF SUNSCREEN

Based on the mechanism of action, sunscreens are broadly classified into three categories namely; [18]

4.1 Physical Sunscreens -They scatter or reflect UV radiation owing to the large particle size [11] Some inorganic filters are as follows:

i. ZnO
It is one of the most used broad-spectrum metal oxide filters due to its ability to absorb and then reflect the UVB and UVA rays [16] [17].

ii. TiO_2
It is also a broad-spectrum filter that protects from UVA and UVB radiations [3]. It exists in either amorphous or crystalline form. The crystalline form can be of three different types: anatase, rutile, and brookite, which have different permeability [7].

iii. Calamine
iv. Kaolin
v. Talc

4.2 Chemical sunscreens (Containing Organic Filters)

They can absorb UV radiation however, it can, in turn, lead to the generation of free radicals, and therefore there is concern regarding the utilization of synthetic chemical filters. [11] [6]

These compounds can be more precisely categorized by their chemical structure.

i. 4-aminobenzoates
ii. Cinnamates
iii. Salicylate esters
iv. Anthranilates
v. Dibenzoylmethanes

4.3. Systemic Sunscreen -These sunscreens accumulate in the skin after getting absorbed and thus offer protection against UV rays. They are not meant for daily use and therefore do not predominate in the market. These include;

i. Ascorbic acid
ii. Tocopherol
iii. Aspirin
iv. Selenium
v. Retinol
vi. Corticosteroids

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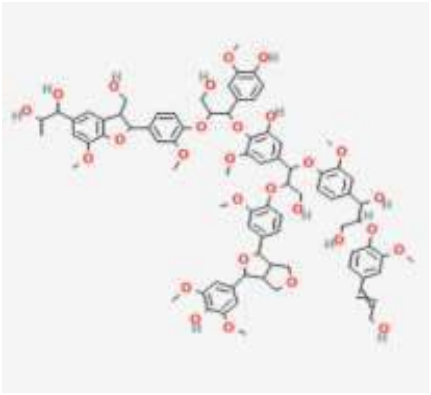
5) SUSTAINABLE APPROACH:

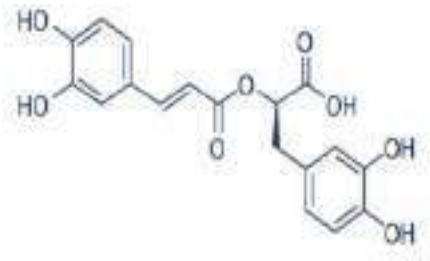
5.1) Lignin



Lignin is a promising alternative UV filter which can also be an effective tint. While acetylation brightens its pigment, it can lower SPF values. Many formulations use iron oxides for UV protection, but technical lignins like kraft and cat lignin possess structures that provide better UVA and UVB protection. [18]

Formulations often include antioxidants to combat free radical damage, which causes aging and inflammation. Lignin's phenolic group stabilizes antioxidant activity, while ortho substitutions, like methoxy groups, further enhance this effect. [17]

5.2) Rosmarinic Acid



It effectively slows down vitamin depletion which in turn decreases oxidation. The phenolic acid contained within it mitigates cellular damage resulting from UV B-induced oxidation by elevating glutathione levels and reducing lipid peroxidation in HepG2 liver cells. Furthermore, it exhibits antioxidant activity that is 3.2 times greater than that of ascorbic acid. [8] Rosmarinic acid alone offers limited UV protection, but when combined with inorganic filters like titanium oxide and zinc oxide, its effectiveness increases. Additionally, its antioxidant properties help prevent free radical damage to the skin.

5.3) *Eucheuma cottonii*

Eucheuma cottonii is a seaweed found in various colors—red, brown, and green—and is commonly farmed in tropical seas. It is a rich source of K-carrageenan, phlorotannins, and flavonoids, demonstrating antioxidant properties that protect against UV-induced free radicals. [2]

5.4) *Hylocereus polyrhizus*

Hylocereus polyrhizus(Red-fleshed dragon fruit) is a vine cactus species. It has purple-red color and high antioxidant content. The peel extract (HPPE) contains bioactive compounds such as ferulic acid, chlorogenic acid, and gallic acid, along with high levels of catechin and vanillin. [23]

High-Performance Liquid Chromatography (HPLC) has identified rutin, which helps inhibit reactive oxygen species (ROS) that can damage cells by stabilizing free radicals.[4] HPPE also contains riboflavin (vitamin B), which aids in recycling glutathione and acts as an important antioxidant, protecting the body from free radical damage and promoting skin cell turnover. [4]

5.5) L-Ergothioneine

Ergothioneine is mainly found in Mushroom varieties. It is observed that photoaged skin can be due to mutations in the mitochondria genome i.e., deletion of large no. of (4977 bp) which is known as "common deletion (CD). When UV rays interact with cells it goes and breaks single and double strands of DNA causing CD, but when tested with EGT there were no CD phenomena seen which helped in concluding that EGT helps in reducing the photo-aging of an individual. [9] Tripeptide glutathione (GSH) which is an abundant intracellular non-protein thiol helps in maintaining redox reactions in cells by interacting with ROS, and RNS. [19] ETG helps in increasing glutathione levels which decrease in the body when exposed to radiation. [2]

5.6) *Moringa Oleifera*

Moringa oleifera, from the *Moringaceae* family is widely known as the "drumstick tree." Studies have proven that *M. oleifera* have antimicrobial, anti-inflammatory, antioxidant, antimicrobial, hypoglycemic activities etc. [6]
M. oleifera leaf extracts, characterized by HPLC, contain the following key chemical constituents;
i. Ellagic acid
ii. Chlorogenic acid
iii. Ferulic acid
iv. Rutin
v. Quercetin

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While the leaf extract has primarily been tested in vitro, it appears to possess considerable potential in sunscreen formulations, owing to the variety of beneficial chemical constituents it contains. [6]

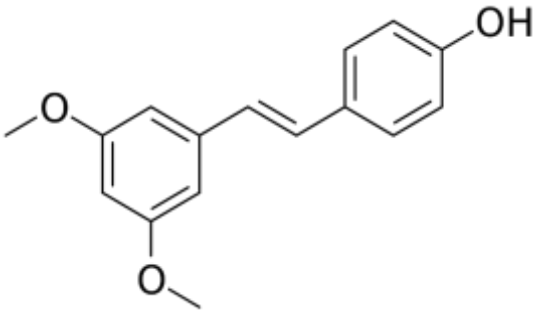
5.7) *Padina Australis*

Antioxidants are effective against photolytic damage. *Padina australis*, a brown alga found in Malaysian waters, contains high levels of phenolic compounds and flavonoids, which can be extracted using ethanol or water. Liquid chromatography-mass spectrometry (LCMS) has shown that ethanol extracts have significantly more concentration of these compounds. [4]

Phenolic compounds can act as endogenous antioxidants by donating electrons. Additionally, the carotenoid fucoxanthin may provide UV protection, improving cell survival and reducing intracellular reactive oxygen species (ROS). [4] Thus, it is a promising source of antioxidants and UV protectants.

5.8) *Pterocarpus Marsupium*

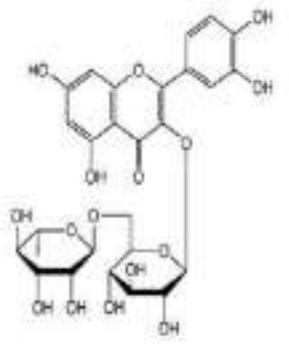
Pterostilbene is a potent stilbenoid classified within the phytoalexin group, and it is extracted from *Pterocarpus marsupium*. This compound plays a crucial role in the plant's defense mechanisms. [6]



It shows its antioxidant activity by reductions in ROS (reactive oxygen species) production which is triggered by hydrogen peroxide as well as UV A radiation. It exhibits free radical scavenging activity that is dose-dependent; specifically, a higher dose in the formulation leads to increased activity. Additionally, it supports the DNA repair mechanism by activating the Nrf2/ARE pathway through PI3K-dependent mechanisms. [5]

5.9) Rutin succinate

Rutin succinate (MS) protects against UV damage by scavenging free radicals linked to photoaging and carcinogenesis. Combining sunscreen filters with MS increases SPF values and helps prevent peroxide radical formation, which can degrade these filters, enhancing their stability. [9]



The sunscreen containing Rutin achieved the highest SPF, indicating that Rutin effectively enhances filter stability and extends the product's shelf life. [9]

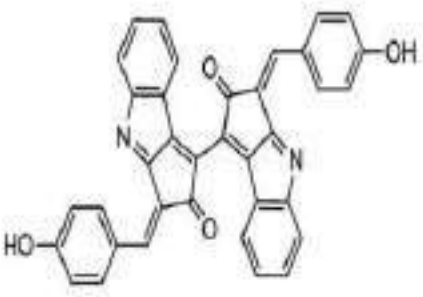
5.10) *Salicornia europaea*

Salicornia europaea or Glasswort is a halophytic plant. It possesses diverse biological properties like anti-inflammatory antioxidant, antihyperlipidemic, etc. [10] The following results were obtained after conducting tests to study its protective effects;

1. Applying water-soluble Salicornia extract improves skin texture.
2. UVB radiation disrupts the structure of keratinocytes, but the extract helps prevent these changes.
3. It corrects the misorientation of mitotic division in keratinocytes, balancing asymmetric and symmetric divisions.
4. Treatment with the extract enhances skin stratification after UVB exposure, though its exact mechanism of action remains to be fully explored. [10]

5.11) *Sargassum Glaucescens*

Sargassum glaucescens is a marine brown alga that belongs to the family *Sargassaceae*. [11]



Marine algae are rich in metabolites which could be used for reducing oxidative stress and preventing skin aging. These metabolites are mycosporine-like amino acids (MAAs), sulphated polysaccharides, polysaccharides, and polyphenols. [26]

Sargassum is also rich in omega (ω)-3 fatty acids involving eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). [20] These compounds help in sun protection by reducing ROS. [11]

5.12) Scytonemin

Scytonema is a cyanobacterial, lipid-soluble metabolite that is found in an extracellular sheath of the organism. [24] This hydrophobic pigment consists of a dimeric molecule with phenol and indole subunits, which protect cellular structures by reducing reactive

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oxygen species (ROS) and minimizing DNA lesions from oxidative damage. This protective role is essential for cellular integrity and health, and the molecule also has anti-inflammatory and anti-proliferative properties. [24]

5.13) Sorbates

Sorbates are preservatives that prevent microbial contamination without changing color, odor, taste, or flavor, with potassium sorbate being the most common alternative to parabens.

UV radiation can lead to sunlight-induced melanoma, resulting in cyclobutane pyrimidine dimers (CPD) that may cause carcinogenic mutations. This risk can be reduced using melanin-based triple state quenchers (TSQ), such as sorbates TSQ, which absorb UV energy and dissipate it as heat, thereby enhancing UV protection. [12]

5.14) *Strychnos Af. Darienensis*

Strychnos af. darienensis, found in Peru, is part of a genus known for its toxic compounds but also contains valuable secondary metabolites like indole alkaloids, phenolic acids, lignans, and flavonoids with potential medicinal benefits. [16]

Flavonoids, such as luteolin and strychnobiflavone, have anti-aging effects on skin fibroblasts by reducing ROS production and protecting cells from UV radiation, even reversing UVB-induced damage. [13]

5.15) Fucoxanthin (Innovation by Incorporating Into SLN)

Fucoxanthin is a natural carotenoid obtained from seaweeds. [22] It has a typical dark yellowish or reddish color and contains a plethora of properties including anti-inflammatory, anti-oxidant, radio-protective, etc. [15]

New drug delivery systems (NDDS), such as Nanostructured Lipid Carriers (NLCs) and Solid Lipid Nanoparticles (SLNs) have core sizes of 10 to 1000 nm. [21] SLNs are particularly effective as drug delivery agents for various reasons:

a) High drug-loading capacity
b) Controlled and target-specific release of phytoconstituents which minimizes side effects. [14]
c) stability during storage, resisting physical and chemical stresses without forming toxic byproducts.

6.CONCLUSION

Natural alternatives are becoming increasingly popular, resulting in a rise in commercial sunscreens containing herbal extracts. Many herbs have proven photoprotective properties, with potential for discovering more.

However, developing organic and environmentally friendly sunscreens faces challenges. Evaluating the effectiveness of herbal extracts through Sun Protection Factor (SPF) can be complex, requiring extensive in vivo and in vitro study data, which is often hard to obtain. To date, no country has officially approved any botanical compound as a UV filter for sunscreen.

Although many herbal candidates may not match the SPF values of synthetic options, their unique properties continue to generate interest in the sunscreen market.

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AN REVIEW ON MILLETS WITH NUTRITIONAL VALUE & SIGNIFICANCE WITH SOME HEALTH BENEFITS OF FINGER MILLET

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ABSTRACT

In 21st century, climatic changes, water scarcity, increasing world population, rising food prices and other socioeconomic impacts are expected to generate a great threat to agriculture and poorest people who live in arid and subarid region. As we know, cereal grains is an important source that plays significant role in human diet. In which, millets are widely grown in the tropics of Africa and Asia and contains major source of carbohydrate and proteins, fatty acid, minerals, vitamins, dietary fibres and polyphenols. Typically millets protein contain higher amount of essential amino acids for e.g. sulphur containing amino acids (methionine and cysteine). Millet is an alkaline forming food. Alkaline based diet is useful to gain optimal health. Another health benefits of millets are to increase gastric emptying time. Millet grounded foods are considered as implicit prebiotic and probiotics with prospective health benefits. Millet based foods are considered with prospective health benefits. Including these grains in the diet may improve health and decrease the risk of diseases.

There are various types of millets such as Sorghum millets, Proso millet, Pearl millet, Foxtail millet, Finger millet, Browntop millet, Barnyard millet, Little millet, Buckwheat millet, Amarnath millet, Kodo millet. Cutlet millet is also known as Ragi in India. The present review article elucidate the information of millets with a major focus on Finger millet by highlighting there Nutritional value and significance with some of their health benefits.

INTRODUCTION

Millets are one of the cereals asides the major wheat, rice and sludge. Millions of people are consuming and cultivating millets in large scale. They are grown mostly in marginal areas under agricultural condition. Interest in the development of policy statement about drought grains is increasing in several developing countries such as India, China and some other countries of Africa because of water scarcity and increasing population. Millets is one of the important drought-resistant crops and sixth cereal crop according to world agriculture production. Also some millets are resistant to pests and disease, short growing season, and productivity under drought conditions compared to major cereals.[1]

The major reasons of decrease in consumption is the lack of awareness of nutritional merits, inconveniences in food preparations, lack of processing technologies, and also the government policy of disincentives towards millets and favouring of force of fine cereals subsidized prices. It's important to explore ways for creating mindfulness on nutritive graces of millets. Now-a-days people are very conscious about their healthy being and overcome metabolic disorders and other diseases. Millets are small seeded with various varieties such as Pearl millet (Pennisetum glaucum), Finger millet (Eleusine coracana), Kodo millet (Paspalum setaceum), Proso millet (Penicum miliceum), Foxtail millet (Setaria italic), Little millet (Panicum sematrense) and Barnyard millet (Echinochloa utilis), Sorghum millet (Sorghum bicolor). [1]

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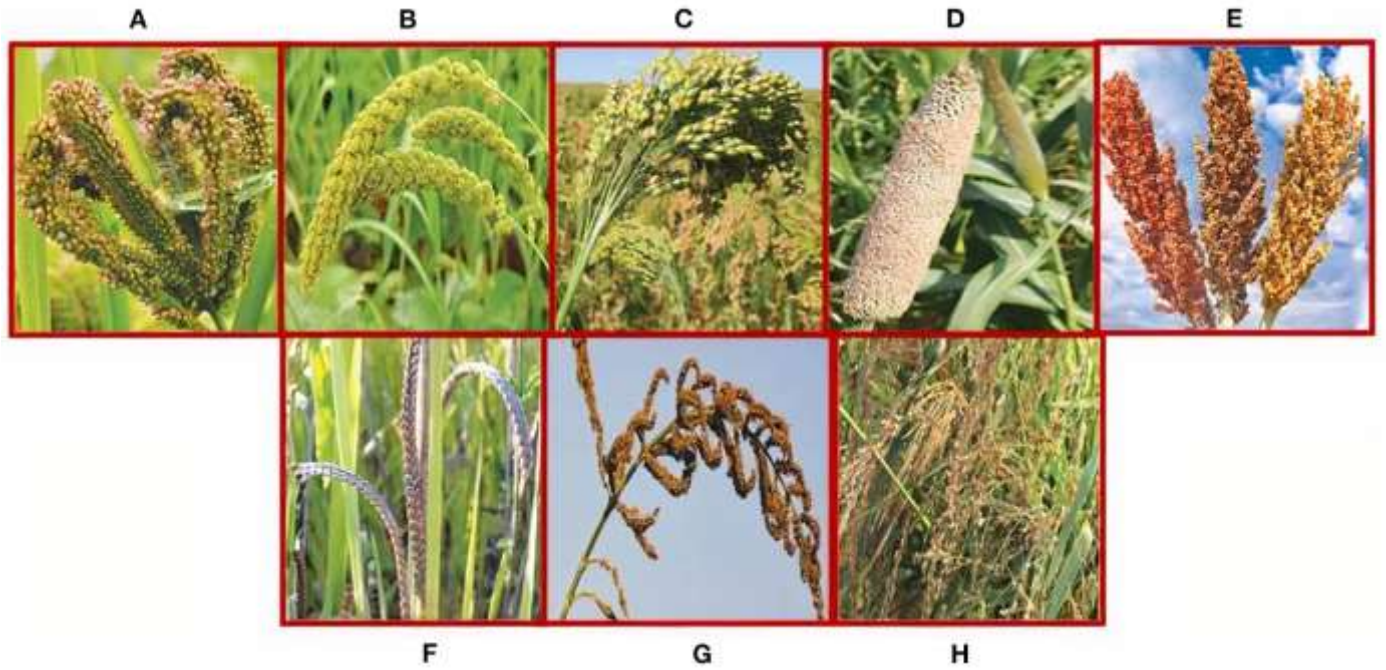

Fig.1: Various varieties of Millet Grains.

The top producer of millet grains is India with an annual production of 3,34,500 tons. In addition to there nutritive value, there are several potential health benefits such as preventing cancer and cardiovascular disease, reducing tumor incidence, cholesterol and rate of fat absorption, lowering blood pressure, delaying gastric emptying time, risk of heart disease and supplying gastrointestinal bulk have been reported for millets.[3]

Millets grains posses proteins ranging from 7-12%, fat varying from 2-5%, carbohydrates in the range of 65-75% and dietary fibres from 15-20%.

Variety	Carbohydrate (g)	Protein (g)	Fat (g)	Ash (g)	Fiber (g)	Ca (mg)	Fe (mg)	Zn (mg)	Thiamin (mg)	Riboflavin (mg)	Niacin (mg)	Energy (kcal)
Sorghum	71	10.4	3.1	1.8	2.0	25	5.4	3.1	0.38	0.15	4.3	329
Finger millet	59–75	6.9–10.9	1.5	2.6	15.2	350	3.9	3.13	0.42	0.19	1.1	336
Kodo millet	72–76	6.2–13.1	3.2–4.9	3.3	5.2	35	1.7	1.9–2.4	0.15	0.09	2.0	353
Foxtail millet	55–69	11.2	4.0	3.3	9.4	31	2.8	2.92	0.59	0.11	3.2	351
Fonio millet	68–75	8.4	3.3	3.4	18.2	20	2.1	1.5	0.17	0.22	1.15	379
Little millet	76	15	4.5	5.4	2.5	17	9.3	5.25	0.30	0.09	3.2	329
Barnyard millet	74	11.0	5.2	4.5	13.6	22	18.6	3	0.33	0.10	4.2	300
Pearl millet	67–72	11.8	5.1	2.2	13.8	42	11.0	3.29	0.38	0.21	2.8	363
Proso millet	64–76	12.6	2.9–11.6	2.7	13.1	15	2.2	2.36	0.41	0.28	4.54	316

Table no.1: Proximate nutrient composition and nutritive value of various millets (g/100g db and mg/100 g db).[4]

Finger Millet

Finger Millet, corcana.L is also known as Ragi and Mandua(India); Kaddo(Nepali);Eleusine, Cultivee, Coracan, Koracan(France); Fingerhirse,(Germany); Kambale, Lupoko, Mawele, Amale, Bule(Zambia), Finger millet, African millet, koracan(England); Wimbi(Kenya); Bulo(Uganda); Dagussa, Tokuso, Barankiya(Ethopia); Poho, Rapoko, Zviyo, Njera, Mazhocole(Zimbabwe).[4]

Finger millet is extensively cultivated in various regions of India and in entire world, India is the major producer of Finger millet which contributes nearly 60% of the production. One of the most important feature of finger millet is its ability to adjust itself in different agro-climatic conditions.[4]

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Nutritional value of Finger Millet:
Finger millet grain has a carbohydrate content of 81%, crude fibre 4.5%, mineral 2.5% and proteins 10% which is comparable with other cereals like rice, maize, millets and wheat. Other than above contents or nutrients finger millets consists various essential amino acids that have a significant impact on how well proteins function. The necessary proportion of amino acids in the finger millet is about 44.5%. With regard to the ratio of essential to non-essential amino acids, as we know ragi has a well balanced amino acids profile.[6]

The various essential amino acids are Arginine, Lysine, Methionine, Lecithin and many others amino acids. Comparison of amino acid except Lysine ranks higher. In usual grains Tryptophan amino acids is frequently absent but it is found in finger millet. The ratio of Valine, Threonine and Lysine in finger millet is balanced compared to other millets. Besides the function essential amino acids are given below:-

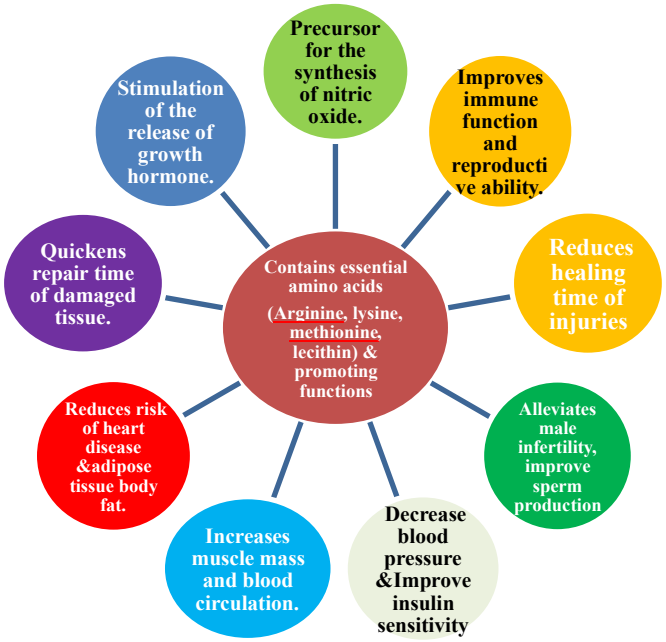

Fig.2: Essential Amino Acids Presents in Finger Millet Contains and its functions[6]

Nutritional significance of Finger Millets
The main constituent of the millet are seed coat, embryo and endosperm. Among several varieties of finger millet such as yellow, white, brown, re, violet and tan colour only the red coloured are cultivated extensively throughout world. The presence of five layered seed fleece in cutlet millet makes it unique compared to other millets similar as foxtail millet, plum millet, Kodo millet and Proso millet. This could be one of the reason for higher dietary fibre in finger millet.[7]

The nutraceuticals importance of finger millet lies in its high content of calcium (0.38%), protein (6-13%), dietary fibre (18%), carbohydrate (65-75%), minerals (2.5-3.5%), phytates (0.48%), tannins (0.61%), phenolic compounds (0.3-3%) and trypsin inhibitory factor and id recognised for its health beneficial effects, such as Anti-Diabetic, Antitumerogenic, Anti-Diarrheal, Antiulcer, Anti-Inflammatory, Atherosclerogenic effects, Antioxidants and Antimicrobial properties.[7]

Before it was believed that polyphenols, phytates, tannins and dietary fibres contents of Cutlet millet act as Anti-nutrients because of their essence chelating and enzyme inhibition conditioning but now it has been verified that these ingredients can contribute to antioxidant exertion, which is an important factor in defying aging and metabolic conditions. Moreover, finger millets is also useful in managing various physiological disorders such as Diabetes mellitus, Hypertension, Vascular fragility, Prevention of oxidation of Low Density Lipoprotein(LDL), Hypercholesterolemia and also improves Gastrointestinal health.[3]

Finger millet is milled with seed coat which is in dietary fibre and micronutrients to prepare flour and the whole meal is utilized in the preparation of traditional foods, such as roti(unleavened breads), ambali(thin porridge) and mudde(dumplings). On diurnal consumption of whole grain of cutlet millet and its products can covers against the threat of cardiovascular conditions, type-II

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diabetes and gastrointestinal cancers. The dietry fibres, phenolics, minerals and vitamins concentrated in the outer layer of the seed coat form the part of food and other there nutritional and health benefits.[4]

Health Benefits of Finger Millets

Several in-vitro and in-vivo studies (animals) have been conducted to explore the health benefits of finger millets.[12]

Several studies are available on the anti-oxidant properties and anti-microbial properties of finger millet. Production of statins (antihypocholestrolemic metabolites) from finger millets was attempted by Venkateswaran and Vijayalakshmhi (2010). α -glucosidase inhibitors play a vital role in the clinical management of postprandial hyperglycemia and established the α -glucosidase and pancreatic α -amylase inhibitory properties of finger millet phenolic extract, whereas it indicates that finger millet phenolics are inhibitors of aldose reductase and snake venom phosphor lipases (PLA_2). Protein glycation is one of the complications of diabetes and protein glycation inhibitors are helpful in management of this complication. Methanolic extracts of finger millets were found to exhibit protein glycation inhibitory properties.[12]

A. Anti-Diabetic

Consuming meals high in fibre and complex carbohydrate help prevent subsequent blood glucose spikes, which is essential for managing diabetes and lowers chronic vascular issues. Finger millets carbohydrates were absorbed and processed very slowly. The advantages of cereal grains were recognized to lowers the incidence of diabetes mellitus and gastrointestinal tract diseases.[11]

B. Anti-Oxidant

Antioxidant substances are becoming more and more common as lipd stabilizer and inhibitors of extreme oxidation. The seed coat of millet contain polyphenols and its constituents, flavonoids and tannins which have multiple uses. They can act as chelators of essence, these both of singlet oxygen and reductants. In edible flours derived from tiny millets, endogenous oxidants are present.[11]

C. Anti-Microbial

According to the phenolics mainly the tannins in the finger millet may provide resistance to fungus infection. Because of high polyphenol content of the seed coat, acidic methanol extracts of the seed coat show greater antifungal and antibacterial properties than whole wheat extract. A structural obstacle towards fungal infection is created by phenolic compounds, particularly tannins in the grains outer layer.[12]

Some of the Health Related Functional Attributes of Finger Millets

I. Antioxidant Property

Advanced antioxidant capacity of cutlet millet is attributed to the high total phenolic content as well as flavonoids similar as catechin, gallocatechin, epicatechin, procyanidin dimmer, posotion of enzymatic and non-enzymatic antioxidants.[13]

II. Anti-Microbial Activity

Polyphenols extract from finger millet seed coat and whole flour active Bacillus cereus, Aspergillus niger and fermented finger millet extract suppress growth of Salmonella sp ., Escherichia coli.[13]

III. Anti-Ulcerative Property

Finger millet incorporated diet prevents mucosal ulceration.[13]

IV. Antiprotein (Albumin) Glycation Property

Finger millet seed coat polyphenols are effective inhibitor of fructose induced albumin glycation.[13]

V. Aldose reductase (AR) Enzyme Inhibitory Property

Finger millet inhibits AR activity which results in the prevention of AR induced cataractogenesis.[13]

VI. Blood Glucose Lowering Effect, Nephroprotective Properties, Cholesterol Lowering

Finger millet incorporated diets reduce serum cholesterol and phenolics from finger millet seed coat matter inhibit the intestinal α -glucosidase and pancreatic amylase thus helps in controlling postprandial hyperglycemia.[14]

VII. Inhibition of Phospholipases (PL)

Galic acid, Quercitin and crude polyphenols extract from finger millet act as potent inhibitor of PLA_2 from snake venom, it indicates the potential application of finger millet in treating inflammatory disorders.[14]

VIII. Natural Probiotic Treatment for Diarrhea

Finger millet drink fermented by lactic acid bacteria used as a therapeutic agent against diarrhea.[14]

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IX. Wound Healing Property

In diabetic patients, wound healing is impaired and studies have shown that finger millet extracts results in ameliorating this impairement by improving the Nerve Growth Factor (NGF) production and improved antioxidant status.[14]

X. Improvement on Hemoglobin Status in children

Excellent factory source of natural iron germinated cutlet millet grounded food showed a general enhancement on hemoglobin status.[14]

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DISORDER OF WHITE BLOOD CELL AND ITS DIAGNOSIS AND TREATMENT

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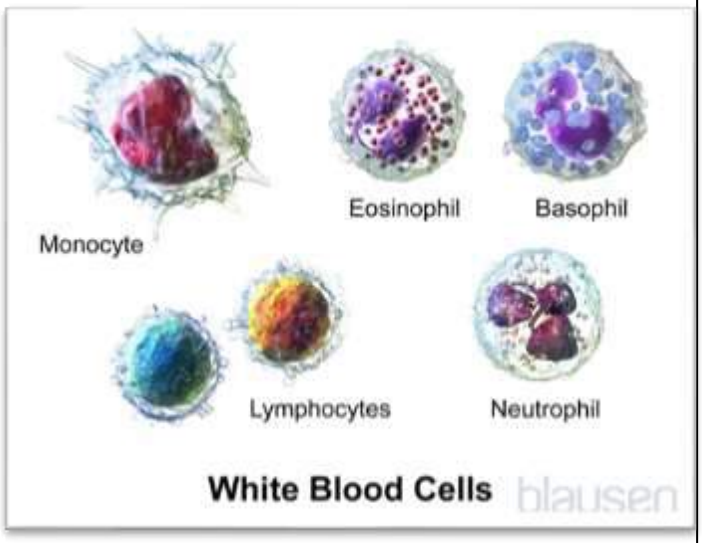
ABSTRACT

- *White blood cells (WBCs), both granulocytes (e.g., neutrophils, eosinophils, and basophils) and mononuclear cells (e.g., monocytes and lymphocytes), are central to the innate and adaptive immune system, serving to mitigate infectious, traumatic, and malignant insults. Knowledge of normal leukocyte development and function is essential to understanding how their absence and/or dysfunction results in disease. While primary neutrophil disorders have been a long-standing mainstay of hematology training, the increasing recognition of neutropenia and other WBC aberrations as a feature of primary immunodeficiency disorders and autoimmune/immune dysregulation disorders reinforces the need for hematologists to have a broad differential in the evaluation of patients with leukocyte abnormalities.*



- *Disorders of white cells are very common in clinical practice. White-cell development and numbers are controlled by a mixture of external stimuli including cytokines, matrix proteins, and accessory cells. Several different white-cell lineages are recognised; each has a role in host defence. Both white-cell deficiency and overproduction can lead to disease. Some forms of inherited white-cell deficiency are potentially treatable with gene therapy*

INTRODUCTION

- WBCs, or white blood cells, are essential for immunological responses to foreign substances and diseases. There are various WBC kinds, and abnormalities in them may be a sign of leukemia or other illnesses. Due to the use of less significant elements, earlier research has poor accuracy and exaggerated performance. Furthermore, these studies frequently overstate accuracy by concentrating on fewer WBC types. The important challenge of using microscopic images to classify WBC kinds is addressed in this study. This study introduces a novel approach using extensive pre-processing with data augmentation techniques to produce a more significant feature set to achieve more promising results. The study compares performance with cutting-edge machine and deep learning models through trials using both traditional deep learning and transfer learning models. According to the findings, a pre-processed feature set and convolutional neural network classifier achieves a significantly better accuracy of 0.99
.
- The proposed method demonstrates superior accuracy and computational efficiency compared to existing state-of- the-art works. Blood is a life-giving fluid that transports oxygen and gives energy to the cells and carries sway carbon dioxide and other waste products. Blood circulating in our body consist of 55 percent plasma, 40 percent Red Blood Cell(RBC), 4 percent of Platelets and 1 percent White Blood Cells (WBC). WBCs are important for healthy immune system. Neutrophils, eosinophil's (acidophilus),

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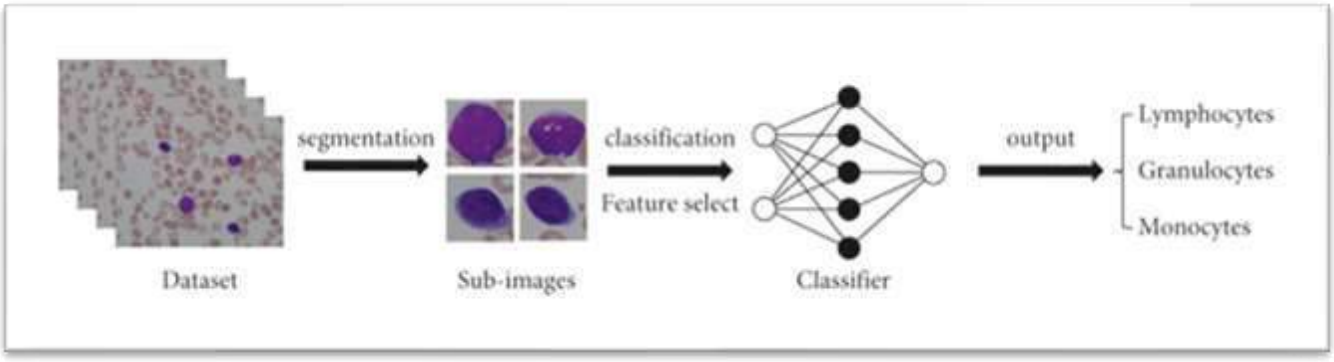
basophils, lymphocytes, and monocytes are the five types of WBCs. All these cells have nuclei, which differentiate them from the other blood cells. The normal white cell count is between 4x 10°/L and 11x 10°/L.

- Abnormalities in blood cells are determined by blood smear test. Irregularity in blood cells result in variations in the number of WBCs. The two types of blood count needed for the diagnoses of blood are Complete Blood count (CBC) and the Differential Blood count (DBC). The most commonly performed hematologic test is Complete Blood count (CBC) and the Differential Blood count (DBC). Blood is a vital fluid that conveys carbon dioxide and other waste materials while also carrying oxygen and energy to the cells. 55% plasma, 40% red blood cells (RBC), 4% platelets, and 1% white blood cells (WBC) make up the blood that circulates throughout our bodies. WBCs are essential to a robust immune system. WBCs come in five different varieties: neutrophils, eosinophils (acidophilus), basophils, lymphocytes, and monocytes.

- The nuclei of each of these cells set them apart from the other blood cells. White blood cell counts typically range from 4x 10°/L to 11x 10°/L. The blood smear test is used to identify abnormalities in blood cells. Variations in the number of WBCs are caused by irregularities in blood cells. The two blood count types required for The Complete Blood Count (CBC) and the Differential Blood Count (DBC) are used to diagnose blood. The Complete Blood Count (CBC) and the Differential Blood Count (DBC) are the most often conducted hematologic tests. WBC detection effectively diagnoses a range of illnesses. As seen in figure 2, it essentially consists of four steps: preprocessing, image segmentation, feature extraction, and classification. The retrieved feature's and classification's accuracy rely on WBC.



White Blood Cell

WBC stands for White Blood Cells, which are a key component of the immune system. They help protect the body against infections, foreign invaders, and diseases. Unlike red blood cells (RBCs), which carry oxygen, WBCs are primarily involved in immune defence.

Types of White Blood Cells (WBCs)

There are five main types of WBCs, each with distinct roles in the immune response. These are typically categorized into **granulocytes** (which contain granules in their cytoplasm) and **granulocytes** (which do not contain granules).

Granulocytes:

- **Neutrophils**

Function: Neutrophils are the most common type of WBC. They are the body's first line of defence against bacterial infections. They work by engulfing and digesting pathogens (phagocytosis).

Appearance: They have a multi-lobed nucleus and granules that contain enzymes to kill microbes.

- **Eosinophils**

Function: Eosinophils are primarily involved in combating parasitic infections and play a role in allergic reactions. They release substances that help kill parasites and modulate inflammatory responses.

Appearance: Their granules stain red or orange with eosin, a dye.

- **Basophils**

Function: Basophils release histamine and other chemicals during allergic reactions and inflammation. They play a role in defending against parasites, though their primary role is in inflammatory responses.

Appearance: They have large, dark granules that obscure the nucleus.

Agranulocytes

- Lymphocytes :

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Types:

1. **B cells**: Produce antibodies to neutralize pathogens.
2. **T cells**: Help regulate immune responses and can directly kill infected cells (cytotoxic T cells).
3. **Natural Killer (NK) cells**: Target and kill virus-infected cells and tumor cells.

Function: Lymphocytes are central to adaptive immunity. They recognize specific pathogens and help the body "remember" them for faster future responses.
Appearance: Lymphocytes have a large, round nucleus and little cytoplasm.

- **Monocytes**

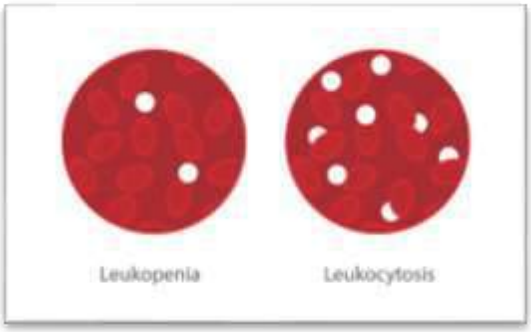
Function: Monocytes are large WBCs that differentiate into **macrophages** or **dendritic cells** once they enter tissues. They are essential for phagocytosis and antigen presentation, helping activate other parts of the immune system.
Appearance: Monocytes have a kidney-shaped nucleus and abundant cytoplasm.

Disorder of WBC :
White blood cell (WBC) disorders can be characterized by either an excess or a shortage of these cells, or by a breakdown in their typical function. WBCs play a vital role in the immune system, which protects the body from infections, foreign invaders, and aberrant cells. These are some of the main categories of WBC problems.

- **Leukopenia (Low WBC Count)**

Leukopenia refers to a decrease in the number of white blood cells, making the body more vulnerable to infections. It can result from various conditions:

- Bone marrow disorders (e.g., aplastic anemia, leukemia)
- Viral infections (e.g., HIV, hepatitis)
- Autoimmune diseases (e.g., lupus)
- Chemotherapy or radiation therapy (which can suppress bone marrow)
- Medications (such as some antibiotics or antipsychotic drugs)



- **Cause of Leukopenia**

1. Disorders of the Bone Marrow
Aplastic anemia is a disorder in which the bone marrow is unable to generate enough white blood cells and other blood cells.

Leukemia or Other Cancers: Normal blood cell production can be disrupted by cancers that affect or spread to the bone marrow.
A collection of illnesses known as myelodysplastic syndromes (MDS) are brought on by malformed or malfunctioning blood cells.
Bone Marrow Infiltration: When the marrow is infiltrated by abnormal cells, such as in lymphoma or metastatic cancer.

2. Immune System Disorders :
White blood cells and other body tissues are attacked by the immune system in systemic lupus erythematous (SLE).
Leukopenia may occasionally result from rheumatoid arthritis as a side effect of the condition or its treatment.

3. Infections
Viral illnesses: Hepatitis, influenza, HIV, and other viral illnesses can cause immediate harm

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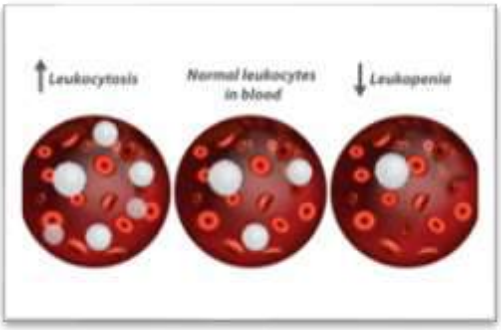
- **Leukocytosis (High WBC Count)**

Leukocytosis is the increase in the number of white blood cells, which can indicate an ongoing infection, inflammation, or other medical conditions: An increase in white blood cells can result from certain malignant or non-cancerous disorders, as well as from the immune system's normal reaction. decrease in white blood cells, which can be caused by cells being destroyed or by not enough cells being made.

- Infections (Bacterial, Viral, Fungal)
- Inflammatory conditions (e.g., Rheumatoid Arthritis, Inflammatory Bowel Disease)
- Leukaemia (Cancer of The Blood and Bone Marrow)
- Stress responses (physical or emotional stress can transiently raise WBC count)
- Tissue damage (e.g., Burns, Heart Attack)



Cause

1. **Chemotherapy:** Many chemotherapy drugs that are used to treat cancer can suppress bone marrow function, leading to leukopenia.Immunosuppressive Drugs: Medications used to treat autoimmune diseases (e.g., methotrexate, azathioprine, and cyclosporine) can also cause leukopenia as a side effect by suppressing the immune system.Antibiotics: Some antibiotics, like sulfonamides and chloramphenicol, can cause bone marrow suppression and lead to leukopenia.

Antithyroid Drugs: Medications used to treat hyperthyroidism (e.g., methimazole) can cause leukopenia in some individuals.

2. Autoimmune Diseases

Systemic Lupus Erythematosus (SLE): A chronic autoimmune disease where the immune system attacks healthy tissues, including white blood cells, potentially causing leukopenia.Rheumatoid Arthritis: Can lead to leukopenia, either due to the disease itself or as a side effect of certain medications used to manage it.

3. Nutritional Deficiencies

Vitamin B12 Deficiency: A lack of vitamin B12 can interfere with the production of white blood cells.Folate Deficiency: Folate (vitamin B9) is essential for the formation of new cells, including white blood cells, and its deficiency can lead to leukopenia. Copper Deficiency: Although rare, copper deficiency can result in leukopenia

4. Leukemia (Cancer of WBCs)

Leukemia is a kind of cancer that affects the bone marrow and blood, causing aberrant white blood cells to be produced out of control. The regular generation of blood cells may be hampered by these aberrant cells. Different forms of leukemia exist, including:

- Abnormal lymphoid cells proliferate rapidly in acute lymphocytic leukemia (ALL).
- Acute Myeloid Leukemia (AML) is a myeloid cell-related leukemia that grows quickly.
- The slow-growing leukemia known as chronic lymphocytic leukemia (CLL) is characterized by aberrant lymphocytes.

Cause

- Rapid production of abnormal white blood cells in the bone marrow
- Abnormal white blood cells crowd out red blood cells and platelets, and can't fight infection
- Bruising more easily on the face and hands

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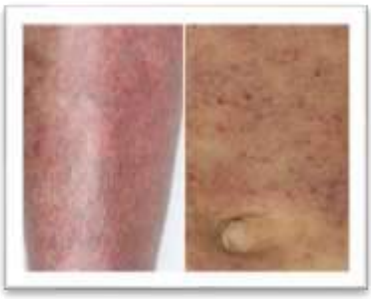
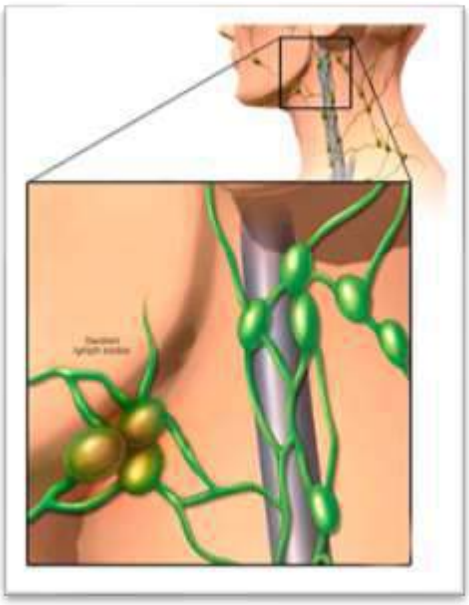
Lymphoma



- A particular kind of cancer called lymphoma develops in the immune system's lymphatic system. The tonsils, bone marrow, spleen, and lymph nodes are all parts of the lymphatic system. Uncontrolled growth of aberrant lymphocytes, a kind of white blood cell, is a feature of lymphoma. These cells can build up in lymph nodes and other organs, impairing the body's defenses against infections. Lymphomas are a heterogeneous group of malignancies that arise from the clonal proliferation of B- cell, T- cell and natural killer (NK) cell subsets of lymphocytes at different stages of maturation. Lymphoma comprises heterogeneous malignancies that arise from the clonal proliferation of lymphocytes. It represents approximately 5% of malignancies. Overall survival is estimated to be 72%.



Symptoms

- Swollen lymph nodes
- Signs and symptoms of lymphoma may include:
- Fever.
- Night sweats.
- Fatigue.
- Itchy skin.
- Painless swelling of lymph nodes in the belly, neck, armpits or groin.
- Pain in chest, abdomen or bones.

Myelodysplastic Syndromes

- A class of diseases known as myelodysplastic syndromes are brought on by malformed or malfunctioning blood cells. Myelodysplastic syndromes are caused by abnormalities in the bone marrow, the spongy substance that makes up your bones and produces blood cells.
- The main goals of managing myelodysplastic syndromes are to reduce symptoms, decrease the progression of the condition, and avoid consequences. Blood transfusions and drugs that increase the formation of blood cells are common interventions. To replace your bone marrow with healthy bone marrow from a donor, a bone marrow transplant—also referred to as a stem cell transplant—may be advised in specific circumstances

Causes

- The bone marrow of a healthy individual produces new, immature blood cells that develop over time. When something interferes with this process, the blood cells fail to mature, leading to myelodysplastic syndromes
- The blood cells either perish in the bone marrow or shortly after entering the bloodstream, rather than growing properly. There are more immature, damaged cells than healthy ones over time, which can result in issues like anemia (fatigue from a lack of healthy red blood cells), leukopenia (infection from a lack of healthy white blood cells), and thrombocytopenia (bleeding from a lack of blood-clotting platelets).
- The cause of the majority of myelodysplastic syndromes is unknown. Others are brought on by exposure to harmful substances like benzene or cancer therapies like radiation and chemotherapy.

Symptoms

In time, myelodysplastic syndromes might cause:

- Fatigue
- Shortness of breath
- Unusual paleness (pallor), which occurs due to a low red blood cell count (anemia)
- Easy or unusual bruising or bleeding, which occurs due to a low blood platelet count (thrombocytopenia)
- Pinpoint-sized red spots just beneath the skin that are caused by bleeding (petechiae)
- Frequent infections, which occur due to a low white blood cell count (leukopenia)

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➢ AUTOIMMUNE DISORDERS

A broad category of illnesses known as autoimmune disorders are defined by immunological abnormalities that result in abnormal B and T cell responses to normal host components. These illnesses can affect people of any age and affect almost any organ system, however they are far more common in women. The clinical presentations of autoimmune disease are very diverse, despite the fact that certain pathways bring various disorders together into a unified group. These symptoms might be anything from minor test anomalies that are easy to overlook to sudden, life-threatening organ failure. Clinically, autoimmune disorders can be either extensive (systemic or non-organ-specific) or limited in their pattern of organ involvement (organ-specific)

Autoimmune diseases are a diverse group of conditions characterized by aberrant B cell and T cell reactivity to normal constituents of the host. These diseases occur widely and affect individuals of all ages, especially women. Among these diseases, the most prominent immunological manifestation is the production of autoantibodies, which provide valuable biomarkers for diagnosis, classification and disease activity

Causes

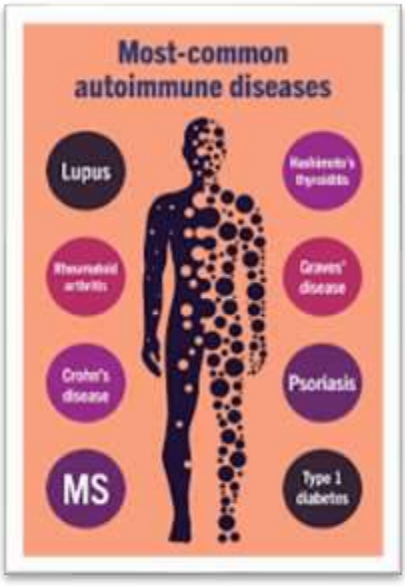
The blood cells in the body's immune system help protect against harmful substances. Examples include bacteria, viruses, toxins, cancer cells, and blood and tissue from outside the body. These substances contain antigens. The immune system produces antibodies against these antigens that enable it to destroy these harmful substances.

When you have an autoimmune disorder, your immune system does not distinguish between healthy tissue and potentially harmful antigens. As a result, your body sets off a reaction that destroys normal tissues

Symptoms:

An autoimmune disorder may result in:

- The destruction of body tissue
- Abnormal growth of an organ
- Changes in organ function
- An autoimmune disorder may affect one or more organ or tissue types. Areas often affected by autoimmune disorders include:
- Blood vessels
- Connective tissues
- Endocrine glands such as the thyroid or pancreas
- Joints
- Muscles
- Red blood cells
- Skin



Neutropenia

Neutropenia is a condition characterized by an abnormally low number of neutrophils, which are a type of white blood cell that plays a key role in defending the body against infections, particularly bacterial and fungal infections. Neutrophils are the most abundant type of white blood cell and are an essential part of the immune system's first line of defense

Neutropenia gets classified as mild, moderate, or severe, depending on the number of neutrophils in a blood sample. The lowest normal limit for adults is about 1,500 neutrophils per microliter of blood by many standards. (Some put the cut-off at 1,800 per microliter.) The range of neutrophil numbers is:

- **Mild neutropenia:** 1,000 – 1,500.
- **Moderate neutropenia:** 500 – 1,000.
- **Severe neutropenia:** Less than 500.

Neutropenia can also be classified as acute (temporary or short-lasting) or chronic (long-lasting), congenital (a condition you're born with) or acquired (a condition that happens over time).

Symptoms:

- ✓ Fever (febrile neutropenia).
- ✓ Fatigue.

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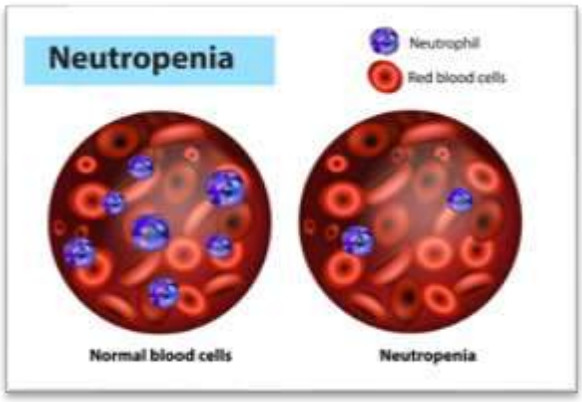
- ✓ Sore throat (pharyngitis).
- ✓ Swollen lymph nodes.
- ✓ Ulcers in your mouth or around your anus.
- ✓ Pain, swelling and rash at an infection site.
- ✓ Diarrhea.
- ✓ Burning with urination or other urinary symptoms (urgency, frequency).



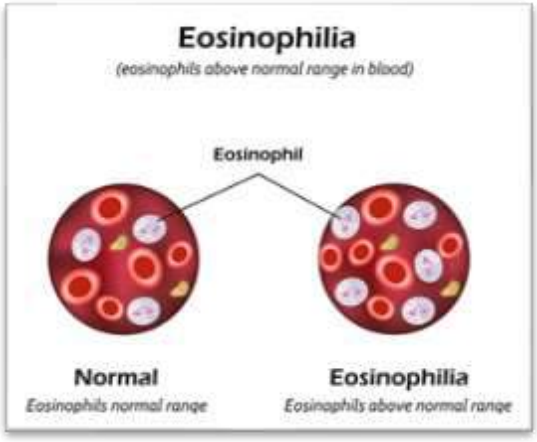
Eosinophilia

Eosinophilia happens when your body produces an unusually high number of eosinophils. Eosinophils are one of several white blood cells that support your immune system. Sometimes, certain medical conditions and medications cause high eosinophil levels Sometimes, eosinophils cause inflammation in specific areas of your body. When this happens, it's called an eosinophilic disorder or hypereosinophilia syndrome (HES). Specific eosinophilic disorders are named for the parts of your body that are affected.

Causes

Destroy foreign substances. Eosinophils consume matter flagged by your immune system as harmful. For example, they fight matter from parasites.

Control infection. Eosinophils swarm an inflamed site when needed. This is important to fight disease. But too much can cause more discomfort or even tissue damage. For example, these cells play a key role in the symptoms of asthma and allergies, such as hay fever. Other immune system issues can lead to chronic inflammation as well



Symptoms

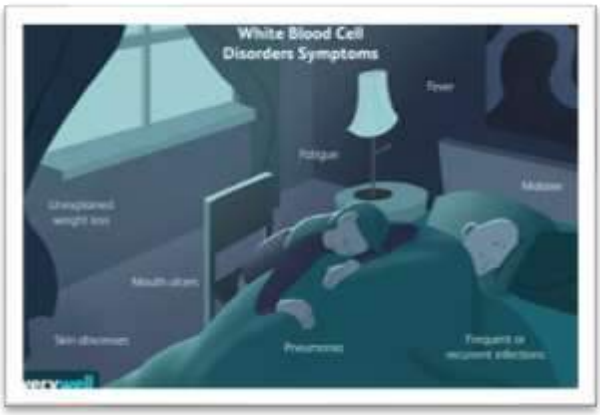
- ❖ Parasitic and fungal diseases
- ❖ Allergic reactions
- ❖ Adrenal conditions
- ❖ Skin disorders
- ❖ Toxins
- ❖ Autoimmune disorders
- ❖ Endocrine conditions.
- ❖ Tumors

➢ **Diagnosis**

One of the first tests used to diagnose a white blood cell disorder is a complete blood cell (CBC). This test measures all of the different types of blood cells in a sample of blood. It also measures the proportion of individual blood cells, which can help narrow the possible causes.
The lab results are compared to a reference range of high and low values. The reference range for the total white blood cell (WBC) count can vary from one lab to the next but is typically described as follows:

- ❖ **Males**: 5,000 to 10,000 cells per microliter of blood (cells/mL)
- ❖ **Females**: 4,500 to 11,000 cells/mL
- ❖ **Newborns under two weeks of age**: 9,000 to 30,000 cells/mL
- ❖ **Children and adolescents**: 5,000 to 10,000 cells/mL

Since white blood cells are produced in the bone marrow, a bone marrow biopsy may also be ordered to get a sample of tissue for evaluation by a pathologist.



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If you require further investigation, you may be referred to a hematologist, a doctor who specializes in blood disorders, or an immunologist, a doctor who specializes in disorders of the immune system.

1.Neutropenia (Low Neutrophils)

Treatment Options for Neutropenia:

- Granulocyte Colony-Stimulating Factor (G-CSF): Medications like filgrastim (Neupogen) or pegfilgrastim (Neulasta) stimulate the bone marrow to produce more neutrophils.
- Antibiotics/Antifungals: If an infection occurs, prompt treatment with antibiotics or antifungals is crucial to prevent serious complications.
- Corticosteroids or Immunosuppressive Therapy: If neutropenia is caused by an autoimmune disease, treatments such as steroids or other immunosuppressive drugs may help.
- Bone Marrow Transplant: In severe cases of neutropenia caused by bone marrow failure or genetic disorders (e.g., Kostmann syndrome), a bone marrow transplant or hematopoietic stem cell transplant may be necessary.
- Discontinuation of Offending Medications: If a medication is responsible (e.g., chemotherapy, some antibiotics), stopping or replacing it may resolve neutropenia.

2. Leukopenia (Low Total White Blood Cell Count)

Treatment Options for Leukopenia:

- Treatment of Underlying Cause: The primary approach is to treat the underlying cause, such as infections, autoimmune diseases, or bone marrow suppression.
- G-CSF and Other Growth Factors: Granulocyte-macrophage colony-stimulating factor (GM-CSF) and G-CSF can be used to stimulate the production of more WBCs in certain conditions.
- Medications: If leukopenia is due to an infection, antiviral or antibacterial drugs may be required. In cases of autoimmune disorders, immunosuppressive drugs (e.g., azathioprine, cyclophosphamide) may be used to reduce immune system activity.

3. Leukocytosis (High White Blood Cell Count)

Treatment Options for Leukocytosis:

- Treating Infections or Inflammatory Conditions: If the elevated WBC count is due to an infection, antibiotics, antivirals, or antifungals will be used to treat the infection. For inflammatory conditions, anti-inflammatory medications or steroids (e.g., prednisone) might be prescribed.
- Chemotherapy: If leukocytosis is caused by leukemia or other cancers of the blood, chemotherapy or targeted therapies (e.g., imatinib for chronic myelogenous leukemia) may be necessary to reduce the number of abnormal WBCs.
- Steroids: In cases of inflammation or autoimmune disorders causing leukocytosis, corticosteroids like prednisone may be used to reduce the production of white blood cells.
- Hydroxyurea: For conditions like polycythemia vera or chronic myelogenous leukemia (CML), hydroxyurea is sometimes used to reduce high WBC counts.

4. Leukemia (Cancer of White Blood Cells)

Treatment Options for Leukemia:

- Chemotherapy: This is the primary treatment for most types of leukemia (e.g., acute lymphocytic leukemia [ALL], chronic lymphocytic leukemia [CLL], acute myelogenous leukemia [AML], chronic myelogenous leukemia [CML]).
- Targeted Therapy: Targeted therapies like tyrosine kinase inhibitors (e.g., imatinib for CML) focus on blocking specific proteins involved in the growth of leukemia cells.
- Radiation Therapy: Radiation may be used to treat certain forms of leukemia or to prepare for a stem cell transplant.
- Stem Cell/Bone Marrow Transplant: For some patients with leukemia, especially those who are refractory to chemotherapy, a bone marrow or stem cell transplant can provide a potential cure by replacing the diseased bone marrow with healthy cells.
- Immunotherapy: In some cases, CAR T-cell therapy (chimeric antigen receptor T-cell therapy) is used to enhance the patient's immune system to target and kill leukemia cells.

5. Lymphocytosis (High Lymphocyte Count)

Treatment Options for Lymphocytosis:

- Infection Treatment: If the lymphocytosis is due to an infection (e.g., mononucleosis or chronic viral infections), antiviral medications or supportive care (hydration, rest, etc.) are used.

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- Chemotherapy and Immunotherapy: In cases of chronic lymphocytic leukemia (CLL) or other lymphocytic leukemias, chemotherapy, targeted therapies (e.g., ibrutinib), and immunotherapy may be necessary.

6. Bone Marrow Disorders (e.g., Aplastic Anemia, Myelodysplastic Syndromes)

Treatment Options for Bone Marrow Disorders:

- Bone Marrow Transplant: For severe bone marrow failure or conditions like aplastic anemia, a bone marrow or stem cell transplant may be required.
- Immunosuppressive Therapy: For diseases like aplastic anemia, drugs like antithymocyte globulin (ATG) and cyclosporine are used to suppress the immune system, which can be attacking the bone marrow.
- Erythropoiesis-Stimulating Agents: Medications that stimulate red blood cell production (e.g., epoetin alfa) can be used when anemia is a concern.
- Chemotherapy: In cases of myelodysplastic syndromes or leukemia, chemotherapy may be used to control abnormal cell production.

7. Autoimmune Disorders Affecting WBCs (e.g., Systemic Lupus Erythematosus, Rheumatoid Arthritis)

Treatment Options for Autoimmune Disorders:

- Immunosuppressive Drugs: Medications like methotrexate,cyclophosphamide, azathioprine, and mycophenolate mofetil are used to reduce immune activity.
- Corticosteroids: Prednisone and other corticosteroids can help manage inflammation and suppress immune responses.
- Biologic Agents: Drugs like rituximab or TNF inhibitors (e.g., etanercept) may be used in autoimmune diseases like rheumatoid arthritis or lupus.

Treatment

- The treatment of white blood cell disorders differs according to the cause. Some treatments are used to cure the disease, while others simply manage the disease and keep it in check. Others still are used to relieve symptoms or help normalize the white blood cell count. Possible treatments include:
- MedlinePlus: White blood count (WBC).
- Antibiotics: Used to treat bacterial infections
- Colony-stimulating factors (CSF): Medications that increase white blood cell production in the bone marrow
- Glucocorticoids: A medication that may treat the underlying immune disorder and may even move neutrophils from outlying sources back to the peripheral blood.9
- Immunosuppressants: Medications that reduce the immune response in people with autoimmune diseases
- Chemotherapy and radiation: Therapies commonly used to treat cancer
- Stem cell transplantation: Used to cure certain blood-related disorders, including myeloproliferative disorders and congenital neutropenia
- Antiparasitic drugs: Used to treat parasitic infections that cause eosinophilia
- Blood component transfusion: This is typically a temporary method to replenish the part of the blood that is lacking until the underlying cause has been handled.

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CONCLUSION

- To sum up, white blood cell (WBC) disorders include a broad spectrum of abnormalities that might impact the immune system's capacity to defend the body against infections, fend off illnesses, or control regular cell functions. Leukopenia (low WBC count), leukocytosis (high WBC count), and different blood malignancies like leukemia or lymphoma are examples of these conditions. These disorders may be inherited, autoimmune, infectious, or the consequence of exposure to chemicals or radiation in the environment.
- Blood tests, bone marrow biopsies, and imaging scans are frequently used in the diagnosis process, and the specific condition will determine the course of treatment. In order to eradicate aberrant cells or restore normal WBC function, management options may involve the use of drugs, chemotherapy, stem cell transplants, or other therapies.
- In the end, early identification and action are Ultimately, as many WBC abnormalities can have a major impact on the body's immunological response and general health, early detection and intervention are essential to enhancing results. The type of disease and the timing of treatment can have a significant impact on the prognosis.
- A white blood cell disorder is one in which the white blood cells are either qualitatively or quantitatively affected. There are many possible causes of this, including infections, genetic disorders, autoimmune diseases, and, in rare cases, cancer. There are even cases in which the cause is unknown.
- White blood cell disorders often require extensive tests to uncover the underlying cause. This may include a complete blood count (CBC) and blood smear but also special procedures like a bone marrow biopsy.
- The treatment of a white blood cell disorder varies by the cause. While some conditions are serious and require aggressive treatments, such as chemotherapy, others may be relatively minor and require little to no treatment.
- Finding the root cause of the aberrant WBC count or function is essential to the diagnosis and treatment of white blood cell diseases, which are complicated processes. Patient outcomes can be greatly enhanced by an early and precise diagnosis made via imaging, genetic profiling, and laboratory testing, followed by specialized therapy. Conservative therapies and supportive care are frequently adequate for benign diseases like infections or moderate leukopenia. Advanced treatments like chemotherapy, targeted medicines, stem cell transplantation, and immunotherapy are essential for controlling and reversing more severe diseases like leukemia, lymphoma, or myelodysplastic syndromes. The prognosis for many individuals with WBC problems is continuously improving due to ongoing research and advancements in precision treatment.

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SKIN CANCER NON MELANOMA

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ABSTRACT

In Caucasians, nonmelanoma skin cancer (NMSC) is the most prevalent type of cancer, and its incidence is steadily rising globally. Seventy-five percent of NMSC cases are basal cell carcinoma (BCC), with the remaining majority of NMSC instances being squamous cell carcinoma (SCC). Although BCC metastases are very uncommon, high-risk SCC metastases can be lethal. We go over the causes, symptoms, and treatment of NMSC in this post.

Context: *The most common cancer in humans to be diagnosed is non-melanoma skin cancer. Skin carcinogenesis is still a poorly understood phenomenon. To better understand the mechanisms underlying malignancy, however, a number of investigations have been carried out; (2) Techniques: With an emphasis on actinic keratosis, squamous cell carcinoma, and basal cell carcinoma, we examined the most recent research on the etiology of non-melanoma skin cancer; (3) Findings: Numerous studies documented molecular and genetic changes that result in skin cancer that is not melanoma. The pathophysiology of non-melanoma skin cancer involves numerous risk factors, such as immunosuppression, UV radiation, and genetic and molecular changes.4) Conclusion Several studies have shown that genetic and molecular changes play a role in skin carcinogenesis, despite the fact that this process is still not entirely understood. Furthermore, a number of risk factors for non-melanoma skin cancer are now understood, making it possible to effectively prevent the development of non-melanoma skin cancer. Our review concentrated on molecular and genetic factors and thoroughly examined a number of factors associated with non-melanoma skin cancer, in contrast to earlier articles on the same subject.*

KEYWORDS: *Actinic Keratosis; Pathogenesis; Precancerous Conditions; Skin Neoplasms*

REVIEW OF LITERATURE

1) D Didona, G Paolino, U Bottoni, C Cantisani

Furthermore, a number of risk factors for non-melanoma skin cancer are now understood, making it possible to effectively prevent the development of non-melanoma skin cancer. Our review concentrated on molecular and genetic factors and thoroughly examined a number of factors associated with non-melanoma skin cancer, in contrast to earlier articles on the same subject.(2)

2) S Razi, M Enayatrad

Skin cancer is becoming more common in the nation. Therefore, health policy makers must give top attention to the plan for the prevention and control of this malignancy.(3)

3) J.Augustin, A.Kis, C.Sorbe, I.Schafer, M.Augustin

Our findings show that the prevalence of skin cancer in Germany is significantly influenced by sociodemographic characteristics, sunlight hours, and regional UV radiation. Clearly, one of the main determinants that should be addressed by preventive measures is individual behavior.(26)

4) Larisa Paramitha Wibawa, Melody Febriana Andardewi, Inge Adi Kristanti, Riesye Arisanty

The prevalence of BCC is rising in Dr. Cipto Mangunkusumo National General Hospital as compared to other forms. Establishing national skin cancer data in Indonesia requires a well-documented skin cancer registry.(25)

5) Rolf-Markus SZEIMIES, Colin A. MORTON, Alexis SIDOROFF and Lasse R. BRAATHEN, Photodynamic

A less invasive treatment with great esthetic outcomes is photodynamic therapy. In addition to being licensed for actinic keratosis in the US, methyl aminolevulinate-photodynamic therapy is already approved for actinic keratosis and basal cell carcinoma in Europe, Australia, and New Zealand.(9)

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6) Czarnecki D
The remainder of the population is the susceptible group. This article examines the NMSC death rate for sensitive populations and the general population since 1971.(17)

7) Samarasinghe, Venura; Madan, Bishal
Seventy-five percent of NMSC cases are basal cell carcinoma (BCC), with the remaining majority of NMSC instances being squamous cell carcinoma (SCC). Although BCC metastases are very uncommon, high-risk SCC metastases can be lethal. This article examines the causes, symptoms, and treatment of NMSC.(16)

INTRODUCTION

According to estimates from the American Cancer Society, the yearly incidence of nonmelanoma skin cancer (NMSC) in the United States is currently over one million instances, which is about equivalent to the total number of human malignancies. BCCs make up the great majority of non-malignant squamous cell carcinomas (NMSCs), while SCCs in about a 4:1 ratio. Many other nonmelanoma skin cancers are caused by a variety of other cell types present in the skin, such as Merkel cells, vascular endothelial cells, lymphocytes, mesenchymal stromal cells, and cells that make up the adnexal structures. Since these entities are rather rare compared to BCC and SCC, we won't discuss them here.(1)

The most common malignancy to be diagnosed is non-melanoma skin cancer (NMSC). Although any kind of skin cell can become the source of a skin cancer, 70% of all NMSC instances are basal cell carcinoma (BCC), and 25% are squamous cell carcinoma (SCC). Both BCC and SCC have a fair prognosis, especially when identified early, despite differences in development patterns, behavior, and probability of spreading.(2)

Skin cancer risk is influenced by a combination of environmental, genetic, and personal factors. Personal and genetic traits that affect skin cancer risk include factors like skin color, eye color, hair color, age, and sometimes immune system deficiencies. Environmental factors include prolonged outdoor activities, changes in lifestyle, heavy alcohol consumption, a diet high in fat, exposure to UV radiation, and living at lower latitudes. Although skin cancer is one of the most common cancers, it is also one of the most preventable. The earlier preventive measures are taken, the greater the impact in reducing the risk. This type of cancer is particularly prevalent in Iran, where there has been little comprehensive research on its trends.(3)

EPIDEMIOLOGY OF SKIN CANCER

Squamous Cell Carcinoma

Squamous cell carcinoma (SCC) is a type of malignant epithelial tumor that often begins as a localized form called carcinoma in situ within the skin's outer layer (epidermis). Over time, it can develop into an invasive cancer. SCC is the most common type of cancer in the mucous membranes and areas where the skin transitions to mucosa, accounting for about 20% of all skin cancers. These tumors usually spread through the lymphatic system and grow aggressively. The same risk factors linked to actinic keratosis (AKs) also contribute to the development of SCC. In the United States, around 200,000 new cases of SCC are diagnosed each year. A study estimates that a Caucasian man born in 1994 has a 9% to 14% chance of developing SCC in his lifetime, while the risk for white women is estimated to be between 4% and 9%.(4)

Skin Cancer Pathophysiology

The development of skin cancer is influenced by multiple factors. The primary cause of both malignant melanoma and non-melanoma skin cancer (NMSC) is ultraviolet radiation (UVR) from sunlight. UVR is made up of two main types of rays: ultraviolet A (UVA) and ultraviolet B (UVB). UVA rays penetrate deeper into the skin and can cause more significant damage, such as the breakdown of skin fibers (elastosis). UVB rays are mainly responsible for sunburns or erythema. UVR leads to various harmful effects, including DNA damage, gene mutations, suppression of the immune system, oxidative stress, and inflammation.(5)

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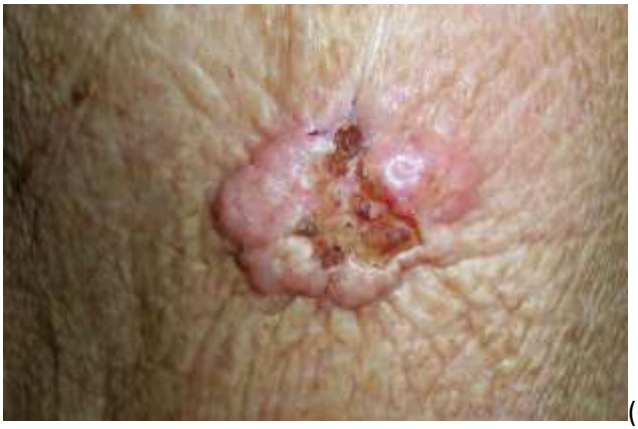
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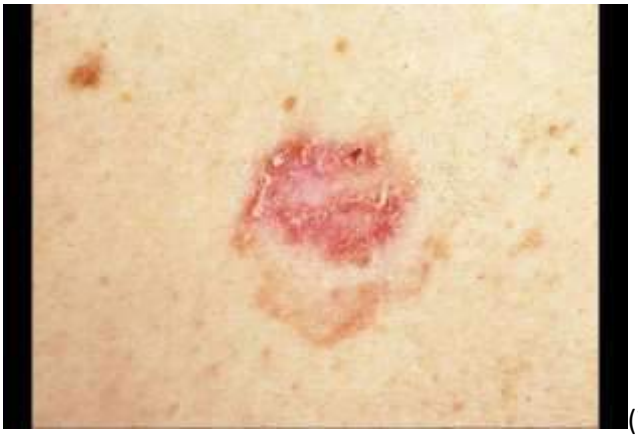
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MECHANISM OF ACTION

Reactive oxygen species (ROS), particularly singlet oxygen, are generated when a photosensitizer is activated by light of the right wavelength. These ROS can disrupt cellular functions or lead to cell death, either through necrosis or apoptosis, depending on their concentration and the specific area of the tissue they affect. Interestingly, there is limited data on the cancer-causing potential of ALA/MAL photodynamic therapy (PDT), with only two case reports, which may have been coincidental. Additionally, a recent study showed that long-term use of topical ALA with blue light exposure did not result in skin tumors in a hairless mouse model. The damage from this treatment mainly targets the tumor, as ALA or MAL preferentially sensitizes growing, iron-deficient tumor cells of epithelial origin, leading to good cosmetic outcomes with minimal risk to surrounding healthy tissue. Unlike systemic photosensitizers, which cause damage to the tumor's blood vessels, ALA/MAL-PDT targets the tumor itself.(9)

Formulation Table

Characteristics of the dataset (10)

Types	Train_Sep	Test	Valid Sum
Melanoma.	5341	1781	8903
Nonmelanoma	5341	1781	8903

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Rising Incidence of Melanoma Varies by Subsite and Sex

The data shows notable differences in melanoma rates between sexes and body sites over time. For example, the rate of melanoma in the arm among white individuals increased by 71% in males (from 1.4 to 2.4 per 100,000) and by 41% in females (from 1.7 to 2.4 per 100,000) between the periods of 1973–1977 and 1983–1987. In the leg, the rate increased by 43% in females (from 2.3 to 3.3) and by 37% in males (from 0.8 to 1.1). The most significant rise occurred in the trunk area, with a 70% increase in males (from 3.0 to 5.1) and a 76% increase in females (from 1.3 to 2.3). Overall, melanoma rates are increasing at all major sites, particularly on the trunk, and these trends are similar for both sexes.(11)

Genetics of Non-Melanoma Skin Cancer and New Candidate Genes

Researchers are continuing to explore the genetic factors that contribute to the development of various cancers, focusing on aspects such as genomic stability and genetic variations that can affect the expression of oncogenes and tumor suppressor genes. In the case of cutaneous carcinomas, UV radiation-induced DNA damage is a key characteristic. It is estimated that just one hour of UV exposure can cause between 100,000 and 200,000 DNA lesions, which, if not properly repaired, can disrupt critical cellular processes like transcription and replication. Recent studies have also shown that non-melanoma skin cancer (NMSC) lesions can accumulate mutations that drive more aggressive cancer forms. The ability of cancer cells to adapt allows them to escape normal cellular control mechanisms.(12)

NMSC and Ultraviolet Radiation

A study conducted in Beijing explored the connection between surface UV radiation and air pollution levels using the TUV4.4 radiative transfer model. The findings showed that the average ozone content in the atmosphere is higher during winter and spring, and lower in summer and autumn. Interestingly, there is an inverse relationship between ozone levels and ground-level UV radiation, meaning that as ozone levels increase, UV radiation decreases. Additional data indicated that UV radiation is reduced by more than 50% on days with high air pollution. In conclusion, the study suggests that in Beijing, there is a clear link between the decrease in UV radiation reaching the ground and the increased levels of ozone and nitrogen oxides in the lower atmosphere.(13)

Radiotherapy

For some patients with non-melanoma skin cancer (NMSC) who cannot undergo surgery, radiotherapy can be an effective treatment alternative. However, its overall success rate is lower compared to methods like Mohs micrographic surgery (MMS) or standard excision with set margins. A meta-analysis by Rowe et al. found a 5-year cure rate of 91.3% for basal cell carcinoma (BCC), while another study showed a 5-year cure rate of 90% for squamous cell carcinoma (SCC). In cases where full surgical removal of the tumor is not possible due to advanced disease, radiation therapy may be used as a palliative option or as additional treatment after surgery, especially for tumors with nerve involvement.(14)

MATERIALS AND METHODS

The Australian Bureau of Statistics (ABS) provided the population data for Australia. Every five years, there is a census, and everyone is required by law to participate. Although the population's countries of birth were noted in every census, the 2001 census was the first to record the population's ancestry [18]. Data on all births and deaths in Australia for the calendar year are provided by the ABS every year. Children born in Australia have their parents' country of birth listed, but not their heritage. Each fatality that was caused by skin cancer is identified as either melanoma or non melanoma skin cancer.(15)

For the diagnosis, the clinician examined the 3D avatar both in a broad overview and a detailed, zoomed-in view, enabling them to assess each lesion from multiple angles. To ensure consistency between the two devices, the clinician was provided with precise details about the number and locations of lesions for each patient. The diagnostic results from dermoscopy and the 3D-TBP zoomed-in view were compared to histopathology to assess their accuracy. Rather than choosing from a range of possible diagnoses, the clinician recorded a specific suspected diagnosis along with a confidence level for each device. The diagnoses were categorized into basal cell carcinoma (BCC), squamous cell carcinoma (SCC), in-situ SCC, other malignant lesions, and benign lesions.The final diagnosis was based on histological results when available. Tumors with clear diagnoses were removed, while benign lesions were treated locally without the need for histological examination. In cases where the diagnosis was uncertain, punch biopsies were performed. Punch or excision biopsies were only used for lesions suspected to be superficial BCC or in-situ SCC if the doctor had low confidence in the diagnosis. Only lesions with histopathological confirmation were included in the calculation of the imaging devices' sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy; clinical diagnoses without histopathological confirmation were excluded.(16)

This retrospective analysis used electronic medical records from kidney transplant patients at Rabin Medical Center. It focused on all adult patients (aged 18 and older) who received a kidney transplant between January 1, 2005, and December 31, 2010. These patients

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were closely monitored by nephrologists at the kidney transplant clinic, and they also attended at least one annual check-up at the transplant dermatology clinic. Patients who experienced graft loss or death within the first year after their transplant, or who were diagnosed with non-melanoma skin cancer (NMSC) in that same period, were excluded from the study. There was no reliable data available regarding the incidence of NMSC before the transplant or details on skin phenotype unrelated to their ancestral background.(17)

DISCUSSION

Although non-melanoma skin cancers are sometimes thought of as non-aggressive tumors, this is only true for tiny lesions that get prompt, appropriate treatment. Locally, both BCCs and cSCCs are distinguished by varying rates of destructive development and tissue invasion. In the case of cSCCs, distant invasion has a low rate of metastasis, while regional tissue invasion happens less frequently through lymph node metastasis [37–39]. Despite having a very low death rate, these tumors are very common and represent a significant worldwide health burden. Furthermore, they are associated with a high rate of morbidity, especially when they impact parts of the face that are sensitive to cosmetics, which frequently calls for difficult reconstructive procedures(18)

Martincorena et al. conducted a study that looked for somatic mutations using ultra-deep sequencing of 74 cancer-related genes from skin biopsies of normal skin taken from sun-exposed eyelid areas across 234 samples from four individuals. They found that the mutation rate in these samples was typical for UV radiation (UVR) exposure, with an average of two to six mutations per megabase per cell, which is similar to the mutation rates seen in many cancers. They observed a high frequency of specific mutations, including CC>TT dinucleotide changes and C>T mutations. Notably, 20% of normal skin cells carried a mutation in the NOTCH1 gene, making it the most frequently altered gene in the study. In skin squamous cell carcinoma (SCC) and other cancers, both copies of NOTCH1 are often inactivated, typically through point mutations and changes in the gene's copy number. Other commonly mutated genes include RBM10,FGFR3, CDKN2A, and NOTCH2.(19)

CONCLUSION

The incidence of Basal Cell Carcinoma (BCC) is increasing at Dr. Cipto Mangunkusumo National General Hospital compared to other types of skin cancer. To establish comprehensive national data on skin cancer in Indonesia, it is essential to create a well-maintained skin cancer registry.(20)

RESULT

An analysis was conducted using data from 70.1 million insured individuals. In 2009 and 2015, the age-adjusted rates of malignant melanoma (MM) and non-melanoma skin cancer (NMSC) were 284.7 and 1126.9 cases per 100,000 insured individuals, respectively, in 2009, and 378.5 and 1708.2 per 100,000 in 2015. There were significant regional variations in prevalence, ranging from 32.9% to 51.6%. The multivariate analysis showed that there were statistically significant positive correlations between the prevalence of MM/NMSC and higher levels of wealth and education.(21)

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A REVIEW ON AI IN CLINICAL RESEARCH AND DRUG DISCOVERY

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ABSTRACT

Clinical trials play a crucial role in bringing new medications, technologies, and procedures to market and into clinical practice. However, only about 10% of these studies successfully navigate the entire process from drug design through all four phases of development. This low completion rate is largely due to the increasing costs and complexities associated with conducting clinical trials. As a result, the health of the population, the standard of care, health economics, and sustainability are all adversely impacted.

Artificial intelligence (AI) has the potential to streamline some of the most tedious processes in clinical trials, such as patient selection, matching, and enrollment. Improved patient selection could not only enhance the efficiency of trials but also reduce the risk of adverse treatments and their side effects. Despite its promise, the widespread adoption of AI technology in clinical trials faces several challenges and necessitates further high-quality prospective clinical validation.

In this review, we explore the prospective applications of AI in clinical research and patient care, highlighting its potential to transform the landscape of clinical trials in the future.

KEYWORDS : *Artificial Intelligence ;Clinical Trials; Drug development,drug discovery; future AI.*

INTRODUCTON

The aim of artificial intelligence (AI) is to create intelligent machines. Key methods within AI include Natural Language Processing (NLP), Machine Learning (ML), Optical Character Recognition (OCR), and Deep Learning (DL) [1]. AI is one of the latest advanced technologies transforming clinical trials. The rapid advancement of information technology and the growing volume of biomedical data provide a solid technical foundation for AI development in healthcare. Researchers are investigating AI applications to improve medical diagnostics, enhance service quality, and reduce the complexity and risks associated with clinical trials [2].

Transforming Eroom's Law into Moore's Law through Artificial Intelligence

Bringing a new drug to market typically takes 10 to 15 years and requires an investment of $1.5 to $2.0 billion. Approximately half of this time and budget is spent on clinical trials, while the other half covers preclinical discovery, testing, and regulatory processes. Despite the continuous increase in R&D spending by pharmaceutical and biotechnology companies, the number of new drugs approved per billion dollars spent has halved roughly every nine years. This trend, which mirrors the reverse of Moore's Law from semiconductor technology, is known as Eroom's Law.(3) It presents a significant challenge to the current clinical development model, especially in an era where blockbuster drugs are becoming less common; such inefficiency in bringing drugs to market is unsustainable.(4)

A major hurdle in the drug development pipeline is the high failure rate of clinical trials. Less than one-third of compounds in Phase II trials progress to Phase III, and over one-third of Phase III trials fail to secure regulatory approval. Since these critical assessments occur late in the R&D cycle—especially with Phase III trials often accounting for about 60% of the total trial costs—the financial repercussions of failed trials can range from $800 million to $1.4 billion, representing a substantial loss in R&D investments(5)

OBJECTIVE

- Clinical trials are essential for evaluating the safety, reliability, and effectiveness of new therapeutics.
- By optimizing data collection to improve recruitment, adherence, and analysis, artificial intelligence (AI) can accelerate trial cycles and enhance patient outcomes.
- AI can automate the generation of analysis reports and intelligently interpret data for integration with downstream systems

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1.The Evolution of AI in Clinical Trials

Artificial Intelligence (AI), a field focused on creating intelligent computer programs, was first defined in 1955. (6)Today, AI is emerging as a powerful solution for numerous healthcare management challenges. The global market for AI-driven clinical trial solutions, particularly in patient matching, is projected to reach USD 1.969 billion by 2030. Clinical research and development, the second fastest-growing area, is expected to expand at a compound annual growth rate (CAGR) of 22.0% from 2023 to 2030.(7)

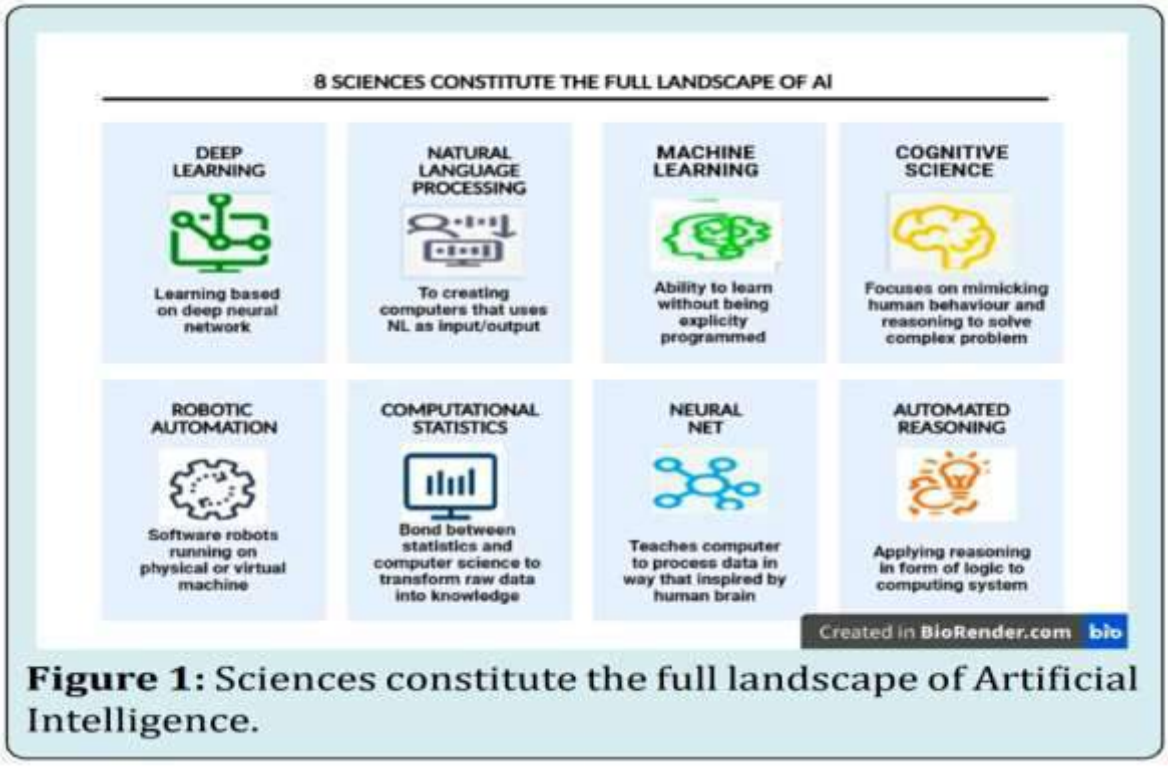

Figure 1: Sciences constitute the full landscape of Artificial Intelligence.

Fig. 1. Sciences Constitute the full landscape of AI

The landscape of clinical research will continue to evolve as these tools advance, opening new opportunities. AI encompasses a wide range of disciplines, represented by eight key areas: Deep Learning (DL), Natural Language Processing (NLP), Machine Learning (ML), Cognitive Science, Robotic Automation, Automated Reasoning, Computational Statistics, and Neural Networks. The progression of AI into a more sophisticated future relies on a variety of interconnected advancements that build on each other.(8)

The evaluation of AI in clinical research focuses on understanding its effectiveness, reliability, and potential impact on healthcare. AI has become an increasingly important tool in clinical research, contributing to drug development, diagnostics, patient monitoring, personalized treatment, and overall improvement in clinical decision-making. Here's an overview of its evaluation:

a. Key Areas of AI Application in Clinical Research

- Drug Discovery and Development:AI is used for predicting drug-target interactions, identifying biomarkers, and repurposing existing drugs. It accelerates the identification of potential therapeutic compounds, significantly reducing the time and cost of drug development.
- Clinical Trials: AI can help in patient recruitment by analyzing medical records to identify eligible participants. It also facilitates adaptive trial designs, where algorithms adjust the trial parameters in real time based on incoming data.

b. Methods of Evaluation

To assess the effectiveness of AI in clinical research, various evaluation criteria are used:

- Accuracy and Precision: Evaluating the model's performance against human experts or existing benchmarks. For example, in diagnostics, AI models are compared with radiologists' assessments.
- Sensitivity and Specificity: These metrics are crucial, especially in diagnostic AI tools. Sensitivity (true positive rate) and specificity (true negative rate) help determine how well the AI model detects the presence or absence of a condition.

c. Challenges in Evaluation

- Data Quality and Availability: High-quality, annotated datasets are needed for training AI models. Clinical data is often fragmented, unstructured, and siloed across different healthcare systems, making comprehensive evaluation challenging.

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- Regulatory Approvals: Regulatory bodies like the FDA and EMA have established frameworks for the approval of AI-based tools in clinical settings. However, the dynamic nature of AI models, which can learn and evolve over time, presents unique challenges for validation and continuous monitoring.

d. Current Trends and Innovations

- Federated Learning: This approach allows AI models to be trained on decentralized data from multiple clinical sites without sharing the raw data, enhancing privacy and enabling broader data access.
- Real-World Evidence (RWE): AI tools are increasingly being evaluated using real-world data (e.g., from EHRs, wearable devices) instead of relying solely on controlled clinical trial data. This provides insights into how AI performs in diverse, everyday clinical environments.

e. Future Directions

- Regulatory Frameworks and Standardization: As AI continues to evolve, there is a need for standardized protocols and guidelines for evaluating AI tools in clinical research. Collaborative efforts between regulatory bodies, healthcare providers, and AI developers are essential.
- Integration with Clinical Workflows: The next step in evaluating AI is to assess its integration into clinical workflows and its impact on healthcare delivery. This includes measuring the efficiency, cost-effectiveness, and patient satisfaction associated with AI-driven tools.

2. Problems with the Traditional Clinical Trial Process

The drug development process often takes an average of 10-15 years, split between Research & Development (R&D) and clinical trials. Approximately 5–6 years are dedicated to R&D, while another 5–7 years are typically needed for clinical trials. This lengthy process requires substantial investment, with costs reaching USD 1.5–2 billion to bring a single drug to market, with clinical trials alone accounting for around half of the total expenditure. Phase III trials, the most complex and resource-intensive, contribute significantly to these costs.(9)

One major challenge in drug development is the high failure rate in clinical trials. Less than one-third of compounds in Phase II move on to Phase III, and over one-third of Phase III compounds are ultimately rejected by regulatory bodies. Due to varying success rates across different trial phases, only about one in ten compounds entering clinical trials receives FDA approval.(10) Each unsuccessful trial represents a considerable financial loss, estimated between USD 0.8 and 1.4 billion, severely impacting overall R&D budgets. Despite these extensive efforts, only about 10% of clinical trials are successful.

Artificial Intelligence (AI) has emerged as a potential solution to these challenges in the clinical trial process. Mining and managing vast datasets from clinical trials, including patient data, is a complex task that AI can help streamline. By leveraging AI, the drug development process can benefit from enhanced success rates across multiple R&D areas, such as target identification, drug candidate selection, biometric data analysis from wearable devices, and predicting drug effects in patients with various diseases.(9)

3. AI in Drug Discovery

The vast chemical space, containing more than \(10^{60}\) molecules, offers a wealth of potential drug candidates. However, the drug development process is often hindered by the absence of advanced technologies, resulting in lengthy and costly procedures. AI can help streamline this process by identifying promising hit and lead compounds, validating drug targets more rapidly, and optimizing drug structure design.(11)

Various applications of AI in drug discovery are illustrated in Figure 3. Despite its benefits, AI encounters significant data challenges, including the scale, diversity, and uncertainty of available data. Pharmaceutical companies often work with data sets containing millions of compounds, which traditional machine learning (ML) tools may struggle to analyze effectively. (12)

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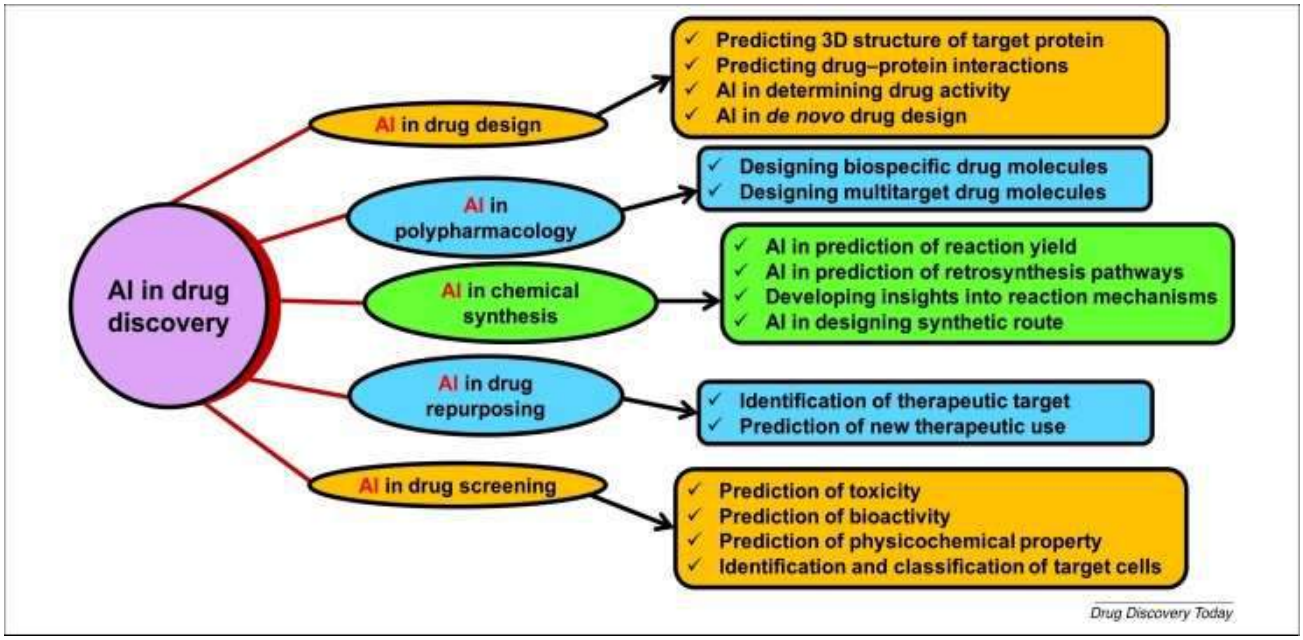

Fig 2:- AI in Drug Discovery

Quantitative Structure-Activity Relationship (QSAR) models can rapidly predict numerous compounds or basic physicochemical properties like log P or log D. However, these models fall short in predicting complex biological properties such as drug efficacy and potential side effects. Additionally, QSAR models often grapple with issues like small training sets, errors in experimental data, and a lack of experimental validation.(13)

To address these challenges, newly developed AI techniques, particularly Deep Learning (DL) and relevant modeling studies, are being utilized for assessing the safety and efficacy of drug molecules through big data analysis. For instance, in 2012, Merck sponsored a QSAR ML challenge to evaluate the benefits of DL in drug discovery. The results showed that DL models significantly outperformed traditional ML approaches in predicting outcomes for 15 absorption, distribution, metabolism, excretion, and toxicity (ADMET) data sets of drug candidates.(14)

4. AI and Clinical Trials

The success of a clinical study often hinges on the initial phases, particularly participant identification. Efficient patient selection and recruitment can significantly enhance a trial's potential effectiveness. Conversely, slow or ineffective recruitment can lead to study failures, resulting in substantial financial losses. This highlights the importance of leveraging AI technology in the early stages of clinical trials.

AI can analyze vast amounts of data to identify patient subsets likely to respond well to a study. For instance, it can examine social media to pinpoint areas with higher incidences of specific diseases, directing recruitment efforts more effectively. By evaluating hospital medical records and informing both healthcare providers and patients about relevant clinical trial opportunities, AI can expedite the identification of suitable participants. Additionally, AI can simplify complex eligibility requirements, making it easier for qualified candidates to applye.(15)

Researchers at Mount Sinai Medical Center in New York, for example, utilized electronic health records (EHRs) and genetic data through topological data analysis (TDA) to classify individuals with type 2 diabetes into three distinct groups. The patterns identified by TDA provided insights into how different patients might respond to treatments or clinical trials.

AI is also at the forefront of analyzing social media data. By examining discussions in patient support groups, AI can identify clusters of illnesses in specific regions, facilitating the rapid identification of potential cohorts for trials. Once a target demographic is established, AI can further streamline the recruitment process, minimizing unnecessary checks and enhancing overall efficiency.

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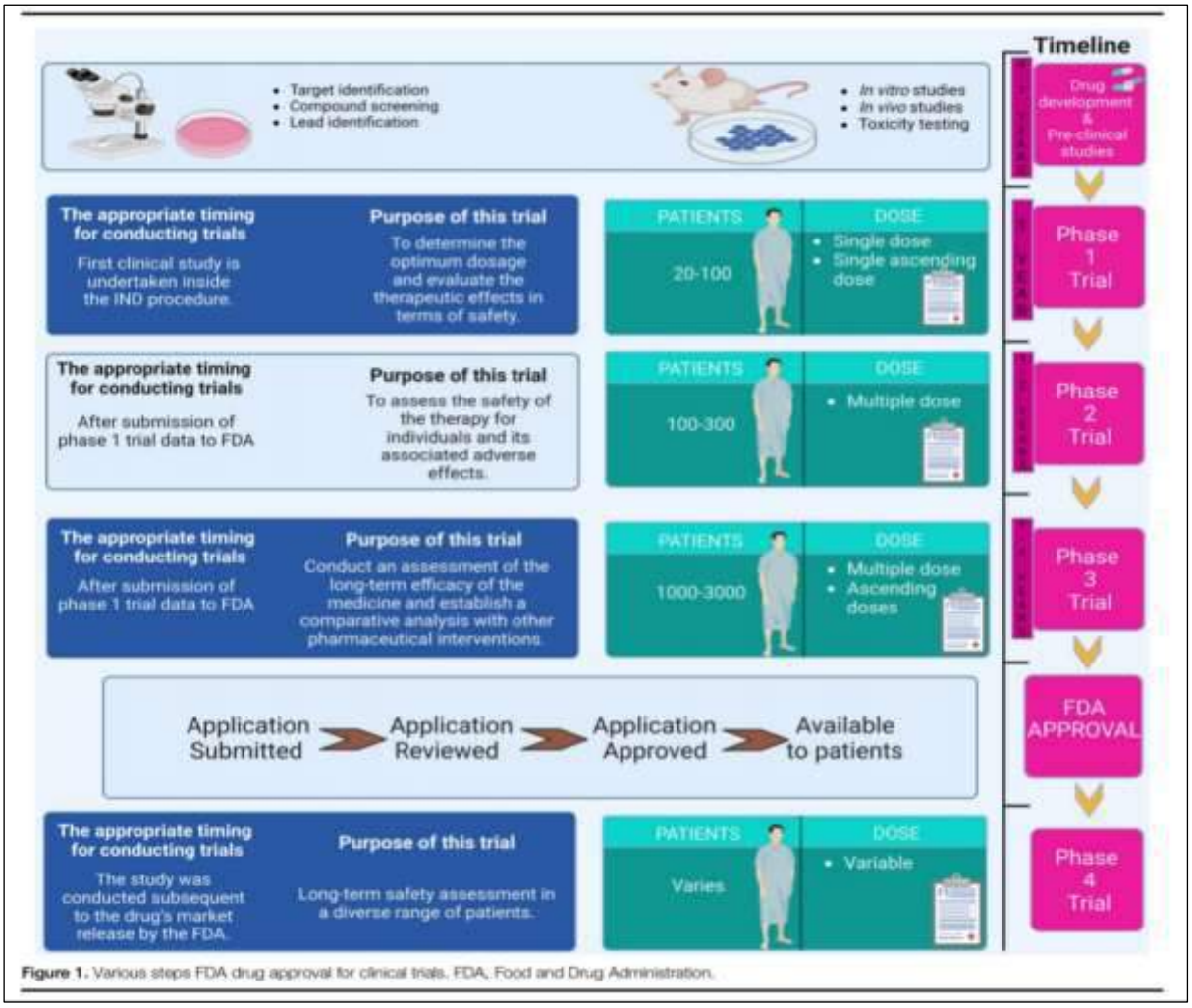

Figure 1. Various steps FDA drug approval for clinical trials. FDA, Food and Drug Administration.

Fig 3. Various steps FDA drug approval for clinical trials

Clinical trial design, patient recruitment, site selection, monitoring, data collection, and analysis are critical components of executing clinical trials. Among these, patient recruitment and selection often present the most significant challenges. As a result, about 30% of phase III trials are terminated early, and 80% of studies fail to meet their enrollment deadlines. Additionally, monitoring multi-centered global studies can be both costly and time-consuming. The time required from the "last subject's last visit" to the submission of data to regulatory bodies, which includes extensive data collection and analysis, adds another layer of difficulty. (16)

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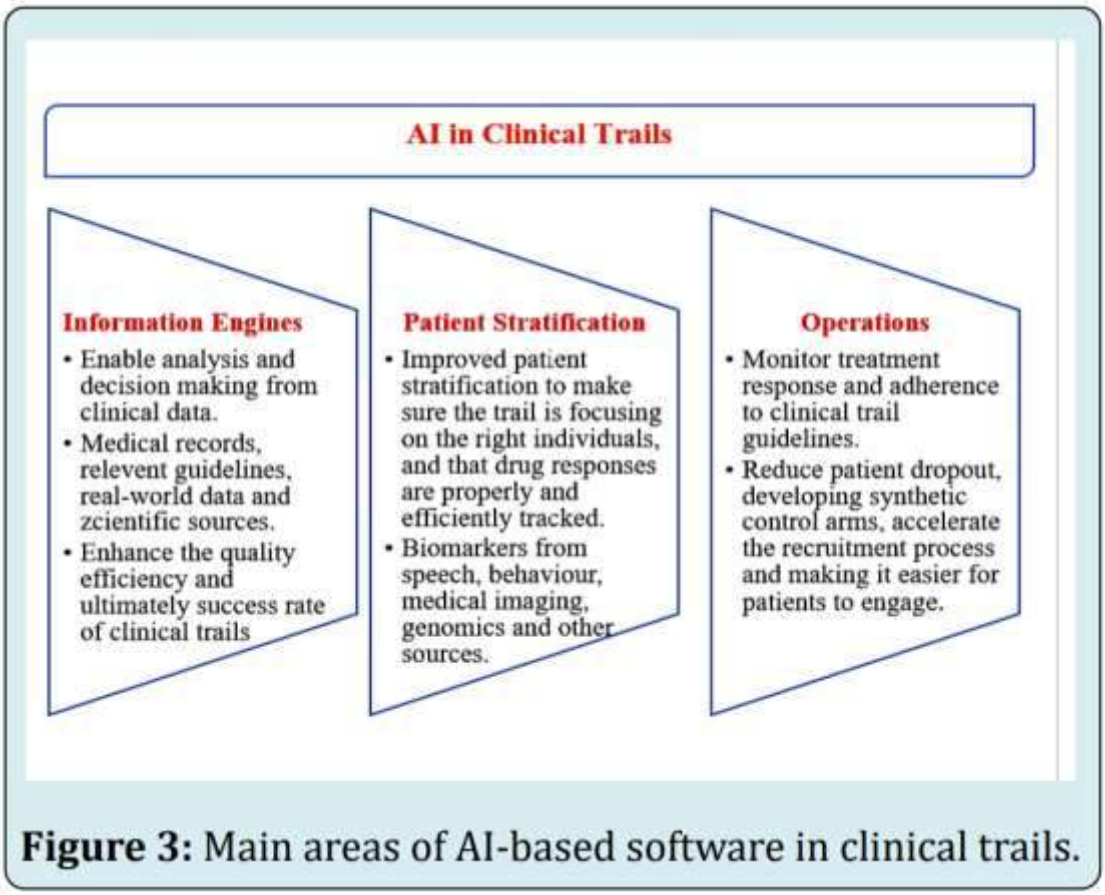

Fig 4:- Main areas of AI-based software in clinical trials

These challenges in clinical trials have been influenced by advancements in artificial intelligence (AI) and digitization. Researchers are exploring AI-based software applications in three key areas: information engines, patient stratification, and trial operations. The potential for AI in clinical trials is significant, offering benefits such as increased efficiency, improved safety (with fewer errors), and cost savings. This technology facilitates faster advancements in research, making it an attractive option for companies worldwide.(17)

5. Artificial Intelligence in Investigator and Site Selection

Selecting effective investigation sites is a critical component of clinical trials. Various site characteristics, such as administrative practices, resource availability, and the expertise of clinicians in the relevant disease area, can significantly impact research timelines and the quality and integrity of data.18Clinical Research Organizations (CROs) can leverage AI technology to identify optimal sites, qualified investigators, and priority candidates. AI can streamline the process by gathering and analyzing relevant data, helping to ensure that the trial adheres to Good Clinical Practice (GCP) guidelines and meets regulatory requirements. This enhances both the efficiency of site selection and the overall success of clinical trials.19

6. Future of AI in Healthcare

The highly regulated healthcare industry has traditionally seen limited use of artificial intelligence. One of the challenges has been the complexity of healthcare itself. To effectively predict health outcomes, we need comprehensive data that includes demographics, protein interactions, gene collaborations, environmental factors, and many other variables. The potential for AI in this space is both daunting and exciting.20

7. AI to Predict Drug Resistance

Can AI predict healthcare outcomes? Researchers are exploring ways to utilize AI and machine learning to forecast responses to chemotherapy treatments in breast cancer patients. The primary challenge is that patients with the same type of cancer do not always respond similarly to treatment.

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AI emerges as a powerful tool for predicting drug responses by analyzing the interactions of multiple genes. Studies have shown that it is possible to identify which breast cancer patients are likely to benefit from the chemotherapy drug Paclitaxel, offering a promising avenue for personalized treatment approaches.

8. Limitations of Current Methods in Drug Discovery

Current medicinal chemistry methods largely rely on a hit-and-miss approach and extensive testing techniques.21 These methods involve screening vast numbers of potential drug compounds to identify those with desirable properties. However, this approach can be slow, costly, and often produces results with low accuracy.22 Additionally, it is constrained by the availability of suitable test compounds and the challenges of accurately predicting their behavior within the body.23,

AI algorithms—such as supervised and unsupervised learning, reinforcement learning, and evolutionary or rule-based algorithms—offer promising solutions to these issues. These techniques analyze large datasets in innovative ways. For example, they can predict the efficacy and toxicity of new drug compounds with greater accuracy and efficiency than traditional methods. Moreover, AI can help identify new targets for drug development, such as specific proteins or genetic pathways involved in diseases.

This capability allows for a broader scope in drug discovery, potentially leading to the creation of novel and more effective medications. While traditional pharmaceutical research methods have seen success in the past, they are limited by their reliance on trial-and-error experimentation and their difficulty in accurately predicting the behavior of new bioactive compounds. In contrast, AI-driven approaches have the potential to enhance the efficiency and accuracy of drug discovery, paving the way for more effective treatments

9. **Conclusions and Summary of the Potential of AI for Revolutionizing Drug Discovery**

In summary, AI holds the potential to transform the drug discovery process by enhancing efficiency and accuracy, accelerating development timelines, and enabling the creation of more effective and personalized treatments. However, the successful integration of AI in drug discovery hinges on access to high-quality data, addressing ethical considerations, and acknowledging the limitations inherent in AI methodologies.

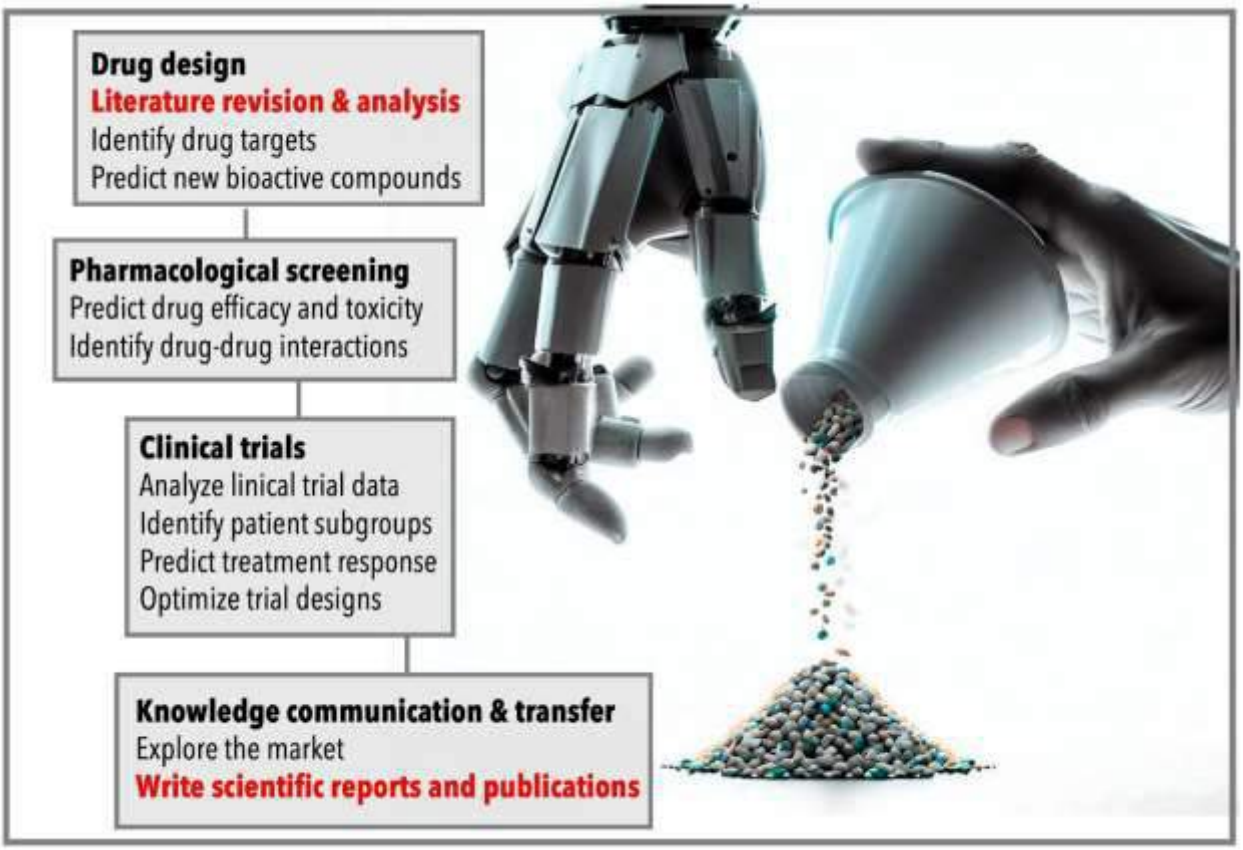

Fig 5:- Drug Design

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Recent advancements in AI, such as data augmentation, explainable AI, and the synergy between AI and traditional experimental methods, present promising strategies to tackle the challenges faced in drug discovery. The increasing interest from researchers, pharmaceutical companies, and regulatory agencies underscores the potential benefits of AI, making this an exciting and promising field of study with the capacity to significantly reshape drug discovery processes.

AI approaches can complement traditional methods, but they cannot replace human expertise. By merging AI's predictive capabilities with the insights of human researchers, the drug discovery process can be optimized and accelerated. This work highlights recent advancements in stages like "Literature Revision and Analysis" and "Writing Scientific Reports and Publications," showcasing the potential of AI tools like ChatGPT to enhance these aspects of drug discovery.24

10. The Role of Machine Learning (ML) in Predicting Drug Efficacy and Toxicity

One of the primary applications of artificial intelligence (AI) in medicinal chemistry is to predict the efficacy and toxicity of potential drug compounds. Traditional drug discovery methods often rely heavily on labor-intensive and time-consuming experiments to determine the effects a compound may have on the human body. This approach is both slow and costly, with results that can vary greatly and are often uncertain. However, AI techniques, particularly machine learning (ML), can address these limitations. By analyzing large amounts of data, ML algorithms can detect patterns and trends that may not be evident to human researchers, facilitating a faster and more efficient drug discovery process.

For instance, deep learning (DL) algorithms have been trained on datasets containing information about known drug compounds and their biological activity. These algorithms can predict the activity of new compounds with high accuracy, suggesting new bioactive compounds that could have minimal side effects. Similarly, ML models trained on large databases of toxic and non-toxic compounds have made significant contributions to identifying and minimizing the toxicity of potential drugs.

Another crucial application of AI in drug discovery is predicting drug-drug interactions, which occur when multiple drugs are taken simultaneously, leading to altered effects or adverse reactions. ML models can detect these interactions by analyzing large datasets of known drug interactions, recognizing patterns, and identifying potential risks. This approach has recently enabled an ML algorithm to predict interactions between novel drug pairs accurately.

The use of AI in this context is also beneficial for personalized medicine, as it allows for customized treatment plans tailored to each patient’s genetic profile and drug response, reducing the risk of adverse reactions.
These examples demonstrate that AI in pharmaceutical research can enhance the accuracy of predictions related to the efficacy and toxicity of potential drug compounds. This can ultimately lead to safer, more effective medications and a faster drug discovery process.
Let's refine your text and present it in clearer, more formal English, while maintaining the focus on precision medicine and AI.

11. Precision Medicine: An AI Approach

Precision medicine aims to deliver the right treatment to the right patient at the optimal time. To truly understand a disease and how to treat it, it is essential to consider the complete biological makeup of the cell. This includes analyzing the genome, proteome, lipidome, and metabolome. Additionally, factors such as mitochondrial function, oxidative states, and ATP production are also critical in understanding cellular behavior.

Traditionally, the analysis of disease cells can take years. However, the power of artificial intelligence (AI) lies in its ability to process and analyze data far more quickly than any human could. Several companies in the market are leveraging AI for this purpose. For instance, Berg uses AI to analyze samples of blood, urine, and tissue from cancer patients, comparing them with samples from healthy individuals. This process generates over 14 trillion data points, which are then fed into AI systems.

The AI system evaluates a vast array of data from the patient's biology, including omics (such as genomics, proteomics, and metabolomics), clinical samples, and demographic information. This helps in understanding the differences between healthy and diseased cells. Once the AI system identifies the characteristics of diseased cells, it can then assist in determining how to restore these cells to a healthy state.

The complexity and scale of this analysis are so immense that it would take humans a lifetime to complete it manually. However, with the assistance of AI, this data can be processed within days or weeks, significantly reducing the time needed for drug development. The result is a targeted therapy, personalized for the individual based on the unique biological makeup of their own body.

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This revised text is structured for clarity and professionalism while highlighting the role of AI in precision medicine. Let me know if you need any additional modifications!
Here's a revised and clearer version of your text on the future of AI in clinical research and healthcare:

12. The Future of AI in Clinical Research and Healthcare

Many healthcare professionals remain skeptical about integrating artificial intelligence (AI) into their practice. However, there are several promising use cases where AI can add significant value, especially in areas where it surpasses human capabilities. Although AI is still in the early stages of development and cannot replace a doctor, the focus now should be on how machine learning can become a powerful enabler for healthcare.

The key question is: "How can AI and machine learning be leveraged to solve the challenges faced by healthcare providers and pharmaceutical companies?" It is crucial to collaborate with doctors and industry stakeholders to identify their specific needs and explore how AI can offer solutions.

AI, designed to mimic human intelligence through computer technology, can assist both healthcare professionals and patients in several ways:
- Analysis and Classification of Medical Data: AI provides a platform for examining, visualizing, and categorizing complex medical information
- Development of Decision Support Tools: AI can create innovative tools to aid in decision-making and clinical research, offering enhanced insights and recommendations.
- Integration of Multiple Disciplines: AI bridges the gap between medicine, software, and cognitive sciences, fostering interdisciplinary collaboration.
- Creation of a Knowledge-Rich Framework: AI contributes to building a robust, content-rich system that supports future scientific research and the broader medical community.

By integrating intelligent AI tools into everyday medical applications, healthcare systems can enhance treatment efficiency, reduce unnecessary costs, and minimize the risk of misdiagnosis. This approach paves the way for more precise and targeted pre-operative and diagnostic strategies.
This revised version is structured and professional, making it easier to understand while preserving the original meaning. Let me know if you need any additional edits or if there are specific points you want to emphasize further!
Here's a refined version of your text focusing on AI advancements in healthcare and surgery, with improved clarity and organization:

13. The Role of AI in Healthcare and Surgical Robotics

AI has made significant strides in advanced tasks and algorithms, becoming an integral component of systems like MRI and computed tomography (CT). These AI-enhanced systems offer the advantage of efficiently acquiring data and synchronizing it with established decision-support databases. Additionally, AI has started transforming the field of surgical robotics, enabling the development of robots that perform semi-automated surgical tasks with increasing precision and efficiency.

One of the ultimate challenges in robotics is replicating human intelligence and movement. Despite these challenges, robotics has made remarkable progress and is now utilized in a wide range of applications, from defense to diagnostics. While robots are not inherently intelligent, they are integrated with software components that make them "smart." Recent advancements in AI—such as neural networking, natural language processing, image recognition, and speech recognition—have greatly expanded the possibilities for robotics, suggesting a bright future ahead.

It is worth noting that one of the biggest barriers to the widespread adoption of medical robotic surgical systems is the high initial capital cost. Many of these systems require new infrastructure and the hiring of specialized staff trained in these procedures, posing a significant challenge to broader implementation.

AI in clinical practice today can be leveraged for automation of routine tasks and other key functions, including:
- Alerts and Updates: AI can monitor patient lab results, medication orders, and provide timely updates. More advanced AI programs can be integrated with patient monitors to detect changes in a patient's condition, triggering alerts when necessary.
- Therapy Planning: Complex treatment plans can benefit from AI tools during the planning phase. An AI system that automatically creates plans based on specific conditions can enhance the value for both doctors and patients.
- Information Retrieval: AI can power sophisticated search engines tailored for complex medical applications, surpassing the efficiency of traditional web crawlers. This helps in the automatic retrieval and updating of medical information.

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- Image Interpretation:AI systems can rapidly identify and interpret medical images, from standard X-rays to complex scans like angiograms, CT, and MRI. These AI-based image recognition and interpretation systems are increasingly being adopted for clinical use.

In conclusion, while there are challenges related to cost and the need for specialized infrastructure, the potential of AI to revolutionize healthcare and surgical robotics is immense. Ongoing research and advancements in AI are paving the way for smarter, more efficient medical technologies, offering promising solutions for the future of patient care.

This version is streamlined and structured, making it easier to read while preserving the original content and intent. Let me know if there are any other areas you'd like to focus on or further refine!
Here is a revised and polished version of your text on the advantages of AI in clinical research and drug discovery25

14. Advantages of AI in Clinical Research and Drug Discovery

1. Faster Data Analysis
   - AI can process and analyze vast amounts of complex medical data much more quickly than traditional methods. This accelerates the identification of potential drug candidates and reduces the overall time required for clinical trials.

2. Enhanced Predictive Modeling
   - Machine learning algorithms can predict patient responses to specific treatments based on genetic, environmental, and lifestyle factors. This leads to more effective personalized therapies and helps identify high-risk patient groups early in the process.

3. Improved Target Identification
   - AI can analyze biological data (e.g., genomics, proteomics) to identify new drug targets, such as proteins or genes associated with diseases. This helps pharmaceutical companies focus on the most promising targets, increasing the likelihood of developing effective drugs.

4. Optimized Clinical Trial Design
   - AI tools enhance the design of clinical trials by analyzing historical data and patient demographics to identify ideal participant populations. This improves patient recruitment, reduces trial dropout rates, and increases the chances of trial success.26

15. Applications of AI in Drug Development

1. Identification and Validation of Drug Targets:
   - AI aids in pinpointing biological targets for new drugs by analyzing large datasets from genomics and proteomics. This helps in identifying proteins or genes associated with diseases, making the drug discovery process more efficient.

2. Designing New Drugs:
   - AI algorithms, such as deep learning models, can design novel drug candidates by exploring chemical spaces, predicting molecular properties, and optimizing compounds for desired biological activity.

3. Drug Repurposing:
   - AI can identify new therapeutic uses for existing drugs by analyzing patterns in biomedical data. This accelerates the drug development process and reduces costs, as the safety profiles of repurposed drugs are already well established.

4. Improving R&D Efficiency:
   - By leveraging AI, researchers can streamline the research and development process. AI helps in aggregating and analyzing vast amounts of biomedical information, reducing time and resources needed, and enhancing decision-making.

5. Patient Recruitment for Clinical Trials:
   - AI can refine the decision-making process for selecting patients for clinical trials by analyzing patient demographics, medical histories, and genetic data. This improves patient recruitment and reduces the dropout rate.27

16. Conclusion

Artificial Intelligence (AI) in clinical trials is an emerging and transformative force, with the potential to revolutionize drug development and create a new paradigm for long-term, sustainable medical research. By integrating AI throughout the drug development and approval process, every stage of a drug's lifecycle can be optimized—from target identification to clinical trials.29

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AI offers solutions to many challenges in clinical trials, where most of the time and money in drug development is spent. AI technologies enhance various aspects of the trial process, including trial design, patient selection, dose optimization, patient adherence, trial monitoring, and endpoint analysis. The use of AI has the potential to significantly improve the efficiency, accuracy, and cost-effectiveness of clinical research.

Regulatory bodies and end-users are optimistic about the integration of AI in healthcare but emphasize the need for AI tools to be transparent, ethical, reliable, and scalable. AI-enabled methodologies promise to unlock new opportunities in clinical research, potentially transforming the future of drug development. However, realizing the full benefits of AI in the healthcare sector may take an additional 5 to 8 years, as widespread adoption is hindered by challenges such as regulatory complexities, the need for clear evaluation guidelines, and the requirement for rigorous clinical validation.

In conclusion, while there are hurdles to overcome, the future of AI in clinical research looks promising. With the right regulatory framework and continued advancements, AI could become a cornerstone of modern healthcare, driving innovation and improving patient outcomes on a global scale.

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A REVIEW ON ANTI DIABETIC TABLET OF SYZYGIUM CUMINI SEED POWDER AND PHYLLANTHUS EMBLICA POWDER.

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ABSTRACT

Diabetes mellitus is the most common endocrine disorder accompanied with many metabolic syndrome. Use of herbal medicines has been an option to treat a great number of disease such as diabetes and its complications. Aim of this study is to develop chewable tablets of Syzygium cumini seed powder and Phyllanthus emblica powder. There are numerous health benefits and nutrient properties of this seed powder, thus it can be used as a nutraceutical.All this formulation were developed with Syzigium cumini seed powder and Phyllanthus emblica as the active ingredient and sodium bicarbonate, microcrystalline cellulose, guar gum, magnesium stearate, microcrystalline cellulose, xanthum gum and stevia were used as excipients. Various evaluations tests were performed to check the stability of the chewable tablet.

KEYWORD : *Anti-diabetic tablet, Syzigium cumini and Phyllanthus emblica.*

INTRODUCTION

Diabetes Mellitus

Diabetes mellitus is an ongoing, metabolic disorder described by rays blood glucose levels that leads over the worldwide in 2017, there where above 450 million people with diabetes mellitus. Diabetes mellitus is the complex group ofdiseases with varieties of causes people or beings with diabetes having high blood glucose levels, also called as high blood sugar or hyperglycemia. Diabetes mellitus are the most common metabolic syndromes.This ways, the body use digested food for energy. The digestive track breakdown of carbohydrates, sugars and stages found in many foods into glucose form of sugar that enters the bloodstream or blood vessels. The two main types of diabetes mellitus are; type 1 diabetes and type 2 diabetes. Type 1 diabetes is caused by a lack of insulin due to destruction of insulin and it's produces beta cells in the pancreas. Type 1 diabetes is typically occurs in children's and young adults.[2] In type 2 diabetes insulin production is proper but cell does not accept insulin does due to this reason increase the level of glucose. Type 2 diabetes may developed most often in middle age and older people who are also increase body weight or obese. Herbal juice has been used sins the down of civilization to maintain health and to treat disease. The treatment of diabetes with synthetic drugs is generally not preferred because of its high cost and side effect for this reason, it is necessary to develop traditional and alternative medicine.

Pathophysiology

The primary hormone that controls the absorption of glucose from the blood into the majority of bodily cells, particularly the muscles, adipose tissue, and liver, is insulin consequently, a key factor in all types of diabetes mellitus is an insulin shortage or an insensitivity of its receptors. The body gets glucose from three primary sources: the breakdown of glycogen, which is stored as glucose in the liver, intestinal absorption of meals, and gluconeogenesis, which is the process by which the body produces glucose from non-carbohydrate components. Insulin is essential for maintaining the body's glucose balance. Insulin can promote the transport of glucose into muscle

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and fat cells, prevent the breakdown of glycogen or the process of gluconeogenesis, and promote the storage of glucose as glycogen. B-cells, located in the pancreatic islet cells of Langerhans, release insulin into the blood in response to an increase in blood glucose levels, usually following meals. About two thirds of the body's cells utilize insulin to take up glucose from the blood and use it as fuel to make other necessary molecules. Reduced insulin release from β-cells and the conversion of glycogen to glucose are the outcomes of lower blood glucose levels. This process is mainly controlled by the hormones, glucagon, which acts in the opposite manner to insulin.

1.Syzigium Cumini

Syzigiumcumini, commonly known as Java plum,black plum or jamun is evergreen tropical tree in the flowering plant family Myrtaceae.[1] This plant start flowering from February to May , plant flowers are fragrant and small about 6 milimetre in diameter. The fruits developed by April to July.[3] The jamun seed contain a glycoside name 'jamboline' which helps in the maintenance of glucose level as in the normal limits. Syzygium cumini (Jamun) contains various phytochemical components such as carbohydrate, protein, vitamin, steroid,alkaloid and phenolic compound.It shows pharmacological activities including anti-viral,Anti-diabetic, anti- pyretic and anti- diarrheal. This plant is used for treatment and in prevention of different disease in homeopathy practice from more than 150 years back in different countries.This plant is specially restoration the body weight and inhibits the excessive blood glucose levels, as well as recovery in the activities of antioxidant enzymes like catalyse, peraoxide and superoxide dismutase.[3]

Mythology

• Ramasubsisted on the fruit in the forest for 14 years during his exile from Ayodhya.[3]
• Lord krishna has been described as having skin the colour of Jamun.[3]

•Scientific Classification (*Syzygiumcumini*) :-

Kingdom :- Plantae
Order :- Myrtales
Family :- Myrtaceae
Genus :- Syzygium
Species :- Syzygiumcumini(L.)
Phylum :- Magnoliophyta
Class :- Magnliopsida
Subclass :- Rodidae

Figure:- *Syzygium Cumin I*seed Powder

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Synonyms
Java plum, Indian blackberry, Jambul, Jambolan, black plum. Ni

Family
Jamun belongs to the Myrtaceae family.

Chemical Constituents
1.Alkaloids: Jamun seeds contain alkaloids like jambosine, jamboline, and jamunine.
2.Flavonoids: The fruit, leaves, and bark of jamun contain flavonoids like quercetin, kaempferol, and myricetin.
3.Phenolic acids: Jamun is a rich source of phenolic acids like gallic acid, ellagic acid, and ferulic acid.
4.Tannins: The fruit, leaves, and bark of jamun contain tannins, which are known for their astringent and antimicrobial properties.
5.Glycosides: Jamun seeds contain glycosides like jambolin, which have been shown to have antidiabetic and antioxidant activities.
6.Terpenoids: The essential oil of jamun contains terpenoids like limonene, beta-pinene, and alpha-pinene.
7.Fatty acids: Jamun seeds contain fatty acids like oleic acid, linoleic acid, and palmitic acid.
8.Vitamins and minerals: Jamun is a good source of vitamins A and C, potassium, magnesium, and iron.

Uses
1.To treat diabetes.
2.Used to treat digestive issues like diarrhea, dysentery and stomach ulcers.
3.To treat respiratory problems like asthma, bronchitis and cough.
4.Used to treat skin condition like eczema, acne and wounds.

Pharmacological Activity
Antidiabetic Activity
Extract of *Syzygium cumini* (aqueous Suspension) were tested for its anti-diabetic Activity at the different dose levels of 1gm, 2gm, 4gm and 6gm/kg body weight. 4gm/kg Dose levelswere found exhibited maximum Hypoglycemic effects (42.64%) in rabbit It is also produced a significant decreased in the Oral administration of S. cumini bark extracts at dose of 300mg/kg body weight exhibited anti-diabetic activity by significantly lowering blood glucose in rats but in case of clinical studies, experiments showing that the tea and extracts prepared from leaves are pharmacologically inert. Patients and physician should be not relying on the putative anti hyerglycemic effects of this tea and perhaps of other folk medicines, that pretend to have such an effects. The investigation of plants with potential clinical utility could start with a clinical trial testing the effects of folk preparation in order to isolate the active principles of those products blood sugar levels (17.04%) in alloxan diabetic rats. The administration of different doses of aqueous suspension of dried seed kernels in rabbit changes blood sugar levels viz, 1 gm, 2gm, 4gm and 6gm/kg body weight indicate that the optimum dose levels are 4gm/kg. The reduction was maximum for the4gm/kg body weight dose levels being42.64% as compared to the other dosages. Oral administration of ethyl acetate and methanol extracts of S. cumini (200 and 400 mg/kg) was showed significant decreased in blood sugar levels. The isolated compound from of S. cumini mycaminose at a dose level of 50mg/kg also showed significant decreased in blood sugar levels.[2]

.2. *Phyllanthus Emblica*
Phyllanthus emblica, commonly known as Indian gooseberry/ amla, has been traditionally used in ayurvedic medicine for its potential antidiabetic properties. Amla (Indian gooseberry) is a gift of nature to mankind. *Phyllanthus emblica* fruit is one of the top selling botanicals having diverse applications in healthcare, food and cosmetic industry. *Phyllanthus emblica* or Amla (Indian gooseberry) is another medicinal plant know for its high vitamin C content and potent antioxidant properties. Amla has been traditionally used for managing diabetes due to its ability to regulate blood sugar levels, enhance insulin secretion and improve pancreatic function. The plants belonging to the genus Phyllanthus are widely distributed through out most tropical and subtropical countries. *Phyllanthus emblica*contains various phytochemical components such as phenolic, flavonoids, tannins, alkaloids, glycosides, terpenoids, vitamins and minerals, protein, fiber.

Scientific Classification (*Phyllanthus Emblica*)
Kingdom :-Plantae
Order :-Mapighiales
Family :-Phyllanthaceae
Genus :-Phyllanthus

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Species :-P. emblica
Phylum :- Magnoliophyta
Class :- Magnoliopsida
Subclass :- Rosidae

Figure.2 *Phyllanthus Emblica* Powder

Synonyms
Amla, Indian gooseberry

Family
Amla belongs to the Phyllanthaceae family, a family of flowering plants that is part of the larger order Mapighiales.

Chemical Constituents
1. Cinnamaldehyde : This is the main component of cinnamon oil, contributing to its distinct aroma and many of its health benefits.
2. Eugenol : Found in ceylon cinnamon, it has antiseptic properties.
3. Coumarin : Present in higher amounts in cassia cinnamon, this compound has anticoagulant properties but can be toxic in large quantities.
4. Tannins : These contribute to the astringent properties of cinnamon.
5. Polyphenols : Including proanthocyanidins, which have strong antioxidant properties.
6. Terpenoids : Such as linalool and beta-caryophyllene, contributing to the spices aroma and potential therapeutic effects.
7. Mucilage and starch : Found in the bark, these contribute to its texture and nutritional properties.

Uses
1. Helps in reducing oxidative stress.
2. May reduce inflammation and pain.
3. May reduce risk factors like high cholesterol and blood pressure.

Pharmacological Activity
Antidiabetic Activity
Amla has anti-diabetic properties because of its high vitamin C concentration, which helps to regulate diabetes. When taken daily for two months, one tablespoon of its juice combined with bitter gourd juice will activate the pancreas and allow it to generate insulin, lowering blood sugar levels. When using this drug, rigorous adherence to dietary restrictions is required. Additionally, it will stop diabetic eye complications. Additionally, it aids in the renewal and regeneration of beta cells, which raises the secretion and production of insulin. The blood sugar levels are significantly lowered by this technique. Tannins are promising medications for the treatment of non-insulin dependent diabetes mellitus because of their capacity to increase glucose absorption and prevent adipogenesis. The extract provided quick protection. Fresh fruit has a diuretic effect. Saffron [more likely to be Curcuma longa, or Indian saffron, than Crocus sativus, or saffron] or a paste made from the fruit alone or in conjunction with Nelumbiumspeciosum, or the Egyptian Lotus and rose water can be

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applied to the pubic area to help with bladder irritation and pee retention. It has anti-inflammatory, febrifuge, and, in a rare case, anti-diuretic properties. The urinary system benefits greatly from amla-berry, which may be useful for anyone experiencing a slight burning sensation when urinating. Instead of forcing water out of the body like diuretic pills do, it promotes the body's natural diuretic function. To put it another way, it aids in the body's waste removal while avoiding over stimulating.

3. Sodium Bicarbonate

• Chemical Formula

NaHCO3 (Sodium Hydrogen Carbonate)

• Physical Properties

1. White, crystalline powder
2. Soluble in water. 3. pH: 8.3 (1% solution)

• Pharmacological Properties

1. Antacid: Neutralizes stomach acid
2. Buffering agent: Maintains pH balance
3. Electrolyte replenisher: Replaces sodium ions

• Therapeutic Uses

1. Heartburn and indigestion
2. Gastro esophageal reflux disease (GERD)
3. Peptic ulcer disease
4. Metabolic acidosis
5. Drug overdose (eg. aspirin barbiturates)

• Contraindications

1. Severe kidney disease
2. Heart failure
3. High sodium levels
4. Metabolic alkalosis

• Side Effects

1. Nausea and vomiting
2. Diarrhea
3. Abdominal pain
4. Flatulence

• Storage and Handling

1. Store in a cool, dry place
2. Protect from moisture and light

4.Guar Gum

• Source : Guar gum is derived from the endosperm of the guar bean (Cyamopsistetragonoloba), primarily grown in India and Pakistan.

• Chemical Composition :

Guar gum is a galactomannan polysaccharide, composed of:

1. Galactose (40-50%)
2. Mannose (50-60%)
3. Protein (5-6%)
4. Fiber (10-15%)

•Properties

1. Thickening agent

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2. Emulsifier
3. Stabilizer
4. Suspending agent
5. Film-forming agent

• Side Effects

1. Gastrointestinal upset
2. Allergic reactions (rare)
3. Intestinal obstruction (rare)

• Dosage

1. Pharmaceutical applications: 0.1-5.0%
2. Food applications: 0.1-2.0%

• Storage and Handling

1. Store in a cool, dry place and Protect from moisture and light

5. Magnesium Stearate

• Chemical Formula :

$Mg(C_{18}H_{35}O_2)_2$

• Physical Properties

1. White, powdery solid
2 . Practically insoluble in water
2. Soluble in ethanol and ether

• Functions

1. Lubricant: Reduces friction between particles
2. Anti-adherent: Prevents sticking to equipment
3. Flow aid: Improves powder flow

• Side Effects

1. Gastrointestinal upset (rare)
2. Allergic reactions (rare)

• Dosage

1. Pharmaceutical applications: 0.5-5.0%
2. Food applications: 0.1-2.0%

• Storage and Handling

1. Store in a cool, dry place
2. Protect from moisture and light

6. Microcrystalline Cellulose (MCC)

• Source

MCC is derived from wood pulp or cotton linters, processed into a purified, partially depolymerized cellulose.

• Physical Properties

1. White, odorless, tasteless powder
2. Particle size: 10-50 µm
3. Density: 1.5-1.6 g/cm4. Solubility: Insoluble in water, organic solvents

• Functions

1. Filler: Increases tablet bulk, weight

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2. Binder: Enhances tablet cohesion, strength
3. Disintegrant: Helps tablet break down in gastrointestinal tract
4. Anti-caking agent: Prevents powder clumping

• Side Effects

1. Gastrointestinal upset (rare)
2. Allergic reactions (rare)

• Storage and Handling

1. Store in a cool, dry place
2. Protect from moisture and light

7. Xanthan Gum

• Source

Xanthan gum is a polysaccharide derived from the bacterium Xanthomonascampestris.

• Physical Properties

1. White or cream-colored powder
2. Soluble in hot and cold water
3. Forms a clear, viscous solution
4. pH: 6.0-7.0

• Functions

1. Thickener
2. Stabilizer
3. Emulsifier
4. Suspending agent
5. Film-forming agent

• Side Effects

1. Gastrointestinal upset (rare)
2. Allergic reactions (rare)

• Dosage

1. Pharmaceutical applications: 0.1-5.0%
2. Food applications: 0.1-2.0%

• Storage and Handling

1. Store in a cool, dry place
2. Protect from moisture and light

8. Stevia

• Source

Stevia is a natural sweetener derived from the leaves of the Stevia rebaudiana plant, native to South America.

• Physical Properties

1. White, crystalline powder
2. 200-300 times sweeter than sugar
3. Soluble in water and ethanol

• Functions

1. Natural sweetener
2. Low-calorie sweetener
3. Non-glycemic sweetener

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- **Side Effects**
  1. Gastrointestinal upset (rare)
  2. Allergic reactions (rare)

- **Dosage**
  1. Pharmaceutical applications: 0.1-5.0%
  2. Food applications: 0.1-2.0%

- **Storage and Handling**
  1. Store in a cool, dry place
  2. Protect from moisture and light

DISCUSSION

From the ancient time to till present, medicinal plants have been playing a key role in the healthcare system of mankind as an extraordinary source of natural medicine. Nowadays the use of herbal products increasing day by day for low or no side effect all over the world. Amla is an important medicinal plant of Ayurveda- an Indian indigenous system of medicine. Due to its strong antioxidant, highest vitamin C contents and essential biological properties amla used to prevent various innumerable health disorders. It can be used as a possible food additive or in nutraceuticals and pharmaceutical industries. Jamun seed powder help to manage diabetes. Due to its strong antioxidant properties and higher vitamins contents the jamun is used to treat various health disorder.

CONCLUSION

The number of people in India with diabetes mellitus is rising daily, most likely as a result of changes in lifestyle, dietary habits (from a traditional, high-fiber diet to a fast-food, post-surgery diet), and genetics. Since the condition was chromic, long-term care was required to avoid consequences from persistently elevated blood glucose levels. Nevertheless, a significant number of adverse effects are linked to these synthetic anti-diabetic medications. At the end of our study, it is concluded from the detail analysis and results that Syzygium cumini (Jamun) and Phyllanthus emblica (Amla) supplemented diet are effective in reducing blood glucose levels. Traditional healers frequently utilize jambolan to treat a variety of illnesses, particularly diabetes and its aftereffects. The majority of the plant's traits are attributed to its several significant chemicals. The pharmacological potential of the other plant components needs to be further investigated, as the majority of pharmacological studies on diabetes were conducted using seeds. Likewise, there aren't many studies on the pharmacological effects of jambolan's phytochemical components. The authors expect that this review will shed light on the role of jambolan in a variety of treatments and suggest that more phytochemical and clinical studies be conducted on this traditional medicinal plant in order to develop safer medications. Amla plant can serve as a natural source for upcoming medication development based on its historical applications in a variety of possible treatments. Therefore, expanding the use of amla for the treatment of different diseases and developing it as a recognized viable and safe dosage form must require our serious study.

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A REVIEW ARTICLE ON HERBAL DENTAL TOOTHPASTE BY USING NEEM STEM EXTRACT

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ABSTRACT

Since many centuries, Ayurveda regarded neem (Azadirachta indica Family: Meliaceae) as a cure for many ail-ments, predominantly due to its superb antimicrobial activity. It has been a practice since time immemorial to use tender twigs of neem as dentifrice. Looking as these facts the possibility of developing an authentic dentifrice from neem extract and formulations were formulated and evaluated for their antimicrobial activity and some formulations were found to have significant antimicrobial activity.The main objective of this review article is to compile the available information related to herbal toothpaste like its introduction, different formulations and different parameters on which these herbal toothpastes can be evaluated. This information can be used by many researcher who wants to make research in this area.These herbal toothpastes can be evaluated by different tests like Physical Examination, Relative density, Abrasiveness, Determination of spreadability, pH determination, Homogeneity, Foaming,Stability, Determination of moisture and volatile matter, Moisture content, Foaming character, Organoleptic evaluation, pH, Fragrance test, Shape retention, Storage stability, Total flavonoid content estimation of Tooth paste Formulation, Stability study (Storage stability), Antimicrobial activity of toothpaste etc.

KEYWORDS: *Herbal toothpaste,Antimicrobial activity, Azadirachta Indica,Neem stem,Formulation.*

INTRODUCTION

The neem has been antibacterial activity it has been evaluated from the ancient times. It has been use for the various activities like as astringent, antiseptic, insecticidal, anti ulcer and for cleaning the teeth in pyorrhea and other dental disease[1].The chewing neem sticks have been widely used in the Indian subcontinent, the Middle East and Africa since ancient time period. Dental caries is steadily increasing in the underdeveloped and developing country[2]. The aim to formulate herbal paste was compare efficacy with other marketed preparations[3].Toothpaste are most common preventive means in oral healt care.Many commercially available dentifrices claim to have anti microbial properties but little research has been conducted to investigate these claims.Therefore this study was conducted to evaluate efficacy of different toothpaste formulations in reducing oral microbial load [4].

Types-

1.Herbal.

2.Non-herbal.

MATERIALS AND METHODS

Collection of tender stem:Tender stem of Azadirachta indica were collected from Shirner village Tq.Ambad,Dist..Jalna.The stems were dried in vacuum oven at 35°C to get coarse powder and fine preparation of paste. Fine neem powder (FNP) was obtained by sifting through muslin cloth.[5]

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Preparation of Extracts

- The tender stem (100 grams) was extracted by two methods.
- Method I: The tender stem (100 grams) was extracted by two methods.
- Method I: Continuous hot extraction (Soxhelate extractor)10with absolute alcohol at 50°C designated as SNE. Method II: Percolation in conical percolator by standard percolation method using water, ethyl alcohol, benzene, petroleum ether and isopropyl alcohol as a solvent11 and designated by PNE.[6]
- These extracts were dried by evaporation in vacuum oven.
- After evaporation, the dried extracts were evaluated for antimicrobial activity.

Formulation of Neem Toothpaste

Toothpaste

A toothpaste or dentifrice is a substance used with a toothbrush for the purpose of cleaning the accessible surfaces of the teeth.

Purpose of Toothpaste

1. Polishing.
2. Cleaning..
3. Removal of stains.
4. Reduce incidence of tooth decay. 5.Reduction of oral malodors.

General toothpaste Formulation Composition Contains

1. Abrasive, Detergents, Water.
2. Humectants, Thickening Agents.
3. Sweeteners,Preservative, flavours.
4. Corrosion Inhibitors.
5. Colorance, Bleaches.
6. Anticaries.
7. Anticalculus Agents.
8. Desensitizing Agents.
9. Antimicrobials /Antiplaque/ Antigengivitis Agents.

Drug Profile

Neem Stem is taken as Active Pharmaceutical Ingredient.

- Kingdom-Plantae.
- Subkingdom-tracheobionta.
- Division-magnoliophyta.
- Subdivision-spermatophyta.
- Order-sapindles.
- Superorder-retinae.
- Class-eudicot.
- Genus-azadirachta.
- Species-A.Indica.
- Family-mahogany.
- Subfamily-meliodeae.
- Tribe-Meliceae.

ADVANTAGES

1. NaturaL ingredients, Reduced chemicals,
2. Antibacterial properties,
3. Fresh breath.
4. Gum health.
5. Sensitive teeth.
6. Environmentally friendly,
7. No artificial sweeteners,

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8. Whitening and stain removal.

DISADVANTAGES

1. Lack of fluoride.
2. Lack of regulation.
3. Allergic reactions.
4. Abrasive nature.
5. Limited availability.

AZADIRACHTA INDICA

Azadirachta Indica has antifungal and antibacterial properties which help eliminate dandruff and strengths your hair. Application of neem oil or extract on the affected area can help reduce pain and discomfort. Hence it is widely used for treating arthritis. Neem is an excellent exfoliant.

Figure.1-Azadirachta Indica

Botanical Description of Neem.

Neem tree belongs to the family Meliaceae which is found in abundance in tropical and semitropical regions like India, Bangladesh, Pakistan, and Nepal. It is a fast-growing tree with 20–23 m tall and trunk is straight and has a diameter around 4-5 ft. The leaves are compound, imparipinnate, with each comprising 5–15 leaflets. Its fruits are green drupes which turn golden yellow on ripening in the months of June–August. Taxonomic position of *Azadirachta indica* (neem).

Pharmacological Activities of Azadiracta Indica ,neem is diseases management through the modulation of various activities.

Figure.2- Pharmacological activities of Neem.

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Scientific classification	
Kingdom:	Plantae
Clade:	Tracheophytes
Clade:	Angiosperms
Clade:	Eudicots
Clade:	Rosids
Order:	Sapindales
Family:	Meliaceae
Genus:	*Azadirachta*
Species:	***A. indica***

Figure.3-Scientific Classification

Clove

Syzygium aromaticum is a spice made from the dried, unopened flower buds of the clove tree. It's native to Indonesia and has been used for centuries in traditional medicine, cooking, and oral care.

Figure.4-Clove.

Synonyms: Lavanga, Devakusuma.
Biological Sources: Clove is obtained from the dried flower buds of the tree syzygium aromaticum.
Family: Myrtaceae.
Chemical Constituents

1. Eugenol: The principal compound (70-90%) responsible for clove's aroma and many of its therapeutic properties, such as analgesic, anti-inflammatory, and antimicrobial effects.
2. Eugenyl acetate: Contributes to the aroma and flavor.
3. Caryophyllene: A sesquiterpene that also contributes to the spicy aroma and has anti-inflammatory properties.

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4. Tannins: Including gallotannic acid, which has astringent properties.
5. Flavonoids: Such as kaempferol, rhamnetin, and eugenin, which contribute to its antioxidant activity.

Uses

1. Reduces inflammation and associated symptoms.
2. Commonly used in mulled wine, chai, and other spiced drinks
3. Used to flavor meats, curries, marinades, and baked goods.

Pharmacological Activities

1. Analgesic: Eugenol has analgesic and anti-inflammatory properties, effective against toothache, headache, and muscle pain.
2. Antimicrobial: Clove oil exhibits antibacterial, antifungal, and antiviral properties, effective against various microorganisms.
3. Anti-inflammatory: Eugenol inhibits inflammatory pathways, reducing inflammation and pain.
4. Antioxidant: Clove oil has antioxidant properties, protecting against oxidative stress and cell damage.
5. Anticancer: Eugenol has been shown to inhibit cancer cell growth and induce apoptosis (cell death).
6. Antidiabetic: Clove oil may help regulate blood sugar levels and improve insulin sensitivity.
7. Cardiovascular: Eugenol may help lower cholesterol levels and prevent blood clotting.
8. Gastroprotective: Clove oil may help protect against gastric ulcers and inflammation.
9. Neuroprotective: Eugenol may help prevent or slow neurodegenerative diseases like Alzheimer's and Parkinson's.

Cinnamon

Cinnamomum Verum is a spice made from the inner bark of the cinnamon tree, native to Sri Lanka. It's a popular ingredient in cooking, baking, and traditional medicine.

Figure.5-Cinnamon

Synonyms: Cinnamon Tavk, Dalchini.

Biological Sources: Cinnamon is obtained from the inner bark of trees from the genus Cinnamomum..The two most commonly used species are: Cinnamomum verum, Cinnamomum cassia.

Family: Lauraceae.

Chemical Constituents

1. Cinnamaldehyde: This is the main component of cinnamon oil, contributing to its distinctive aroma and many of its health benefits.
2. Eugenol: Found in Ceylon cinnamon, it has antiseptic and anesthetic properties.

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3. Coumarin: Present in higher amounts in cassia cinnamon, this compound has anticoagulant properties but can be toxic in large quantities.
4. Tannins: These contribute to the astringent properties of cinnamon.
5. Polyphenols: Including proanthocyanidins, which have strong antioxidant properties.
6. Terpenoids: Such as linalool and beta-caryophyllene, contributing to the spice's aroma and potential therapeutic effects.

Uses

1. Helps in reducing oxidative stress.
2. May reduce inflammation and pain.
3. May reduce risk factors like high cholesterol and blood pressure.
4. Helps in alleviating digestive issues such as indigestion, bloating, and gas.

Pharmacological Activities

1. Antioxidant: Neutralizes free radicals, protecting against oxidative stress and cell damage.
2. Anti-inflammatory: Inhibits inflammatory pathways, reducing inflammation and pain.
3. Antimicrobial: Exhibits antibacterial, antifungal, and antiviral properties, effective against various microorganisms.
4. Antidiabetic: Improves insulin sensitivity, reduces glucose levels, and enhances glucose uptake in cells.
5. Cardiovascular: Lowers cholesterol, triglycerides, and blood pressure, reducing cardiovascular risk.
6. Neuroprotective: May help prevent or slow neurodegenerative diseases like Alzheimer's, Parkinson's, and multiple sclerosis.
7. Anti-cancer: Inhibits cancer cell growth, induces apoptosis (cell death), and prevents tumor formation.
8. Analgesic: Relieves pain by inhibiting pain pathways and reducing inflammation.
9. Anti-allergic: Inhibits allergic reactions, reducing histamine release and inflammation.

Honey

Honey is antimicrobial and antibacterial properties make it a popular ingredient in natural toothpastes.

Figure.6-Honey

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Benefits of Honey in Toothpaste

1. Antimicrobial properties: Honey inhibits growth of bacteria, viruses, and fungi, reducing plaque, bad breath, and gum inflammation.
2. Antibacterial properties: Honey's acidity (pH 3.5-4.5) creates an environment unfavorable to bacterial growth, reducing tooth decay and gum disease.
3. Anti-inflammatory properties: Honey's antioxidants and polyphenols reduce inflammation, alleviating gum sensitivity and swelling.
4. Natural sweetener: Honey replaces refined sugars, making toothpaste more appealing to children and those with dietary restrictions.
5. Moisturizing properties: Honey's humectant properties help retain moisture, soothing dry mouth and lips.

Types of Honey Used in Toothpaste

1. Manuka honey: Known for its unique antibacterial properties (UMF rating).
2. Raw honey: Unfiltered, unpasteurized honey retains its natural enzymes and nutrients.
3. Organic honey: Free from pesticides, herbicides, and synthetic additives.

Xanthan Gum

Xanthan gum is a popular food additive and ingredient in various industries.

Figure.7-Xanthan Gum.

Xanthan gum is a polysaccharide (complex carbohydrate) derived from the bacterium Xanthomonas campestris. It's produced through fermentation and purified for use in various applications.

Properties and Benefits

1. Thickening agent: Xanthan gum is an effective thickener, stabilizer, and emulsifier.
2. Viscosity control: Regulates fluid viscosity, improving texture and flow.
3. Stability: Enhances stability in emulsions, suspensions, and foams.
4. Temperature tolerance: Remains effective across a wide temperature range.
5. pH tolerance: Stable in acidic and alkaline environments.
6. Non-toxic: Generally recognized as safe (GRAS) for human consumption.

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Uses

1. Food industry: Salad dressings, sauces, beverages, dairy products, baked foods.
2. Cosmetics: Toothpaste, mouthwash, skincare products, hair care.
3. Pharmaceuticals: Tablet coatings, capsules, ointments.
4. Oil and gas: Drilling fluids, well stimulation.
5. Textiles: Dyeing, printing, finishing.

Titanium Dioxide

Titanium Dioxide is a versatile, widely used in toothpaste.

Figure.8-Titanium Dioxide

Properties

1. White pigment.
2. High refractive index.
3. Opacity and brightness.
4. Chemical inertness.
5. UV resistance.

Uses

1. Paints and coatings: Pigment for white paint, varnishes, and coatings.
2 .Plastics: Adds whiteness, opacity, and UV resistance.
3. Cosmetics: Pigment in sunscreen, skincare, and makeup products.
4. Food: Food coloring (E171) in confectionery, baked goods, and beverages.
5. Pharmaceuticals: Coatings for tablets, capsules, and pharmaceutical products.
6. Paper: Pigment for paper coatings and fillers.
7. Ceramics: Used in ceramic glazes and enamels.

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Pottasium Nitrate

Potassium Nitrate (KNO3) is a common ingredient in toothpastes, particularly those designed for sensitive teeth.

Figure.9-Pottasium Nitrate

Uses

1. Desensitizing agent: Potassium nitrate helps alleviate tooth sensitivity by blocking the dentinal tubules (tiny channels) in the teeth, reducing the flow of fluids and sensations to the nerves.
2. Pain relief: It has analgesic and anti-inflammatory properties, providing temporary relief from toothache pain.
3. Antibacterial properties: Potassium nitrate has been shown to inhibit the growth of certain bacteria, which can contribute to tooth decay, gum disease, and bad breath.

Types of toothpastes containing potassium nitrate:

1.Sensitivity toothpastes: Toothpastes specifically designed for sensitive teeth, such as Sensodyne.

2. Desensitizing toothpastes: Toothpastes that aim to reduce tooth sensitivity, often containing potassium nitrate as the active ingredient.

3. Anti-plaque toothpastes: Some toothpastes that target plaque and gingivitis may also contain potassium nitrate.

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- **Sorbitol**

Figure.10-Sorbitol

Sorbitol is a sugar substitute derived from corn syrup, widely used in food, pharmaceuticals.

Properties

1. Sweetness: 60% as sweet as sugar
2. Solubility: Highly soluble in water
3. Viscosity: Thickening agent
4. Humectancy: Retains moisture

Uses

1. Food industry: Sugar substitute in sugar-free products (gum, candy, baked goods)
2. Pharmaceuticals: Excipient in tablets, capsules, syrups
3. Cosmetics: Moisturizer in skincare, haircare products
4. Toothpaste: Humectant, sweetener

Health Benefits

1. Low-calorie sweetener: Suitable for diabetes management.
2. Oral health: Prevents tooth decay, reduces plaque.
3. Digestive aid: Relieves constipation, diarrhea.
4. Skin health: Hydrates, soothes skin irritations.

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Sodium Bicarbonate

Sodium Bicarbonate (NaHCO3), also known as baking soda it is a versatile compound with various applications**.**

Figure.11-Sodium Bicarbonate

Properties

1. pH level: 8.3 (alkaline)
2. Solubility: Highly soluble in water
3. Chemical formula: NaHCO3

Uses

1. Baking:Leavening agent in baked goods (cakes, cookies, bread)
2. Cooking: Tenderizer for meat, vegetables, and beans
3. Personal care:Toothpaste, mouthwash, shampoo, and skincare products
4. Medicine:Antacid, anti-inflammatory, and laxative properties
5. Cleaning:Natural cleaner, odor absorber, and scrubbing agent
6. Industrial: Paper manufacturing, textile industry, and water treatment

Health Benefits

1. Digestive aid: Relieves heartburn, indigestion, and bloating
2. Oral health: Neutralizes acid, whitens teeth, and freshens breath
3. Skin care:Soothes sunburn, acne, and itchiness
4. Muscle relief:Reduces muscle cramps, spasms, and soreness
5. Immune system: Supports immune function and reduces inflammation

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Methyl Paraben

Methyl Paraben is a widely used preservative in personal care products, pharmaceuticals, and food.

Figure.12-Methyl Paraben

Properties

1. Chemical formula: C8H8O3.
2. Solubility: Soluble in water, ethanol, and propylene glycol.
3. pH level: 4.5-5.5.

Uses

1. Personal care products: Cosmetics, skincare, haircare, and oral care.
2. Pharmaceuticals: Preservative in creams, ointments, and injectables.
3. Food: Preservative in baked goods, beverages, and dairy products.
4. Medical devices: Preservative in medical instruments and equipment.

Benefits

1. Antimicrobial properties: Effective against bacteria, yeast, and mold.
2. Preservative: Extends product shelf life.
3. Stability: Enhances product stability and texture.

Sodium Lauryl Sulfate

Sodium Lauryl Sulfate is a widely used surfactant in personal care products.

Figure.13-SLS

Properties

1. Chemical formula: C12H25SO4Na
2. Solubility: Soluble in water, ethanol, and propylene glycol
3. pH level: 5.5-7.5

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Uses

1. Personal care products: Shampoos, soaps, toothpastes, mouthwashes, and body washes
2. Pharmaceuticals: Emulsifier, wetting agent, and solubilizer
3. Industrial applications: Textile industry, paper manufacturing, and oil drilling

- **Benefits**

1. Foaming agent: Creates rich, creamy lather
2. Emulsifier: Mixes oil and water-based ingredients
3. Surfactant: Reduces surface tension, improving product spreadability
4. Cleansing agent: Effective at removing dirt, oil, and grime

- **Types of Toothpaste**

1. Anti cariës-clove.
2. Plaque&prevention-Neem stem.
3. Tooth whitening-Alum, Titanium dioxide, clove.
4. Sensitivity-Potassium nitrate,Potassium citrate.
5. Tartar control-Aloevera.
6. Fresh breath-Alum.cinnamon.menthol.
7. Sweetning agent-Honey, Sod.saccharine.
8. Thickening agent-Xanthan gum.
9. Foaming agent-SLS, Baking Soda.
10. Humectant-Sorbitol, Propylene glycol.
11. Ph-Sod. Bicarbonate.
12. Preservative-Methyl paraben,Ethyl paraben.
13. Solvent-Water.

Formulation

1. Polishing Agents / Abrasive Agents: The abrasives or the polishing agents are used to polish the teeth and remove food debris adhered to the surface of the teeth. They are used in concentration of about 20 - 50% of the total formulation.[11]
2. Foaming Agents / Surfactants: They are also known as wetting agents. The mechanism of cleansing action is by reducing the surface tension at the interface of the adhered material and enamel of the teeth.[12]
3. Humectants: Humectants are used in order to prevent the rapid drying of dentifrices. They prevent excessive moisture loss from the product. They may additionally impart plasticity to the final product.[13]
   The concentration of the humectant used in the formulation may vary from 20% to 40% (13).
   Ceiling/ Binding Agents: The binding agents are used in order to hold the solid and the liquid components together to form a smooth paste and maintain its property, particularly during storage.[14] They prevent bleeding from the paste and also add up to the body and viscosity of the final formulation .[14]
4. Flavouring Agents: Flavouring agents may comprise the most proprietary and most crucial part of the formulation essential to meet the consumer preferences. They are generally a mixture of edible volatile oils consisting of spearmint and peppermint oil as major components [12].
5. Preservatives: Preservatives are used in the formulation in order to maintain the properties of the product throughout the storage period and to improve the shelf-life of the product. Generally, a mixture of 5% methyl paraben and 0.02% propyl paraben is the most effective and commonly used combination preservatives.[14]

Preparation of Toothpaste

1.Dry Gum Method

In this method, all the solid components of the formulation like abrasive agent, binding agent etc., except the surfactants are mixed together in a dry mixer.
The mixer may be an agitation mixer which consists of slow rotating blades.
The liquid components such as the humectants and water are gradually added to the dry mix.
The mixing process is carried out till a smooth paste is formed.
The remaining ingredients like the surfactants and the flavouring agents are added to the homogenous paste under vacuum (12,15),

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2.Wet Cum Method

In this method, all the liquid components are mixed together to form a liquid phase. The binding agent is then mixed with the liquid phase with uniform stirring in order form mucilage.

The solid ingredients excluding the surfactants are then gradually added to the mucilage with uniform mixing in an agitation mixer, in order to form a homogenous paste.

The remaining ingredients i.e., the surfactants, the flavoring agents, coloring agents are added under vacuum the homogeneous paste. [16,17]

DISCUSSION

The aim of study was to formulate herbal base product was compare the efficacy with conventionally marketed formulated toothpaste and evaluated the various parameter like colour, spredability, foamability, extrudability and anti-bacterial activity. However, there is approach to provide the formulation for commercial production of herbal dental product with environmental friendly attributes. Toothpastes have evolved immensely since their earliest forms, when they served primarily as a toothbrush aid to attempt to make the teeth less yellow and freshen the mouth. Toothpaste was made long ago. The most important ingredient in toothpaste is fluoride.

CONCLUSION

In order to achieve the multi-claim products required for the dental care category, it is necessary for the formulator to use a variety of different ingredients. This places a number of demands on the development process. Innovations in the areas of pharmaceutical technology have contributed to the formulation of the products having superior efficacy as well as other attributes that may contribute to clinical response and patient acceptability. Improved clinical efficacy and tolerability, along with conditioning signals, should encourage patient compliance with oral hygiene further complementing professional efforts directed at disease prevention. Neglected Oral problems can lead to permanent loss of tooth and some leads to cancer and severe disorders to avoid this is different oral cosmeceuticals were used like toothpastes, mouth rinse etc.along with this points below have to be followed regularly:Brushing thoroughly twice a day and flossing daily II. Eating a balanced diet and limiting snacks between meals.Using dental products that contain fluoride, including toothpaste.Rinsing with a fluoride mouth rinse.Making sure that your children under 12 drink fluoridated water or take a fluoride supplement they live in a non-fluoridated area.By following this oral hygiene is maintained and problems can be minimized.

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OVERVIEW OF CLINICAL TRAILS FOR NEW DRUG SAFTY AND EFFICACY

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ABSTRACT

Clinical trials is a testing research of a new drug safety and efficacy. Pre-clinical studies starts before clinical trials. In pre-clinical trial may look at whether a drug is safe or the side effects it causes; later trials aim to test whether a new treatment is better than existing treatment.

Clinical trials study on different phases that are phase 0, 1,2,3,4. Main purpose of phase 0 to help speed up and streamline the drug approved the process. In phase 1 trials to find out about closes and side effects. A phase 2 clinical trial is to evaluate the effectiveness and safety of a new drug or drug combination for a particular indication. Then in phase 3 study that tests the safety and how well a new treatment works compared with a standard treatment. The main objective of phase 4 trials is to check the drug's performance in real life scenarios. The Phase 4 studies include all studies performed after drug approved and related to the approved indication.

INTRODUCTION

Clinical research is a branch of medical science that involves studies and trials designed to evaluate new treatments, drugs, medical devices, or diagnostic tests. It aims to gather scientific evidence about the effectiveness and safety of interventions to improve patient care, guide medical practice, and inform public health decisions.

Clinical research typically involves several phases and types of studies, including:

- **Clinical Trials**: These are controlled studies that test new drugs, treatments, or interventions. Clinical trials often follow a specific structure, such as randomized controlled trials (RCTs), to ensure reliable results.
- **Observational Studies**: In these studies, researchers observe participants in their natural settings without intervening or changing their behavior. Examples include cohort studies or case-control studies.
- **Epidemiological Studies**: These studies focus on understanding the distribution and determinants of diseases in populations. They help identify risk factors and preventive measures.

Overall, clinical research is essential for developing evidence-based treatments and therapies, and it plays a critical role in advancing public health and medical practices.

Whenever we search out a new medicine then there is need of to check out that tests how well new medicines technique work in a human being. A clinical trial is a research study that test a new medical treatment or a new way of using an existing treatment 'to see if it we'll be a better way to prevent and screen for diagnose or treat disease [1]. Developers of a new drug, biological and medical devices must ensure product safety, demonstrate medical safety, and demonstrate medical benefits in human and mass produce the product [2].

For any new drug to enter in clinical trial, it must pass preclinical studies Pre-clinical studies including in vitro i.e. test tube or laboratory that is outside the body. Studies and trials on animal population .wide range of dosage of the study drug is given to animal subject or to an in vitro substrate in order to obtain preliminary efficacy, toxicity and pharmacokinetic information [1] One challenges to the validity of such trial is the tendency for assessment of outcomes to systemically deviate from truth because of predisposition in observers such as from hope or expectations [3].

Today, there are two internationally recognized human research guidelines that form the basis for the conduct of ethical clinical trial. We have chosen to use the term ethical codes rather than ethical guidelines. A code of practice defines professional rules according to which people in a particular profession are expected behave .other human research guidelines /codes of practice have emerged over the past century ,such as Nuremberg trial at the end of second world war[4]

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HISTORY OF CLINICAL TRIALS

The evolution of clinical research traverse a long and fascinating journey the the recorded history of clinical trials goes back to the biblical description in 500 B.C. [6]562 B.C. 1537: pre-James Lind era :

The world's first clinical trials is recorded in the 'book of Daniel ' in the Bible [7].Avicenna (1025 AD) in his encyclopedic 'canon of medicine ' describes some interesting rules for the testing of drug [8]. He suggested that in the clinical trial a remedy should be used in it's natural state in disease without complication .the first clinical trial of a novel therapy was conducted accidently by the famous surgeon ambrosia pare in 1537[7,9].The term clinical trial simulation may have been first used to describe a game entitled "instant experience."[10].

800: Arrival of placebo:

It took another century before the emergence of another important mile stone in the history of modern clinical trial; the placebo. The word first appeared in medical literature in the early 1800 [7].1943: The first double blind controlled trial patulin for common cold:

The medical analysis council (MRC) Britain dole out an attempt 1943. To analyze patulin treatment for (an extract of genus Penicillium patulinum) the respiratory disorder. This was the primary run comparative trial with synchronal management within the general population in recent time [11].

John wood wall, an English military medico of country Malay Archipelago company, had suggested the consumption of citrus, (it has AN antiscorbutic effect) from the seventeenth century, but their use didn't become widespread [12].Main text :

Clinical research is a branch of medical science that involves studies and trials designed to evaluate new treatments, drugs, medical devices, or diagnostic tests. It aims to gather scientific evidence about the effectiveness and safety of interventions to improve patient care, guide medical practice, and inform public health decisions.

Clinical research typically involves several phases and types of studies, including:

- **Clinical Trials**: These are controlled studies that test new drugs, treatments, or interventions. Clinical trials often follow a specific structure, such as randomized controlled trials (RCTs), to ensure reliable results.
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- **Epidemiological Studies**: These studies focus on understanding the distribution and determinants of diseases in populations. They help identify risk factors and preventive measures.

Phases of Clinical Trials

Clinical trials usually progress through four phases:

Phase I: Tests safety, dosage, and side effects on a small group of healthy participants. of a clinical trial is the first stage in testing a new drug, treatment, or intervention in humans. It is primarily focused on assessing the **safety**, **dosage**, and **side effects** of the new drug or treatment. The main goal is to determine whether the intervention is safe enough to move on to further testing in larger groups of people.

- **Participant Population**:
  - Phase 1 trials typically involve a small group of healthy volunteers (20 to 100 people). In some cases, if the drug is for a specific disease (e.g., cancer), patients with the disease may be involved.
  - Healthy volunteers are usually preferred because it allows researchers to assess how the body reacts to the drug without the influence of disease-related factors.

- **Safety and Dosage**:
  - The primary goal is to evaluate the **safety** of the drug or intervention. Researchers test for any **adverse effects** and determine the highest dose that can be safely administered.
  - This phase also helps establish the **optimal dosage** (i.e., the dose that provides the best balance of efficacy and minimal side effects).
- Focus on Pharmacokinetics and Pharmacodynamics:
  - Pharmacokinetics: How the body absorbs, distributes, metabolizes, and excretes the drug (ADME).
  - Pharmacodynamics: The effects of the drug on the body, including its mechanism of action and any physiological responses.
- Monitoring and Data Collection:
  - Participants are closely monitored for any adverse events (side effects) and any changes in vital signs, lab tests, or physical assessments.
  - This data is crucial for determining whether the drug should proceed to Phase 2, where larger trials can begin to assess efficacy.

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Phase 2

- **Clinical Trial** is the second stage of clinical testing in the development of a new drug or treatment. It typically follows a successful Phase 1 trial, which focuses on assessing the safety, tolerability, and pharmacokinetics of a new drug in a small group of healthy volunteers or patients.
  - Efficacy Testing: The main goal of Phase 2 is to determine whether the drug or treatment is effective in treating the condition it is intended for. This is usually done by testing the drug in a larger group of patients who have the condition the drug is meant to treat.
  - Safety and Side Effects: Phase 2 also continues to monitor the drug's safety profile, including potential side effects and adverse reactions, but in a larger sample of people. This phase helps identify any common or severe side effects that may not have appeared in Phase 1.
  - Optimal Dosage: Researchers use Phase 2 trials to determine the optimal dose of the drug—what is most effective while being the least harmful. This often involves testing several different dosages to compare their effects.

Characteristics of Phase 2 Trials

- **Participants**: Usually between 100 and 300 patients with the disease or condition under study.
- **Duration**: Can last several months to 2 years, depending on the disease and the nature of the drug.
- **Study Design**: May be randomized, controlled, and often blind (either single or double-blind) to reduce bias. Some Phase 2 trials also include placebo groups.
- **Endpoints**: Primary endpoints often involve measures of efficacy (e.g., tumor shrinkage, symptom reduction), while secondary endpoints may include safety, quality of life, or biomarkers.

Phase 3

- A **Phase 3 clinical trial** is a critical stage in the clinical development of a new drug or treatment, following successful Phase 1 and Phase 2 trials. Phase 3 trials are typically the last step before a drug or treatment is submitted for regulatory approval by agencies like the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA)
  - **Confirm Efficacy**: Phase 3 trials are designed to provide definitive evidence that the new treatment is effective in treating the targeted condition, and that its benefits outweigh any risks. The trial often compares the new drug to a placebo or an existing standard-of-care treatment.
  - **Monitor Long-term Safety**: In addition to assessing efficacy, Phase 3 trials are also focused on gathering more comprehensive data on the drug's safety profile, including rare or long-term side effects that might not have appeared in earlier phases.
  - **Establish Dosing and Administration Protocols**: While Phase 2 trials may have identified the optimal dose, Phase 3 trials aim to confirm the most effective and safest dosing regimen over an extended period, sometimes looking at different populations or patient subgroups (e.g., elderly, children, or those with co-morbidities).

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 Support Regulatory Submission: The data gathered during Phase 3 trials are the primary evidence submitted to regulatory authorities to seek approval for the new treatment. A successful Phase 3 trial is often a prerequisite for marketing approval.

➢ **Characteristics of Phase 3 Trials**

Participants: Phase 3 trials usually involve a much larger sample size than earlier phases, often ranging from several hundred to several thousand patients. These patients typically have the disease or condition the drug is intended to treat, and the trial is conducted across multiple sites, sometimes internationally.

Study Design: Phase 3 trials are often randomized, double-blind, and controlled, meaning neither the participants nor the researchers know who is receiving the experimental treatment and who is receiving the control (e.g., placebo or standard treatment). This helps reduce bias and ensures more reliable results.

Duration: Phase 3 trials can last from several months to a few years, depending on the nature of the disease, the treatment, and the specific endpoints being studied.

Endpoints: The primary endpoints focus on clinical outcomes that directly relate to patient health, such as survival rates, disease progression, symptom relief, or quality of life. Secondary endpoints might include biomarkers, patient-reported outcomes, or other factors relevant to treatment impact

Phase 4

Clinical Trial, also known as a **post-marketing study**, is conducted **after a drug or medical device has been approved** by regulatory agencies (like the FDA or EMA) and is available on the market. The primary goal of Phase 4 trials is to gather more data on the drug's long-term effectiveness, safety, and overall risk-benefit profile in a broader population, once it is being used outside of the controlled conditions of the earlier trial phases.

Here's a breakdown of the key objectives and characteristics of Phase 4 trials

1. Safety Monitoring

- **Long-term safety:** Phase 4 trials can detect rare side effects or long-term risks that were not apparent in earlier phases due to the limited sample size and duration of Phase 1-3 studies.
- **Real-world data:** Since the drug is being used in the general population, Phase 4 studies help to identify potential interactions with other medications, contraindications, or adverse reactions that might not have been previously observed.

2. Efficacy in a Broader Population

- **Diverse patient groups:** Drugs may be tested in different age groups, ethnic populations, or in patients with comorbidities who were excluded from earlier trials. This helps determine how effective the drug is across diverse groups.
- **Expanded indications:** Phase 4 trials may explore new uses for the drug or confirm its effectiveness for conditions other than the original approved indication (off-label uses).

3. Comparative Effectiveness

- **Head-to-head studies:** Some Phase 4 trials compare the new drug with other available treatments to see which is more effective or safer in the real world.

4. Cost-effectiveness Analysis

- Assess whether the drug or treatment is cost-effective compared to alternatives, considering the broader economic impact of widespread use

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Objective and scope of ICH good clinical trials

- Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. The objective of this ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.
- The guideline was developed with consideration of the current good clinical practices of the European Union, Japan, and the United States, as well as those of Australia, Canada, the Nordic countries and the World Health Organization (WHO).
- This guideline should be followed when generating clinical trial data that are intended to be submitted to regulatory authorities. The principles established in this guideline may also be applied to other clinical investigations that may have an impact on the safety and well-being of human subjects.

➢ **The objective** of **ICH Good Clinical Practice**:

The objective of **ICH Good Clinical Practice (GCP)** is to ensure the safety, well-being, and rights of trial participants, as well as the integrity and reliability of clinical trial data. GCP provides a set of internationally recognized ethical and scientific quality standards for designing, conducting, recording, and reporting clinical trials. Its primary goals include:

- **Protection of Participants**: Ensuring that the rights, safety, and confidentiality of clinical trial participants are upheld at all times.
- **Scientific Integrity**: Ensuring that clinical trials are scientifically sound, well-designed, and carried out to produce valid and reliable results.
- **Compliance with Ethical Principles**: Ensuring that clinical trials are conducted in accordance with ethical principles, particularly the Declaration of Helsinki, and regulatory requirements.
- **Data Accuracy and Reliability**: Ensuring that the data generated from clinical trials is accurate, complete, and verifiable, contributing to credible conclusions about the efficacy and safety of a treatment or intervention.

the **scope** of ICH International Council for Harmonisation:

➢ **The** scope of ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) covers a broad range of areas related to the development, registration, and post-market surveillance of pharmaceuticals. ICH's aim is to harmonize the technical requirements for drug development and approval across major pharmaceutical markets, including the United States, Europe, and Japan, while promoting global public health and safety.

The Specific Scope of ICH includes

1. Clinical Trials and Good Clinical Practice (GCP):

- **ICH E6**: Guidelines on Good Clinical Practice (GCP) provide a unified standard for designing, conducting, and reporting clinical trials across international borders. This ensures that clinical trials are scientifically sound and that the safety, well-being, and rights of participants are prioritized.
- Covers ethical considerations, safety monitoring, data integrity, and regulatory compliance in clinical research.

2. Pharmaceutical Development and Quality:

- **ICH Q series** (e.g., ICH Q8, Q9, Q10): These guidelines relate to the development and manufacturing of pharmaceutical products, focusing on aspects like quality by design (QbD), quality risk management, and lifecycle management of medicines.
- Covers topics like stability testing, quality assurance, and the overall lifecycle of a pharmaceutical product from development to post-marketing.

3. Regulatory Harmonization:

- ICH aims to harmonize technical and regulatory standards across the key pharmaceutical regions (U.S., Europe, Japan, and more recently, other regions such as Canada, Switzerland, and the WHO) to streamline the drug approval process and reduce duplication.
- The goal is to create a more efficient process for drug development and approval, while maintaining high standards for safety and efficacy.

4. Pharmacovigilance and Safety Monitoring:

- **ICH E2E**: Guidelines on pharmacovigilance and the monitoring of post-market drug safety.
- These standards help in monitoring adverse drug reactions and other safety concerns during clinical trials and after a product has reached the market, ensuring patient safety and regulatory compliance.

5. Biotechnology and Biopharmaceuticals:

- **ICH S6**: Guidelines for the preclinical safety evaluation of biotechnology-derived pharmaceuticals.
- This scope includes specific guidelines for the development of biologics (e.g., monoclonal antibodies, gene therapies, vaccines) and their approval processes.

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6. Statistical Principles and Data Analysis:

- ICH guidelines also cover the statistical methods required in clinical trials, such as proper randomization, blinding, sample size calculations, and handling of missing data, to ensure the accuracy and validity of trial outcomes.

7. Pharmaceutical Registration

Q	S	E	M
"Quality" Topics, i.e., those relating to chemical and pharmaceutical Quality Assurance (Stability Testing, Impurity Testing, etc.)	"Safety" Topics, i.e., those relating to in vitro and in vivo pre-clinical studies (Carcinogenicity Testing, Genotoxicity Testing, etc.)	"Efficacy" Topics, i.e., those relating to clinical studies in human subject (Dose Response Studies, Good Clinical Practices, etc.)	"Multidisciplinary" Topics, i.e., cross-cutting Topics which do not fit uniquely into one of the above categories (MedDRA, ESTRI, M3, CTD, M5)

- ICH supports the development of technical documentation and standardized formats for regulatory submissions, such as the **Common Technical Document (CTD)**, which is used for drug registration worldwide.
- The CTD structure is designed to be used for the submission of marketing authorization applications to regulatory authorities across various jurisdictions.

8. Ethical and Social Considerations:

- **ICH E7**: Guidelines on the conduct of clinical trials in special populations (e.g., pediatrics, geriatrics, and patients with chronic diseases).
- Ensures that clinical trials address diverse patient needs and uphold ethical standards in all patient groups.
-

Overview of ICH topic selection of drug in clinical trial

- The **selection of a drug** for a clinical trial is a crucial step in the development of a new therapeutic agent, as it directly impacts the design, conduct, and outcomes of the trial. This process involves a comprehensive evaluation of several factors to ensure that the drug is suitable for testing in humans and that it has the potential to provide meaningful benefits to patients. Below are key considerations and steps involved in the **selection of a drug for a clinical trial**:

1. Preclinical Data and Evidence

Before a drug is tested in humans, a significant amount of preclinical data must be gathered. This data helps establish a foundation for clinical testing.

Pharmacology: The drug's mechanism of action, target(s), and biological effects should be well understood.

Toxicology: Safety profiles, including any potential toxicity, side effects, and doses that are likely to be safe for human testing, must be established through animal models and laboratory studies.

Pharmacokinetics (PK): Studies to determine how the drug is absorbed, distributed, metabolized, and excreted (ADME), as well as its half-life and other relevant factors.

Pharmacodynamics (PD): Understanding the drug's effect on the body, including the dose-response relationship, is essential.

2. Regulatory Approval (IND/CTA Submission)

Before initiating clinical trials, the sponsor (usually the drug developer) must submit an application to regulatory authorities:

- Investigational New Drug (IND) Application: In the U.S., the sponsor submits an IND to the FDA to gain approval to begin clinical testing in humans. In other regions, this process is referred to as a Clinical Trial Application (CTA) submitted to local regulatory agencies (e.g., EMA in Europe, PMDA in Japan).
- The application includes the results of preclinical studies, proposed clinical trial protocols, and other key data such as the drug's manufacturing information and proposed dose.

3. Efficacy Potential

The drug must show promise in terms of **efficacy** or therapeutic benefit based on preclinical data, including:

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Target Disease**: The drug should address an unmet medical need or show significant potential to improve the management of an existing disease.**
Mechanism of Action (MoA)**: The drug should have a well-understood MoA that is expected to have a clinically meaningful effect on the disease process. This could include targeting specific receptors, enzymes, proteins, or pathways involved in the disease.**
Preclinical Efficacy**: Positive results from preclinical models (such as animal models) or in vitro (cell culture) testing, showing that the drug has the potential to exert a beneficial effect in the target disease.**

4. Safety Profile

The safety of the drug is paramount when selecting a candidate for clinical trials. A thorough **risk assessment** must be performed, including:

- **Toxicity**: Preclinical studies should identify any potential for acute or chronic toxicity, organ damage, or other harmful effects at various dose levels.
- **Side Effects**: Preclinical models should also look for signs of side effects, such as cardiovascular, neurotoxic, or reproductive toxicity, that could impact clinical trial safety.
- **Dose Range**: The highest dose that is well tolerated in animals (without causing toxicity) can help define the starting dose in human clinical trials.

5. Formulation and Route of Administration

The drug must be formulated in a manner suitable for clinical testing, and the route of administration must be determined.

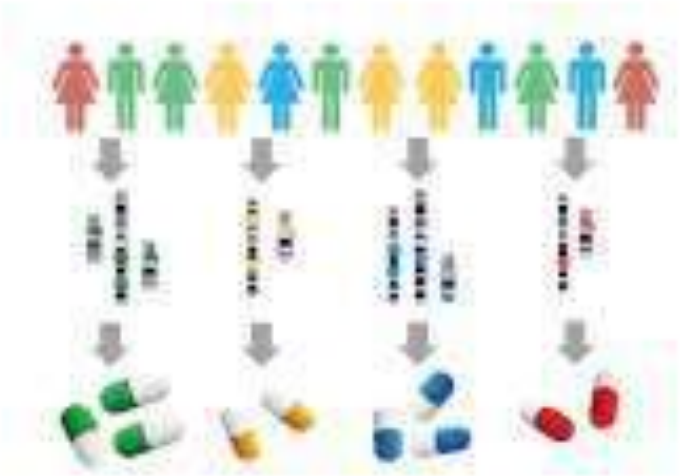
- **Formulation**: This could be in the form of oral tablets, injectable solutions, topical creams, or other forms. The formulation must be stable, effective, and suitable for the intended patient population.
- **Route of Administration**: The route (oral, intravenous, subcutaneous, etc.) needs to be feasible for both the clinical trial and for potential future clinical use. This choice can affect the drug's bioavailability and ease of use.

6. Regulatory and Ethical Considerations

- **Ethical Justification**: The drug must have a strong ethical rationale for clinical testing. For instance, the potential benefits to patients should outweigh the risks.
- **Ethics Committee/Institutional Review Board (IRB) Approval**: In addition to regulatory approval, the drug and the trial protocol must undergo ethical review to ensure that the trial will be conducted with respect for participants' rights and safety.

7. Patient Population

The selection of the appropriate patient population for the clinical trial is critical for the trial's success:



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Target Population: The drug must be tested in the population for which it is intended (e.g., cancer patients, patients with chronic diseases). Inclusion and exclusion criteria are defined to select individuals who are most likely to benefit from the drug and who meet safety requirements.
Pre-existing Conditions: Consideration should be given to any comorbidities, which might affect the drug's safety or efficacy.
8. Clinical Trial Design and Feasibility
Study Design: The choice of trial design (e.g., randomized controlled trial, open-label study) should be based on the drug's characteristics, including its expected effect, safety profile, and the target population.
Endpoints: Primary and secondary endpoints must be defined clearly to measure the drug's effectiveness (e.g., symptom reduction, survival rates, biomarkers).
Feasibility: The ability to recruit patients, the trial's geographic locations, timelines, and costs should all be considered.
9. Market Considerations
While not directly related to clinical trial selection, practical considerations for the commercial potential of the drug may influence its selection for trial:
Competitive Landscape: Whether the drug offers a new or improved approach to treating a disease that has existing therapies.
Market Need: The potential demand for the drug and the market gap it aims to fill.
Regulatory Pathway: The possibility of obtaining fast-track approval, orphan drug status, or breakthrough therapy designation, which could expedite the clinical trial process.

Selection of Drug
A small group of healthy volunteers (often 20–100) participate in the initial round of human testing. This stage is mostly concerned with assessing pharmacokinetics, safety, and tolerance. The maximum tolerated dose (MTD) of the medication is determined by administering it at ever greater doses. Phase 2: A bigger group of people with the ailment the medication is intended to treat—typically several hundred—participate in this phase. Its objective is to evaluate the medication's safety profile and efficacy. This stage is primarily concerned with early signs of treatment efficacy.

Phase 2: This phase involves a larger group of participants (usually several hundred) who have the condition the drug is designed to treat. It aims to assess the drug's efficacy and further evaluate its safety profile. This phase is more focused on preliminary indications of therapeutic effectiveness.

Phase 3: A much larger group of participants (hundreds to thousands) are involved in this phase, which aims to confirm the drug's effectiveness, monitor side effects, and compare it to commonly used treatments. Phase 3 trials are usually multicenter, randomized, and controlled studies. Data from this phase is often submitted for regulatory approval.

Phase 4: These are post-marketing studies conducted after a drug has been approved and is on the market. They help monitor long-term safety, effectiveness, and rare adverse effects that might not have been detected in earlier trials.
2. Regulatory Oversight and Ethical Considerations
Drug use in clinical trials is tightly regulated by government agencies such as:
U.S. FDA (Food and Drug Administration)
EMA (European Medicines Agency)
Other national regulatory bodies
Ethical principles include:
Informed consent: Participants must understand the potential risks and benefits of participating and voluntarily agree to it.
Safety monitoring: Ongoing safety assessments are conducted, including monitoring adverse events (side effects) through mechanisms like Data Safety Monitoring Boards (DSMBs).
Randomization and blinding: Randomized controlled trials (RCTs) are considered the gold standard, and blinding (where the participants or researchers do not know which treatment is being given) helps reduce bias.
3. Drug Administration in Trials
The actual use of the drug in clinical trials can take different forms, including:
Oral administration (e.g., pills, tablets)
Injectables (e.g., intravenous or subcutaneous)
Topical (e.g., creams or ointments)
Inhalation (e.g., nebulizers, inhalers)
Implants (e.g., slow-release capsules or devices placed under the skin)
The method of administration depends on the drug's formulation and the intended use.

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4. Placebo and Control Groups
Many clinical trials use a placebo (an inactive substance) or an active control (another treatment) to compare the effects of the new drug against a baseline. This helps to determine whether any observed effects are truly due to the drug itself and not other factors (e.g., psychological effects or natural disease progression).
5. Pharmacovigilance and Adverse Events
Adverse events (AEs) and serious adverse events (SAEs) are closely monitored during clinical trials. These could range from mild side effects (e.g., headache, nausea) to more severe reactions (e.g., organ toxicity, life-threatening conditions). If serious side effects occur, the trial may be paused or terminated.
Pharmacovigilance systems are put in place to track and analyze adverse events, even after a drug is approved for use, to ensure ongoing safety.
6. Participant Eligibility and Drug Use Criteria
Inclusion criteria: Specifies the characteristics required for participants to be eligible, such as age, gender, and diagnosis of the condition.
Exclusion criteria: Details factors that would disqualify individuals from participating, like pre-existing conditions or concurrent medication use that could interfere with the study results.
The drug is often tested in different population subgroups to understand its effects across varying age groups, genders, and ethnicities.
7. Risks and Benefits of Drug Use in Trials
Participants face certain risks in clinical trials, especially in earlier phases:
Unforeseen side effects or adverse reactions.
Ineffective treatment or treatment that is no better than existing options.
Possibly receiving a placebo (in randomized controlled trials), meaning they might not receive any active treatment.
However, the potential benefits of participating in clinical trials include:
Access to new treatments that may not yet be available to the general public.
Close monitoring by medical professionals during the trial.
Contributing to medical research that could benefit others with the same condition.
8. Monitoring and Data Collection
Data is systematically collected on how participants respond to the drug. This includes:
Efficacy outcomes (e.g., improvement in symptoms, disease markers)
Safety outcomes (e.g., adverse events)
Pharmacokinetic and pharmacodynamic data (e.g., drug absorption, metabolism)
Data are analyzed to determine if the drug works as intended and whether it is safe for broader use.

CONCLUSION

Drug use in clinical trials is a critical part of the medical research process, enabling new treatments to be tested in human populations under controlled conditions. Rigorous oversight ensures participant safety, and the results help shape future therapeutic strategies. The process is designed to balance risk with potential benefits, contributing to the overall advancement of medical knowledge and treatment options.

In the context of clinical trials, drug use during clinical phases refers to the administration and monitoring of an investigational drug (or therapeutic intervention) in human participants across different phases of the clinical trial process. Each phase of clinical trials serves a specific purpose in evaluating the safety, efficacy, pharmacokinetics, and overall suitability of a drug for public use. Let's break down how drug use is managed and evaluated at each clinical phase.

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CLINICAL RESEARCH AND ADR MONITORING

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ABSTRACT

Clinical research is a branch of healthcare science that involves the systematic investigation of human health and disease to improve diagnostic, preventive, and therapeutic practices.

It encompasses various study designs, including observational studies, clinical trials, and translational research, aimed at enhancing patient care and advancing medical knowledge.

Clinical research is fundamental in evaluating the safety and efficacy of new drugs, medical devices, and treatment protocols, ultimately influencing regulatory approvals and healthcare guidelines.

The field faces challenges like recruitment, retention of participants, and balancing scientific rigor with practical application.

Advances in digital health, data analytics, and personalized medicine are shaping the future of clinical research, fostering innovation and more patient-centered approaches.

The ultimate goal is to bridge the gap between laboratory discoveries and real-world applications, improving healthcare outcomes globally.

KEY WORDS: *Study Design , Study Protocol , Ethical Considerations , Study Population , Interventions and Controls, Outcome Measures , Data Collection and Management , Statistical Analysis .*

INTRODUCTION

Clinical research is a branch of medical science that involves the study of human participants to evaluate the safety, efficacy, and effectiveness of medical interventions, including drugs, devices, treatments, and diagnostic tools.
It is essential in the advancement of medicine and plays a critical role in bringing new therapies to patients.

- Clinical research provides evidence for new and improved medical practices, such as treatment modalities, management approaches, diagnoses, and prevention strategies
- Understanding how to develop a study question and choose study designs is critical to fully grasp what clinical research entails and why it is important
- Clinical studies can be broadly classified into two design categories: observational, in which researchers only collect available data, and experimental, in which investigators control the exposure
- Every type of study serves a unique purpose, but only randomized controlled trials can determine causality between independent and dependent variables
- A component of medical and health research intended to produce knowledge essential for understanding human disease, preventing and treating illness, and promoting health. Clinical research embraces a continuum of studies involving interaction with patients, diagnostic.

Clinical Trial's

Clinical trials are research studies conducted to evaluate the safety, efficacy, and effectiveness of medical interventions, including drugs, medical devices, therapies, or diagnostic tools.

They are essential for advancing medical knowledge and ensuring that new treatments are both safe and beneficial for patient.
Clinical trials are prospective biomedical or behavioral research studies on human participants designed to answer specific questions about biomedical or behavioral interventions, including new treatments (such as novel vaccines, drugs, dietary choices, dietary supplements, and medical devices) and known interventions that warrant further study and comparison.

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Clinical trials generate data on dosage, safety and efficacy.
Clinical trials are systematic research studies conducted to evaluate the safety, efficacy, and effectiveness of medical interventions such as drugs, vaccines, medical devices, and treatment protocols.

The primary goal of clinical trials is to improve patient care by testing innovative approaches to preventing, diagnosing, and treating diseases

Purposes of Clinical Trial's

1) Assessing Safety
2) Evaluating Efficacy
3) Developing Better Treatments
4) Preventing Diseases
5) Improving Quality of Life
6) Advancing Personalized Medicine

Goal's Clinical Trial's

- **Aimed at improving medical care, advancing scientific knowledge, and ensuring patient safety.**

1. Evaluating Safety
2. Supporting Regulatory Approval
3. Advancing Medical Knowledge
4. Promoting Personalized Medicine
5. Improving Patient Outcomes
6. Exploring Preventive Measures

2. Phases of Clinical Trial's

A. Preclinical Phase (Before Human Testing)
B. Phase I: First-in-Human Trials
C. Phase II: Efficacy and Safety Trials
D. Phase III: Large-Scale Trials
E. Phase IV: Post-Marketing Surveillance

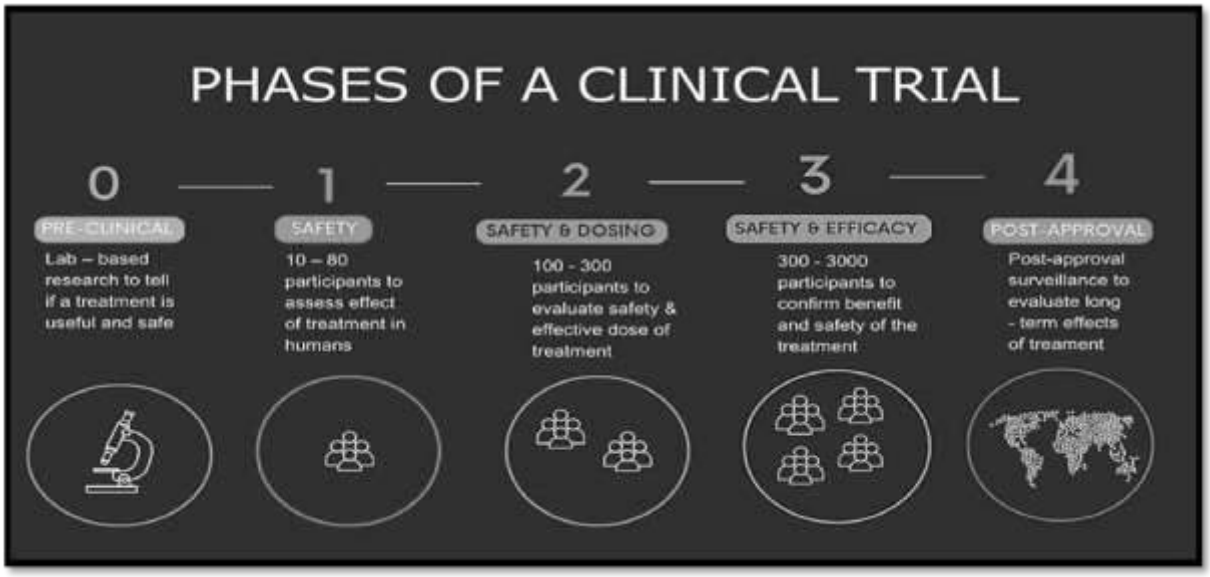

Fig. 3 Phases of Clinical Trial's

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A. Preclinical Phase (Before Human Testing)

The preclinical phase is the first stage of research conducted before new drugs, treatments, or medical interventions are tested on humans. **It aims to assess the potential efficacy and safety of a treatment through laboratory and animal studies.**
This phase is critical for identifying promising candidates and ensuring they meet safety standards before advancing to human clinical trials.

Objective

1. **Discovery and Target Identification**
2. **Lead optimization**
3. **In Vitro Studies (Cell-Based Studies)**
4. **In Vivo Studies (Animal Testing)**
5. **Formulation Development**

B. Phase I: First-in-Human Trials

Phase 1 clinical research is the first stage of human clinical trials in drug development.
Its main objective is to evaluate the safety, dosage, and pharmacokinetics (how the drug is absorbed, distributed, metabolized, and excreted by the body) of a new drug or treatment.
It is typically conducted after preclinical studies, which involve laboratory and animal testing, have shown initial promise regarding the drug's safety and efficacy.

Participants: Phase 1 trials typically involve a small number of healthy volunteers (20-100) participant.

Objectives

- **Safety**
  The primary goal is to assess the safety of the drug, identify any potential side effects or adverse reactions, and determine if the drug is safe enough to proceed to the next phase.
- **Dose-Escalation**
  Researchers begin by administering a very low dose of the drug to a few participants and gradually increase the dose in subsequent groups to determine the maximum tolerable dose (MTD) and the dose at which side effects become intolerable.

Study Design

- **Single Ascending Dose (SAD)**:
  In this design, participants receive a single dose of the drug, and the dose is gradually increased in different groups of participants until the MTD is found.
- **Multiple Ascending Dose (MAD)**:
  This design involves giving participants multiple doses of the drug over several days or weeks, again with increasing doses to assess the effects of prolonged exposure.

Goals of Phase 1

- **Safety Profile**
  The most important goal is to assess the safety of the drug and identify any potential risks or harmful side effects.
- **Dosage**
  Establish the appropriate dosage range for further testing in Phase 2 clinical trials.
- **Pharmacokinetics and Pharmacodynamics**
  Collect initial data on how the drug works in the body.

C. Phase II: Efficacy and Safety Trials

A Phase 2 clinical trial is a critical stage in the drug development process, coming after Phase 1 trials and before Phase 3 trials.
The primary focus of Phase 2 is to evaluate the effectiveness of a drug or treatment, continue to assess its safety, and further refine its optimal dosage.

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Objective

1. Effectiveness (Efficacy)

The main goal of Phase 2 is to assess whether the drug or treatment works as intended in patients who have the condition or disease the drug is meant to treat.

2. Safety (Adverse Effects and Toxicity):

Although Phase 1 trials primarily focus on safety, Phase 2 continues to monitor for any potential side effects or adverse reactions.

3. Dose Range

Phase 2 studies explore the optimal dose or dosage range that balances effectiveness and safety.

Duration of Phase 2 Trials

Duration: Typically lasts between 6 months and 2 years, depending on the disease being studied, the drug's mechanism of action, and the desired endpoints.

Moving from Phase 2 to Phase 3

If the Phase 2 trial shows that the drug is both effective and safe at a reasonable dose, it moves on to Phase 3

D. Phase III: Large-Scale Trials

Phase 3 clinical trials are a critical stage in the development of new drugs, medical devices, or treatments.
These trials are designed to confirm the effectiveness and safety of an intervention in a larger, more diverse population, and they form the basis for regulatory approval by agencies such as the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA).

Main Objectives

1. Confirm the efficacy of the intervention
2. Compare the intervention to existing treatments
3. Assess optimal dosing and administration

- **Trial Design**

Randomization: Participants are randomly assigned to different treatment arms (e.g., new drug vs. placebo or standard treatment).

Control group: A group of participants that receives either a placebo (an inactive treatment) or the standard of care for comparison.

- **Duration**

Phase 3 trials can last from several months to several years, depending on the condition being studied and the treatment being tested.

Challenges in Phase 3 Trials

Recruitment:

Finding enough eligible participants can be a challenge, especially for rare diseases or when strict inclusion/exclusion criteria are applied.

Ethical Issues:

There may be ethical concerns, especially when studying potentially life-saving treatments.

E. Phase IV: Post-Marketing Surveillance

o Post-Phase 3: Post-Marketing Surveillance

This helps detect any long-term or rare side effects that were not evident during Phase 3 trials.
Phase 4 clinical trials, also known as post-marketing surveillance trials, occur after a drug or treatment has been approved by regulatory authorities (like the FDA) and is available on the market.

These trials are designed to monitor the long-term safety, effectiveness, and overall impact of the drug or treatment in a broader population.

Phase 4 trials can also assess the drug's performance in various subgroups of patients and in realworld conditions, which may differ from the controlled environment of earlier phases.

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Key Word's : - Long-Term Safety Monitoring , Effectiveness in the General Population , Comparative Effectiveness , New Uses , Risk Management.

Trials

- **Registry Studies:**
  Large observational studies where data is collected from patients over time to monitor drug effects in a real-world setting.
- **Post-Approval Safety Studies**:
  Studies specifically designed to gather more information about the safety of a drug after it has been widely distributed.
- **Observational Studies**:
  Researchers observe how patients are treated in normal clinical practice without assigning specific interventions.
- **Patient Surveys and Reporting**:
  Patients or healthcare providers may be asked to report side effects, which contribute to the overall safety data.

Challenges

Data Collection

Because Phase 4 trials often involve larger, more diverse populations, data collection can be more complex and harder to control.

Cost

Post-marketing surveillance can be expensive, as it may require long-term follow-up with large numbers of patients.

Compliance

Patients may not always follow protocols as strictly as in earlier trial phases, which can make it harder to interpret results.

In short, Phase 4 trials are a critical part of the drug approval process, offering insights into a medication's safety and effectiveness once it's widely used in the general population.

Ethical Consideration

Ethical considerations in clinical research are critical to ensuring the rights, safety, and well-being of participants, as well as maintaining the integrity and trustworthiness of the scientific process.

Clinical research typically involves human subjects, and it is therefore necessary to apply ethical principles that safeguard their dignity, autonomy, and rights while contributing to scientific knowledge.
Clinical research plays a critical role in health care delivery.
It's through clinical research that scientists develop new treatments, cures and preventive measures that help mediate the spread of disease.

Key Elements of Ethical Consideration

1. Informed Consent

Participants must voluntarily agree to participate in research after being fully informed about the study's nature, risks, benefits, and alternatives.

2. Risk and Benefit Assessment

The ethical principle of beneficence dictates that research should aim to benefit participants or society, while minimizing harm.

Minimal Risk:

Risks should be as low as possible, particularly in vulnerable populations (e.g., children, pregnant women, or individuals with cognitive impairments).

Maximizing Benefit:

Efforts should be made to ensure that the study has the potential for meaningful scientific or therapeutic benefits.

Monitoring Risks:

An independent Data Safety Monitoring Board (DSMB) or similar oversight mechanisms may be employed to monitor the safety of participants throughout the study.

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4. **Confidentiality and Privacy**

Respecting the privacy and confidentiality of participants is essential in clinical research. Researchers are obligated to protect sensitive information, including medical history, personal details, and any data collected during the study.

Data Protection:

Confidentiality must be maintained by anonymizing or de-identifying data whenever possible, and using secure systems for data storage and transmission.

Legal and Ethical Guidelines:

Researchers must comply with data protection laws (e.g., GDPR in Europe, HIPAA in the United States) to ensure participants' rights are respected.

❖ **ADR Monitoring & Reporting**

Adverse Drug Reactions (ADRs) refer to any harmful, unintended, and undesirable effects that occur when a drug is administered at normal therapeutic doses.

These reactions can range from mild side effects to life-threatening conditions, and their monitoring is crucial to ensuring the safety and efficacy of medications.

In healthcare, **ADR monitoring and reporting** play a critical role in identifying, evaluating, and mitigating the risks associated with drug use.

This process involves systematic data collection from various sources, including healthcare providers, patients, clinical trials, and post-marketing surveillance programs. Advanced tools like **electronic health records (EHRs**), data mining algorithms, and artificial intelligence have revolutionized ADR monitoring, enabling rapid detection and analysis of drug-related risks.

ADR monitoring is essential for regulatory authorities, pharmaceutical companies, and healthcare institutions to make evidence-based decisions regarding drug approvals, label modifications, or withdrawals.
Public awareness and active participation in ADR reporting further strengthen pharmacovigilance efforts.

ADR Monitoring

ADR monitoring involves the ongoing surveillance of the effects of medications in patients, specifically focusing on detecting adverse reactions that may not have been identified in clinical trials.

ADR Reporting

ADR reporting refers to the process of documenting and communicating suspected ADRs to relevant regulatory bodies, healthcare authorities, or pharmaceutical companies**.**

➢ **Fig. 4 Chart For ADR (Adverse Drug Reaction) Reporting Drug Lisinopril, Metformin, Aspirin, Amoxicillin.**

Date of Reported	2024/11/01	2024/11/03	2024/11/05	2024/11/07
Patient ID	001	002	003	004
Age/Sex	58/M	45/F	70/M	21/F
Drug(S) Involved	Lisnopril	Metformin	Aspirin	Amoxicillin
Dosage & Administration	10 mg saily	500 mg dealy	75 mg dealy	250 mg TID
Adverse Reaction	Dizziness, Cough	Nausea, Vomiting	Gastrointestinal Bleading	Skin Rash
Severty	Moderate	Mild	Severe	Mild
Outcome	Recovered	Ongoing	Hospitalized	Recovered
Date of Onset	2024/10/30	2024/11/02	2024/11/04	2024/11/06

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Date of Resolution	2024/11/05	N/A	N/A	2024/11/08
Reporter (Phisician/Pharmacist/Patient)	Dr. Mansi (gynecologist)	Sidheshwar (Pharmacist)	Dr. Gautam	Nurse
Type of ADR	Type A (columnon)	Type B (uncommon)	Type C (Dose related)	Type B (Uncommon)
Reporting Source	Hospital	Patient	Physician	ER Department
Follow-up-Action taken	Dose Adjustment, Monitoring.	Symptom Management.	Immediate Discontinuation, Blood Transfusion.	Discontinued Drug, Antihistamine Given.

Purposes of ADR Monitoring & Reporting

1. Safety Assessment

- **Identifying harmful effects**
  ADR monitoring helps detect and assess the harmful effects of drugs that may not have been identified during clinical trials due to limited sample sizes or trial conditions.
- **Risk mitigation:**
  By identifying ADRs, healthcare professionals can take steps to mitigate risks, such as adjusting dosage, changing medications, or issuing safety warnings.

2. Regulatory Compliance

Pharmacovigilance requirements:
Regulatory bodies like the FDA, EMA, and WHO require ongoing ADR reporting and monitoring as part of pharmacovigilance to ensure that drug products remain safe for public use.

- **Labeling updates:**
  ADR data can lead to updates in drug labeling, including new warnings or contraindications, helping to guide healthcare providers in making safer prescribing decisions.

3. Post-market Surveillance

Long-term safety monitoring:
ADR monitoring continues after a drug is approved and released to the market. This helps identify rare, long-term, or delayed side effects that may not have been evident in pre-market clinical trials.

- **Population diversity:**
  In the real-world population, patients often have diverse conditions, comorbidities, and genetic differences that may result in ADRs not seen in controlled clinical trials.

Important's of ADR Reporting & Monitoring

1. Ensures Patient Safety

- **Identification of Risks:**
  Monitoring ADRs helps identify potential risks associated with a drug. By collecting data from realworld use, healthcare professionals can detect rare, unexpected, or severe reactions that might not have been identified during clinical trials.
- **Preventing Harm**
  Early detection of ADRs can lead to appropriate changes in treatment protocols, dosage adjustments, or even the removal of unsafe drugs from the market, ultimately preventing further harm to patients.

2. Improves Drug Safety Profile

Data for Risk Assessment:
Continuous ADR reporting allows healthcare providers, regulators, and pharmaceutical companies to assess the risk-benefit ratio of medications in diverse populations.

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This can lead to better labeling, warnings, or contraindications for specific groups of patients (e.g., children, pregnant women, elderly).

- **Labeling Updates**:
  Information from ADR reporting systems can prompt revisions in drug labels to reflect known side effects, ensuring that patients and clinicians are better informed.

3. Enhances Pharmacovigilance

Global Collaboration:

ADR monitoring contributes to pharmacovigilance, the science of detecting, assessing, and understanding drug-related risks. International collaboration through databases like VigiBase ensures a global perspective on drug safety.

4. Enhances Pharmaceutical Development

Informs Drug Development:

ADR data can also be used by pharmaceutical companies to improve the design of future drugs, refine formulations, or develop new drugs with fewer side effects.

Companies may use ADR information to enhance the clinical trial process for subsequent drug candidates.

- **Continuous Feedback Loop:**
  By analyzing ADRs, pharmaceutical companies gain valuable feedback about their drugs' performance in the real world, which can influence both marketing strategies and product improvements

➢ **Who Reports ADRs**

A Who Report in the context of ADR (Adverse Drug Reaction) typically refers to a report issued by the **World Health Organization (WHO)** on adverse drug reactions. The WHO maintains a global pharmacovigilance system to monitor and report adverse drug reactions, particularly through the WHO Collaborating Centre for International Drug Monitoring based in **Uppsala, Sweden**. This center operates the **Uppsala Monitoring Centre (UMC),** which collects and analyzes reports of adverse drug reactions from healthcare professionals, patients, and regulatory agencies worldwide.

➢ **Regulatory Frameworks**

Global Pharmacovigilance: International organizations, including the WHO's **Uppsala Monitoring Centre (UMC),** collect and analyze ADR data from all over the world.

The goal is to detect safety signals, identify risks, and provide guidance on the safe use of medicines globally.

National Regulatory Agencies

Countries have their own pharmacovigilance systems to manage ADR data. In the U.S., the FDA operates the MedWatch system, while the EMA in Europe coordinates reporting through the EudraVigilance database.

➢ **Reporting Systems**

Spontaneous Reporting Systems:

These systems allow healthcare professionals or patients to voluntarily report ADRs. In the U.S., MedWatch is the primary system for spontaneous reporting.

In Europe, similar reporting is done through national databases linked to EudraVigilance.

Electronic Reporting:

Many countries have introduced electronic methods for reporting ADRs, which have streamlined the process, making it easier for healthcare providers and patients to submit ADR information.

Challenges in ADR Monitoring and Reporting:

Underreporting:

A significant challenge is that many ADRs go unreported, especially in cases where the reaction is mild or not immediately recognized as related to a drug.

- **Incomplete Data:**
  The data gathered may be insufficient for a full understanding of the ADR, which can delay decisionmaking.

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- **Complexity in Causality Assessment:**
  Determining whether a drug is the cause of an adverse event can be difficult, especially when other factors (e.g., co-existing diseases, drug interactions) are involved.

Benefits of ADR Monitoring and Reporting:

Improved Drug Safety:
Ongoing ADR surveillance helps identify risks associated with medications, leading to better understanding of their safety profiles.

- **Risk Minimization**:
  With early detection of ADRs, manufacturers and healthcare providers can take proactive measures, such as adjusting dosage recommendations or issuing warnings to patients.

CONCLUSION

Clinical research plays a pivotal role in advancing medical knowledge and improving patient outcomes.
By investigating the safety and efficacy of new interventions, clinical trials provide valuable insights that guide treatment decisions and enhance the quality of care.

Furthermore, research findings inform evidence-based guidelines, empowering healthcare providers to deliver personalized and effective therapies tailored to individual patient needs.

Clinical data management is an essential aspect of clinical research, ensuring that the data collected is organized and accessible for analysis and reporting.

- Conduct clinical trials to compare the effectiveness of different treatment options that are already approved for clinical use,
- Combine novel therapies developed by different sponsors,
- Develop therapies for rare diseases,
- Determine optimal duration and dose of treatment with drugs in clinical use,
- Test multimodality therapies, such as radiation therapy, surgery, or devices in combination with drugs,

Clinical research serves as the foundation of evidence-based medicine, driving advancements in disease prevention, diagnosis, treatment, and patient care. The outcomes of clinical research contribute to the development of safer and more effective therapeutic interventions, while also shaping clinical guidelines and healthcare policies.
Despite its transformative potential, clinical research faces challenges such as ethical considerations, patient recruitment, and resource constraints. Addressing these issues requires collaboration among stakeholders, adherence to ethical principles, and innovative approaches to study design and execution.

In conclusion, clinical research is indispensable for improving health outcomes and enhancing the quality of life.
ADR monitoring and reporting are essential components of the pharmacovigilance framework, ensuring that drugs are used safely and effectively.
Ongoing improvements in reporting systems, increased awareness among healthcare professionals, and robust regulatory oversight will continue to enhance patient safety and the overall benefit-risk profile of medications.

Adverse Drug Reaction (ADR) monitoring and reporting are indispensable components of pharmacovigilance, ensuring the safe and effective use of medicines.
By systematically identifying, evaluating, and addressing drug-related risks, ADR monitoring protects public health and enhances patient outcomes.
The success of ADR programs depends on active participation from healthcare professionals, patients, and regulatory authorities, alongside the integration of advanced technologies for data collection and analysis.

In conclusion, ADR monitoring and reporting are vital to fostering trust in healthcare systems, improving the therapeutic landscape, and safeguarding public health.
A collaborative, proactive approach to ADR vigilance will continue to enhance drug safety and promote global health standards.

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Result

The result of clinical research can refer to the outcomes of a clinical trial or study designed to evaluate the safety, efficacy, or impact of a medical treatment, drug, procedure, or device. The specific results depend on the type of research being conducted,

Adverse Drug Reaction (ADR) monitoring typically involve assessing and reporting on the safety profile of a drug or treatment based on the identification, evaluation, and documentation of any negative or unintended effects that patients experience after taking a medication. ADR monitoring is crucial in clinical research and post-marketing surveillance to ensure that drugs are used safely and effectively.

The result of Adverse Drug Reaction (ADR) reporting typically involves several outcomes, depending on the process and objectives. Below are some key aspects of ADR reporting results:

Efficacy: This refers to whether the treatment or intervention being studied works as intended. It might be measured in terms of improved health outcomes, reduced disease symptoms, or cure rates.

Safety: Clinical research also assesses the safety of treatments, looking for potential adverse effects, side effects, or long-term risks. Safety data often include the frequency and severity of any negative reactions observed in participants.

Statistical Significance: Research results are often presented in terms of statistical significance. This shows whether the results observed are likely due to the treatment rather than chance. A p-value of less than 0.05 is often used to indicate significance.

Comparative Effectiveness: Some clinical trials compare new treatments to existing ones or to a placebo, helping to understand how effective a new drug or therapy is in relation to current options.

Quality of Life: Some studies measure how a treatment affects patients' quality of life, including their physical, emotional, and social well-being.

Patient-Reported Outcomes: These are measures of health outcomes based on reports from patients themselves, such as symptom improvement or the experience of side effects.

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A REVIEW: MOLECULAR MECHANISM: TO STUDY DRUG LIPID INTERACTION

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ABSTRACT

Since Singer and Nicolson's fluid mosaic model was introduced, our understanding of membrane organization has evolved. Rather than being homogeneous bilayers of lipids dispersed uniformly, plasma membranes are actually lipid complexes with laterally separated membrane domains, such as caveolae and lipid rafts. The pharmacokinetic features of medications, including their transport, distribution, and accumulation, ultimately impact their efficacy. Research conducted in both in vivo and cell culture settings has demonstrated the critical role that drug-lipid interactions play in these processes. Drug effectiveness can be estimated using liposome model membrane systems in a variety of ways. Estimating the quantity of drug carried into cells as well as its route of transport is also possible with lipid model membranes.

The aim of the experiment is to study molecular mechanism of drug lipid interaction

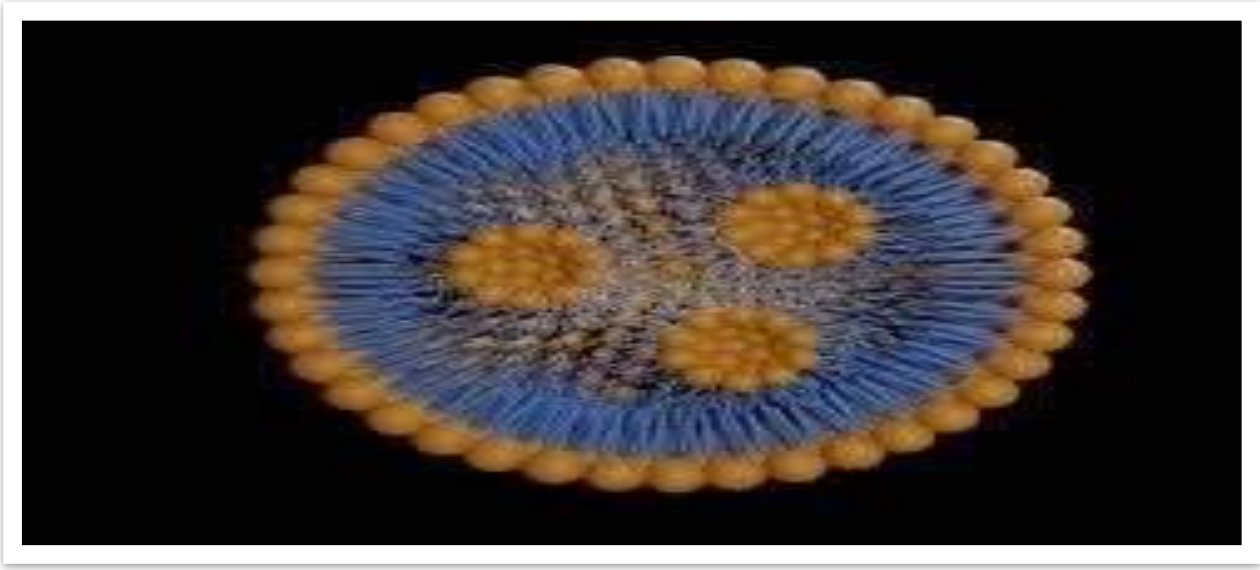

Fig 1 : Liposome

REVIEW OF LITERATURE

1. **AM Seddon, D Casey(1)** The field of drug–membrane interactions is one that spans a wide range of scientific disciplines, from synthetic chemistry, through biophysics to pharmacology. Cell membranes are complex dynamic systems whose structures can be affected by drug molecules and in turn can affect the pharmacological properties of the drugs being administered. In this tutorial review we aim to provide a guide for those new to the area of drug–membrane interactions and present an introduction to areas of this topic which need to be considered …
2. **Jumper, R Evans, A Pritzel, T Green, M Figurnov(2**) Proteins are essential to life, and understanding their structure can facilitate a mechanistic understanding of their function. Through an enormous experimental effort 1, 2, 3, 4, the structures of around 100,000 unique proteins have been determined 5, but this represents a small fraction of the billions of known protein sequences 6, 7.

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Structural coverage is bottlenecked by the months to years of painstaking effort required to determine a single protein structure. Accurate computational approaches are needed to address this gap.

3. **A Kusumi, TK Fujiwara, R Chadda(3)** The recent rapid accumulation of knowledge on the dynamics and structure of the plasma membrane has prompted major modifications of the textbook fluid-mosaic model. However, because the new data have been obtained in a variety of research contexts using various biological paradigms, the impact of the critical conceptual modifications on biomedical research and development has been limited**.**
4. **LJ Pike - Journal of lipid research, 2006 – ASBMB(4)** The recent Keystone Symposium on Lipid Rafts and Cell Function (March 23–28, 2006 in Steamboat Springs, CO) brought together biophysicists, biochemists, and cell biologists to discuss the structure and function of lipid rafts. What emerged from the meeting was a consensus definition of a membrane raft:" Membrane rafts are small (10– 200 nm), heterogeneous, highly dynamic, sterol-and sphingolipid-enriched domains that compartmentalize cellular processes. Small rafts can sometimes be stabilized.
5. **TPW McMullen, RNAH Lewis(5)** The existence of relatively large and longlived detergent-insoluble, sphingolipid-and cholesterol-enriched, liquid-ordered lipid raft domains in the plasma membranes of eukaryotic cells has become widely accepted. However, we believe that the evidence for their existence is not compelling despite extensive work on both lipid bilayer model and biological membranes. We review here the results of recent studies, which in our view call into question the existence of lipid rafts in membranes, at least in the form commonly

INTRODUCTION

The primary components of the cell membrane, which are a wide range of distinct lipids, proteins, and polysaccharides, make it an extremely complex and diversified system. Amphipathic phospholipids make up the majority of the continuous lipid bilayer matrix found in cell membranes. The cell membrane, which acts as a cell's border, is crucial to a drug's absorption, distribution, metabolism, and excretion (ADME).[1] With the solution to the sequence problem, the general structure for a single protein domain has been found, marking the most spectacular enormous leap forward in life science since the identification of the double helix structure of DNA.[2] The idea of membrane organization has evolved gradually since Singer and Nicolson proposed a fluid mosaic model; in this model, lipid complexes with laterally separated membrane domains, such as lipid rafts and caveolae, constitute plasma membranes rather than homogeneous bilayers of uniformly distributed lipids.[3] Lipid rafts are membrane domains that are different from other membrane structures, being tiny (10-200 nm), diverse, dynamic, and high in sphingolipids and cholesterol.[4] Because they divide membranes into functional sections and give membrane proteins a place to reside, lipid raft membrane domains are crucial for cellular signal transduction and trafficking.[5-8] Membrane lipid rafts and caveolae are localized or host clusters of pharmacologically significant receptors, ion channels, and enzymes.[9-12] The route of pharmacological action can first be understood in terms of the straightforward receptor/channel/enzyme and ligand interaction described in the classic mechanistic theory, given the placement of receptors, ion channels, and enzymes in membrane lipid rafts. The second idea is that medications could alter the organizational integrity of lipid rafts by acting on membrane lipids, which would modify the activity of ion channels, enzymes, and receptors that are embedded in membrane domains. If medications interact more favorably with lipid rafts than with non-raft overall membrane lipid bilayers, it would be interesting to find out if this interaction at the membrane lipid level is connected to the pharmacological and cytotoxic effects of drugs. Although cholesterol is necessary for the creation of rafts and caveolas, the regulating effects of membrane domains on ion channels and receptors were verified by lowering the amount of cholesterol in plasma membranes.13-16

General mechanisms of Drug-Membrane Interactions

Passive Diffusion

According to Fick's law, passive diffusion is the net transfer of chemicals from a high concentration area to a low concentration area. It is a major route for the penetration and absorption of drugs. Drug molecules can contact their binding sites contained in the lipid bilayer by either directly crossing the membrane or diffusing laterally through the membrane.[17-18] A drug's concentration gradient or its difference in saturation degree, or equilibrium solubility, between the two sides of the membrane can be the driving force behind passive diffusion. [19] Because of their capacity to interact with the hydrophobic tail of the lipid bilayer, small hydrophobic drug molecules can diffuse across the plasma membrane quickly. In contrast, unless they are very small and have an ideal net charge, hydrophilic or ionized molecules do not readily diffuse across the bilayer.[20-21] Conversely, high hydrophobicity hinders the bioavailability of the active medicinal components since it may cause them to be stuck in the lipid membrane due to strong hydrophobic bonding. The integrity of the membrane as a protective barrier is discovered to be destroyed by this unwanted drug-membrane binding. [22] Consequently, the medicine must have the best possible affinity—or lipophilicity—for the lipophilic membrane environment.

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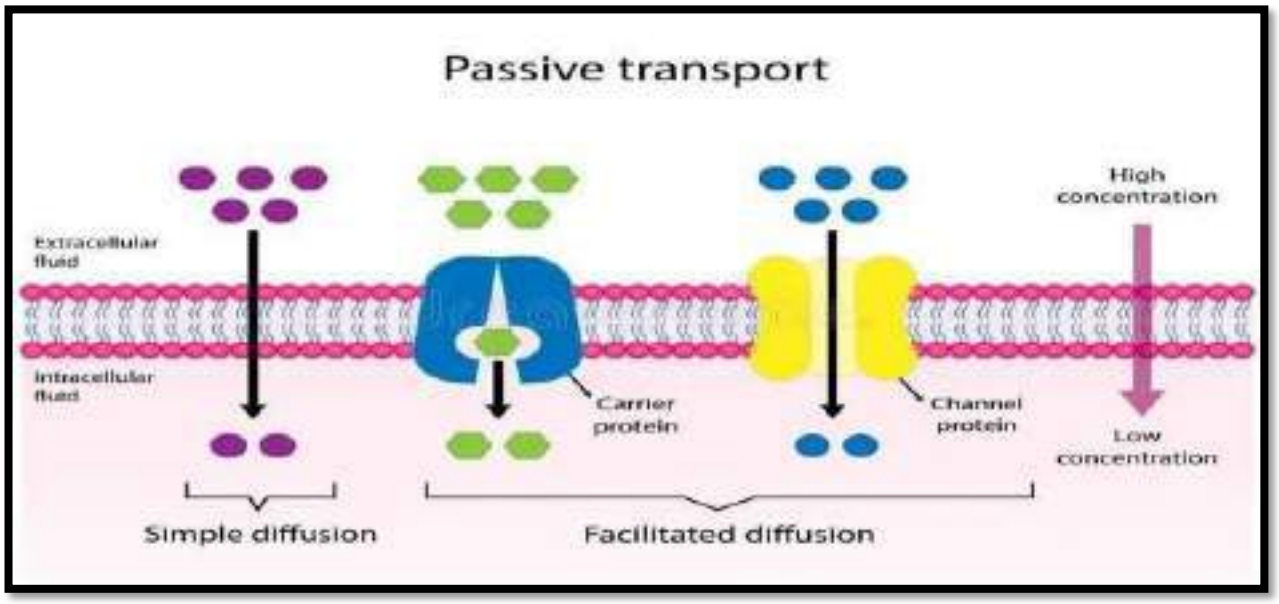

Fig 2 : Passive diffusion

Protein- Mediated Transport

This form of transport is facilitated by certain membrane proteins that offer continuous protein-lined routes through lipid bilayers, allowing some drug molecules to enter or exit cells more easily. The two primary protein types implicated in this kind of transport are typically classified as carriers or channels. In facilitated diffusion, channel proteins create pores in the membrane that permit water-soluble molecules—those that are charged or have polar groups—to flow through, whereas carrier proteins literally alter their structure to facilitate the passage of particular molecules across membranes in a process known as active transport. **Interactions Of Model Lipid Membrane With Drug :**

It is unavoidable for drug-lipid interactions to occur since many drug molecules have intracellular targets, which means they must cross one or more phospholipid bilayers in order to reach the intracellular targets and cause a reaction. Research in both in vivo and cell culture settings has demonstrated the importance of drug-lipid interactions in the pharmacokinetic (transport, distribution, and accumulation) aspects of drug action, which in turn affect the medications' overall effectiveness. Therefore, in order to produce powerful medications, it is essential to comprehend how these interactions affect the pharmacokinetic features of drugs. **Drug :**

Antibiotics :

Better explanations for the findings from in vivo and cell culture experiments have been offered by biophysical research. In J774 macrophage cells, for example, Michot et al.[23] found appreciable variations in the cellular accumulation and intracellular activity of four closely similar fluoroquinolone derivatives, in the following order: ciprofloxacin < levofloxacin < garenoxacin < moxifloxacin. Ciprofloxacin efflux in J774 macrophages was found to be the cause of the lower ciprofloxacin accumulation as compared to moxifloxacin acquisition.[24] It was unknown, meanwhile, why the ciprofloxacin transporter showed varying susceptibilities to efflux. The contrasts between the two medications' cellular accumulation and intracellular activity were explained by biophysical studies of the interactions of fluoroquinolone derivatives (moxifloxacin and ciprofloxacin) with lipid model membranes.[25-27]

Antifungal Drugs

Using Langmuir model membranes, Corvis et al.[28] investigated the behavior of griseofulvin, an antifungal drug, at a biologically analogous SP of 30 mN/m. It was proposed that the cell membrane's capacity to identify a specific molecule may play a role in the mechanism of action of griseofulvin.

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Antipsychotic Drugs

Hidalgo et al.[29] examined how the antipsychotic medications trifluoperazine and chlorpromazine affected lipid monolayers, discovering that even minute amounts of these medications cause surface potential and SP to alter. The authors deduced from this data that the lipids have to respond to these medications cooperatively; yet, the binding of these pharmaceuticals results in modifications to several lipids that go well beyond the site of drug binding. The method by which these medications exert relatively nonspecific effects over the lipid membrane may be explained by the cooperative action of the lipid membrane, as revealed in our work.

Liposome Model Membranes As Prediators Of Drug Efficacy

Drug efficacy evaluations frequently employ liposome model membrane systems. The partition coefficient, a measurement of the quantity of a drug that will permeate and/or pass across a lipid membrane into a biological system, is typically used to assess the efficacy of pharmaceuticals. When estimating partition coefficients for pharmaceuticals, an isotropic two-phase solvent solution, like a combination of octanol and water, is typically used. [30] According to a number of studies, liposome model membranes are a more accurate substitute for conventional partition coefficient estimation techniques because the latter are unable to take into consideration potential ionic interactions between medications and lipids, especially when the pharmaceuticals are charged. In the case of Rodrigues et al.[31] rifampicin and dibucaine, which are ionized at physiological pH, were found to have different partition coefficient values with water-dimyristoyl-L-α-phosphatidylglycerol (DMPG) (anionic liposome) and water-DMPC (zwitterionic liposome) compared to neutral drugs, which displayed similar partition coefficient values in both water-DMPG and water-DMPC systems. Electrostatic interactions between the head groups of lipids and ionized drugs—that is, the interaction between cationic dibucaine and anionic DMPG head groups— were the reason for the variation in partition coefficient values. The findings indicate that liposomes, as opposed to octanol-water, provide superior systems for measuring partition coefficients due to their ability to replicate the hydrophobic portion and the externally charged polar surface of phospholipids found in natural membranes.

Estimating the quantity of drug carried into cells as well as its route of transport is also possible with lipid model membranes. Using a variety of biophysical methods, Baciu et al. [32] investigated the interactions between cationic amphiphilic drugs (CADs) and lipid model membranes. The findings demonstrated that active transport and diffusion are not the only mechanisms underlying CADs. It was demonstrated that CADs caused the double-chain PCs to split into mono-chain PCs and fatty acid via this process. When monochain PCs are concentrated enough, they can form micelles that can move the medication to other intracellular membranes by separating from the membrane.

Additionally, model membranes have been employed to study the toxicity process, especially at drug concentrations that have been shown to be harmful in vivo. Amphotericin B (AmB) is an antibiotic with potent antifungal properties that is very hazardous to mammalian cells. [33,34]

Interactions Of Plymers And Drug Delivery Systems With Lipid Membrane

It has been demonstrated that the interfacial characteristics of polymeric coatings applied to drug delivery systems or the drug delivery systems themselves affect how well the systems interact with biological environments and, in turn, how well they deliver biotherapeutic agents to cells and tissue. Several polymers, such as poly(vinyl alcohol) (PVA)[35],poly(ethylene oxide) (PEO)[36],chitosan[37], are utilized as coatings in the creation of drug delivery devices. It has been demonstrated that the size of drug delivery systems and physical properties of these polymers, such as their hydrophilicity, hydrophobicity, and surface charge, can greatly affect how efficiently they interact with lipids. The effectiveness of drug delivery systems in delivering biotherapeutic drugs to cells and tissue can be affected by these polymers in one of two ways. To effectively construct drug carrier systems and gain a deeper comprehension of the mechanisms underlying drug delivery system absorption or harmful effects, a more comprehensive understanding of the interactions between lipid-drug delivery systems and polymers is therefore important. The degree of disruption caused by PAMAM dendrimers in lipid bilayers is dependent on their size and charge, as demonstrated by a biophysical analysis of the interactions between SLBs and amine-terminated generation 7 and 5 (G7 and G5) poly(amidoamine) dendrimers. [38-40]

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CONCLUSION

The transport of pharmaceuticals and drug delivery systems across biological barriers can be better understood by means of straightforward yet efficient drug lipid interaction investigations conducted with model membranes. Druglipid interaction studies using model membranes may offer a sensible method for both drug development and discovery, as well as for creating effective drug delivery systems, with a deeper comprehension of the mechanisms of interactions.

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REVIEW ON ARTIFICIAL INTELLIGENCE THAT ARE USED IN A TREATMENT OF CANCER

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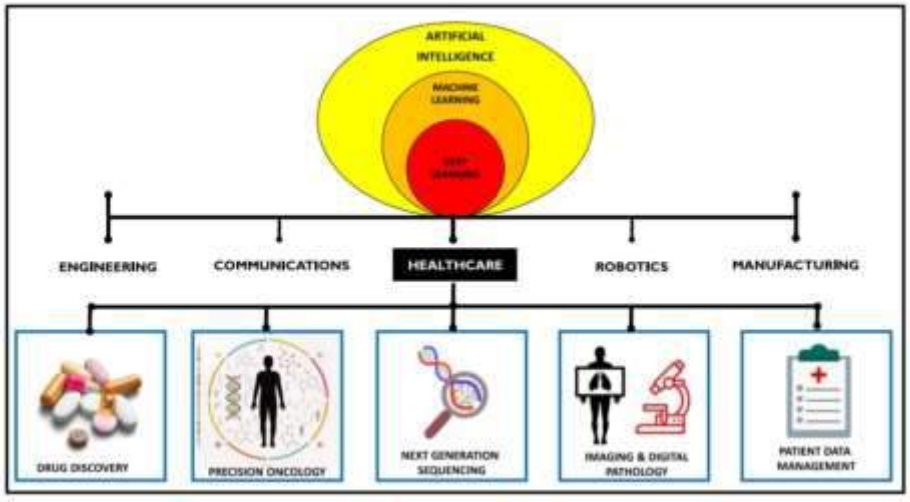
ABSTRACT
Artificial intelligence (AI) uses mathematical algorithms to replicate human thinking and tackle difficult healthcare problems, such as complex diseases like cancer. In the past decade, AI has rapidly advanced, showing great promise for enhancing decision-making, especially since humans struggle to process large amounts of data quickly. Cancer is a complicated disease with numerous genetic and epigenetic variations.AI-based algorithms have great potential to identify genetic mutations and abnormal protein interactions early on. Modern biomedical research is focused on integrating AI technology into clinics in a safe and ethical way.AI assistance for pathologists and physicians could greatly improve predictions of disease risk, diagnosis, prognosis, and treatment options. The use of AI and machine learning in cancer diagnosis and treatment represents the future of personalized medical care, allowing for quicker development of tailored therapies for each patient. With AI systems, researchers can collaborate in real-time and share knowledge digitally, potentially helping millions. This review focuses on how connecting biology with artificial intelligence can revolutionize clinics and help oncologists provide precise treatments.

KEYWORDS: *Artifcial intelligence, Machine learning, Cancer diagnosis, Treatment, Therapeutic interventions*

INTRODUCTION

The term "artificial intelligence" (AI) was first used at the Dartmouth Summer Workshop in 1956, where it was generally described as "thinking machines." In simple terms, AI refers to a machine's ability to learn, recognize patterns, and make decisions based on new data. AI is a broad term that often includes machine learning and deep learning.

Machine learning is a subset of AI, and deep learning is a type of machine learning that uses complex artificial neural networks with multiple layers. Recently, deep learning has become very popular, especially for tasks like face recognition and image classification. This capability has extended to cancer research and medicine, allowing for the automatic and accurate detection of cancer in images, which can help relieve pathologists and radiologists from repetitive tasks.



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Early Detection, Diagnosis, and Staging of Cancer

The timing of cancer detection, the accuracy of diagnosis, and staging are crucial factors that influence how aggressive a tumor is and affect clinical decisions and patient outcomes. In recent years, AI has significantly advanced this important area of oncology, achieving results that can match those of human experts while also providing benefits like scalability and automation.

Making Cancer Diagnoses More Accurate

Deep learning models are increasingly being used to diagnose cancer and identify cancer subtypes from histopathologic and other medical images. Deep neural networks (DNNs) are powerful algorithms that can analyze large images, such as H&E-stained whole slide images from biopsies or surgical samples.

These models have proven very effective at classifying images, such as determining whether a digitized slide contains cancer cells. They achieve high accuracy in distinguishing tumor cells from healthy ones (with area under the curve scores above 0.99). DNNs are also used for more complex tasks, like differentiating closely related cancer subtypes (e.g., adenocarcinoma vs. adenoma in gastric and colon cancers or adenocarcinoma vs. squamous cell carcinoma in lung tumors) and detecting benign versus malignant tissues.

Cancer Staging and Grading

Cancer staging and grading, which determine how aggressive and advanced the cancer is, are crucial parts of the diagnostic process. Staging influences treatment decisions, such as whether to adopt a watchful waiting approach or pursue aggressive treatments like radiotherapy, surgery, or chemotherapyFor prostate cancer, staging is done using the Gleason score, which combines two scores based on the prevalence of tumor cells in two areas of a slide. Deep neural networks (DNNs) have shown promise in predicting Gleason scores from histopathology images of prostate tumors. For example, Nagpal and colleagues used whole slide images from prostatectomy specimens to train a DNN model (Inception-V3) and a k-nearest-neighbor classifier to predict Gleason scores. Their model achieved a prediction accuracy of 0.70, compared to 0.61 from a panel of 29 independent pathologists.Cancer staging can also be done using radiology images. Zhou and colleagues developed a deep learning method based on SENet and DenseNet to predict the grade (low vs. high) of liver cancer from MRI images, achieving an area under the curve (AUC) of 0.83. Overall, these studies suggest that AI has promising applications in cancer staging, performing comparably to trained experts despite some limitations in AUC scores.

On the Road to Early Cancer Detection

AI is making progress in the early detection of cancer through emerging minimally invasive techniques, such as liquid biopsies for circulating tumor DNA (ctDNA) or cell-free DNA (cfDNA). Liquid biopsies, which can be obtained through simple blood tests, offer the potential for early cancer detection, monitoring relapse risk over time, and guiding treatment options.For instance, the microsatellite instability (MSI) status can be predicted from ctDNA in patients with endometrial cancer to help inform immunotherapy treatments. Chabon and colleagues developed a machine learning method called Lung-CLiP, which predicts the likelihood of ctDNA in blood samples from lung cancer patients. This method first estimates the probability that a cfDNA mutation is linked to the tumor, using an elastic net model and features like cfDNA fragment size. It then combines this information with copy-number scores using an ensemble classifier with five different algorithms to predict the presence of ctDNA in the blood.The method showed modest predictive performance, with area under the curve (AUC) scores ranging from 0.69 to 0.98, depending on the cancer stage. There is also a trade-off between specificity and sensitivity in these predictions.

DETECTING CANCER MUTATIONS USING MACHINE LEARNING

The widespread use of next-generation sequencing (NGS) has enabled thousands of cancer laboratories to routinely sequence cancer genes, exomes, and genomes. While various computational tools can identify genetic variants and mutations in NGS data, they often struggle in situations like low coverage or complex, repeat-rich areas of the genome.Some researchers have approached mutation detection as a machine learning problem. For example, DeepVariant is a deep neural network (DNN) method based on the Inception-V2 architecture. It detects variants from aligned NGS reads by first creating read pileup images for potential variants, turning it into an image classification task. Then, it predicts the probabilities of different genotype states (homozygous reference, heterozygous variant, or homozygous variant). This method won an award for best performance in SNP detection at the second precision FDA Truth Challenge in 2016.

DISCOVERY OF THERAPEUTIC TARGETS AND DRUGS

Drug discovery and development typically involves high costs and significant time commitments. Making access to various treatments more affordable is essential.

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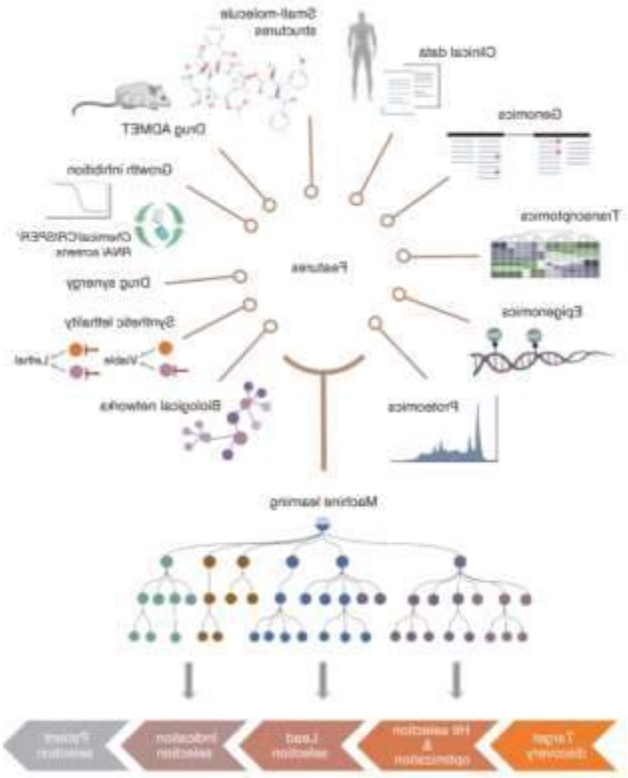

Artificial Intelligence (AI) in Cancer Medical Imaging

Artificial intelligence (AI) is transforming cancer medical imaging. Deep learning algorithms play a crucial role in healthcare by enhancing disease monitoring, diagnosis, surgical assistance, and overall disease management.In oncology, AI is particularly important in radiology across various imaging techniques like X-rays, ultrasounds, CT scans, MRIs, PET scans, and digital pathology. These advanced algorithms analyze images quickly and accurately, helping to differentiate between normal and abnormal findings. This distinction is vital for early cancer detection, which improves patient outcomes.AI enhances medical imaging by improving image quality, aiding in image interpretation, and advancing radiomics. Looking ahead, the focus will be on increasing efficiency and reducing costs in medical imaging.

1) Radiographic imaging

AI has made significant advancements in healthcare, especially in medical imaging. Extracting important data—like size, shape, and position—from medical images is vital for accurate diagnosis and treatment. However, this process can be slow and subject to human error, particularly with complex tumors. Therefore, there is a strong need for automated analysis in clinical care.To ensure accurate analysis of medical images, three key strategies are essential:

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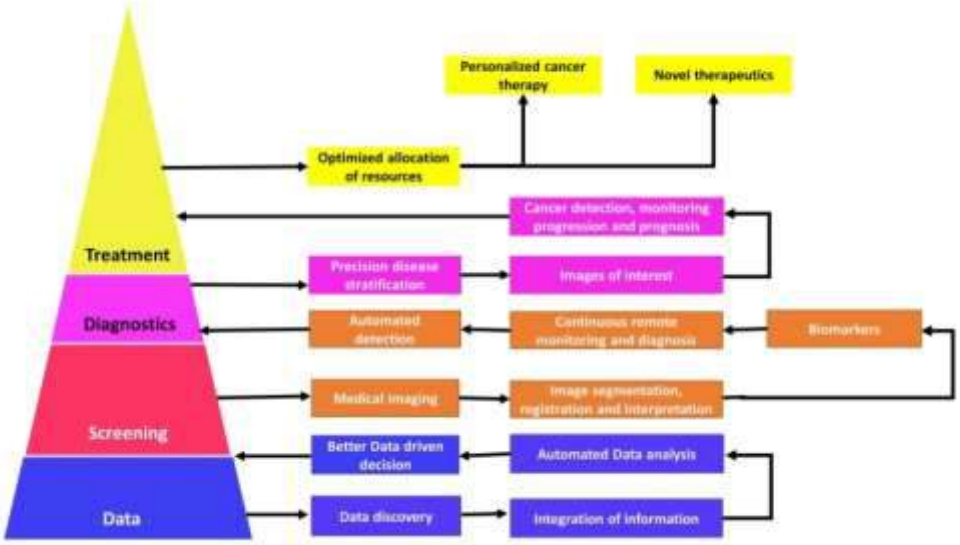
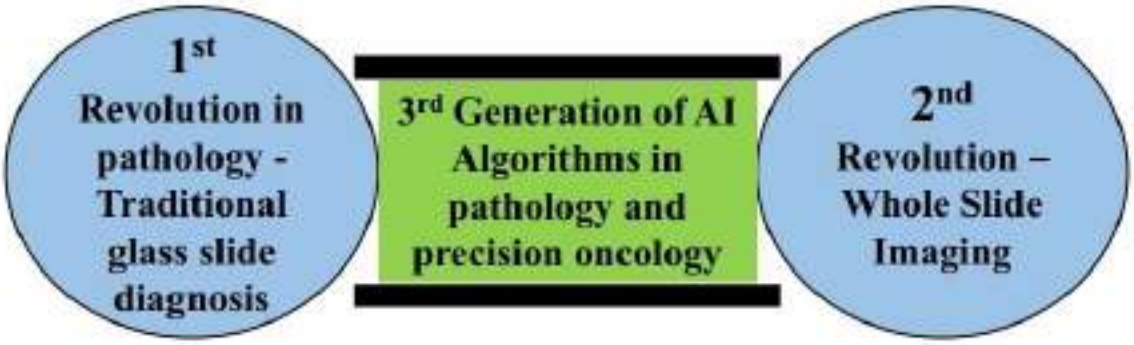


1. Image Segmentation: This identifies the area of interest in an image and marks its boundaries.
2. Image Registration: This establishes how different images relate spatially to each other.



3. Image Visualization: This extracts important data for clear interpretation.

Despite these developments, challenges persist due to the complexity of the data, the objects within the images, and validation issues. In many countries, especially developed ones, cancer diagnosis and treatment often involve a Multidisciplinary Team (MDT). These teams are specialized by cancer type and consist of various healthcare professionals who collaborate to decide on the best treatment plan.For example, an MDT for thoracic cancer might include a pulmonologist, radiologist, histopathologist, clinical nurse, radiotherapy oncologist, chemotherapy oncologist, palliative care physician, and thoracic surgeon, along with an administrator.The main advantage of this approach is that it allows for the selection of the most effective and current treatments, chosen by a team of experienced experts working together.

Digital Pathology

Pathology is the diagnosis of disease through the examination of body tissue, typically viewed under a microscope on glass slides. Certified pathologists usually make these diagnoses. However, traditional methods relying on glass slides can be time-consuming and prone to errors, leading to delays in second opinions and affecting patient care.To improve this process, diagnostic pathology is increasingly adopting digital imaging technologies. One of the latest innovations is Whole Slide Imaging (WSI), which allows for the viewing of entire slides as high-resolution scannedimages. This method not only improves image quality but also offers a more efficient way to store images compared to traditional glass slide storage.

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AI for diagnosis of Colorectal Cancer

As technology advances, it's no surprise that AI is being used to improve how we diagnose cancer. AI helps make diagnoses more accurate and precise (Huang et al., 2019). One of its key advantages is handling large amounts of data and uncovering patterns that human experts might miss (Huang et al., 2019). Efforts to improve medical imaging now focus on using deep learning to detect cancer more effectively. These tools can scan and interpret images faster, improve workflows, enhance image quality, and even use 3D technologies to extract better images (Liu et al., 2018a; Topol, 2019; Thompson et al., 2018; Li et al., 2018).

While AI seems like a perfect fit for medical imaging, its potential in pathology and diagnosing genetic diseases is just as exciting and worth exploring. This could mean improving current medical tests or discovering new ways to identify diseases. Ultimately, enhancing imaging and testing methods with AI could bring transformative changes to healthcare.

Table 1 Potential implementation of Artifcial intelligence (AI) for epidemiology of colorectal cancer

	Definition	Function example	In colorectal cancer
GeoAI (Janowicz 2020)	Subfield of spatial data science to process geographic information using AI	Image classification, object detection, geo-enrichment	Etiological studies, such as food consumption, genetic predisposition, healthcare variance
Digital epidemiology—Global Public Health Intelligence Network (Tarkoma et al. 2020; Dion et al. 2015)	Increase situational (public health events) awareness and capability and global network links	Early detection of SARS	Increase global capacity to early-detect risks and tumor burdens
Digital epidemiology—HealthMap (Tarkoma et al. 2020; Dodson et al. 2016)	Utilizing online informal sources for disease surveillance	Real-time surveillance on COVID-19	Achieve a comprehensive view of global tumor burden
Digital epidemiology—Program for Monitoring Emerging Diseases (Tarkoma et al. 2020; Hii et al. 2018)	Exploiting the Internet and serving as a warning system	Early reports on COVID-19	Monitoring of emerging etiological factors associated with colorectal cancer

Understanding how AI is applied to visual imagery interpretation starts with exploring Convolutional Neural Networks (CNNs). These are specialized artificial neural networks designed to handle image data (Wu, 2017). By analyzing large datasets of images, CNNs learn patterns to recognize new objects and improve their performance over time. Since they are a branch of AI, they also allow for optimization and adaptability (O'Shea and Nash, 2015).Another key concept is computer vision, where AI processes and interprets real-time visual data from cameras or videos. This technology can be applied to tools like the endoscope, which is crucial for diagnosing colorectal cancer.

In CNNs, one common method for object detection is the replicated feature approach, where copies of a feature detector are used to scan an image from different positions (Le, 2018). This approach has several advantages:

1. It reduces the number of free parameters.
2. It works across different scales and orientations.
3. It creates feature maps by replicating detectors, enabling consistent detection across the entire image (Le, 2018).

This Method Benefits Neural Networks by

1. Preserving translation invariance, ensuring features remain recognizable even when shifted.
2. Sharing useful features across all image areas, a concept known as invariant knowledge (Le, 2018).

These features make CNNs powerful tools for visual interpretation,particularly in medical imaging.

To understand how AI is used in visual imagery, it's important to start with Convolutional Neural Networks (CNNs). These are special types of artificial neural networks designed to work with image data (Wu, 2017). By analyzing large sets of images, CNNs learn to identify patterns and recognize new objects. Since they are part of AI, they can improve and adapt over time (O'Shea and Nash, 2015).AI also processes visual data in real time through a field called computer vision, which involves interpreting images or videos from cameras. This is especially useful in tools like the endoscope, which is important for diagnosing colorectal cancer.A common method CNNs use for object detection is called the replicated feature approach. This involves using multiple copies of the same feature detector to analyze an image from different positions (Le, 2018). This approach has key advantages:

1. It reduces complexity by lowering the number of parameters.
2. It works across different sizes and orientations.
3. It allows the same features to be recognized anywhere in the image, which is called invariant knowledge (Le, 2018).

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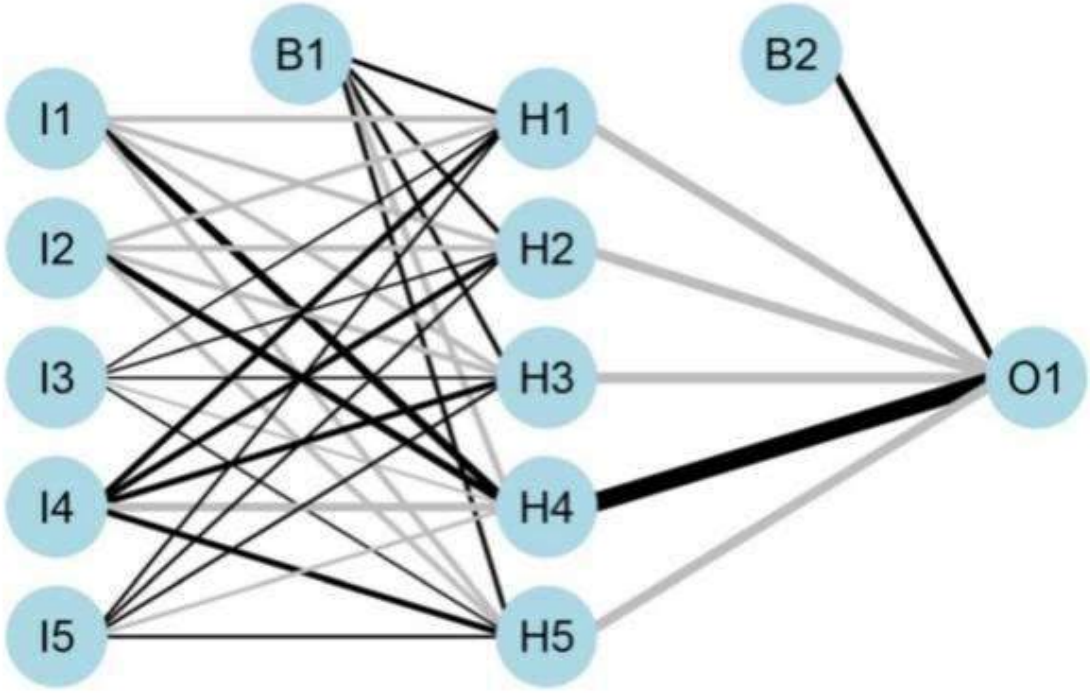
Overall, CNNs are powerful tools for analyzing images and are especially helpful in medical applications like detecting cancer.



An artificial neural network (ANN) consists of four main components: an input layer (I), hidden layer (H), bias layer (B), and output layer (O). The connections between these layers are adjusted during training based on feedback.Positive correlations are shown with black lines, while negative correlations are shown with grey lines.The thickness of each line represents its importance or significance.This structure enables the ANN to process new inputs and generate specific outputs based on the learned patterns.In endoscopy, moving instruments can create unwanted artifacts that interfere with accurate diagnoses (Zhang and Xie, 2019). Researchers analyzed various datasets to develop methods for reducing the number of artifacts detected by segmentation tools.

Recently, Ali et al. conducted a large-scale study comparing 23 segmentation algorithms using common datasets (Ali et al., 2020). They found that while most algorithms performed similarly in detecting artifacts, many struggled with larger artifacts. This poses a significant challenge, as larger artifacts can lead to misinterpretations or false-positive findings (Ali et al., 2020).

Direct methods using CNNs in endoscopy have focused on diagnosing polyps. Misawa et al. developed their own algorithms to identify colorectal polyps from video datasets (Misawa et al., 2018). Their algorithm's results were compared to annotations made by two experts, considered the gold standard. The study found that the AI correctly diagnosed flat lesions, which are the hardest to identify, 64.5% of the time (100/155 cases) and correctly identified 94% of all test polyps (Misawa et al., 2018; Kudo et al., 2019; Liu et al., 2018b).
Building on this work, Mori et al. tested the same algorithm in a live experiment using an endocytoscope, which offers over 500x magnification while functioning like a regular endoscope (Mori et al., 2019). Six patients underwent the procedure, and the AI successfully identified all cases in real time as either adenoma or hyperplastic polyps. New features included:

1. A color change in the screen's corner to indicate abnormalities.
2. A warning sound.
3. The ability to distinguish between neoplastic and non-neoplastic polyps in real time using microscopic imaging (Mori et al., 2019).

Mori et al. suggest that incorporating deep learning into colonoscopies offers several benefits beyond improved diagnostic accuracy. These include:

1.Reducing variations in detection rates.
2.Providing better teaching tools for endoscopists and trainees.

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3. Minimizing unnecessary polypectomies (Mori et al., 2017).
AI-powered endoscopy research has grown significantly, as shown by multiple studies (Ichimasa et al., 2018; Nakajima et al., 2020; Lai et al., 2021; Yamada et al., 2019; Chen et al., 2018; Repici et al., 2020; Kudo et al., 2020; Mori et al., 2018; Nguyen et al., 2020; Deding et al., 2020). However, challenges remain, such as:
1.Technological limitations.
2.Lack of regulations and clinical trials.
Feasibility issues and risks of misdiagnosis (Kudo et al., 2019; Mori et al., 2017).A significant limitation is the scarcity of available datasets in this field. Since AI relies on data for training and improvement, this limits its capacity to learn and grow (Mori et al., 2017).In CT and MRI imaging, CNNs have also been impactful, particularly in detection, segmentation, and classification of images (Yamashita et al., 2018; Shan et al., 2019). For colorectal cancer, however, research on their use is limited. A notable example is a study by Shan et al., which demonstrated that AI can reconstruct low-dose CT scans effectively, indirectly improving patient health. Advancements in imaging technology have focused on reducing radiation exposure for patients during scans, minimizing unwanted side effects (Sharma and Aggarwal, 2010). One promising method is using deep learning for attenuation correction in PET/MR images, referred to as deep MRAC. This approach enhances image quality,leading to better diagnostic accuracy and improvements in segmentation techniques (Pesapane et al., 2018; Lundervold and Lundervold, 2019).

Table 2 Endoscopic studies involving artifcial intelligence for diagnosis and prediction of colorectal cancer

Ichimasa et al. (2018)	SVM	Prediction of lymph node metastasis post endoscopic resection of T1 colorectal cancer	100%	66%	–	69%
Nakajima et al. (2020)	CNN	Automatic diagnosis system by computer-aided diagnosis (CAD) based on plain endoscopic images	81%	87%	0.888	84%
Lai et al. (2021)	DNN	Improve polyp detection and discrimination by CAD	100%	100%	–	74–95%
Yamada et al. (2019)	CNN	Develop a real-time detection system for colorectal neoplasm	97.3%	99%	0.975	Good and excellent*
Chen et al. (2019)	DNN	Develop a CAD diagnosis system to analyze narrow-bind images	96.3%	78.1%	–	90.1
Repici et al. (2020)	CNN	To assess the safety and efficacy of a computer-aided detection (CADe) system	–	–	–	–
Kudo et al. (2020)	CNN	To determine diagnostic accuracy of EndoBRAIN	96.9%	100%	–	98%
Mori et al. (2018)	SVM	Evaluate the performance of real-time CADe with endocytoscope	91.3–95.2%	65.6–95.9%	–	–
Nguyen et al. (2020)	CNN	To pre-classify the in vivo endoscopic images	19.6–87.4%	42.5–90.6%	–	52.6–68.9%
Deding et al. (2020)	–	To investigate relative sensitivity of colon capsule endoscopies compared with computer tomography colonography	2.67#	–	–	–

SVM: support vector machines; CNN: convolutional neural network; DNN: deep neural network; AUC: area under the curve from the receiver operating characteristics; *shown using intersection over the union (IOU); #relative sensitivity

AI technology in medical imaging, such as endoscopy and CT/MRI, is not yet fully optimized for complete implementation. Human technicians remain essential for interpreting images accurately (Tajbakhsh et al., 2016). Pesapane et al. emphasize that machines are unlikely to replace radiologists entirely but highlight the importance of collaboration between radiologists and computer scientists to create better diagnostic tools, even if it reduces job opportunities in the field (Tajbakhsh et al., 2016). Lundervold et al. note that computational medicine is becoming a permanent part of healthcare, underscoring its integration into mainstream practices (Ribeiro et al., 2016).One area of focus is improving colonoscopy through AI, particularly in detecting polyps. This involves enhancing computer learning to better recognize shapes and boundaries, suggesting that refining existing technologies is more practical than developing new ones from scratch (Ali et al., 2020; Misawa et al., 2018; Borkowski et al., 2019; Marley and Nan, 2016).However, challenges remain in using convolutional neural networks (CNNs) for image and object recognition. These include:Image distortions caused by pixel abnormalities or poor-quality images.Variability in anatomy among individuals, which can lead to misinterpretations.Differences in patient positioning or anatomy affecting image accuracy.Difficulty in distinguishing relevant details from artifacts, such as bubbles or gases, that do not affect diagnosis (e.g., neoplasia)

Role of AI in surgery

AI is showing great promise in the field of surgery. Ichimasa et al. found that AI significantly reduced the need for unnecessary additional surgeries following endoscopic resection of T1 colorectal cancer (CRC) compared to clinical guidelines in the U.S. (NCCN), Europe (ESMO), and Japan (JSCCR). This was achieved using a support vector machine (SVM) for supervised machine learning, which helped identify patients who truly required further surgical intervention (Ichimasa et al., 2018 In another development, Meng et al. conducted a multicenter diagnostic study using AI to analyze early-stage CRC. This study involved 4,390 images of intraepithelial neoplasm, achieving an impressive diagnostic accuracy of 0.963 in the internal validation set (Kalis et al., 2018)

Typical fow diagram of WFO procedure

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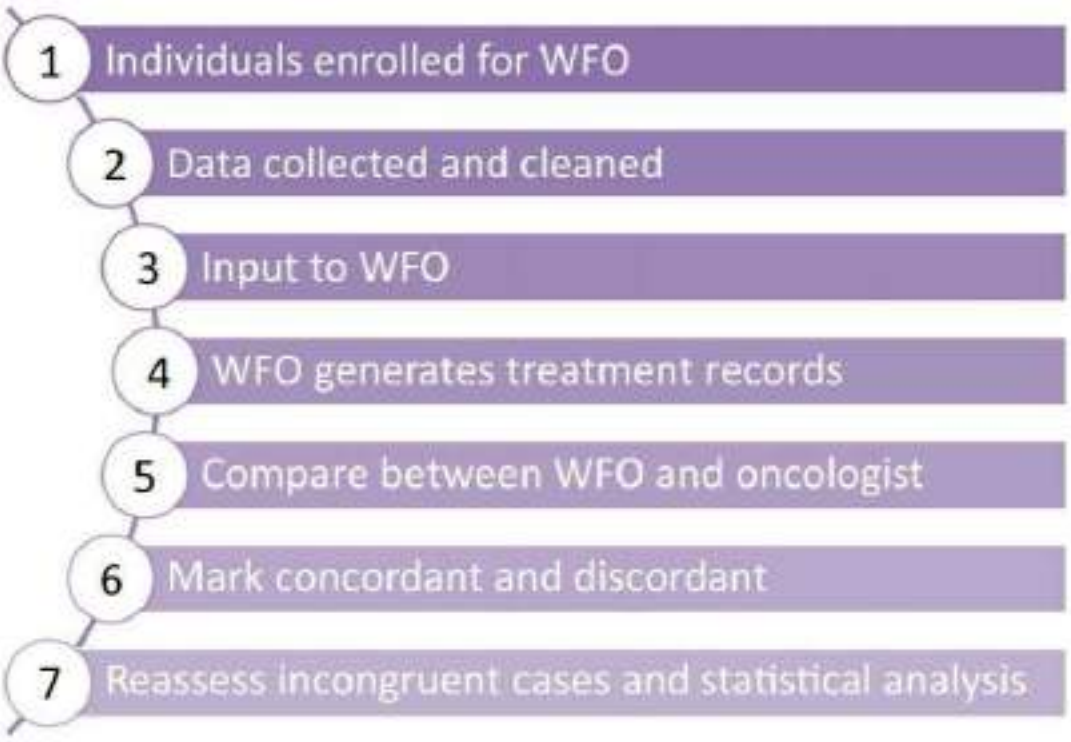
In terms of both sensitivity and specificity. Additionally, the authors stated that this approach is reliable for the early and effective prevention of colorectal cancer (CRC) (Kalis et al., 2018).



CURRENT CHALLENGES AND FUTURE PERSPECTIVES

AI great potential to improve cancer care and research, with high accuracy in laboratory settings that could transform traditional practices has in cancer diagnosis and treatment. However, the key question is when AI can be fully integrated into clinical settings for regular use by doctors and patients.

AI relies on data, and for it to work effectively in healthcare, the data must represent the entire population. It's clear that race, gender, and socioeconomic factors impact cancer risk and outcomes. For example, studies show that certain cancers, like prostate cancer, have race-specific differences in how they develop and progress. However, most datasets used to train AI models in cancer care are biased, often underrepresenting minority groups. The largest cancer dataset, TCGA, is mainly composed of white individuals, and many datasets lack diverse data, especially for metastatic cancers.Another challenge is that current cell lines used in cancer research do not perfectly match real-world patient profiles because they can change genetically over time. Newer, more stable models like patient-derived organoids could help fill this gap. Additionally, while data sharing is important for AI model development, access to data across platforms is still limited, especially for private or restricted datasets. As more inclusive and accessible datasets emerge, these challenges can be addressed.Another key issue is ensuring that AI models are transparent and reproducible. Sharing the code behind these models and explaining themethods used would help others validate and apply them. While code sharing is becoming more common, it’s not yet universally adopted. High-profile journals are starting to require code submissions, which is a step in the right direction.

AI models often focus on image and omics data, but another valuable resource is electronic health records (EHRs), which contain rich patient history. However, EHRs are often unstructured and messy, requiring cleaning and standardization. Efforts are underway to improve how EHRs are organized and analyzed, making them more useful for AI predictions.

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For AI to be widely accepted in the clinic, clinicians need to trust AI's decision-making. One way to build this trust is by measuring and communicating the uncertainty in AI predictions. Uncertainty can arise from issues like data quality, biases, or model errors. Ongoing research is working on ways to quantify and address these uncertainties, which will improve AI models and help integrate them into clinical practice.

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A REVIEW ON ARTIFICIAL INTELLIGENCE IN HOSPITAL PHARMACY

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ABSTRACT

Artificial Intelligence (AI) is rapidly transforming healthcare, including the field of hospital pharmacy, by enhancing the accuracy, efficiency, and safety of pharmaceutical services. This review explores the diverse applications of AI in hospital pharmacy, highlighting its potential to revolutionize drug management, clinical decision support, and patient safety. AI-driven tools and algorithms are being utilized to optimize medication dispensing, improve inventory management, and reduce human errors in prescription processes. Machine learning models and predictive analytics facilitate personalized medicine by enabling pharmacists to predict patient responses to drugs and monitor adverse drug reactions effectively. Furthermore, natural language processing (NLP) assists in extracting valuable insights from clinical data, supporting evidence-based practices. Despite these advancements, challenges remain, including data privacy, integration with existing healthcare systems, and the need for specialized training for pharmacists. This review synthesizes current evidence on AI applications in hospital pharmacy, discusses key technological and ethical considerations, and outlines future directions for AI integration to improve patient outcomes and operational efficiency in hospital pharmacy settings.

KEWWORDS : *AI in Hospital pharmacy, History of AI in pharmacy, Application AI in Hospital Pharmacy*

INTRODUCTION

The integration of artificial intelligence (AI) in healthcare has revolutionized various domains, including hospital pharmacy. As hospitals and healthcare systems adopt digital transformation strategies, AI offers innovative solutions to enhance patient care, optimize operational efficiency, and improve clinical outcomes. In hospital pharmacy, AI has the potential to transform traditional practices, enabling more precise medication management, error reduction, and resource optimization. This review explores the diverse applications of AI in hospital pharmacy, including drug dispensing, medication management, personalized pharmacotherapy, and clinical decision support systems. By examining recent advancements and evidence-based outcomes, this review aims to provide insight into how AI-driven tools are reshaping hospital pharmacy and the implications for patient safety, workflow efficiency, and cost-effectiveness.

Artificial intelligence (AI) is transforming hospital pharmacy by enhancing efficiency, improving patient safety, and personalizing care. In drug dispensing, AI-powered robotic systems and automated dispensing cabinets streamline operations, reducing human error and ensuring accurate labeling, dosage, and inventory management. Medication management benefits from AI's predictive analytics, which help prevent adverse drug events, optimize dosing, and monitor patient adherence through integration with electronic health records (EHRs) and wearable devices. Personalized pharmacotherapy is advancing as AI processes genomic and clinical data to customize treatments based on individual patient profiles, enhancing therapeutic outcomes while minimizing risks. Clinical decision support systems (CDSS) are another critical area where AI provides evidence-based insights, suggesting optimal therapies and flagging potential contraindications, significantly improving decision-making processes. Moreover, AI enhances workflow efficiency by automating repetitive tasks, prioritizing interventions, and supporting telepharmacy for remote consultations and prescription management. Cost optimization is achieved through predictive tools that forecast drug demand, prevent waste, and optimize inventory. Additionally, AI strengthens risk management by predicting drug shortages, identifying supply chain inefficiencies, and detecting fraud. Despite these benefits, challenges such as data privacy, integration with legacy systems, ethical concerns, and the need for training must be addressed. Looking ahead, the future of AI in hospital pharmacy includes innovations like real-time predictive modeling, blockchain for supply chain transparency, and AI-driven clinical trials, promising further advancements in personalized medicine and operational excellence.

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HISTORY OF AI IN PHARMACY AND HOSPTAL PHARMACY

The history of artificial intelligence (AI) in pharmacy and hospital settings is a relatively recent but rapidly evolving area. AI has been integrated into various aspects of pharmacy and healthcare to improve medication management, optimize clinical workflows, and enhance patient outcomes. Here's a detailed history:

1. Early Concepts (1950s-1980s)

1950s-1960s: Foundations of AI

The concept of artificial intelligence as we understand it today began taking shape in the 1950s. Early work in AI, including pioneering figures such as Alan Turing and John McCarthy, laid the groundwork for future applications of AI. The advent of early computers made it possible to automate simple tasks, but healthcare and pharmacy were not yet major areas of focus for AI.

1960s-1970s: Medical Expert Systems and Early Automation

By the late 1960s and early 1970s, the first attempts were made to apply AI to healthcare. Early AI systems such as MYCIN (developed in the 1970s at Stanford University) were created to diagnose infectious diseases and recommend treatments based on a series of inputs, including patient symptoms. MYCIN was an early example of a medical expert system, which is a type of AI designed to simulate the decision-making ability of a human expert.

In pharmacy, the automation of drug dispensing began. Automated dispensing machines (ADM) started to emerge, but the integration of AI into pharmacy settings remained rudimentary.

2. Early Automation and Clinical Decision Support Systems (1980s-1990s)

1980s: Emergence of Clinical Decision Support Systems (CDSS)

Clinical decision support systems (CDSS), which use AI to assist healthcare professionals in making clinical decisions, began to see wider adoption in hospitals. These systems often relied on expert systems to provide recommendations for drug therapy, drug interactions, and dosages.

1990s: Hospital Pharmacy Automation

During the 1990s, robotic dispensing systems were introduced in some hospitals to automate the distribution of medications, improving accuracy and efficiency. Systems like the Pharmacy Robotic Dispensing System (RDS) were developed to help reduce human error in the manual preparation and dispensing of medications. The use of barcoding technology also began to become commonplace in hospitals, facilitating better tracking and administration of drugs.

Additionally, the development of more advanced drug interaction databases and the integration of electronic health records (EHRs) created opportunities for more sophisticated AI-powered tools in hospital settings.

3. Integration of AI into Pharmacy and Healthcare (2000s-2010s)

2000s: Advancements in Machine Learning and Big Data

The 2000s marked the beginning of more advanced machine learning (ML) and data analysis techniques being applied to healthcare. AI began to be used in predicting patient outcomes, identifying high-risk patients, and optimizing drug therapy. AI models were trained using large datasets, including medical records, clinical trials, and drug databases, which provided insights into patterns that could help improve patient care.

2010s: AI in Medication Management and Personalized Medicine

By the 2010s, AI was increasingly used to personalize drug therapies. Algorithms could analyze genetic data, patient health information, and previous treatment outcomes to recommend individualized treatment plans. The introduction of AI-driven clinical decision support systems allowed pharmacists to better understand complex drug regimens and optimize the choice of therapy.

Robotic Process Automation (RPA) also began to gain ground in pharmacies for routine administrative tasks, such as inventory management, drug procurement, and prescription processing.

AI systems, such as IBM's Watson Health, started to show potential in the integration of hospital pharmacy.

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APPLICATION OF AI IN HOSPITAL PHARMACY

1. MEDICATION DISPENSING AND AUTOMATION

Automated Dispensing Cabinets (ADCs): AI-powered ADCs reduce human error in dispensing, improve inventory management, and ensure secure medication access. AI algorithms help predict usage patterns and automatically replenish stock, reducing waste and shortages.

Robotic Dispensing Systems: AI-driven robots, combined with automation, can package, label, and distribute medications, minimizing manual errors. These systems can handle high-demand environments and ensure consistency in medication dispensing. Intelligent Inventory Management: By analyzing usage data and medication turnover, AI can predict medication needs, optimize storage, and reduce expired medications. For example, machine learning (ML) algorithms can detect unusual patterns in inventory that may indicate pilferage or unusual drug usage.The integration of artificial intelligence (AI) into hospital pharmacy has brought transformative advancements, particularly in medication dispensing and automation. These innovations address critical challenges, such as medication errors, inefficiencies in manual processes, and inventory mismanagement. AI-powered systems and technologies not only enhance operational efficiency but also play a pivotal role in ensuring patient safety and cost-effectiveness. Below, we explore the major applications in detail.

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Automated Dispensing Cabinets (ADCs)
Automated Dispensing Cabinets (ADCs) are secure storage units that streamline the medication dispensing process by automating drug access and inventory management. With AI integration, these cabinets have evolved significantly:

Reduction in Human Error: ADCs utilize AI algorithms to ensure that only the correct medication, dosage, and quantity are dispensed. Barcode scanning and RFID tagging further enhance accuracy, reducing the risk of administering incorrect medications.

Inventory Optimization: AI continuously monitors usage patterns to predict future medication demand. By analyzing factors like patient demographics, seasonal illnesses, and historical data, ADCs automatically reorder stock when thresholds are met, ensuring a continuous supply of critical drugs.

Secure Medication Access: AI-enabled ADCs provide multi-level authentication mechanisms, such as biometric scans, to restrict access to authorized personnel only. This prevents unauthorized usage and enhances the tracking of controlled substances.

Waste Reduction: AI predicts expiration timelines based on usage trends and stock levels, allowing pharmacies to redistribute medications approaching their expiry dates, thus minimizing wastage.

Robotic Dispensing SystemsAI-driven robotic dispensing systems represent a leap forward in automating pharmacy operations. These systems are particularly suited for environments with high medication turnover, such as hospitals with large patient volumes.

High Precision and Accuracy: Robots, equipped with machine learning (ML) capabilities, can precisely measure, package, label, and dispense medications. This reduces human involvement in repetitive tasks, minimizing risks associated with fatigue or oversight.

Enhanced Speed and Consistency: Unlike humans, robots maintain consistent performance regardless of workload. In high-demand settings, these systems can dispense hundreds of prescriptions daily without compromising accuracy.

Integration with Electronic Health Records (EHRs): Robotic systems communicate seamlessly with EHRs to validate prescriptions, cross-check patient allergies, and ensure compliance with dosage guidelines before dispensing medications.

Error Reduction: By eliminating manual steps in the dispensing process, robotic systems significantly lower the likelihood of errors in medication packaging or labeling.

Intelligent Inventory Management
Inventory management is critical in hospital pharmacies, where ensuring the availability of essential medications can be a matter of life and death. AI introduces intelligent solutions that optimize inventory levels and detect anomalies.

Predictive Analytics for Demand Forecasting: AI uses historical data, patient admissions, and seasonal trends to predict medication needs accurately. For instance, during flu seasons, the system can preemptively stock antiviral drugs to meet increased demand.

Real-Time Monitoring: AI algorithms continuously analyze inventory levels in real-time, identifying low-stock items and triggering replenishment orders before shortages occur. This ensures smooth pharmacy operations and uninterrupted patient care.

Detection of Unusual Patterns: ML algorithms can detect irregularities in medication usage, such as sudden spikes in demand for controlled substances. Such patterns might indicate pilferage, misuse, or prescribing trends that need investigation.

Reduction of Expired Medications: AI ensures that medications are rotated based on expiration dates, prioritizing the dispensing of older stock first. By avoiding overstocking and redistributing unused medications, hospitals can significantly reduce wastage.

Case Studies and Real-World Examples
Cleveland Clinic's Integration of ADCs: Cleveland Clinic successfully implemented AI-powered ADCs, resulting in a 20% reduction in medication errors and a 30% improvement in inventory turnover. The system's predictive algorithms ensured that critical medications were always in stock, even during peak demand periods.

Robotic Dispensing in Europe: A major hospital in Germany adopted robotic dispensing systems integrated with EHRs, reducing prescription preparation time by 50%. The robots also eliminated discrepancies in labeling, which previously accounted for 15% of medication-related incidents.

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AI in Inventory Management in Singapore: A Singaporean hospital used AI-driven inventory systems to monitor and optimize medication turnover. This system flagged irregular usage patterns, which led to the discovery of theft in the pharmacy. Additionally, the hospital reduced medication wastage by 40% within the first year of implementation.

Benefits of AI-Driven Medication Dispensing and Automation
Enhanced Patient Safety: By ensuring accurate dispensing and reducing human errors, AI protects patients from adverse drug events (ADEs), which are a leading cause of hospital readmissions.

Increased Efficiency: Automation frees up pharmacists to focus on clinical responsibilities, such as patient counseling and medication therapy management, rather than administrative tasks.

Cost Savings: Hospitals save on costs through reduced medication wastage, fewer errors, and optimized inventory levels, leading to better financial performance.

Compliance and Accountability: AI systems maintain detailed logs of all dispensing activities, ensuring compliance with regulatory standards and facilitating audits.

Challenges in Implementation
Despite its potential, integrating AI in medication dispensing and automation comes with challenges:

High Initial Costs: Setting up AI-powered systems requires significant investment in technology and training.

Integration Issues: Ensuring compatibility with existing hospital infrastructure, such as EHRs, can be complex.

Data Security: Protecting sensitive patient data from cyber threats is a critical concern.

Adaptation by Staff: Pharmacists and staff may require extensive training to effectively use these technologies.

Future Directions
The future of AI in medication dispensing and automation is promising, with innovations such as:
IoT-Enabled Devices: Integration of Internet of Things (IoT) devices for real-time tracking and monitoring of medication usage.

Blockchain for Security: Blockchain technology can enhance transparency and traceability in the pharmaceutical supply chain.

Advanced Robotics: Next-generation robots with AI-powered vision and learning capabilities could further streamline complex dispensing tasks
By addressing current challenges and leveraging emerging technologies, hospital pharmacies can achieve unprecedented levels of efficiency, safety, and cost-effectiveness in medication dispensing and automation.

2. CLINICAL DECISION SUPPORT SYSTEMS (CDSS)

Drug-Drug Interaction Alerts: AI systems help reduce alert fatigue by assessing the severity of interactions and presenting high-priority warnings to pharmacists. Machine learning models can prioritize these alerts based on patient profiles and historical data.
Medication Appropriateness Analysis: AI models assess patient-specific factors (e.g., age, renal function, other comorbidities) to evaluate the appropriateness of prescriptions, helping pharmacists prevent adverse drug events.

Predictive Analytics for Adverse Drug Reactions (ADRs): Machine learning can identify patients at higher risk for ADRs, using data from electronic health records (EHRs), which can help in timely intervention by the pharmacy team
Clinical Decision Support Systems (CDSS) are transforming pharmacy practices by leveraging AI to enhance patient safety and optimize medication management. One key application is in generating Drug-Drug Interaction (DDI) alerts, where AI systems reduce alert fatigue by filtering and prioritizing warnings based on the severity of interactions and patient-specific factors, ensuring pharmacists focus on critical issues. Additionally, these systems evaluate medication appropriateness by analyzing parameters such as age, renal function, and comorbidities to prevent adverse drug events. Predictive analytics further enhance safety by using machine learning models to identify patients at high risk for adverse drug reactions (ADRs), drawing on electronic health records to enable timely interventions. These innovations streamline clinical workflows, reduce errors, and improve patient outcome

Clinical Decision Support Systems (CDSS) are sophisticated tools designed to aid healthcare professionals, including pharmacists, in making evidence-based clinical decisions, improving patient care, and reducing medication-related risks. One significant

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application of CDSS in pharmacy is the management of Drug-Drug Interaction (DDI) alerts. Traditional alert systems often overwhelm healthcare providers with high volumes of notifications, many of which are clinically insignificant, leading to "alert fatigue" and potential oversight of critical issues. AI-driven CDSS addresses this by assessing the severity and relevance of drug interactions using patient-specific factors, such as existing conditions, medication history, and laboratory results. This enables the system to prioritize high-risk interactions and present pharmacists with actionable, high-priority alerts.

Another critical role of CDSS is in medication appropriateness analysis, where AI models evaluate prescriptions against patient-specific factors like age, renal and hepatic function, and coexisting medical conditions. For example, an elderly patient with impaired kidney function may require adjustments to the dosage or selection of specific medications to minimize the risk of toxicity or adverse events. By analyzing this data, CDSS assists pharmacists in identifying and resolving potential issues before they result in harm.
Furthermore, predictive analytics powered by machine learning enhances the ability of CDSS to foresee adverse drug reactions (ADRs). These systems analyze vast datasets, including electronic health records (EHRs), demographic information, genetic profiles, and treatment histories, to identify patterns and risk factors that might predispose patients to ADRs. For instance, a patient with a history of allergic reactions to certain antibiotics can be flagged as high-risk when prescribed a similar medication. This allows pharmacists to intervene early, suggesting alternative therapies or monitoring plans to prevent complications.

Overall, CDSS integrates advanced analytics and patient-centered data to enhance decision-making in pharmacy practice, reducing errors, improving efficiency, and ensuring safer and more personalized patient care.

3. PERSONALIZED MEDICINE AND PHARMACOGENOMICS

Precision Dosing Algorithms: AI can determine individualized medication doses based on genetic, demographic, and clinical factors. For instance, in anticoagulant therapy, AI models analyze variables that influence drug metabolism to recommend personalized dosages, reducing the risk of adverse events.

Pharmacogenomic Data Integration: AI systems interpret pharmacogenomic data, aiding pharmacists in selecting medications that align with a patient's genetic profile. This is particularly valuable in oncology and psychiatry, where genetic factors significantly affect drug response.

Predictive Modeling for Therapy Optimization: By using historical data and patient biomarkers, AI predicts optimal therapeutic options, aiding pharmacists in recommending treatment adjustments that improve efficacy and minimize side effects. Personalized medicine and pharmacogenomics represent the forefront of modern healthcare, aiming to tailor medical treatment to individual patients based on their unique genetic makeup, demographics, and clinical characteristics. Artificial intelligence (AI) plays a pivotal role in this domain, enabling precision in drug therapy and optimizing outcomes while minimizing risks. Below is a detailed exploration of how AI enhances personalized medicine and pharmacogenomics through precision dosing algorithms, pharmacogenomic data integration, and predictive modeling for therapy optimization.

Precision Dosing Algorithm

AI-driven precision dosing algorithms revolutionize the way medications are prescribed by customizing doses for individual patients. Traditional dosing regimens often rely on standardized guidelines that may not account for interpatient variability, leading to suboptimal outcomes or adverse drug events. AI systems overcome this limitation by analyzing complex datasets, including genetic, demographic, and clinical information.

Anticoagulant Therapy Example: Medications like warfarin, commonly used in anticoagulation therapy, have a narrow therapeutic index, meaning small variations in dosage can lead to either therapeutic failure or significant bleeding risks. AI models integrate patient-specific data—such as genetic polymorphisms in CYP2C9 and VKORC1 enzymes, age, body weight, and concurrent medications—to calculate individualized warfarin doses. This reduces trial-and-error dosing and enhances safety.

Dynamic Dose Adjustments: AI systems continuously learn from real-time patient data, such as INR (International Normalized Ratio) values in anticoagulated patients, to adjust dosing dynamically. This ensures the medication remains effective while minimizing the risk of complications.

Pharmacogenomic Data Integration

Pharmacogenomics examines how genetic variations affect an individual's response to drugs, offering a pathway to truly personalized medication selection. However, interpreting pharmacogenomic data is complex and requires advanced computational tools. AI excels in integrating and analyzing this data to provide actionable insights for pharmacists.

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Medication Selection Based on Genetic Profiles: AI systems analyze genetic markers associated with drug metabolism, efficacy, and toxicity. For instance, in oncology, pharmacogenomic data is critical for selecting targeted therapies like tyrosine kinase inhibitors or immunotherapies, which are effective only in patients with specific genetic mutations. Similarly, in psychiatry, genetic polymorphisms in enzymes such as CYP2D6 and CYP3A4 influence the metabolism of antidepressants and antipsychotics. AI helps pharmacists recommend medications that align with these genetic profiles, reducing trial-and-error prescribing.

Streamlining Complex Data: Pharmacogenomic testing generates vast amounts of data that can be challenging to interpret manually. AI platforms consolidate this data into user-friendly dashboards, highlighting actionable findings and guiding pharmacists in their decision-making processes.

Improving Accessibility: AI tools democratize the use of pharmacogenomics by integrating test results directly into electronic health records (EHRs), where they are readily available to healthcare providers during prescribing.

Predictive Modeling for Therapy Optimization
Predictive modeling, powered by machine learning and AI, enables the anticipation of treatment outcomes based on patient-specific biomarkers and historical data. These models provide insights into the most effective therapeutic strategies for individual patients, assisting pharmacists in optimizing treatment plans.

Historical Data Utilization: AI systems analyze large-scale datasets, including previous patient responses to similar therapies, to predict how a current patient might respond. This is particularly useful in chronic disease management, such as diabetes or hypertension, where therapy adjustments are common.

Biomarker-Based Predictions: AI integrates clinical biomarkers—such as lab results, imaging data, and genetic markers—to forecast treatment efficacy and side effect profiles. For example, in cancer therapy, AI can predict which patients are likely to respond to specific chemotherapy regimens based on tumor markers and genetic data, allowing pharmacists to collaborate with oncologists in designing personalized treatment plans.

Dynamic Treatment Adjustments: As treatment progresses, AI models learn from patient responses, enabling continuous refinement of therapeutic strategies. This is critical in conditions like autoimmune diseases, where response to medications like biologics varies significantly among individuals.

Real-World Applications and Benefitt
AI-driven personalized medicine and pharmacogenomics have several real-world applications that directly benefit pharmacy practice:
Oncology: AI assists in selecting targeted therapies based on tumor genetics, improving survival rates while reducing toxicity.

Cardiology: In conditions like atrial fibrillation, AI recommends anticoagulant doses tailored to genetic and clinical factors, preventing strokes while minimizing bleeding risks.

Psychiatry: AI leverages pharmacogenomic insights to personalize antidepressant and antipsychotic therapy, reducing the time to achieve therapeutic response.

Infectious Diseases: Pharmacogenomic data and AI guide the selection of antimicrobials to minimize resistance and adverse effects.

Challenges and Future Directions
Despite its promise, the integration of AI into personalized medicine and pharmacogenomics faces several challenges:

Data Privacy and Security: Ensuring the confidentiality of genetic and clinical data is paramount.

Integration into Clinical Workflows: Seamless incorporation of AI tools into existing systems and EHRs requires careful planning and training.

Cost and Accessibility: Expanding access to AI-driven pharmacogenomic tools in resource-limited settings remains a challenge.

Regulatory Oversight: The use of AI in clinical decision-making requires robust regulatory frameworks to ensure accuracy and reliability

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The future of personalized medicine lies in advancing AI capabilities, fostering interdisciplinary collaboration, and expanding access to these technologies. As AI continues to evolve, its role in pharmacogenomics and precision medicine will undoubtedly grow, transforming pharmacy practice and improving patient outcomes.

4. MEDICATION RECONCILIATION AND PATIENT SAFETY

AI-Assisted Medication Reconciliation: By comparing various sources of medication lists, AI helps identify discrepancies, ensuring continuity of care during transitions such as hospital admissions and discharges.

Error Reduction and Quality Control: Machine learning algorithms can detect and predict patterns associated with medication errors. For instance, NLP algorithms can analyze unstructured text in EHRs to identify common points of error, like look-alike or sound-alike drugs.

Natural Language Processing (NLP) for Safety Alerts: NLP can scan clinical notes and discharge summaries to identify potential medication-related risks, providing pharmacists with actionable safety alerts in real-time.

Medication reconciliation is a critical process in healthcare, designed to ensure that patients receive accurate and complete medication lists across transitions of care, such as hospital admissions, transfers, and discharges. It plays a pivotal role in preventing medication errors, enhancing patient safety, and ensuring continuity of care. However, this process is labor-intensive and prone to human error. Artificial intelligence (AI), particularly through advanced algorithms and natural language processing (NLP), has emerged as a transformative tool to optimize medication reconciliation and improve patient safety. Below is an in-depth exploration of AI's applications in medication reconciliation and error prevention.

AI-Assisted Medication Reconciliation

Medication reconciliation involves comparing different sources of medication information (e.g., patient-reported lists, pharmacy records, electronic health records, and discharge summaries) to identify and resolve discrepancies. AI systems streamline and enhance this process by automating the identification and resolution of inconsistencies

How AI Enhances Medication Reconciliation

Data Integration: AI can seamlessly gather and cross-reference medication data from multiple sources, such as electronic health records (EHRs), pharmacy management systems, and patient-reported information. By consolidating this data into a unified view, AI helps reduce errors arising from fragmented information.

Discrepancy Detection: Machine learning algorithms are trained to detect discrepancies, such as omitted medications, duplicate entries, or incorrect dosages. For example, an AI system can identify that a patient's prescribed dose of a medication in one system differs from what is listed in another.

Transition of Care: During hospital admissions or discharges, discrepancies in medication lists are common. AI systems identify these inconsistencies in real-time, prompting healthcare providers to reconcile medications before patients transition to the next phase of care. This ensures continuity and reduces risks of adverse events.

Case Study Example

AI-driven medication reconciliation platforms have been implemented in hospitals, where they have demonstrated the ability to reconcile complex medication lists more quickly and accurately than manual processes, reducing errors and saving valuable time for pharmacists.

Error Reduction and Quality Control

Medication errors, including prescribing, dispensing, and administration errors, are a leading cause of adverse drug events (ADEs) globally. AI plays a vital role in error detection, prediction, and prevention, significantly enhancing quality control in pharmacy practice.

Machine Learning Algorithms for Error Detection

AI systems use machine learning to analyze historical data and identify patterns associated with medication errors. These systems learn from past incidents to predict and prevent similar errors in real-time.

Look-Alike, Sound-Alike (LASA) Drugs: One common source of errors is confusion between medications with similar names or packaging. AI systems use image recognition and text analysis to flag LASA drugs during the prescribing or dispensing process, prompting pharmacists to verify the selection.

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Dosage and Frequency Errors: AI algorithms cross-check prescribed dosages and frequencies against standardized guidelines and patient-specific factors (e.g., age, renal function) to ensure appropriateness. For instance, an AI system can detect that a prescribed dose exceeds the maximum recommended dose for a pediatric patient

Predictive Analytics for Risk Management
AI systems can also predict high-risk scenarios where medication errors are more likely to occur. For example, during peak hospital admission times, AI can alert pharmacy staff to double-check medications for accuracy, reducing the likelihood of errors under pressure.

Real-Time Monitoring
Advanced AI systems integrate with pharmacy workflows to provide real-time alerts. For instance, if a pharmacist inputs a drug into a system, the AI immediately checks for potential interactions, contraindications, or dosage errors and generates a warning if necessary.

Natural Language Processing (NLP) for Safety Alerts
Natural language processing (NLP), a branch of AI that focuses on understanding and interpreting human language, plays a crucial role in identifying medication-related risks hidden within unstructured clinical data, such as physician notes, discharge summaries, and patient histories.

How NLP Works in Medication Reconciliation and Safety
Scanning Clinical Notes: NLP algorithms analyze unstructured text in EHRs, such as physician notes or discharge summaries, to identify discrepancies, omissions, or potential safety concerns related to medications. For example, if a discharge summary mentions a drug but it is missing from the reconciled medication list, NLP can flag this discrepancy for review.

Identifying Risk Factors: NLP can extract information about patient-specific risk factors, such as allergies, renal impairment, or prior adverse drug reactions, from clinical narratives. This information is then used to generate safety alerts for pharmacists.

Improving Documentation Accuracy: NLP ensures that important medication-related information is accurately documented and reflected in the patient's medication list, reducing the risk of omissions or misinterpretations

Real-Time Safety Alerts
NLP-driven safety alerts provide actionable insights to pharmacists at the point of care. For instance, if an NLP algorithm identifies that a prescribed drug is contraindicated based on a patient's clinical notes, it can immediately alert the pharmacist, who can intervene to prevent a potential adverse event.

Integration with Electronic Health Records (EHRs)
The effectiveness of AI in medication reconciliation and patient safety depends on its integration with existing EHR systems. Advanced AI systems integrate seamlessly with EHR platforms to provide real-time support to healthcare professionals.

Automated Workflows: AI automates repetitive tasks, such as cross-referencing medication lists or updating records, allowing pharmacists to focus on clinical decision-making.

Actionable Dashboards: AI systems generate user-friendly dashboards within EHRs, summarizing discrepancies, risks, and recommended actions for pharmacist

Continuous Learning: Integrated AI systems learn from ongoing data to refine their algorithms, improving accuracy and efficiency over time.

Benefits of AI in Medication Reconciliation and Patient Safety
The integration of AI into medication reconciliation and safety processes offers several tangible benefits:
Enhanced Accuracy: By automating complex processes, AI reduces human errors and ensures more accurate medication lists.

Time Efficiency: AI systems complete reconciliation tasks faster than manual processes, allowing pharmacists to dedicate more time to patient care.

Improved Safety: AI-driven alerts and error prevention mechanisms significantly reduce the risk of adverse drug events.

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Cost Savings: Preventing medication errors and adverse events reduces healthcare costs associated with hospital readmissions, prolonged stays, and additional treatments.

Challenges and Future Directions
Despite its potential, the adoption of AI in medication reconciliation and safety faces several challenges:

Data Quality and Interoperability: AI systems require high-quality, interoperable data from various sources to function effectively.

Implementation Costs: The initial investment in AI technologies can be high, particularly for smaller healthcare organizations.

Training and Adoption: Healthcare professionals, including pharmacists, need training to effectively use AI tools and integrate them into clinical workflows.

Regulatory and Ethical Concerns: Ensuring the security and privacy of patient data used by AI systems is critical.
Future advancements in AI, such as more sophisticated NLP algorithms and improved predictive analytics, will further enhance medication reconciliation and safety. With ongoing innovation, AI is poised to become an indispensable tool in pharmacy practice, improving patient outcomes and transforming healthcare delivery.

5. OPERATIONAL EFFICIENCY AND WORKFLOW OPTIMIZATION

AI-Powered Scheduling and Staffing: AI systems can optimize pharmacy staffing and shift scheduling based on patient volume predictions and peak demand times, ensuring optimal resource allocation and reducing overtime costs.

Workflow Automation and Task Prioritization: AI algorithms prioritize pharmacy tasks based on urgency, patient need, and medication criticality, improving workflow efficiency and reducing bottlenecks in prescription processing.

Supply Chain Management and Logistics: AI assists in managing the supply chain, helping to forecast medication demand, adjust stock levels, and streamline procurement processes to prevent shortages and ensure timely availability of medications.

Artificial Intelligence (AI) is revolutionizing pharmacy operations by addressing inefficiencies, streamlining workflows, and optimizing resource management. As the demand for healthcare services grows, the integration of AI-powered tools into pharmacy operations has become essential for ensuring seamless service delivery, cost-effectiveness, and improved patient care. Below is an in-depth discussion of how AI enhances operational efficiency in pharmacy management through optimized scheduling, workflow automation, and supply chain logistics.

AI-Powered Scheduling and Staffing
Efficient staffing and scheduling are critical for maintaining operational productivity and ensuring that pharmacies meet patient needs without overburdening staff or incurring excessive costs. AI systems enhance scheduling and staffing by analyzing data and predicting demand patterns.

AI Applications in Scheduling
Demand Forecasting: AI models analyze historical data, such as patient volume, prescription trends, and seasonal variations, to predict peak demand times. For instance, AI may identify that flu season results in a surge of prescriptions, prompting the need for increased staffing during this period.

Optimal Shift Allocation: AI systems use predictive analytics to recommend shift schedules that align with patient volume, ensuring sufficient staff coverage during busy times while avoiding overstaffing during low-demand periods.

Dynamic Adjustments: AI-powered tools can make real-time adjustments to staffing based on unexpected changes, such as an influx of patients due to a local outbreak or emergency.

Benefits of AI-Driven Scheduling
Reduced Overtime Costs: By aligning staffing with demand, AI minimizes the need for overtime, leading to cost savings.

Improved Employee Satisfaction: Balanced workloads and fair shift allocations contribute to better job satisfaction and reduced burnout among pharmacy staff.

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Enhanced Patient Care: Sufficient staffing ensures shorter wait times and improved service quality, enhancing patient experiences

Case Example
In hospitals and large retail pharmacies, AI scheduling tools have demonstrated the ability to reduce labor costs by up to 15% while maintaining optimal service levels during peak periods.

Workflow Automation and Task Prioritization
AI optimizes pharmacy workflows by automating repetitive tasks and prioritizing activities based on urgency, patient need, and medication criticality. This reduces bottlenecks, ensures timely prescription processing, and allows pharmacists to focus on clinical tasks

Task Prioritization
AI algorithms analyze real-time data to rank tasks by importance. For example:

Urgent Prescriptions: Prescriptions for critical medications, such as antibiotics or life-saving drugs, are flagged and prioritized for immediate processing.

Patient-Specific Alerts: AI systems alert pharmacists to tasks requiring immediate attention, such as resolving drug interactions or preparing high-risk medication orders.

Workflow Automation
Prescription Processing: AI streamlines the intake, validation, and dispensing of prescriptions by automating data entry, insurance verification, and medication labeling.

Clinical Decision Support: Integrated AI systems provide pharmacists with real-time insights on drug interactions, dosage adjustments, and contraindications, speeding up clinical decision-making.

Inventory Replenishment: Automation ensures that inventory management tasks, such as restocking and tracking expiration dates, are handled efficiently without manual intervention

Benefits of Workflow Optimization
Reduced Errors: Automation eliminates manual errors in prescription processing and inventory management.

Increased Efficiency: AI reduces processing times, enabling pharmacies to handle larger prescription volumes without compromising accuracy.

Better Use of Resources: Pharmacists can focus on patient counseling and clinical activities, enhancing the quality of care

Real-World Example
Large pharmacy chains, such as CVS and Walgreens, have implemented AI-driven workflow systems that reduce prescription processing times by 20-30%, enabling them to serve more patients efficiently.

Supply Chain Management and Logistics
Efficient supply chain management is essential for ensuring the timely availability of medications, avoiding shortages, and minimizing waste. AI transforms supply chain operations by providing accurate demand forecasting, optimizing stock levels, and streamlining procurement processes.

Demand Forecasting
AI algorithms analyze historical sales data, prescription trends, and external factors (e.g., seasonal illnesses, demographic shifts) to predict medication demand. This ensures pharmacies maintain adequate stock levels without overordering.

Example: AI may predict an increase in demand for antihistamines during allergy season or vaccines during flu season, prompting timely procurement.

Inventory Management
AI systems monitor stock levels in real-time and identify medications nearing expiration or running low. This helps prevent:
Stockouts: Ensuring critical medications are always available.

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Overstocking: Avoiding excess inventory that leads to waste
Procurement Optimization

Vendor Selection: AI evaluates supplier reliability, pricing trends, and delivery times to recommend optimal procurement strategies.

Order Automation: AI automates purchase orders based on predefined thresholds, ensuring timely replenishment without manual oversight

Logistics Optimization
AI-powered tools enhance logistics by optimizing delivery routes and schedules for medication distribution, ensuring timely delivery to retail pharmacies, hospitals, and patients.

Benefits of AI in Supply Chain Management

Cost Savings: Reduced waste and efficient procurement lower overall supply chain costs.

Improved Availability: Accurate demand forecasting ensures critical medications are always in stock.

Operational Resilience: AI helps pharmacies adapt to unexpected disruptions, such as supply chain delays or demand surges

Case Study
Pharmaceutical distribution companies have used AI to reduce inventory holding costs by 10-15% while maintaining over 95% product availability across pharmacy networks.

Integration Across Pharmacy Operations
The integration of AI tools into pharmacy operations creates a cohesive system that enhances overall efficiency. Advanced platforms combine scheduling, workflow automation, and supply chain management into a unified interface, enabling seamless communication and decision-making.

Interoperability with Existing Systems
AI systems integrate with electronic health records (EHRs), inventory management platforms, and workforce management tools, ensuring smooth data exchange and coordinated operations.

Real-Time Insights
AI provides pharmacy managers with real-time dashboards that highlight key performance metrics, such as prescription processing times, staffing levels, and inventory status, enabling proactive decision-making.

Continuous Learning and Improvement
AI systems use machine learning to continuously improve their performance by learning from historical data and adapting to new trends. For instance, a scheduling system may refine its predictions based on changes in patient demographics or seasonal trends.

Challenges and Future Directions
While AI has immense potential to transform pharmacy operations, its adoption comes with challenges:
Initial Costs: Implementing AI systems requires significant investment in technology and training.

Data Quality and Security: AI systems rely on high-quality data, and ensuring data privacy is critical.

Resistance to Change: Staff may be hesitant to adopt new AI-driven processes without adequate training and support.

Regulatory Compliance: AI systems must adhere to healthcare regulations, such as HIPAA, and demonstrate reliability in critical decision-making processes

Future Directions
Personalized Pharmacy Services: AI could enable more personalized services, such as customized medication packaging and delivery.

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Advanced Predictive Models: Future AI systems may incorporate broader datasets, such as social determinants of health, to improve demand forecasting and patient care.

Global Optimization: AI could facilitate better coordination across global supply chains, addressing medication shortages more effectively.

AI-powered tools for scheduling, workflow automation, and supply chain management are revolutionizing pharmacy operations by improving efficiency, reducing costs, and enhancing patient care. As these technologies continue to evolve, their integration into pharmacy practices will drive further innovation and operational excellence.

6. TELEPHARMACY AND REMOTE CONSULTATIONS

AI Chatbots for Patient Queries: In telepharmacy settings, AI-driven chatbots can provide immediate responses to common patient questions about medications, dosages, and potential side effects, freeing pharmacists to focus on complex cases.

Remote Monitoring and Alerts: AI systems can monitor patients remotely and alert pharmacists if there are signs of medication non-adherence or complications, enabling timely intervention and support.

Video Consultation and AI-Assisted Diagnostics: AI tools can assist pharmacists in remote consultations by analyzing data from wearables or other devices, aiding in real-time health assessments and medication adjustments.

Telepharmacy, supported by advancements in AI, has revolutionized the delivery of pharmacy services, particularly for patients in remote or underserved areas. By leveraging AI-driven tools, telepharmacy enhances patient engagement, improves medication management, and ensures timely interventions, all while optimizing pharmacists' time for more complex cases. Here's a detailed exploration of how AI is enabling these advancements:

AI Chatbots for Patient Queries

AI-powered chatbots are increasingly integrated into telepharmacy platforms to handle routine patient inquiries. These chatbots use natural language processing (NLP) to understand and respond to common questions about medications, dosages, administration methods, and side effects.

24/7 Availability: Patients can access chatbot assistance at any time, reducing dependency on pharmacists for basic information.

Efficient Triage: Chatbots can categorize questions based on complexity, addressing simple queries directly and escalating more complex issues to a pharmacist. For example, a chatbot can guide a patient on how to take an antibiotic while referring cases of drug interactions or adverse effects to a pharmacist.

Patient Education: Chatbots offer tailored educational resources, such as videos or infographics, to enhance understanding of medication regimens and encourage adherence

Impact

By managing routine queries, AI chatbots free up pharmacists to focus on high-priority tasks, such as clinical decision-making and patient consultations. Additionally, patients benefit from quick, reliable answers, improving satisfaction and medication adherence.

Remote Monitoring and Alerts

AI systems play a critical role in telepharmacy by enabling remote patient monitoring and generating actionable alerts based on real-time data.

Monitoring Non-Adherence: AI analyzes data from electronic pill dispensers, mobile apps, or wearables to track medication adherence. If a patient misses doses or shows irregular usage patterns, the system alerts the pharmacist, allowing for timely intervention.

Complication Detection: Advanced AI models can detect early signs of complications, such as changes in vital signs or symptoms reported via telehealth apps. For example, AI could flag an increase in heart rate or blood pressure in a patient taking antihypertensive medication, prompting a pharmacist to review and adjust the treatment plan.

Personalized Interventions: Based on the patient's history and current condition, AI systems can suggest tailored interventions, such as reminders, counseling sessions, or changes in medication regimens

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Impact
This proactive approach helps prevent adverse events, reduces hospital readmissions, and supports patients in managing chronic conditions effectively, all while maintaining continuous pharmacist oversight.

Video Consultation and AI-Assisted Diagnostics
Telepharmacy platforms increasingly incorporate video consultations, enabling pharmacists to interact with patients remotely while using AI tools for enhanced diagnostic support.

Real-Time Health Assessments: AI systems analyze data from patient-provided inputs or wearable devices during consultations, offering insights into health trends. For example, AI might interpret glucose levels from a diabetic patient's wearable device to recommend dosage adjustments for insulin.

Symptom Analysis: AI algorithms assist pharmacists by analyzing reported symptoms or device-generated data to identify potential issues, such as side effects or contraindications.

Support: During consultations, AI provides pharmacists with evidence-based recommendations, such as alternative medications or dosage adjustments, tailored to the patient's unique profile

Impact
Video consultations combined with AI-driven diagnostics enhance the quality of remote care by empowering pharmacists to make informed decisions, ensuring that patients receive personalized and timely treatment adjustments without the need for in-person visits.

7. PHARMACOVIGILANCE AND DRUG SAFETY MONITORING

Adverse Event Detection and Reporting: AI algorithms analyze data from EHRs, social media, and adverse event databases to detect and flag potential side effects early, aiding in timely reporting to regulatory authorities.

Signal Detection from Real-World Data: Machine learning models can identify signals indicating emerging drug safety issues from vast datasets, enabling proactive safety measures.

Automated Surveillance for High-Risk Drugs: AI can continuously monitor high-risk medications, such as opioids or anticoagulants, to detect unusual prescribing patterns and potential misuse.

Pharmacovigilance, the science of monitoring and ensuring drug safety, has been significantly advanced by AI-driven technologies. These tools streamline the detection and management of adverse events, identify safety signals, and ensure vigilant monitoring of high-risk medications, contributing to safer therapeutic practices and regulatory compliance.

Enhanced a Adverce Event Detection and Reporting
AI algorithms are revolutionizing the detection and reporting of adverse drug reactions (ADRs) by analyzing diverse and expansive data sources. These include electronic health records (EHRs), patient forums, social media platforms, and adverse event databases.

Automated Analysis: AI models rapidly process unstructured text in clinical notes or patient-reported data to identify patterns linked to specific drugs and side effects.

Timely Alerts: Real-time monitoring enables the early flagging of potential ADRs, facilitating swift action by healthcare providers and reporting to regulatory authorities.

Improved Data Accuracy: AI reduces underreporting and inconsistencies often associated with manual ADR reporting, ensuring comprehensive pharmacovigilance.

Siganal Detection From Real World Evidence
AI and machine learning models excel at analyzing vast datasets to detect safety signals that might be missed through traditional methods.

Integration of Big Data: AI combines information from clinical trials, post-marketing surveillance, pharmacy records, and wearable devices to identify emerging drug safety concerns

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Proactive Measures: These tools highlight trends or anomalies, such as unexpected reactions in specific populations, prompting timely investigation and mitigation.

Predictive Insights: By identifying patterns over time, AI enables predictive pharmacovigilance, forecasting potential risks before they manifest broadly.

Continuous Surveillance of High-Risk Medications Certain medications, such as opioids, anticoagulants, and immunosuppressants, require ongoing surveillance due to their elevated risk profiles. AI enhances this process through continuous and automated monitoring.

Misuse Detection: AI identifies unusual prescribing or usage patterns, such as excessive doses or combinations linked to abuse, ensuring rapid intervention.

Patient Monitoring: Tools assess compliance and track real-time health data to alert clinicians to potential risks, such as bleeding complications with anticoagulants.

Regulatory Support: By generating actionable insights, AI aids pharmaceutical companies and regulatory agencies in maintaining safety standards for high-risk drugs.

8. PATIENT ADHERENCE AND BEHAVIORAL ANALYTICS

Adherence Monitoring via Wearables: AI algorithms analyze data from wearables or smartphone apps to monitor medication adherence, providing pharmacists with insights into patient compliance patterns.

Predictive Modeling for Non-Adherence: By analyzing patient demographics, medical history, and socioeconomic factors, AI can identify individuals at risk of non-adherence, allowing pharmacists to initiate targeted interventions.

Customized Patient Engagement Strategies: AI systems segment patients based on behavior and preferences, enabling pharmacists to tailor adherence-promoting strategies, such as reminders, educational content, or counseling.

AI is transforming patient adherence and behavioral analytics by leveraging data from wearables and smartphones to monitor and improve medication adherence. Wearables collect real-time data, and AI algorithms analyze these patterns, alerting pharmacists to potential non-compliance. Predictive models also assess patient demographics, medical history, and socio-economic factors to identify those at risk of non-adherence, allowing for early intervention. AI systems further segment patients based on their behavior and preferences, enabling pharmacists to implement personalized strategies, such as targeted reminders, educational materials, or counseling, to promote adherence and improve patient outcomes.

CONCLUSION

The integration of Artificial Intelligence (AI) in hospital pharmacy has the potential to revolutionize medication management by enhancing patient safety, optimizing operational processes, and improving clinical decision-making. AI applications in medication management, prescription validation, personalized medicine, drug discovery, and dispensing automation are already showing promising results, offering a higher level of precision and efficiency than traditional systems. However, challenges such as data privacy, security concerns, high implementation costs, and resistance from healthcare professionals must be addressed to unlock AI's full potential. Additionally, ethical considerations, including accountability and algorithmic bias, must be carefully managed to ensure equitable and safe AI applications in pharmacy.

Looking ahead, AI technologies will likely continue to evolve, offering new innovations such as more advanced clinical decision support tools and personalized treatments based on genetic information. With continued investment and research, AI can play a critical role in transforming hospital pharmacy practices, making them safer, more efficient, and more aligned with the growing demands of modern healthcare.

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NUTRITIONAL VALUE ESTIMATION FROM BAMBUSA VULGARIS

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ABSTRACT
Bamboo shoots (Bambusa vulgaris) are a high-nutrient plant used in traditional medical systems for treating diseases. Phytochemically, they contain carbohydrates, glycosides, saponins, alkaloids, flavonoids, phenolics, tannins, phytosterols, and triterpenoids. Ethnopharmacologically, they have analgesic, antipyretic, antidiabetic, anti-inflammatory, antioxidant, antiviral, anti-kidney stone, hepatoprotective, diuretic, and anti-anxiety properties.
KEY WORDS: *Bamboo, nutrients, glycosides, antioxidant, Tannins, Oxalate, phytate , antinutrients*

INTRODUCTION

One kind of open bamboo clump is called golden bamboo.
Originally from southern China's Yunnan Province and Indochina, this golden bamboo has been widely grown and naturalized in a number of locations. Bamboo gold is one of the biggest and easiest-to-identify species of bamboo. [1]The clusters that Bambusa vulgaris develops are not thorny and are rather loose. It features dark green foliage and lemon-yellow stalks with green streaks. The stems have thick walls, are initially tough, are not flexible, are not straight, and are difficult to split. Densely tufted stems are 4–10 cm thick and can reach heights of 10–20 m (30–70 ft). The trunk droops at the ends and can be either straight or flexible, bending alternatively in various directions. The walls of the trunk are fairly substantial. Nodes went up a little. It is 20–45 cm (7.9–17.7 in) long. From the center trunk node to the top, certain branches grow. The leaf blade is lanceolate and thin.[2]Bamboo young shoots have traditionally been consumed as a vegetable in many Asian nations and are said to be high in protein, fiber, carbs, and minerals while being low in fat and sugar.[3]It is stated that the shoots contain more nutrients than the majority of typical vegetables.[4]Bamboo is said to alleviate fever and regulate hydration in the body.[5]It has been discovered to have nutraceutical and antioxidant qualities, including enhancing bowel movement and reducing blood cholesterol.[6]

Determination of Proximate and Mineral Composition

Proximate composition was determined using standard methods according to AOAC as follows.After 5 g of the sample were dried at 105°C to constant weight, the moisture content was ascertained. Protein content was computed by multiplying the proportion of nitrogen by 6.25 and was ascertained using the semi-micro Kjeldahl technique. By utilizing petroleum spirit (b.p. 40–60°C) and Soxhlet's method, fat was extracted. After the extract was dried in an oven, the fat was measured gravimetrically. Five grams of the sample were burned at 550°C until the ash turned gray in order to measure the amount of ash. Two grams of the material were successively boiled under reflux in 1.25% H2SO4 and 1.25% NaOH to evaluate the fiber content. Following filtration, the residue was cleaned with ether and alcohol, dried, and then burned for one hour at 500°C. The weight difference between the pre- and post-incineration states was converted to a percentage of fiber content.By deducting the total of moisture, fat, ash, fiber, and protein content from 100, the amount of carbohydrates was found. Using a block heater to digest ground samples with H2SO4H2O2, the minerals were extracted, and the digest was then diluted to 50 milliliters using de-ionized water. A plasma spectrometer that was inductively linked was used to identify particular minerals[.7]

Determination of Total Polyphenols, Total Flavonoids and Antioxidant Activity

- Determination of Total Polyphenols

:The Waterman and Mole method was used to determine the total polyphenol content. Aqueous 50% methanol was used to extract ten milligrams of dry and ground material, which was heated to 80°C for an hour. Folin-Ciocalteau reagent was used to react one milliliter of the extract, and the absorbance at 760 nm was measured using gallic acid as the standard.[8]

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-Sample Extraction for Flavonoids and Antioxidants

According to Harbone's instructions, the sample was extracted for the measurement of flavonoids and antioxidant activity. 100 milliliters of methanol were poured to 250 milliliter flasks containing five grams of the dry sample powder. After sealing the flasks firmly with parafilm and covering them with aluminum foil, they were shook for three hours. After being extracted for 72 hours in the dark, they were filtered, concentrated to 20 milliliters, and stored in tightly-sealed vials. These solutions were used to create working concentrations.[9]

-Quantitative Determination of Flavonoids

The Jagadish et al. method using aluminum chloride colorimetric method was employed to determine the flavonoids. 4 ml of distilled water and 1 ml of plant extract were added to a 10 ml volumetric flask. Then, 0.3 ml of a 5% sodium nitrite solution was added and allowed to stand for three minutes. Next, 0.3 ml of a 10% aluminum chloride solution was added and allowed to stand for five minutes. After adding two milliliters of 1 M sodium hydroxide, distilled water was added to raise the volume to 10 ml. Using a spectrophotometer set to detect absorbance at 415 nm, the amount of total flavonoids was determined by calculating the calibration curve of standards made from quercetin.
[10]

Determination of Free Radical Scavenging Activity

At 517 nm, the extracts' capacity to scavenge radicals was assessed against the 1,1-diphenyl-2-picrylhydrazyl (DPPH) radical. The extract was produced in methanol at concentrations of 0.01, 0.1, 1.0, 2.0, 5.0, and 10.0 mg/ml, and the results were expressed on a dry matter basis. At the same concentrations as the extracts, vitamin C served as the reference. 3.0 ml of methanol and 0.5 ml of 1 mM DPPH in methanol were added to a test tube containing one milliliter of the extract. Only methanol and DPPH were used to create a blank solution. Absorbances were measured after the mixture was left in the dark for half an hour. [11]

Determination of Antinutrients

As inositol hexa-phosphates, phytotates are found in plants and are known to form strong complexes with certain dietary elements, including proteins, zinc, and iron, reducing their bioavailability in the body and leading to health issues. The phytate content of the foreign and native species differed significantly ($p<0.05$), as Table 1 illustrates. The highest concentrations were found in B. vulgaris (2.7%), D. giganteus (2.4%), and Y. alpina (0.8%). Dongmeza et al. discovered that dried bamboo leaves contained 1.8–3.4% phytates.[12]

Tannins Content

Plant tannins are substances that resemble polyphenols and are present in fruits, vegetables, and seeds. They are known to bind proteins, which lowers the body's ability to use them. According to Wang et al. [13], the Fargesia yunnanensis bamboo species, which grows in China, contains up to 1.71% tannins. Table 1 displays raw shot values for the species examined in this study that were less than 0.03%. While other writers have recorded 0.1% in the same vegetable , Omobolanle reported 0.88% in fresh amaranthus. Given that tannins are soluble in water , boiling is expected to further lower their levels, which means that cooking may not have any negative health effects. [12]

Phytate Content

Inositol hexa-phosphates, or phytotates, are found in plants and are known to form strong complexes with dietary elements like zinc, iron, and proteins. This reduces the minerals' bioavailability in the body and can lead to health issues. Table 1 demonstrates that there was a significant difference ($p<0.05$) in the phytate content of the native and alien species. The highest concentration was found in B. vulgaris (2.7%), D. giganteus (2.4%), and Y. alpina (0.8%). Dried bamboo leaves contained 1.8–3.4% of phytates, according to Dongmeza et al. [12].

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Table no.1Concentration of Tannins, Phytic Acid and Oxalates in Fresh Bamboo Shoots[12]

Bamboo species	Tannin content (% CE)	Phytic acid (%)	Oxalates (%)
B. vulgaris	0.024±0.001[a]	2.70±0.10[a]	1.2±0.1[a]
D. giganteus	0.030±0.001[a]	2.40±0.30[a]	1.0±0.1[b]
Y. alpina	0.007±0.001[a]	0.83±0.07[b]	0.7±0.0[c]

Data are presented as mean ± SD (n=3). Mean values within each column followed by different letters differ significantly at $p<0.05$. CE=Catechin equivalent.

Oxalate Content

Oxalic acid is a common component of most plants and is regarded as an anti-nutrient. It can be found in the form of a free acid, soluble potassium and sodium salts, and insoluble calcium, magnesium, and iron salts. Given that soluble oxalates seem to be more bioavailable than insoluble oxalates, the kind of oxalate salts found in diet may be significant.It has been claimed that oxalates have a minimum fatal dosage of 4-5%. [12]Table 1 ($p<0.05$) displays that there was a substantial difference across the bamboo species evaluated, with values ranging from 0.7% to 1.2%, and B. vulgaris having the highest value. In young shoots, Mukda et al. reported roughly 0.3%, but other authors discovered levels ranging from 0.1 to 0.69%.[14]

CONCLUSION

The study's findings demonstrate that the bamboo species' shoots are just as rich in significant macronutrients as those of edible species that are comparable. In particular, the grown ones have higher levels of calcium, magnesium, and zinc than other varieties that have been recorded from other regions of the world. High concentrations of flavonoids and polyphenols were discovered in the shoots, which suggested that they had a significant impact on human health as vital antioxidants. Therefore, bamboo can be used to combat malnutrition and food insecurity while also preserving good bodily health. Because the anti-nutrient levels in the shoots were often lower than in other popular vegetables, the body could receive higher-quality nutrients from the bamboo shoots.

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STUDY ON SEISMIC ANALYSIS OF CONCRETE STRUCTURES WITH AND WITHOUT BRACING

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ABSTRACT

Bracing in concrete buildings are used to handle lateral stresses caused by earthquakes, wind, and other factors. It is one of the most effective solutions for lateral load resisting systems. Concrete-framed high-rise structures are becoming widespread in major cities. Engineers have resorted to braced concrete framed constructions as a low-cost approach to withstand seismic stresses. In this study, Dynamic Analysis using Response Spectrum Analysis is performed on low-, mid-, and high-rise concrete structures with various bracing methods. The purpose of this research was to explore and compare the seismic analysis findings of various kinds of structures with and without bracing systems. For this reason, the G+4 Storey, G+12 Storey, and G+16 Storey concrete building models are employed in the same arrangement but with alternative bracing methods such as the X brace, V brace, and single diagonal edge brace. The commercial program ETABS2018 is utilized for analysis. Results are derived by taking into account characteristics such as base shear, displacement, and storey drift of concrete structures.

KEY WORDS: *Concrete Structure, Seismic load, Braced system, Braced framed structure, Response spectrum analysis, ETABS 2018.*

1. INTRODUCTION

Earthquake is the most dangerous phenomenon because of its unpredictability and massive devastation power. Earthquakes do not kill people; human lives and properties loss as a result of the demolition of structures. During strong earthquakes, building frames collapse, resulting in direct human loss. Various studies are carried out to determine the reason of collapse in various types of structures when they are subjected to strong seismic stimulation. Massive demolition of high-rise structures demonstrates that such an inquiry is urgently needed in emerging countries like India. People are drawn to high-rise constructions due to rapid urban population expansion, limited construction space, and high land costs. Previous earthquakes in India have demonstrated that not just non-engineered structures, but also engineered ones, must be designed to withstand seismic loads. By incorporating steel bracing into the structural system, structural response can be improved. There are 'n' number of possibilities to arrange steel bracing , such as cross bracing X', diagonal bracing 'D', and 'V' type bracing, Knee bracing and New O-grid bracing.

1.1 BRACED FRAMED STRUCTURE

A braced frame is a type of structural system that is widely employed in structures that are subjected to lateral loads like wind and seismic pressure. A braced frame's members are usually built of structural steel, which can act in both tension and compression. Vertical loads are carried by the frame's beams and columns, while lateral loads are carried by the bracing system. Brace placement, on the other hand, might be troublesome since it can interfere with the façade's design and the placement of openings. Bracing has been expressed as an internal or external design feature in buildings with high-tech or post-modernist styles.

1.2 ADVANTAGES OF BRACED FRAMED STRUCTURE

1. Bracing minimizes lateral storey displacement, storey drift, axial force, and bending moment in columns to a significant extent.
2. Braced frames withstand wind and seismic stresses better than non-braced structures.
3. It is inexpensive, simple to erect, and straightforward to design to provide the needed strength and stiffness.
4. The reduction in lateral displacement is a significant benefit. In this situation, concentric (X) bracing is more effective than eccentric (V) bracing.

1.3 OBJECTIVES

1. To study seismic behaviour of concrete structure with and without bracing.
2. Enhancing the Structural Stability of concrete structure during earthquake.
3. Comparative study of earthquake resistant Capacity of various Bracing Systems.
4. To recommend best suited bracing systems for concrete structure.

1.4 SCOPE OF THE STUDY

In this world of most the buildings are reinforced concrete structures, and some of them are designed for earthquake loads. And also, in reinforced concrete structures bracing system are very rarely used, so in this research Response Spectrum analysis of G+4, G+12, G+16 Storeyed reinforced

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concrete buildings with different type of steel bracing is carried out by using commercial software ETABS 2018, and different parameters such as Base Shear, Displacement and Storey Drift are compared.

2. MODELLING

For analysis purpose 3 types of buildings and 3 types of steel bracing are considered which are split into:

1. 4 Models of G+4 Storeyed building, one is without bracing and others are with X, V, Single edge diagonal bracing .
2. 4 Models of G+12 Storeyed building, one is without bracing and others are with X, V, Single edge diagonal bracing .
3. 4 Models of G+16 Storeyed building, one is without bracing and others are with X, V, Single edge diagonal bracing .

Different parameters such as Base shear, Story drift, Story stiffness are compared for these models. The overall plan dimension is 20mX20m. symmetric building has uniform storey height of 3m throughout. The building consist of 6 bays in both direction and steel braces are inserted in the first and last 2 bays.

3. MODEL DESCRIPTION

In this research, Response Spectrum Analysis was performed to study the behaviour of unbraced and braced frames. Analysis is carried out by using ETABS2018 software. Each building is designed using IS 1893:2016, IS 875(Part 3): 2015 and IS 456:2000. In the following Table 1. all the parameters of 12 buildings are same except the bracing type.

Table -1: Model Details

Sr no.	Parameter	Type/Value
1	Structure Type	Concrete Structure
2	Shape of Model	Square shape
3	Size of Model	20x20m
4	Number of Storey	G+4, G+12, G+16 Storey
5	Number of Models	12 Models
6	Floor to Floor height	3m
7	Slab Thickness	200mm
8	Grade of Concrete	M30
9	Grade of Steel	Fe415
10	Type of Bracing	X, V, Single diagonal Edge Bracing
11	Imposed Load	3 kN/m^2
12	Seismic zone	III
13	Zone Factor	0.16
14	Soil Condition	Type-II
15	Importance Factor	1.2
16	Response Reduction Factor	5
17	Damping Ratio	0.05

4. 3D VIEW OF MODELS IN ETABS

Following are the 3D pictures of all 12 models with and without bracing which are used for the research work in ETABS.

4.1 G+4 STOREY BUILDING MODELS

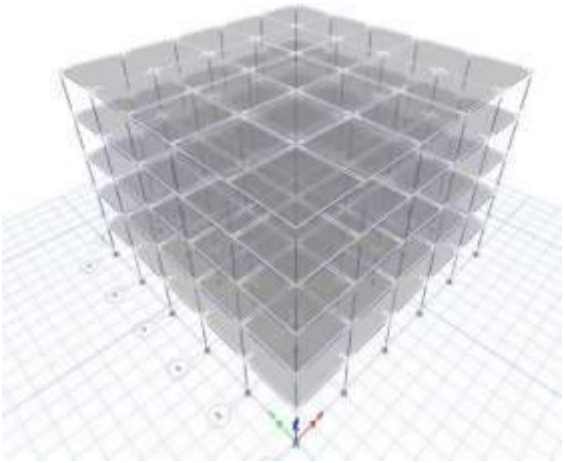

Fig 4.1 G+4 Storey model without bracing

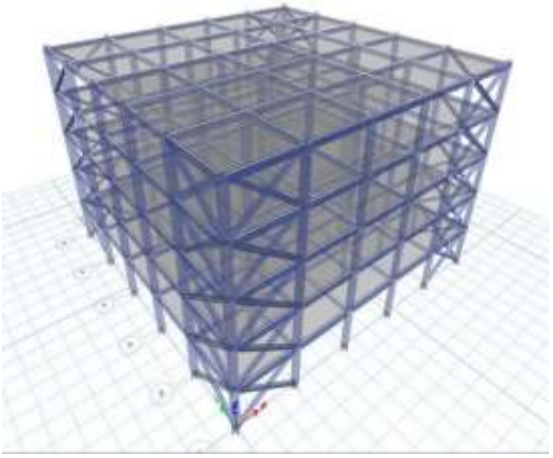

Fig 4.2: G+4 Storey model with X bracing

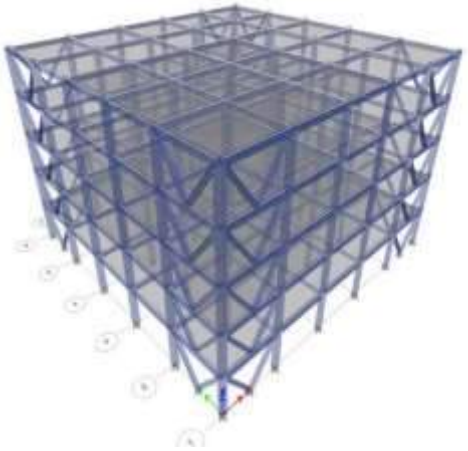

Fig 4.3: G+4 Storey with V bracing

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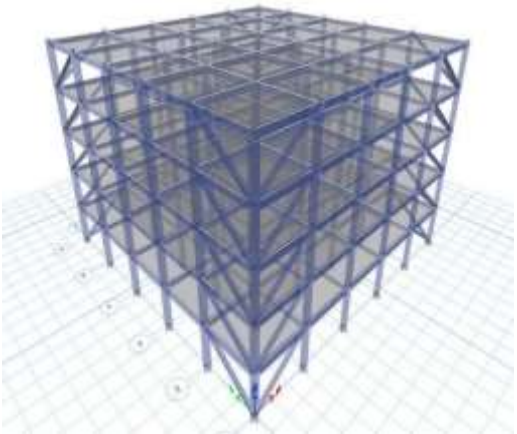

Fig 4.4: G+4 Storey model with Single diagonal edge bracing

3D view of G+4 concrete frames without bracing and with X bracing, V bracing and single diagonal bracing are represented in these figures. These models are used for the response spectrum analysis. Section properties are same for all 4 models. bracing are provided in the end bays of frames in each direction.

4.2 G+4 STOREY BUILDING MODELS

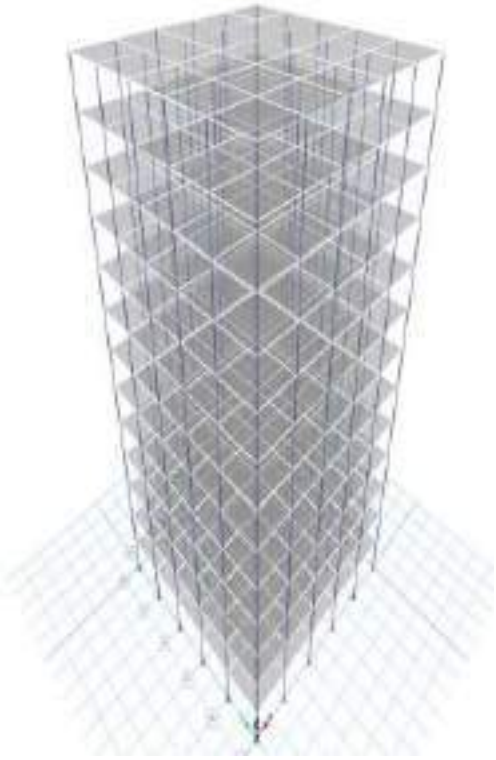

Fig 4.5: Storey model without bracing

3D view of G+12 concrete frames without bracing and with X bracing, V bracing and single diagonal bracing are represented in these figures. These models are used for the response spectrum analysis. Section properties are same for all 4 models. bracing are provided in the end bays of frames in each direction.

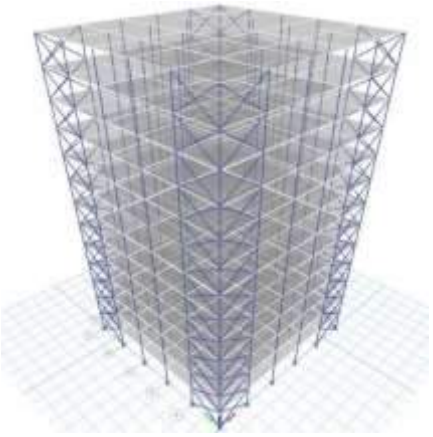

Fig 4.6: G+12 Storey model with X bracing

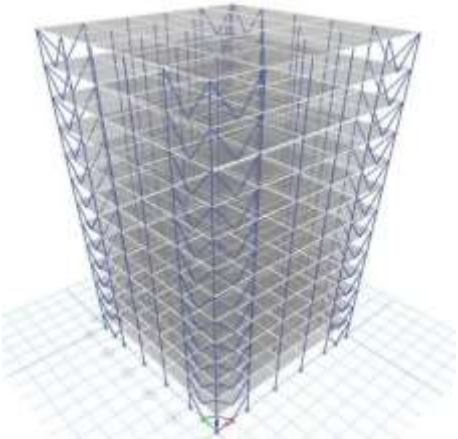

Fig 4.7: G+12 Storey with V bracing

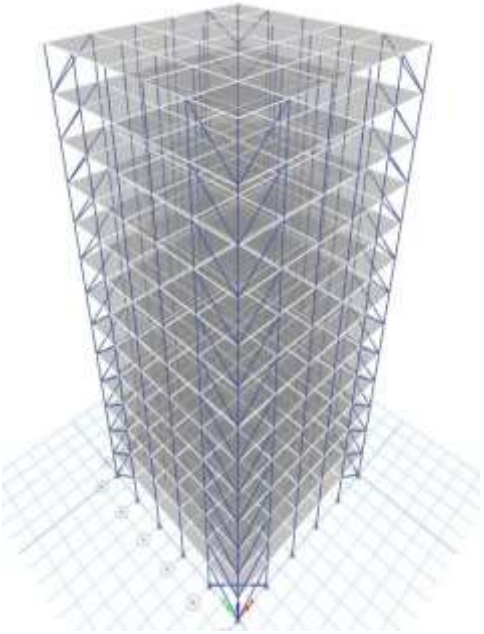

Fig 4.8: G+12 Storey model with Diagonal edge bracing

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4.3 G+16 storey Building Models

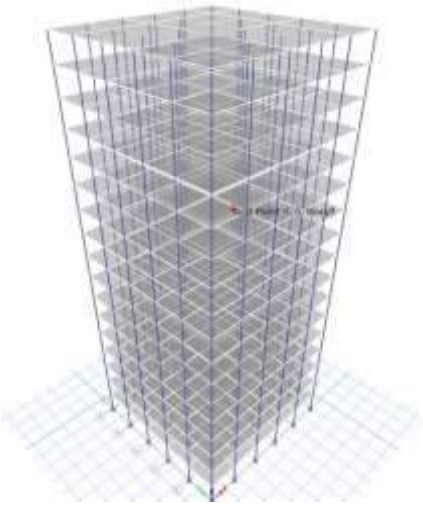

Fig 4.9: G+16 Storey model without bracing

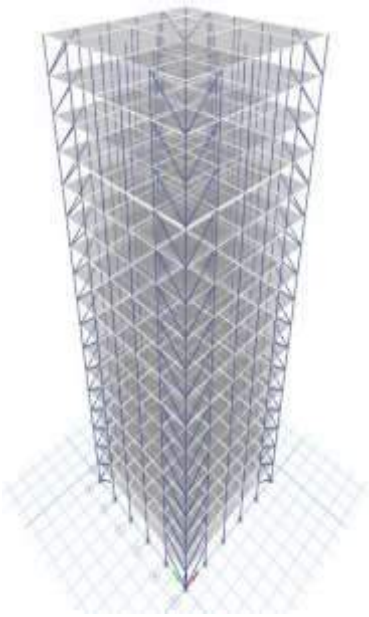

Fig 4.12: G+16 Storey model with Single Diagonal Edge bracing

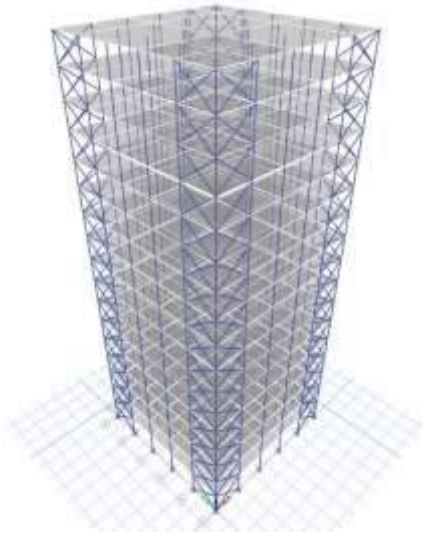

Fig 4.10: G+16 Storey model with X bracing

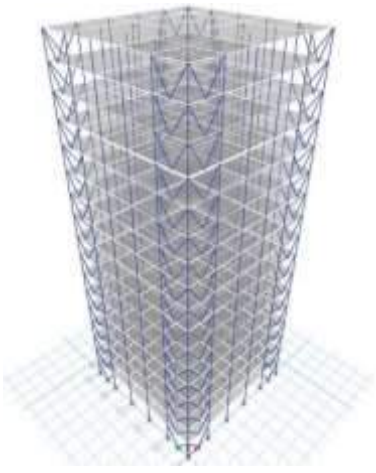

Fig 4.11: G+16 Storey with V bracing

3D view of G+16 concrete frames without bracing and with X bracing, V bracing and single diagonal bracing are represented in these figures. These models are used for the response spectrum analysis. Section properties are same for all 4models. bracing are provided in the end bays of frames in each direction.

After assigning the sectional properties to the concrete frame, 3D models were generated. After that Response Spectrum Analysis was performed to study the behaviour of unbraced and braced frames. Analysis is carried out by using ETABS2018 software. After analysis, we concluded that by increasing the lateral stiffness of the concrete frame, base shear of the frame will obviously increase. Here, the values of displacement, storey drift and base shear of 12 models are shown in graphical representation. bracing change the stiffness of the moment resisting frames. Hence, it has a significant effect on the shear force and bending moment of columns as they take most of the lateral loading acting as a truss member i.e., they can take only tension or compression. The total base shear found out is smaller for smaller height building as compared to larger height. From the analysis output data, it is evident that at the same floor level the storey drift of larger height model is found to be greater than that of the smaller. Base shear of concrete frame with bracing systems increased as seismic weight of building is increased.

5. RESULTS AND DISCUSSIONS

Response spectrum analysis was carried out to evaluate the performance of concrete building with and without bracing under the action of lateral forces. After the response spectrum analysis, following results were obtained and are represented in graphical format and compared.

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5.1 RESPONSE SPECTRUM ANALYSIS RESULTS FOR G+4 STOREY BUILDING

1. Maximum Storey Displacement:

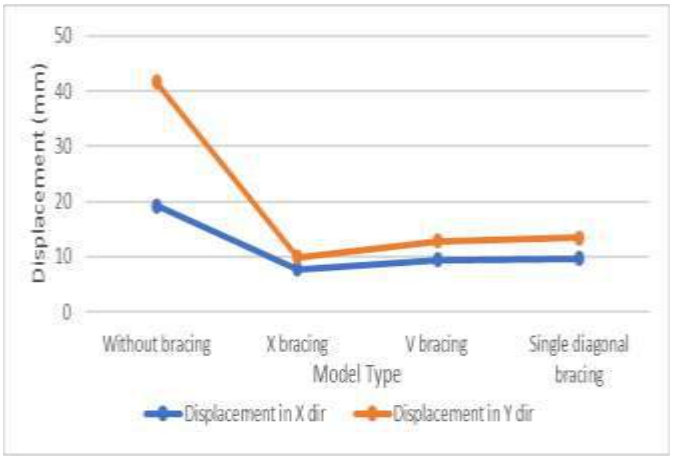

Fig 5.1: Maximum storey displacement in X, Y direction

It is observed that the storey displacement in the models with bracing is reduced compared to the displacement in the model without bracing. X bracing proved to be very effective than V and Diagonal bracing as displacement is reduced by a large amount i.e., in X direction it is 19.221mm for model without bracing and reduced to 7.704mm for model with X bracing.

2. Base Shear

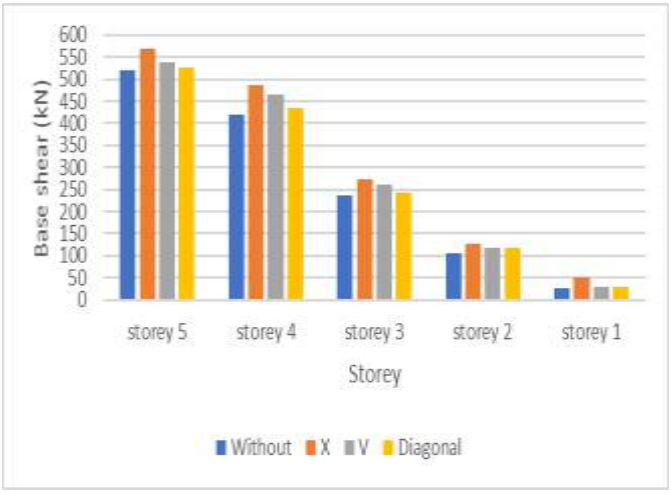

Fig 5.2: Base Shear results for G+4 storey building

It is observed that the base shear in X bracing system is more as compared to other diagonal, V bracing system. The base shear produced in X and Y direction is same because stiffness of building is same in both directions.

3. Storey Drift

The graphs of storey drift are given for X and Y direction for without and with different bracing systems

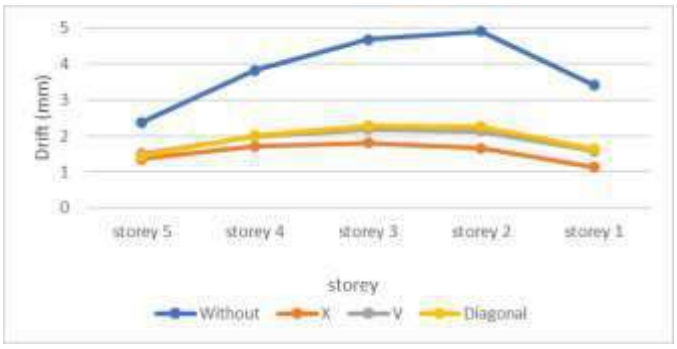

Fig 5.3: Storey drift for G+4 Storey model in X direction

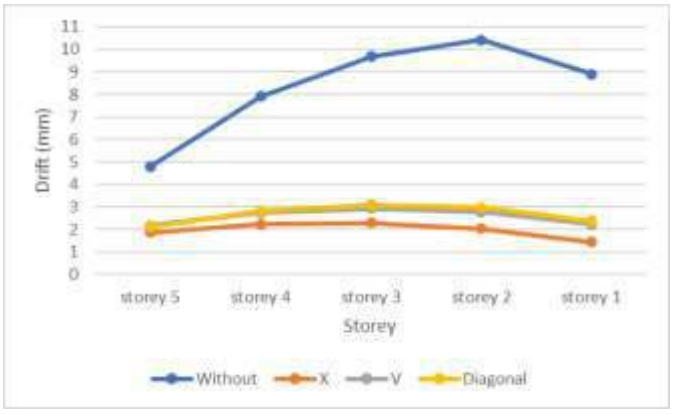

Fig 5.4: Storey drift for G+4 Storey model Y direction

It can be seen that minimum storey drift in both X and Y direction is in X bracing than other bracing . Maximum drift is observed in storey 2 i.e., 10.4mm for model without bracing and it is reduced to 2.02mm for X bracing, 2.7mm for V bracing and 2.9mm for diagonal bracing systems in X direction and same is the case for Y direction also. Other 2 bracing i.e., V and Diagonal are also proved to be effective.

5.2 RESPONSE SPECTRUM ANALYSIS RESULTS FOR G+12 STOREY BUILDING

1. Maximum Storey Displacement:

The maximum storey displacement observed is the last story of the model after the analysis is given in the graphical representation below:

Fig 5.5 Storey displacement in X, Y direction

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It is observed that the storey displacement in the models with bracing is reduced compared to the displacement in the model without bracing. X bracing proved to be very effective than V and Diagonal bracing as displacement is reduced by a large amount i.e., in X direction it is 109.85mm for model without bracing and reduced to 62.718mm for model with X bracing.

2. Base Shear

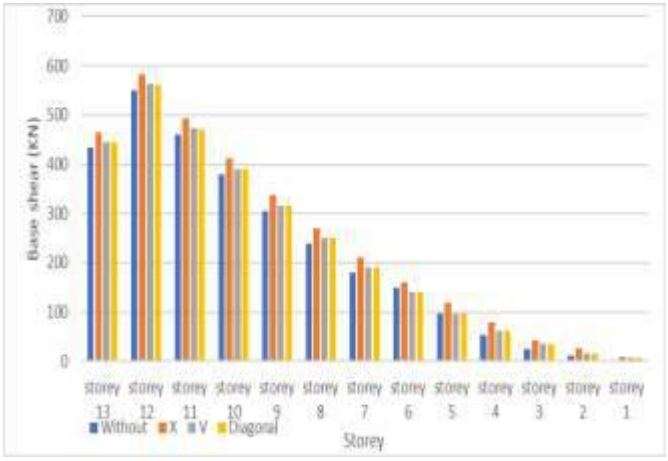

Fig 5.6: Base Shear results for G+12 storey building

It is observed that the base shear in X bracing system is more as compared to other diagonal, V bracing system. Base shear in models with V and Diagonal bracing is almost same. The base shear produced in X and Y direction is same because stiffness of building is same in both directions.

3. STOREY DRIFT

The graphs of storey drift are given for X and Y direction for without and with different bracing systems:

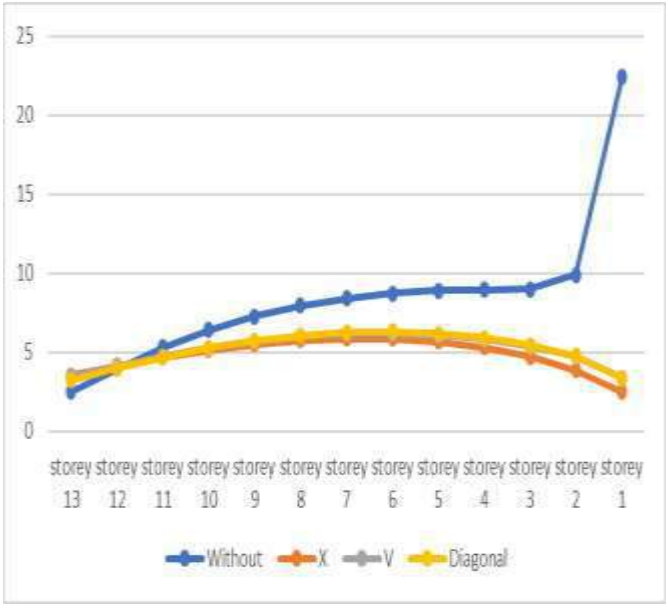

Fig 5.7: Storey drift for G+12 Storey model X direction

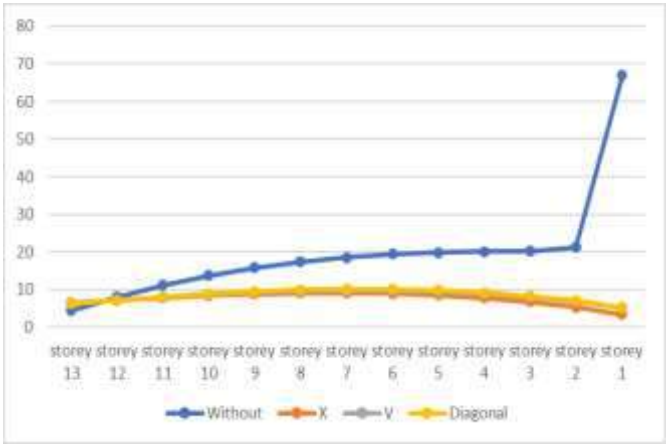

Fig 5.8: Storey drift for G+12 Storey model in Y direction

It can be seen that minimum storey drift in both X and Y direction is in X bracing than other bracing . Maximum drift is observed in storey 1 i.e., 22.447mm for model without bracing and it is reduced to 2.51mm for X bracing, 3.38mm for V bracing and 3.35mm for diagonal bracing systems in X direction and same is the case for Y direction also. Other 2 bracing i.e., V and Diagonal are also proved to be very effective.

5.3 RESPONSE SPECTRUM ANALYSIS RESULTS FOR G+16 STOREY BUILDING

1. Maximum Storey Displacement:

The maximum storey displacement observed is the last story of the model after the analysis is given in the graphical representation below:

Fig 5.9: Maximum storey displacement in X, Y direction It is observed that the storey displacement in the models

with bracing is reduced compared to the displacement in the model without bracing. In this model the displacement reduced for models with bracing is almost same for all 3 bracing systems. A large decrease is observed in Y direction as displacement is 83.3mm for model without bracing and it is reduced to 55.39mm for model with X bracing.

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2. BASE SHEAR

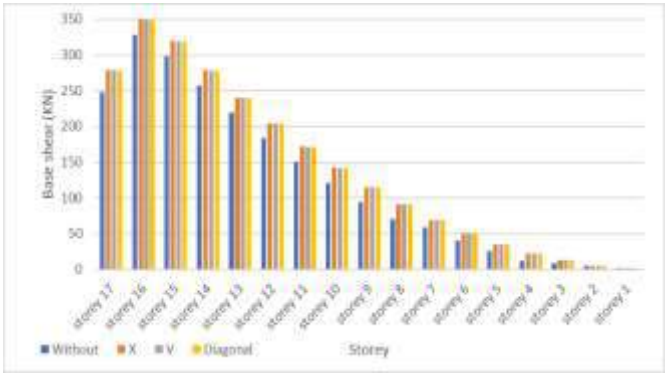

Fig 5.10: Base Shear results for G+16 storey building

It is observed that the base shear in models with bracing is increased compared to models without bracing. Base shear in models with X, V and Diagonal bracing is almost same. The base shear produced in X and Y direction is same because stiffness of building is same in both directions.

3. STOREY DRIFT

The graphs of storey drift are given for X and Y direction for without and with different bracing systems:

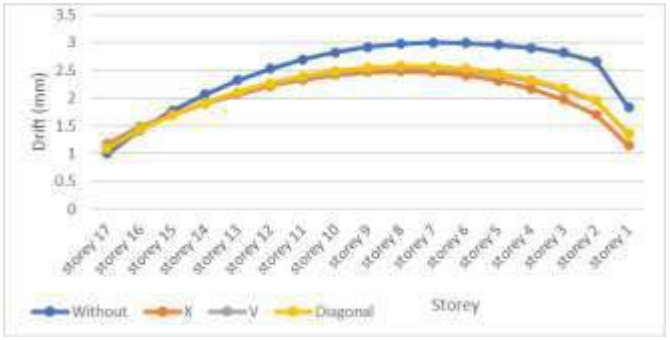

Fig 5.11: Storey drift for G+16 Storey model x direction

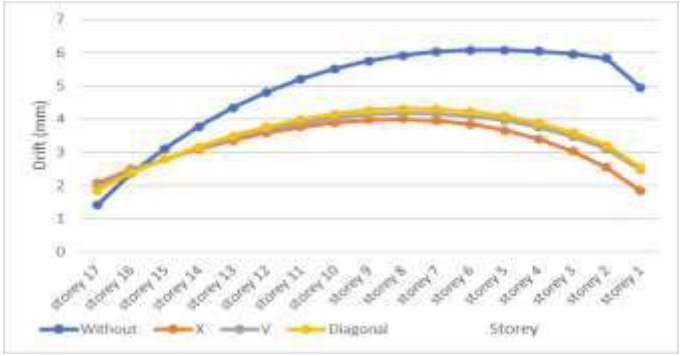

Fig 5.12: Storey drift for G+16 Storey model Y direction

It can be seen that minimum storey drift in both X and Y direction is in X bracing than other bracing . Maximum drift is observed in storey 6 i.e., 2.995mm for model without bracing and it is reduced to 2.41mm for X bracing, 2.49mm for V bracing and 2.53mm for diagonal bracing systems in X direction and same is the case for Y direction also. Other 2 bracing i.e., V and Diagonal are also proved to be very effective.

6. CONCLUSIONS

Response Spectrum Analysis is used in this study to determine which type of bracing is most suitable in resisting lateral deformation in a multistory RC framed building. The seismic analysis is carried out using the assumption that all of the structures are in seismic zone III. Based on the analysis, the following findings have been drawn:

1. Maximum Storey Displacement

The maximum storey displacement of the model is reduced by X bracing is more than V and diagonal bracing. X bracing reduced the displacement by 59% in G+4 Storey, 43% in G+12 Storey, 17% in G+16 Storey models.

2. Base Shear

The increase in the base shear is almost same for all 3 types of bracing systems. The base shear is increased by 8.7% in G+4 Storey, 5.61% in G+12 Storey, 6.19% in G+16 Storey models. The increase in base shear for X and Y direction is same as stiffness is same for both directions.

3. Storey Drift

The decrease in storey drift is more in models with X bracing than models with V and diagonal bracing. In X direction Storey drift is decreased by 66.19% for G+4 Storey, 88.19% for G+12 Storey and 20% for G+16 Storey models and in Y direction it is decreased by 80.5% for G+4 Storey, 86.4% for G+12 Storey and 40% for G+16 Storey.

Following are the concluding remarks of the research work:

1. Steel bracing are proved effective and can be used as an alternative to the other strengthen or retrofitting techniques for the structures.
2. With the application of bracing, the lateral drifts are significantly reduced, and based on these findings, the ideal concentric system to use would be the X braced system, which had the best overall performance.
3. Building with X type of bracing is found to be most effective under the action of lateral loads and it is the most suitable type of bracing to increase the seismic performance of the concrete structures.
4. The V type bracing also gave better results in displacement and storey drift when compared to other models.
5. The single diagonal edge bracing also gave positive results but after comparing the results it is not a suitable bracing system for concrete structures compared to X and V bracing as the reduction in the displacement and drift is very less

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EXAMINATION OF MULTI-STOREY STRUCTURES USING A HYBRID STEEL BRACING SYSTEM AND SHEAR WALL

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ABSTARCT
The seismic performance of hybrid steel structures that use steel bracings and concrete shear walls as lateral force-resisting elements is examined in this research. The study looks at the displacement, responses, and plate stresses that the structural models under earthquake loading undergo, with a particular focus on seismic Zone-V, which stands for areas with the greatest seismic activity. The findings demonstrate the substantial influence of seismic forces in these areas by showing that structures in Zone-V show the greatest displacement and reactivity. Furthermore, plate stresses increase in proportion to the seismic zone's intensity, highlighting the increased strain on building components. Notwithstanding these difficulties, the hybrid bracing and shear wall system is remarkably successful in reducing seismic stresses, guaranteeing structural stability and resilience in the event of an earthquake. This study emphasizes how crucial it is to choose structural systems that are suitable for seismic risks, especially in high seismic zones, and how effective hybrid systems are in improving seismic performance.

KEYWORDS: *shear walls, bracing systems, multistorey buildings, lateral forces, structural stability*

1. INTRODUCTION

Multi-storey structures are essential elements of urban environments, addressing the growing needs for residential, commercial, and institutional areas. As population densities increase and land availability decreases in metropolitan regions, the development of high-rise structures becomes essential for optimal land use. The structural design and engineering of these structures have distinct problems, notably in maintaining structural integrity, stability, and resilience under diverse loads, including gravitational, lateral, and environmental influences such as wind and seismic activity. One of the primary factors in the design of multi-storey buildings is the choice of a suitable structural system that can endure loads while upholding performance and safety criteria. Conventional structural solutions, including reinforced concrete (RC) shear walls and steel moment frames, have been widely used in the construction of tall buildings, each presenting distinct benefits and drawbacks.

Recently, there has been an increasing interest in hybrid structural systems that integrate the advantages of several materials and building methods to enhance performance and efficiency. A notable hybrid system gaining importance is the integration of shear walls with steel bracing components. This system combines the benefits of increased lateral stiffness and strength from shear walls with the ductility and energy dissipation properties of steel bracing systems. This introduction establishes the framework for analyzing multi-storey structures using a hybrid shear wall-steel bracing structural system. The subsequent sections will examine the structural behavior, design considerations, and performance assessment of this hybrid system, with the objective of elucidating its efficacy and appropriateness for tall building construction under diverse environmental and loading situations. This work aims to provide new ideas for the safe and resilient design of multi-storey buildings via a thorough analysis of this hybrid structural system.

2. REVIEW OF LITERATURE

Thejaswini R.M. et al [1] found that in the modelling, material is considered as an isotropic material. The 3d building model generated in is shown in STADD Pro. A simplified probabilistic risk analysis (PRA) procedure is presented forthe seismic reliability of G+7 storey RCC building by considering effect of with and without floating column in the modelling. Thomsen IV, J. H. et al [2] observed that the moment about X and moment about Z are compared by equivalent static analysis method. The above building models are generated using the software STAAD Pro 8Vi and areanalyzed using equivalent static method.

Vijay Kumara Gowada et al [3] found that in this paper modern construction technology, floating column is becoming a typical feature for multistory buildings in urban India. Such practices are highly undesirable in buildings built in seismically active areas. Due to this floating column the moments in columns, storey drifts, storey shears and other factors tends to increase which leads to strength reduction in structures.

Nanduri, PMB Raj Kiran, et al [4] found that this study emphasizes about recognizing the presence of floating column in multistoried buildings and how to reduce the risk factor of earthquake effects by strengthening the floating columns building with Bracings. In

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this present study four models are used namely, 'Model 1 (G+9 Normal RC Building)', 'Model2 (G+9 RC Floating column Building)', 'Model 3 (G+9 RC Floating column Building with Bracings at corner)', 'Model4 (G+9 RC Floating column Building with Bracings at centre)'.

Chung, Kwangryang, et al [5] observed that seismic analysis is carried out on all four models using Equivalent static method and Response spectrum method in two zones (III, V) respectively. Comparison of results Storey shears, Storey Drifts, Maximum Displacement, Time period and Base shear for all four models are executed. As the Model 4 throw inbetter results compared to other Models, its performance is reviewed using pushover analysis and the performance levelsare discussed by comparing Model 4 with Model 3. This seismic assessment is executed using ETABS software as perthe code book IS:1893-2002.

3. METHODOLOGY

Following models in STAAD-PRO carried out:

1. G-4 Steel Building (without shear wall / bracings)
2. G-4- Steel Building EQ-2
3. G-4- Steel Building EQ-3
4. G-4- Steel Building EQ-4
5. G-4- Steel Building EQ-5
6. G-5 Steel Building (without shear wall / bracings)
7. G-5- Steel Building EQ-2
8. G-5- Steel Building EQ-3
9. G-5- Steel Building EQ-4
10. G-5- Steel Building EQ-5

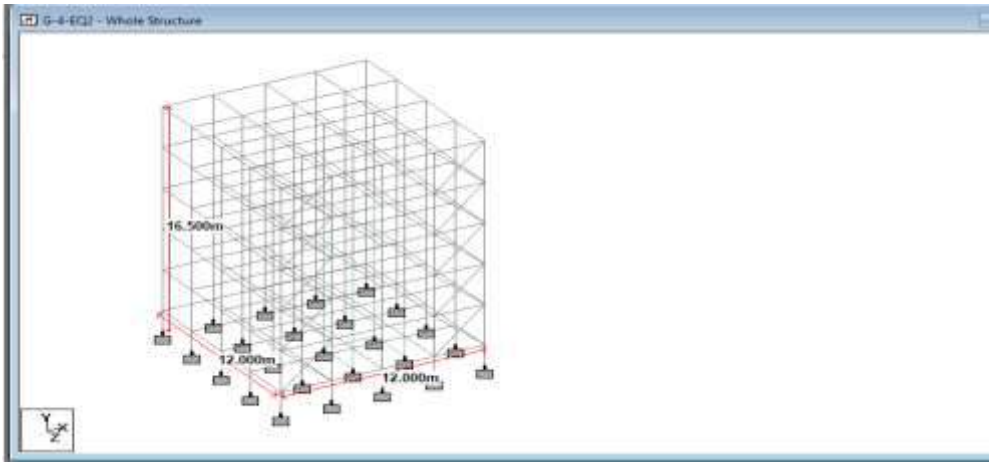

Fig.1: Geometry of G-4 Steel Building

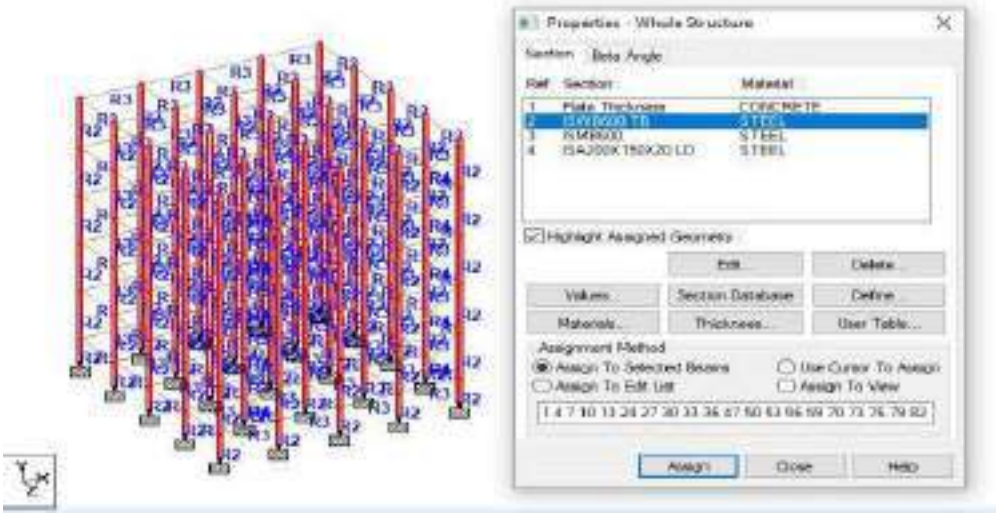

Fig.2 : Properties Assigned to the steel building

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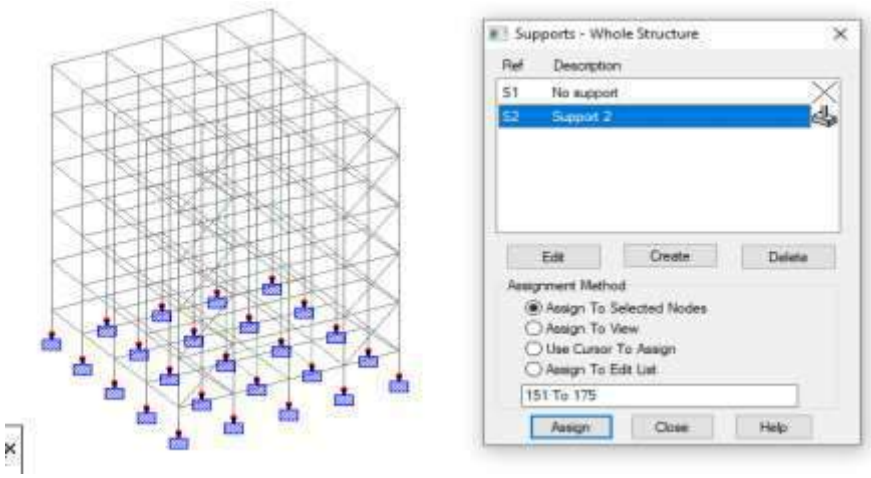

Fig.3 : Supports Assigned to the steel building

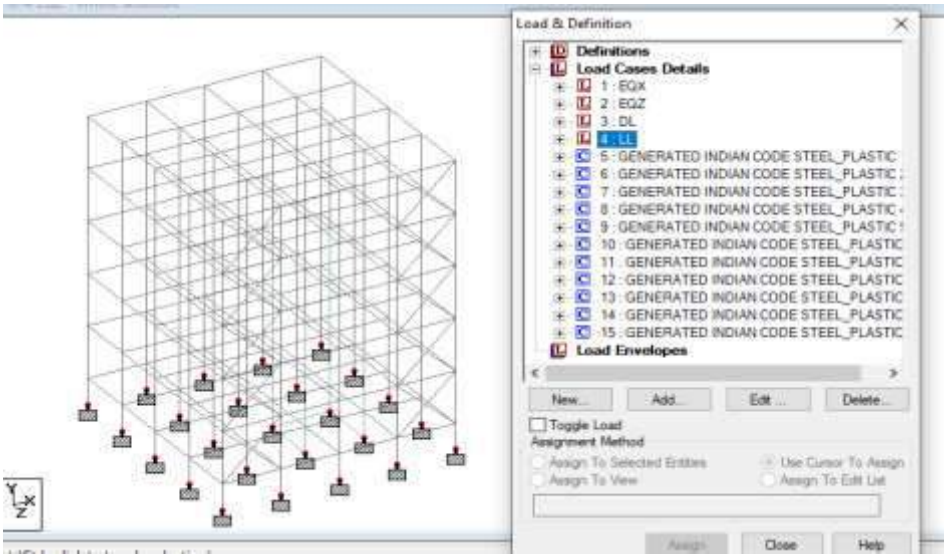

Fig.4: Load Assigned to the steel building

4. RESULTS

Following results are obtained in the STTAD-PRO software

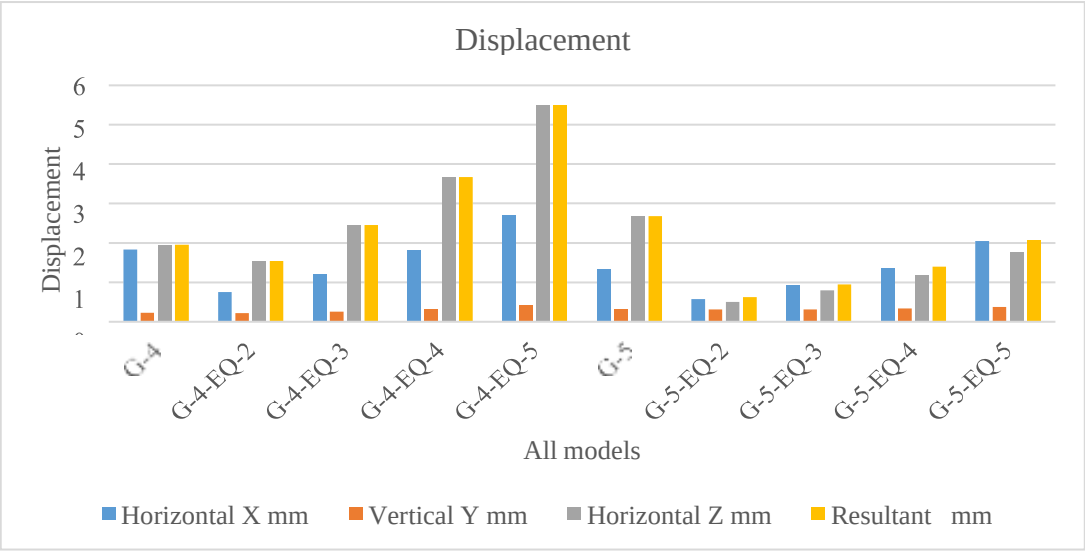

Fig.5: Displacement for all the models

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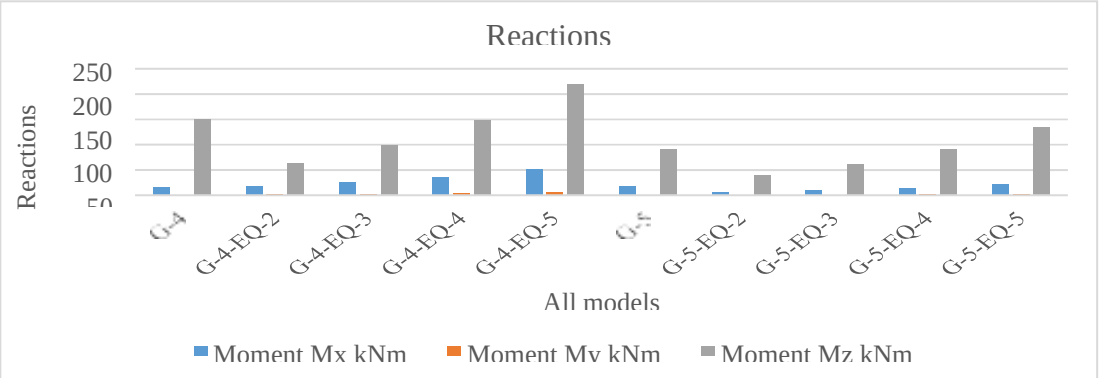

Fig.6: Reactions for all the models

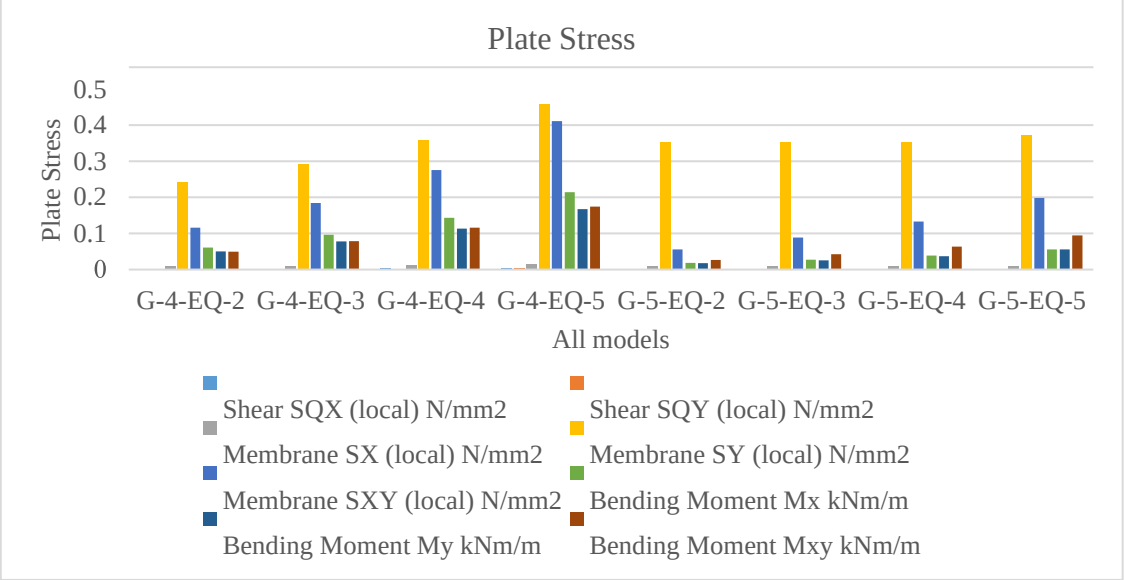

Fig.7 : Plate Stresses for all the models

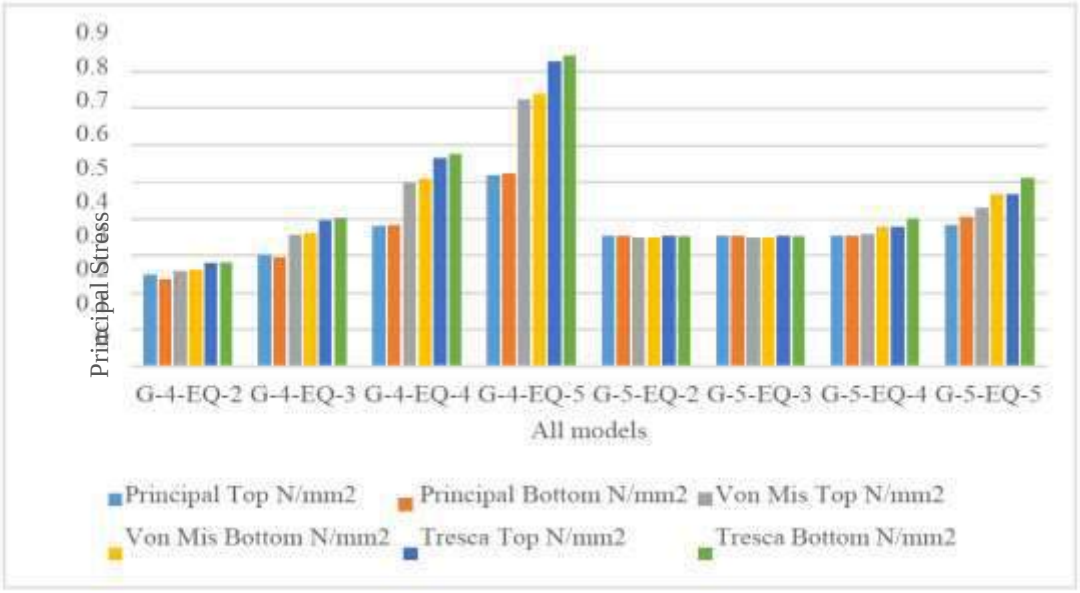

Fig.8: Principal Stresses for all the models

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5. CONCLUSIONS

This excerpt appears to discuss the seismic performance of different structural systems, particularly concrete shear walls and steel bracings, in hybrid steel buildings subjected to earthquake loading, with a specific focus on seismic Zone-V.

Hybrid Structural System:

The term "hybrid" suggests that the building employs a combination of concrete shear walls and steel bracings as its primary lateral force resisting system. This approach is common in seismic design, as it combines the strengths of both materials to enhance overall structural performance.

Displacement and Reactions:

The statement indicates that the maximum displacement and reactions occur in models located in seismic Zone-V. Seismic Zone-V typically represents regions with the highest level of seismic activity and therefore experiences the most significant ground motion during earthquakes. Consequently, structures in Zone-V are subjected to larger displacements and higher forces, leading to increased reactions at the supports.

Plate Stresses:

The observation that plate stresses increase as the seismic zone becomes more severe is consistent with the behavior expected in earthquake-prone regions. Higher seismic forces experienced in Zone-V lead to increased demands on building components, including floor plates. This results in higher stress levels within the plates, which can affect their performance and may necessitate design modifications or reinforcement.

Effectiveness of Hybrid System:

The conclusion that the hybrid shear wall and bracing system are effective in counteracting seismic forces suggests that the chosen structural configuration successfully mitigates the effects of seismic loading. Hybrid systems leverage the strengths of both concrete and steel elements to provide robust resistance against lateral forces, ensuring the structural integrity and stability of the building during earthquakes.

Overall, this excerpt highlights the importance of selecting appropriate structural systems and designs to withstand the challenges posed by seismic activity, particularly in high seismic zones like Zone-V. It underscores the effectiveness of hybrid structural systems in enhancing seismic resilience and reducing the vulnerability of buildings to earthquake- induced damage.

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THE ROLE OF THE PHARMACIST IN MANAGING CHRONIC PAIN

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ABSTRACT
Chronic pain is a pervasive health issue affecting millions of individuals worldwide, leading to significant functional impairment and diminished quality of life. Pharmacists are uniquely positioned within the healthcare system to play a crucial role in managing chronic pain. This review explores the various roles pharmacists can undertake in chronic pain management, including medication management, patient education, and collaboration with healthcare teams. Additionally, the article discusses the challenges pharmacists face in this evolving field and the implications for future practice.

KEYWORD : *Medication management, patient education and counseling, interdisciplinary Introduction, Addressing the Opioid Crisis, Pharmacogenomics and Personalized Medicine, Challenges in Chronic Pain Management, Digital Health and Monitoring Tools.*

INTRODUCTION

Chronic pain, defined as pain lasting longer than three months, can result from various conditions, including injuries, surgeries, and diseases (Bicket & Mao, 2015). It affects approximately 20% of adults globally, significantly impacting their daily activities and mental health (Gudin & Fudin, 2020). Managing chronic pain is complex and often requires a multidisciplinary approach. Pharmacists are integral to this process due to their expertise in pharmacotherapy, patient education, and healthcare collaboration (Fudin et al., 2016; Pergolizzi et al., 2017). This review aims to examine the multifaceted role of pharmacists in managing chronic pain, highlighting their contributions to optimizing pain relief while minimizing the risk of medication-related complications. When patients move from one type of care setting to another, pharmacists can help with pain management by offering services like medication reconciliation.(Mariette Sourial, Michelle D Lese 2017)

Role of Pharmacists in Chronic Pain Management

1. Medication Management

One of the primary roles of pharmacists in chronic pain management is medication therapy management (MTM). Pharmacists can conduct comprehensive medication reviews, assessing the appropriateness, efficacy, and safety of prescribed therapies. They are essential in ensuring safe opioid prescribing and monitoring for potential misuse (Chou et al., 2015). For instance, pharmacists can implement screening tools to evaluate patients' pain levels and medication adherence, allowing for timely adjustments in therapy (Kahan et al., 2011).

2. Patient Education and Counseling

Patient education is vital for effective chronic pain management. Pharmacists play a crucial role in counseling patients about their medications, including proper usage, potential side effects, and interactions with other drugs (Dole et al., 2007). By providing tailored education, pharmacists empower patients to manage their pain effectively and understand the importance of adhering to their treatment plans (Gagne et al., 2008). Furthermore, pharmacists can offer non-pharmacological strategies, such as physical therapy and cognitive-behavioral therapy, as complementary approaches to pain management (Ha et al., 2018).

3. Interdisciplinary Collaboration

Collaboration among healthcare providers is essential for managing chronic pain. Pharmacists can work alongside physicians, nurses, and other healthcare professionals to develop comprehensive pain management plans tailored to individual patients (Matzke & Curry, 2019). Effective communication within healthcare teams enhances the quality of care and ensures that all providers are aware of the patient's medication regimens, potential drug interactions, and ongoing treatment goals (Gellad & Good, 2012).

4. Addressing the Opioid Crisis

The opioid crisis has prompted a reevaluation of pain management strategies, and pharmacists are at the forefront of these efforts. They play a critical role in opioid stewardship by educating patients about the risks associated with opioid use and promoting safe

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disposal practices (Abdel Shaheed et al., 2020). Additionally, pharmacists can assist in opioid tapering strategies, helping patients safely reduce their dependence on these medications (Jackson & Goins, 2020). By implementing screening and monitoring programs, pharmacists can identify patients at risk for opioid misuse and intervene appropriately.

5. Pharmacogenomics and Personalized Medicine

Pharmacogenomics- the study of how genes affect a person's response to drugs- holds promise for optimizing pain management. Pharmacists can utilize pharmacogenomic information to tailor medication selections to individual patient profiles, enhancing therapeutic outcomes and minimizing adverse effects (Knezevic et al., 2018). By integrating pharmacogenomic testing into practice, pharmacists can contribute to personalized pain management approaches that improve patient adherence and satisfaction.

Challenges in Chronic Pain Management

Despite the vital role pharmacists play in managing chronic pain, several challenges persist. Limited access to pain management resources and the stigma surrounding opioid use can hinder effective interventions (Gravina et al., 2015). Additionally, pharmacists may face barriers related to training and continuing education, which can affect their confidence and competence in managing chronic pain (Gudin & Fudin, 2020). Addressing these challenges through advocacy, education, and policy changes is essential for enhancing the pharmacist's role in chronic pain management.

Digital Health and Monitoring Tools

The integration of digital health tools such as wearable devices, mobile applications, and telehealth platforms allows pharmacists to monitor patient pain levels and adherence to therapy in real-time (Jones et al., 2024)

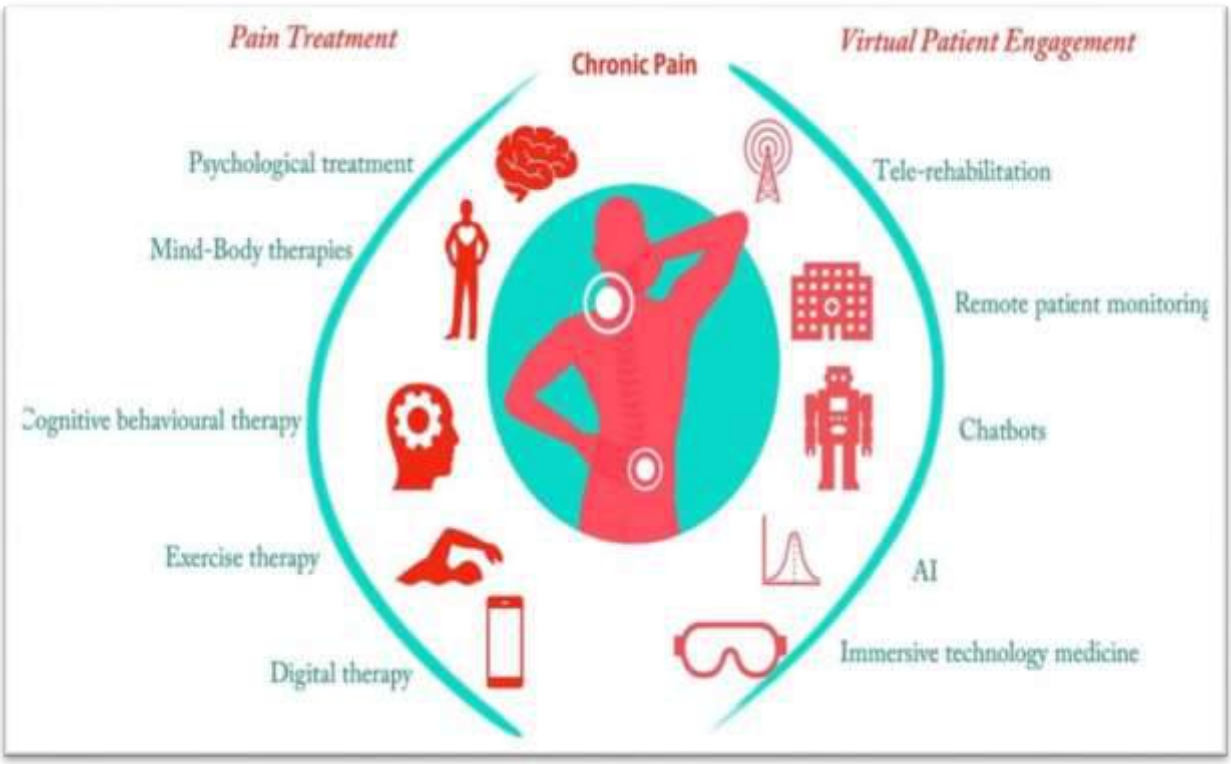

FIGURE 1 | Chronic pain treatment and digital patient engagement methods. (Rejula V, Anitha J, Belfin RV and Peter JD (2021)

Benefits of Exercise

- Power Adaptability
- Reduced risk of cardiovascular disease
- Improved bone health
- Lower risk of metabolic syndrome
- Enhanced mental clarity
- elevated mood
- elevated pain management

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- **The Advantages of Exercise**
  - Perticular impairment correction (e.g., improved range of motion)
  - Decrease in disability (e.g., being able to walk without a cane)
  - An increase in involvement, such as going back to work
  - Pain Management
  - Health Advantages (Heather R. Kroll, MDa,b 2015)

Future Direction: Integration of Pharmacogenomics in Chronic Pain Management by Pharmacists

Proposed Direction:
The integration of pharmacogenomics into chronic pain management offers a promising avenue for pharmacists to enhance patient care. By utilizing genetic testing, pharmacists can predict individual responses to pain medications, minimize adverse drug reactions, and tailor treatment plans to optimize therapeutic outcomes. This approach aligns with personalized medicine, ensuring that pain management strategies are both effective and safe for each patient.

Justification
Genetic variations significantly influence the metabolism and efficacy of analgesics. For instance, variations in the CYP2D6 gene impact the metabolism of opioids like codeine, leading to either inadequate pain relief or toxicity. Pharmacists, equipped with pharmacogenomic knowledge, can identify such genetic predispositions, recommend appropriate medication adjustments, and educate patients and healthcare providers on personalized treatment strategies.

Implementation Strategies
1. Establishing collaborative frameworks between pharmacogenomics laboratories and pharmacies to ensure accessibility to genetic testing.
2. Developing training programs and continuing education for pharmacists on interpreting pharmacogenomic data.
3. Advocating for policy changes to include pharmacogenomic services within pharmacists' scope of practice.
4. Conducting clinical studies to validate the cost-effectiveness and patient outcomes of pharmacogenomics-guided pain management.

Potential Impact
Incorporating pharmacogenomics into chronic pain management could reduce trial-and-error prescribing, enhance patient satisfaction, and contribute to better pain control, especially in populations with complex genetic profiles.

CONCLUSION
Pharmacists are key players in managing chronic pain, offering critical expertise in medication management, patient education, and interdisciplinary collaboration. As the healthcare landscape evolves, pharmacists must continue to adapt and expand their roles in pain management to address the complexities of chronic pain effectively. Future research should focus on developing and evaluating pharmacist-led interventions in chronic pain management, as well as exploring strategies to overcome existing barriers to practice.

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COMPREHENSIVE REVIEW ON: LANTANA CAMARA PHYTOCHEMISTRY, ETHNO PHARMACOLOGY

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ABSTRACT
Lantana Camara belong to verbenaceaefamily. Lantana Camara also known as lantana. The genus lantana consists of 150 PA tropical species used as traditional medicines all around the world. Lantana Camara is well known to cure several disease & used in various folk medicinal preparations. India has rich traditional of plant based knowledge in health care. Lantana camara is formulated for use in cuts and wounds in a limited number of formulations (e.g., ointments and creams). Amoung the large number of herbal drugs existing in India, very few studied systematically so far. Plant is used to treat asthma, abdominal disorder, cancer, swelling& ulcer. The present review aims to document the medicinal properties of L. camara its future prospects for the further scientific investigation for the development of effective therapeutic compounds. The stem, root and leaves contain many of the bioactive compounds responsible for various therapeutic applications such as cancers, chicken -pox, ,asthma, ulcers, swellings, eczema, tumours, high blood pressure, bilious fevers, catarrhal infections, rheumatism, malaria, antiseptic, antispasmodic, carminative and diaphoretic.

KEYWORD: - *Lantana Camara, Medicinal Plant, Herbal Drug.*

I. INTRODUCTION[1,2,3]

Medicinal plants represent an important source of medically important compounds. Since ancient time, medicinal plants are used to cure several types of health problems[2].Lantana camara is known by different name in various different languages in India viz, Raimuniya (Hindi), Chaturangi and Vanacehdi (Sanskrit), Arippu and Unnichedi (Tamil), Airproof, Poochedi, Konginipoo and Nattachedi (Malayalam), Thirei, Samballei and Nongballei (Manipuri), Tantani and Ghaneri (Marathi), Pulikampa (Telegu), Kakke and Natahu (Kanada).L. camara is distributed throughout India where there is a moderate to high summer rainfall and well-drained sloping sites. Lantana camara Linn. is a flowering ornamental plant belonging to family Verbenaceae[3].lantana Camaralinn is considered as a notorious weed & popular ornamental plants. Lantana Camara used in traditional medicine system for treatment of cuts, swelling, ulcers, cataract, fever, itches& rheumatism. [4] The plant-based, traditional medicine system continues to play an essential role in health care, with about 80% of the world's inhabitants relying on traditional medicines for their primary health care. Several researchers have reported antimicrobial activity of leaves and their essential oil. It is one of the world's worst weed and a popular ornamental plant. The genus is a difficult one to classify taxonomically since species are not stable and hybridisation is widespread, shape of inflorescence changes with age, and flower colours vary with age and maturity.

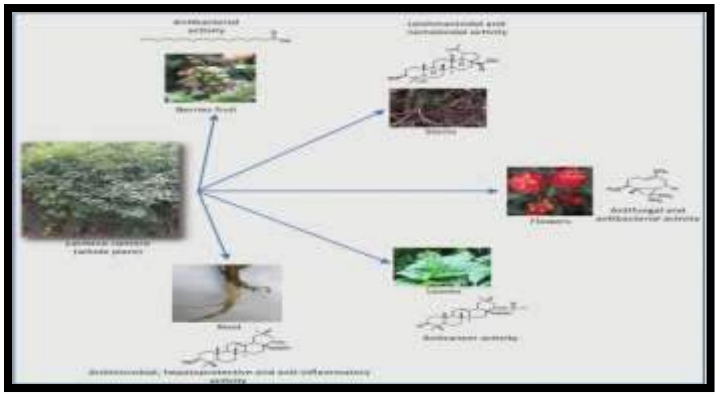

Figure No.1: Effects of parts of plant (lantana camara).

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II. PLANT DESCRIPTION[4,5,6]

L. camara is a robust, low, upright or subscandent shrub with a tetrangular stem, thick, recurved leaves, and a potent black current odor. The plant can extend to a width of 2.5 meters and reach heights of 1 to 3 meters. Oval or rectangular, acute or subacute, crenate serrate, rugose above, and scabrid on both sides are the characteristics of the leaves. The green leaves measure 3–8 cm in length and 3–6 cm in width.Rough hairs cover the stem and leaves. Umbels are tiny flowers that are held in bunches. The flower's color typically changes as it ages, sometimes shifting from orange to white to red in different shades. Almost all year long, the axillary head of flowers has a yellow neck. The calyx is little. Stem: Tetrangular stem, stout recurved pickles and covered with bristly hairs. Leaves: Opposite, simple, scented leaves with long petioles and rough, oval-shaped surfaces. Seeds: Initially seeds are green colored, turn into purple and finally black when they get matured. Flowers: Small, flower held in clusters (called umbels). Color usually orange, sometime white, pink. Fruits:- Round, fleshy, two-seeded bean, poisonous.

- Barriers fruits: - Antibacterial activity.
- Stems: - Nematicidal activity.
- Flower: - Antifungal & Antibacterial activity.
- Leaves: - Anticancer Activity.
- Roots: - Antimicrobial, hepato protective & anti-inflammatory activity.

Figure No.2: Morphology of Lantana camara Linn.
A) Flower, B) fruits, C) leaves) plant, E) stem, F) Roots.

Taxonomy [7]

- ✓ **Kingdom:** Planate
- ✓ **Division:** Magnoliophyta
- ✓ **Class:** Magnoliopsida
- ✓ **Order:** Lamiales
- ✓ **Family:** Verbenaceae;
- ✓ **Genus:** Lantana
- ✓ **Species:** Lantana camara Linn.

General Characteristic

Table No.1:- General characteristics of lantana Camara.

Characteristics	Description
Native	Tropical region in central & South America
Synonym	Camera Vulgarise
Distribution	Naturalised in countries at 35°N & 35°S latitudes
Conservation Status	Alien
Plant Category	Annuals & biennials, ground covers
Plant Characteristics	Poisonous
Foliages Characteristics	Fragrant, evergreen
Foliages Color	Pink Yellow
Propagation Method	From Herbaceous stem cuttings

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III. CHEMICAL CONSTITUENTS[8,9]

Phytochemicals analysis of the leaves of L camara showed that the plant contained alkaloids, glycosides, steroids, saponins, flaonoids,coumarins, tannins, carbohydrates, hydlroxy anthraquinones, anthraquinones glycosides, proteins, plytosteroids, fixed oils, fats(9). A chemical examination of the floral extract and leaves revealed ten comparable lipid and carbohydrate compositions. The extracts from the leaves had more lipids, whereas the flowers had more carbohydrates than the leaves. The polyphenol content of L. camara was 917.60 mg/100 g in the leaves and328.56mg/100 g in the stem, while flavonoids content was 3.29 mg/100 g in the leaves and 8.03 mg/100 g in the stem L. camara leaves yielded 0.8% of essential oil. A-guaiene, a-humulene,a-copaene,acubebene,a-selinene,ß-elemene,ßselinene,delta-cadinene, germacrene D, B, aromadendrene, caryophylleneoxide, nerolidol, and spathulenol represented the major components of the essential oil of L camara[9].However, 26 compounds were characterized form essential oil of L.camara from Tamil Nadu regions, these included: Bicycloelemene, a-cubebene, a-copaene, ß-elemene, bicyclo, germacrene, a-guaiene,a-humulene, aromadendrene, naphthalene, germacrene D, ß-selinene, epi-bicyclosesquiphellandren, a-selinene, 1-hydroxy-1, 7-dimethyl-4-iso, ß-cadinene, caryophyllene oxide, veridifloral naphthalenamine,4-bromo, (-)-spathulenol, isospathulenol, tetracyclo, delta-cadinene,1-napthalenol.

Traditional Use of lantanacamara [10]

Table No2: Traditional use of lantana Camara.

Parts	Traditional uses
Leaves	Cuts, rheumatism, ulcer, catarrhal infection, tetanus, malaria, cancer, chicken pox, asthma, swelling, eczema, high blood pressure, bilious fever, ataxy of abdominal viscera, sores, measles, cold and fever
Whole plant	Bronchitis
Berries/Fruits	Fistula, pocks, tumors and rheumatism
Flowers	Chest complaint in children
Powdered root	Given with milk to treat stomachache and as a vermifuge, toothache
Bark	Astringent and used as a lotion in cutaneous eruptions, leprosy ulcers
Lantana oil	Skin infection, itches, and as an antiseptic for wounds
Plant extract	Drought-tolerant plant so good candidate for xeriscaping. Employed in the folk drug for the treatment of cancers, chickenpox, measles, asthma, ulcers, swellings, eczema, tumors, high blood pressure, bilious fevers, catarrhal infections, tetanus, rheumatism and malaria

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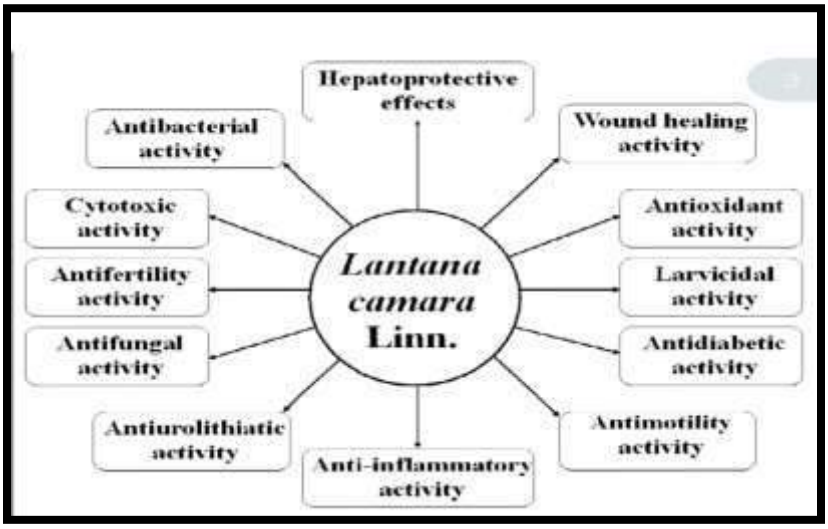
IV. MEDICINAL PROPERTIES OF LANTANA CAMARA LINN[11]

Figure No 3: Medicinal properties of lantana Camara



1. Antibacterial Activity

The leaves and flowers of some L. camara plant types have been shown to have antibacterial properties. While Staphylococcus aureus showed weak antibacterial activity, three distinct solvent extracts of the leaves and flowers of four distinct varieties of L. camara showed strong antibacterial activity against E. coli, Bacillus subtilis, and P. aeruginosa. There have been reports of antibacterial activity inethanolic extracts of L. camara leaves and roots. The microdilution method was used to measure the antibacterial activity in vitro. Staphylococcus aureus, Proteus vulgaris, Pseudomonas aeruginosa, Víbriocholareae, Escherichia coli, and two multiresistant strains of E. coli and S. aureus were all susceptible to the extracts' antibacterial activity.

2. Antifungal Action

The antifungal properties of L. camera's ethanol and hot water extract were tested against fungi that cause brown and white rot in wood. Both extracts demonstrated effective antifungal activity against the fungi that cause white and brown rot, but at very low concentrations (0.01%), ethanol extract showed great promise. Additionally, L. camara was tested against Alternaria sp., which causes a variety of plant diseases, particularly in vegetable plants. Using the food poison plate method, the antifungal activity was assessed at three distinct extract concentrations: 10 mg/ml, 15 mg/ml, and 20 mg/ml. L. camara demonstrated strong antifungal activity against Alternaria sp. at a dosage of 20 mg/ml.

3. Antimicrobial Effects

The antimicrobial activity of the petroleum ether, methanolic, and water extracts of L. camara was investigated against Bacillus subtilis, Escherichia coli, and Candida albicans. At concentration of 250 mg and more, petroleum ether and methanolic extracts of the leaves showed potent antibacterial and antifungal activity.

4. Antioxidant Effects

Antioxidant activity of L. camara of aerial parts methanolic extract, its tractions and purified compounds (lantadeneoleanolic acid, and lantanilic acid) were determined using 1, 1-diphenyl-2 picrylhydrazyl (DPPH). The methanolic extract showed 67% inhibition of DPPH free radical with ECs value of: 875 Hg/ml, the three fractions were also active and exhibited 70%, 72%, and 65% inhibition, respectively, with ECsovalue of 375 ug/ml (10).

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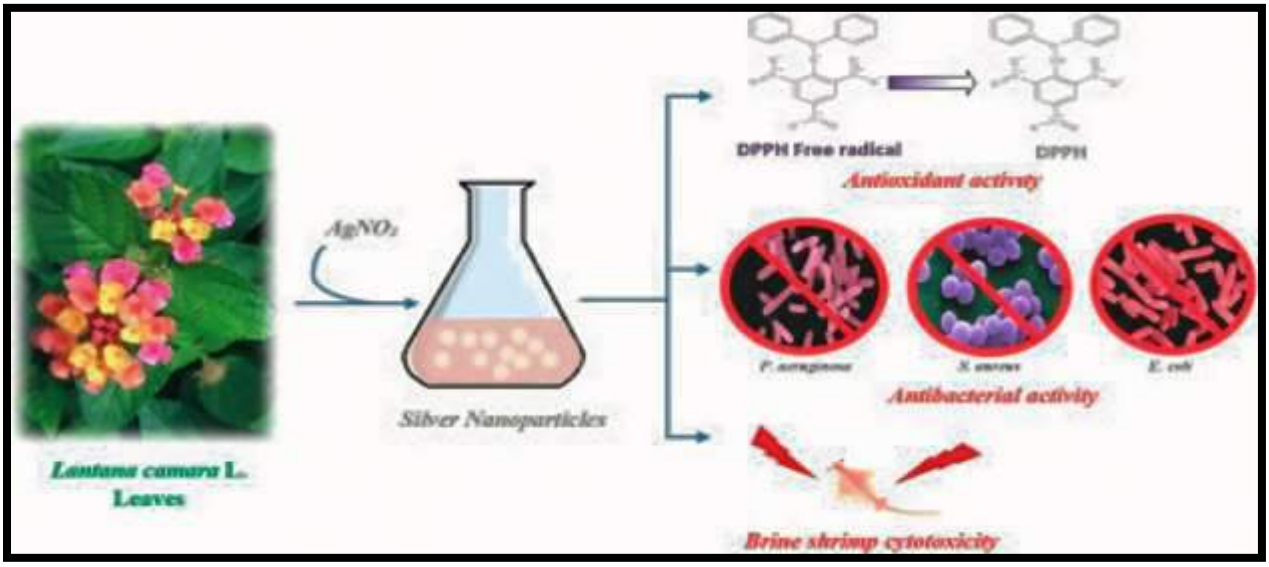

Figure No.4: Antioxidant activity of lantana camera.

5. Wound Healing Activity

Wound healing property of aqueous extract of leaf of L. camara was reported in rats. Topical application of the extract on the wound (100 mg/kg/day) significantly enhanced the rate of wound contraction (98%), synthesis of collagen and decreased wound healing time.

6. Effect on Red Blood Cells

An aqueous extract of Lantana camara was tested for its effects on RBC shape and osmotic fragility. The results showed a significant ($p < 0.05$) increase in hemolysis and changes to RBC morphology when the extract was present. These Lantana camara effects could be linked to certain pharmacological characteristics of the chemical components in the aqueous extract.

7. Antiulcerogenic Activity

Antiulcerogenic activity of the methanol extract of leaves of L. camara was reported on asprin, ethanol and cold resistant stress induced gastric lesions in rats. Pre-treatment of the effected rats with the extract (200 and 400 mg/kg bodyweight) showed significant protective effect in aspirin induced, ethanolinduced and cold restraint stress induced ulcers in rats. The extract resulted in dose dependent antiulcerogenic activity in all models.

8. Antifilarial Activity

Antifilarial activity of crude extract of L. camara stem was reported. The extract and its chloroform fraction resulted in the death of adult Brugiamalayi and sterilised most of the surviving female worms in the rodent model Mastomyscoucha.

9. Anti fertility Activity (Embryo Toxicity):

Effects of hydro alcoholic extract of L. camara leaves were studied on fertility, general reproductive performance and teratology in female albino Wistar rats. The extract interfered in the frequency of fetal skeleton anomalies from dam's treated with the extract and induced embryo toxicity as indicated by postimplantation loss, without any signs of maternal toxicity.

V. CONCLUSION

The demand for herbal medications has significantly increased in recent years. It is well known that plants have a wide variety of chemical components with numerous pharmacological characteristics. Medicinal plants have yielded numerous potent and effective medications for the treatment of terrible illnesses. Therefore, it is evident that research on medicinal plants is crucial for human welfare in terms of producing herbal medications. One of these fundamental medicinal plants that have been utilized in traditional medicine all around the world is Lantana camara. Numerous Phytochemical studies have revealed that the plant is abundant in both essential oils and significant chemical components. Numerous chemical components, including steroids, coumarin, monoterpenoids, flavonoids, and diterpenes, have been identified in L. camara. The greatest number of pharmacological studies conducted. Leaf extracts of lantana exhibit antimicrobial, fungicidal, insecticidal and nematicidal properties. Which possess antimicrobial, immunosuppressive and anti tumour activity.

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THE DEVELOPMENT STRATEGY FOR SPORTS TOURISM

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ABSTRACT
This article discusses the consideration of tourism as a means of physical education and explores issues such as overcoming natural obstacles and combining physical exercises with load carrying.
KEY WORDS: *Tourism, means of physical education, physical exercises, physical education, the use of forms and methods of tourism during excursions, means of physical education, competition in tourism.*

Tourism serves as an essential means for the harmonious development of the population, strengthening their health, and educating the modern person as a well-rounded individual. The relevance of developing tourism as a social phenomenon is evident in its inclusion alongside other means aimed at preserving and strengthening people's health and ensuring meaningful leisure for the country's population. The Decree of the President of the Republic of Uzbekistan dated January 5, 2021, "On Additional Measures for the Accelerated Development of Tourism in the Republic of Uzbekistan", includes an annex with a plan of measures for 2021 to implement the Concept for the Development of the Tourism Sector in the Republic of Uzbekistan for 2021-2025. This plan outlines the tasks of analyzing the current state of sports tourism in the country and developing a strategy for further developing sports tourism.

The role of tourism in the gross domestic product of countries is steadily increasing, says President Shavkat Mirziyoyev [1]. Therefore, tourism development should also be a priority economic task in the new Uzbekistan striving to accelerate economic growth rates. The development of national tourism in Uzbekistan has been analyzed as a process evolving in harmony with various fields of social life. The study considers the tourism system as an open, holistic, and consistent system with unique features, goals, tasks, and structure. In this direction, we can also say that tourism is one of the most popular and affordable means of physical health improvement for people at the current stage of social development. This focus on tourism is not without reason.

One of the principles of societal development is to nurture a well-rounded individual, which necessitates participation in various activities to diversify the ability to meet social needs. Utilizing tourism as an active means of personal development facilitates the formation of essential life skills, enhances physical capabilities, and positively impacts the development of moral, volitional, and intellectual qualities. Moreover, tourism involves engaging participants in various socially beneficial activities.

In our country, physical education—an integral part of continuous education—is closely linked with the formation of a well-rounded individual. Therefore, all means, forms, and methods of the physical education system should ensure the dialectical connection of physical education with practical labor and defense activities, and health-improvement measures should be directed towards nurturing a well-rounded individual. According to Dmitriy Kirsanov, "national tourism represents inbound tourism within the country and tourism related to national development [2]". V.A.Kvartalnov defines national tourism as "a set of activities in the field of domestic and inbound tourism, providing services to tourists by their fellow citizens [3]". M.Q.Pardaev, R.Atabaev, B.R.Pardaev believe that "national tourism involves tourists traveling from one place to another within their own country for tourist purposes [4]". From the above, it is clear that tourism cannot be considered a short-term entertainment; it primarily serves personal interests, intellectual, labor, moral, and aesthetic education. Practical experience shows that proper physical development cannot be achieved solely through tourism in the overall long-term system of physical education. Engaging in tourism is beneficial only when combined with other means in the system, such as games, gymnastics, and sports. Tourism is allocated a special group in the physical education system because it allows individuals to acquire the knowledge, skills, and competencies necessary for their lives.

Transforming tourism into a strategic sector of the economy remains a priority task for us, says President Shavkat Mirziyoyev. One of the most important tasks of the government is to increase the number of tourists visiting our country to 10 million in the coming years. Thus, tourism is characterized by its natural application as a means of physical education. It includes various physical

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activities of different forms and contents. These are movements carried out over long distances in rare locations and group efforts in natural conditions [1]. Their goal is to address educational, health, and sports-related tasks by forming skills necessary for production, military, and everyday activities in individuals. In tourism, educational, health, and sports-related tasks fall into the category of general tasks, meaning their resolution is achieved collectively, regardless of the age and specific physical preparation of the participants. For example, during a journey, the educational task is directly addressed through the influence of the group on each participant, fostering collectivism and subordination of personal interests to community interests. Furthermore, the duration of movement and physical exercises gradually increase in camp conditions, enhancing endurance and voluntary qualities.

In addition to educational tasks, educational goals are also addressed during travel. This means integrating pre-acquired knowledge in regional studies, natural history, and topography, thus confirming theory with practice. The methodology of developing skills and abilities in travel conditions is also improved. The health issue is resolved through a well-organized route that adheres to optimal regimes of physical exertion and active rest, utilizing the positive effects of natural factors on all body functions while following personal and public hygiene rules. Regular travelers who engage in running or swimming can mitigate the adverse effects of physical load adaptation. Adaptation refers to the process of new adaptive shifts occurring in the body due to prolonged physical exertion. In such cases, there is a need to temporarily direct the individual to a slightly different type of activity associated with the current physical load. Periodic travel for a person engaged in physical education helps maintain a high level of physical fitness.

Overall, regarding sports tasks in tourism, three points should be emphasized. Firstly, tourism activities help to create a general physical preparation base necessary for any sport. Secondly, they provide special training for participating in competitions in tourism techniques. Thirdly, tourist hikes are regulated by sports classifications, which in turn require the appropriate sports training of participants, meaning that sports classification helps to implement the principle of maximum load in tourism. Specific tasks in tourism, depending on the goal, are related to special preparation for a particular trip. For example, traveling to historical sites in Uzbekistan requires special preparation to choose a route saturated with historical monuments and landmarks. In this case, it demands studying numerous literary sources to obtain information about the historical events that occurred within the proposed travel framework.

On the route, this information should be supplemented by the directed search activities of the participants. Post-trip archival research helps to create a more holistic understanding of the significance of certain historical events. Thus, trips to historical sites in Uzbekistan are aimed at educating young people in a spirit of military patriotism. Educational tourist trips require training sessions on the techniques and tactics of tourism, the selection and preparation of campsites, and the provision of appropriate conditions for cooking, thus solving the problems of developing such skills among participants, which will help them independently organize and conduct tourist activities in the future.

Complex category trips are associated with the preliminary preparation of their participants. Some challenging trips are undertaken to test tourist equipment. Separate tourist expeditions address national economic tasks (studying glaciers, flora, and fauna in hard-to-reach areas, mapping and updating maps, meteorological observations). Tourism should be systematically considered as a phenomenon to fully align with its goals and objectives. As a phenomenon, tourism represents a system of unique events, where its components can be identified as ideological, naturalistic, scientific, methodological, organizational and managerial, programmatic, and normative foundations. Tourism—comprising planned trips, excursions, hikes, climbs, and walks—does not create any material benefits but is viewed as a factor aimed at developing physical abilities and qualities and promoting active recreation. It is known from the trips of geologists and hydrogeographers that they plan their trips to create material value. In physical education, its specific aspects are utilized. Overcoming certain natural obstacles during tourist trips fosters intellectual, physical, moral, and aesthetic qualities in people.

It fosters qualities such as teamwork, fearlessness, strength, and endurance. Travel enhances skills and abilities to adapt to living and working conditions in mountainous and rural environments. Tourism is rich in physical exercises applicable in practical life conditions compared to other physical education factors. Consequently, they stand out for their practicality and applicability.

As a means of physical education, tourism has the following key features:

1. Practicality: It promotes independent activity and initiative. It develops and enhances skills such as leadership, management, orientation, route selection and navigation, and map reading.
2. Simultaneous development: Tourism simultaneously develops physical qualities and movement skills without focusing on specialized traits needed in specific sports.
3. Practical exercises: Preparation for and participation in trips involve practical exercises such as walking, running, overcoming obstacles, and other essential physical activities.
4. No specific physical fitness requirement: Like sports, tourism does not require a certain level of physical fitness for participation.

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5. Variable impact: Physical exercises during tourism affect the body differently based on climatic conditions (cold, heat, wind) and route terrain.
6. Competition: Strength testing and competition play a central role in tourism.
7. Leadership: Participants elect their leader, who must be over 16 years old and experienced. The leader participates with the group and undertakes additional tasks such as studying the route, participants, and equipment, and solving practical issues. If the participants are young tourists, a specialist guide over 19 years old is appointed.
8. Main form: The primary form of tourism activity is hiking, utilizing all necessary forms and methods of tourism, developing essential movement skills [5].

Training sessions encompass activities like swimming, climbing, working with topography, and overcoming obstacles. Tourism is considered a means of physical education, recommending the combination of overcoming natural obstacles and carrying loads with physical exercises. The exercises used in the educational process are categorized according to historically established physical education systems. However, as these systems evolve and new advanced exercises are developed, they no longer fit into the historically accepted categories. Based on their characteristics, these new exercises often differ significantly from gymnastics, games, sports, or tourism exercises.

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THE USE OF PROVERBS, SAYINGS AND FOLK EXPRESSIONS IN POETRY IN FOLKLORE

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ABSTRACT
In this article, it is given the methods of using proverbs, adages and folk expressions in poetry, to enlarge related speech, to develop literary-esthetic ideas, to form the culture of speech and to ensure the impressive effect of speech on Reading subject in the primary education
KEY WORDS: *Proverb, adage, folk expression, poetry, vocabulary, speech, related speech, story, the meaning of word.*

It is well-known that proverbs and idioms, some of the most active genres of folk oral creativity, are widely used in written literature. Indeed, "They serve as adornments to the creator's speech and an essential factor in bringing characters to life... as proverbs and idiomatic expressions unique to the oral speech style are commonly found in the works of any writer or poet". In fact, proverbs and wise sayings play a crucial role in enriching the language of literary works for writers and poets. Researcher L.Sharipova concludes on this matter: "Expressions and phrases characteristic of oral speech cannot be considered mere folklorisms, because while they occur regularly in language, like proverbs and sayings, they lack specific genre markers as a product of literary creation". True, expressions and phrases typical of oral speech lack genre markers in literary literature, yet, considering that they are passed down orally from generation to generation and carry significant meaning in literature, it is appropriate to classify them as simple folklorisms. In this regard, we believe Prof. B.Sarimsoqov has drawn the correct conclusion.

Observing our poets' work, we come across unexpected modifications of folk proverbs, sayings, wise words, and idioms that conform to poetic demands. Omon Matjon's poems also contain numerous examples of proverbs, sayings, folk idioms, and expressions typical of oral speech. In the quatrains included in his collection Ardaxiva, the poet has used the essence of several Uzbek folk proverbs to create lines that resonate deeply with readers:
Divided in two, a group of friends,
Their drive has waned, the path narrowed.
They once stood under one banner, now
One half here, the other holds the staff.

In this quatrain, the poet reinterprets the meanings of proverbs like "A lone horse's dust may rise, but its fame won't," "When six are divided, they quarrel; when four are united, they reach the sky," and "Birds cannot fly without wings, just as humans cannot live without friends," effectively conveying his message to the reader. The following lines also artistically reflect the theme of unity found in the proverbs mentioned:
Unity is the harmony of heart and flower,
Unity is the bond of conscience and tongue.
Unity – the unity of ninety-two Uzbek clans,
The unity of a hopeful people looking toward tomorrow.

We know that a person's greatest enemy is his own desires. Many ideas on this topic are mentioned in the Qur'an, hadiths, and wise folk sayings. In the works of our classical poets such as Ahmad Yassavi, Suleyman Baqirgani, Alisher Navoi, and Sufi Ollayor, desires are likened to devils or serpents. In the following quatrain by Omon Matjon, the folk proverb "Desire is my disaster, casting me into a burning fire" is uniquely reinterpreted, artistically depicting the harmful consequences of desires through symbols of birds, Mosh, and hunger:
One day, I looked closely at a bird:

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It was snared by desire, caught by Mosh's stare.
A thousand thanks to God for sparing me hunger,
Leaving me wings of thought and consciousness!

In Uzbek folk proverbs, ideas of patriotism and humanity are often glorified. Proverbs about one's homeland especially emphasize loyalty to the homeland and the need to protect it as one would their own eyes. Proverbs like "If your homeland is safe, your face won't pale," "Your homeland is your golden cradle," "Even if you leave religion, don't leave your people," and "The nightingale loves the garden, as man loves the homeland" beautifully express the idea that a person can only find true happiness and fulfillment in their homeland. In many poems, feelings of love for one's homeland, patriotism, and humanity are exalted, harmoniously reflecting the poet's ideas through the meanings of proverbs and wise sayings:
May the farmer never see his harvest lacking,
May friends gather, morning and evening.
Let peoples live on their own land,
Asking for nothing from others.

As we know, the art of quoting proverbs and wise sayings in poetry is referred to as irsali masal in classical literature. The purpose of quoting proverbs and wise sayings in poetry is to enhance the aesthetic impact of the conveyed idea and ensure it reaches the reader more effectively. Lutfi's ghazal beginning with the line "Each moment your tresses fall at your feet" is a high example of irsali masal. The poet created a fine piece by employing the people's wise sayings and expressions in each verse. Observing the work of Omon Matjon, we find that in his poem "Do'st ko'nglini ovlang, ey yoronlar" (O Friends, Console the Heart of Your Friend), written in ghazal style and included in his collection In the Free Airs, he harmoniously intertwines the content of proverbs and wise sayings with the meaning of his verse:
Console the heart of your friend, Oh friends,
Do not take lightly the deeds of saints.
Do not betray friends for a single fault,
Distracted by markets full of lies.
For a man, beauty lies in word and deed,
Worthless is the earth with no fertile seed.
On the throne you called them distant kin,
But now, those kin flee, dispersing thin.
If Sir and Jayhun flow from Tianshan,
Dams hold, yet rivers long for free span.
At each step, wonder, without asking,
The foolish try to teach wisdom, unmasking.
Swear a thousand words without listening
Devils up to the head.
The road is long, your life is the label of Truth,
The khagans are leaders of the ambassador.

In the above verses, the sayings of the Uzbek people such as "A person sees is intelligence", "Loyalty to a friend is loyalty to a hand", "Everyone needs you in your state", "The work of the ignorant is to teach the mind" fulfill the poet's ideological and artistic intention. was used as a means of enhancement and provided an effective delivery of the poem.

Folk proverbs create a world of unique images. In this, the effectiveness of the idea is increased mainly with the help of artistic image tools such as simile, metaphor, revitalization, qualification:
The eye has a lock of eyelashes that keep it clean.
A good wall against your lust and tongue.
The body is a chain of property,
But the ear is always open, what's the secret?!

In these four, a system of original artistic symbols was created with the help of metaphor. That is, an eyelash is a lock that keeps the eyes clean, and a member of the body is a chain of property. As the meaning of the proverb "The tongue is the fortress of the tooth" is instilled into the poem, the philosophical and artistic idea that a person should always listen to good words and advice is put forward through the method of opposition.

If we pay attention to the structure of folk proverbs, we often see that the main meaning and conclusion are clearly manifested through the method of contrast. Contrast method was an important tool in bringing out the main conclusion, ideological and artistic

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content in the following four poems of the poet. To do this, the literary people of our people's proverb "What does a full belly have to do with a hungry one" changes its form:
They say no, don't go as soon as you have something to do.
Shoot all the way through the gap.
When the strong reach out to the weak,
The value of every ember in the country increases.

In addition to folk proverbs and wise sayings, stable phrases and expressions specific to the folk language are also effectively used in folklore. Expressions that are widely used among the people are aimed at revealing the reality and character of the hero:
The world is a market, you know, my child.
Don't get lost in the rasta.
If you distinguish a broker from a merchant,
It's okay if you don't put nuts in your sheep.

Among our people, instead of the word to deceive, the expression to fill one's chest with empty walnuts is used. The poet uses this phrase in a different way and quotes the phrase "If you didn't put a bunch of nuts in your sheep" in the sense of not being deceived about his hero. The expressions used in the next second and third stanzas of the poem also provided a lively and effective expression of the idea:
A dear feeling of love appears in the heart,
There is a soul in the heart.
Where you need to save your happiness,
Don't sacrifice your life in vain.
Many high mountains adorn our country,
The river and tributaries come down from his shoulder.
What pears pass by in front of you,
You can hang the whip on the stake.

Someone's skin also increased (an indication of punishment); All of a sudden, a job came to the fore (to come with work); Many walk by swallowing the words (in silence); If you have written the right sentence, your heart will be in a thousand fists (fearing and worried); Incorporation of phrases such as "I will put my teeth in my teeth" (to be patient, endure) into the content of poetic verses is one of the skill criteria that determine the artistic image of the poet's work.

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A BRIEF REVIEW ON MOLINSPIRATION AND PASS STUDY

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ABSTRACT

Calculation of molecular properties and bioactivity of the simple drug molecules like aspirin, paracetamol, and the drugs of your choices using the online server molinspiration.

ABOUT MOLINSPIRATION; Molinspiration is a privately owned company focused on development and application of modern cheminformatics techniques, especially in connection with the web. Molinspiration was founded in 1986 as a spin-off of Bratislava University.

ABOUT PASS STUDY: Post-authorisation safety studies (PASS) are essential in monitoring the safety and effectiveness of pharmaceutical products after they have been approved for public use. While pre-marketing clinical trials provide vital information on a drug's efficacy and safety, they are often limited by sample size, duration, and patient population diversity. PASS are conducted to gather real-world data on the long-term safety and effectiveness of medicines once they are widely used. This review aims to explore the role of PASS in pharmacovigilance, including study designs, methodologies, regulatory requirements, and challenges associated with their implementation.

KEYWORDS: *Molinspiration, Post-authorisation safety studies, Bioactivity Score, Drug likeness, Mol. Properties.*

1. INTRODUCTION

Molinspiration is a renowned software and informatics company that plays a pivotal role in the pharmaceutical and biotechnology industries. With a primary focus on providing cutting-edge cheminformatics tools and software solutions, Molinspiration has significantly contributed to the field of drug discovery and medicinal chemistry. Its suite of software applications and predictive models has proven invaluable to researchers and scientists in their quest to design and develop novel pharmaceutical compounds.

Molinspiration's software offerings are diverse and cater to a wide range of tasks crucial in the drug development process. One of its core functionalities is property prediction, where its tools can accurately estimate various molecular properties such as lipophilicity, solubility, and bioavailability. These predictions are pivotal in selecting and optimizing potential drug candidates, saving time and resources in the drug development pipeline.

Virtual screening is another key aspect of Molinspiration's software suite. It enables researchers to virtually assess the potential of thousands of compounds for their biological activity against a specific target. This high throughput screening approach helps identify promising lead compounds, expediting the early stages of drug discovery.

Molinspiration's software is an indispensable resource for the pharmaceutical and biotechnology sectors. It empowers researchers to make data-driven decisions, accelerates drug discovery, and ultimately contributes to the development of safer and more effective medications. The company's dedication to advancing cheminformatics and computational chemistry tools has positioned it as a leader in the field, driving progress in the quest for new and improved drugs.

post-authorisation safety study (PASS) included by the pharmaceutical company in the Risk Management Plan (RMP) of the product at the time of its marketing authorisation application. The authors point out the limitations of the clinical trials to genuinely reflect real-world settings and concerns, and post-authorisation safety studies are particularly important for regulatory authorities to further evaluate the safety of medicines as used in clinical practice.

PASS may inform regulators in taking measures for the protection of patients and the safe use of the medicine. Examples of (risk minimisation) measures that may be taken include an amendment of the product information or a restriction of the use of the product to some indications or some categories of patients. The regulatory oversight of PASSs by the EMA Pharmacovigilance Risk Assessment Committee (PRAC) includes an in-depth review of the study protocol and its results in order to assess the possible impact of the outcomes.

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The ETNA VTA study is a good illustration of a PASS conducted voluntarily. It aimed to gain further insight into the use of edoxaban in routine clinical practice, including compliance to the summary of product characteristics (SmPC), the use of a heparin lead-in, dosing patterns and the consideration of concomitant diseases.

2. MOLECULAR PROPERTIES PREDICTION AND DRUG LIKENESS BY MOLINSPIRATION

2.1 Molecular Properties Prediction

Physicochemical parameter such as TPSA, MW, Drug Likeness & MiLogP (octanol/water partition coefficient) is calculated by the methodology developed by Molinspiration software. These parameters play a vital role in generation and determination of bioactivity of chemical entity.

2.2 Drug Likeness

Drug likeliness is a qualitative means of analysis to check whether the given molecule is a drug or not and it is defined as a complex balance of various molecular properties and structural features which determine whether a particular molecule is similar to the known drugs. Activity of all test compounds and standard drug (Ampicillin) were analyzed under six criteria of known successful drug activity in areas of GPCR ligand, ion channel modulator, kinase inhibitor, nuclear receptor ligand, protease inhibitor and enzyme inhibitor by the molinspiration software.

2.3 Antibacterial Activity

All the compounds synthesized were screened in vitro for anti-bacterial activity against Staphylococcus Gram aureus positive bacteria and Staphylococcus epidermidis and Gram negative bacteria- Escherichia coli and Pseudomonas aeruginosa using disc diffusion method at 30 µg/ml concentration, ampicillin (30 µg/ml) was taken as standard. Dimethyl sulphoxide was used a control.

2.4 Evaluation of drug likeliness based on Lipinski's rule of five

Lipinski's rule of five is helpful in describing molecular properties of drug compounds required for estimation of important pharmacokinetic parameters such as absorption, distribution, metabolism, and excretion. The rule is helpful in drug design and development.

Table 1: Molecular property of Phytochemical Compounds

S.No	Phytochemical compounds	MiLogP	TPSA	natoms	nON	nOHNH	nviolations	nrotb	volume	MW
1	Dodecanoic acid	5.038	37.299	14.0	2	1	1	10	224.215	200.322
2	Ethyl caprylate	3.701	26.305	12.0	2	0	0	8	191.338	172.268
3	Glycine (trifluoroacetyl)-methyl butyl ester	2.007	55.405	16.0	4	1	0	7	208.642	241.209
4	Capric acid ethyl ester	4.711	26.305	14.0	2	0	0	10	224.941	200.322
5	α - Tocopherol	8.847	29.462	30.0	2	1	1	11	457.697	416.690
6	n- Hexadecanoic acid	7.059	37.299	18.0	2	1	1	14	291.422	256.430

3. BIOACTIVITY SCORE

Bioactivity of the drug can be checked by calculating the activity score of GPCR ligand, ion channel modulator, nuclear receptor legend, kinase inhibitor, protease inhibitor, enzyme inhibitor. All the parameters were checked with the help of software Molinspiration drug-likeness score online (www.molinspiration.com). Calculated drug likeness score of each compound and compared with the specific activity of each compound, and the results were compared with standard drug. For organic molecules the probability is if the bioactivity score is (>0), then it is active, if (-5.0-0.0) then moderately active, if (< -5.0) then inactive.

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Drug score values indicate overall potential of a compound to be a drug candidate. Mol inspiration is a web-based tool used to predict the bioactivity score of the synthesized compounds against regular human receptors such as GPCRs, ion channels, kinases, nuclear receptors, proteases and enzymes.

Table 2: Bioactivity score of Phytochemical Compounds

S.No	Phytochemical compounds	GPCR ligand	Ion Channel Modulator	Kinase inhibitor	Nuclear receptor ligand	Protease inhibitor	Enzyme inhibitor
1	Dodecanoic acid	-0.27	-0.04	-0.75	-0.24	-0.36	0.04
2	Ethyl caprylate	-0.85	-0.34	-1.25	-0.84	-0.86	-0.40
3	Glycine (trifluoroacetyl)-methyl butyl ester	-0.38	-0.38	-0.88	-0.31	-0.18	-0.12
4	Capric acid ethyl ester	-0.60	-0.21	-0.93	-0.57	-0.62	-0.23
5	α - Tocopherol	**0.25**	**0.15**	-0.22	-0.22	**0.29**	**0.25**
6	n- Hexadecanoic acid	0.02	0.06	-0.33	-0.33	-0.04	0.18

4. MOLINSPIRATION ANALYSIS

In Molinspiration Log p measures the totality of fragment-based aids and correction factors. This method processes all organic and organometallic molecules. Topological polar surface area (TPSA) is the sum of fragment contributions, O and N centred polar fragments are considered. It is a good descriptor containing drug absorption plus intestinal absorption, bioavailability, and blood-brain barrier penetration. Molecular volume is based on group contributions. mostly drug-like molecules. Several bonds are rotatable, it is a measure of molecular flexibility. it is a fine descriptor of the oral bioavailability of drugs. Rotatable bond is distinct for any single non-ring bond, limited to a non-terminal heavy atom. The Lipinski rule of five affirms, that most drug-like molecules have log P ≤ than or equal to 5, molecular weight ≤ than or equivalent to 500, number of hydrogen bond acceptors ≤ than or equivalent to 10 and number of hydrogen bond donors less than or equal to 5. Molecules crossing more than one of these rules may have encountered the problems of bioavailability. The rule is known as the Lipinski Rule of five. Molinspiration software is written in java software, it is a molecular properties computation toolkit, Molinspiration is applied in the process of a large number of molecules in batch mode and can process data of about 10000 molecules per 60sec, it is way in through web interface directly on the internet.

5. PROCEDURE

i. Molinspiration link

https://www.molinspiration.com

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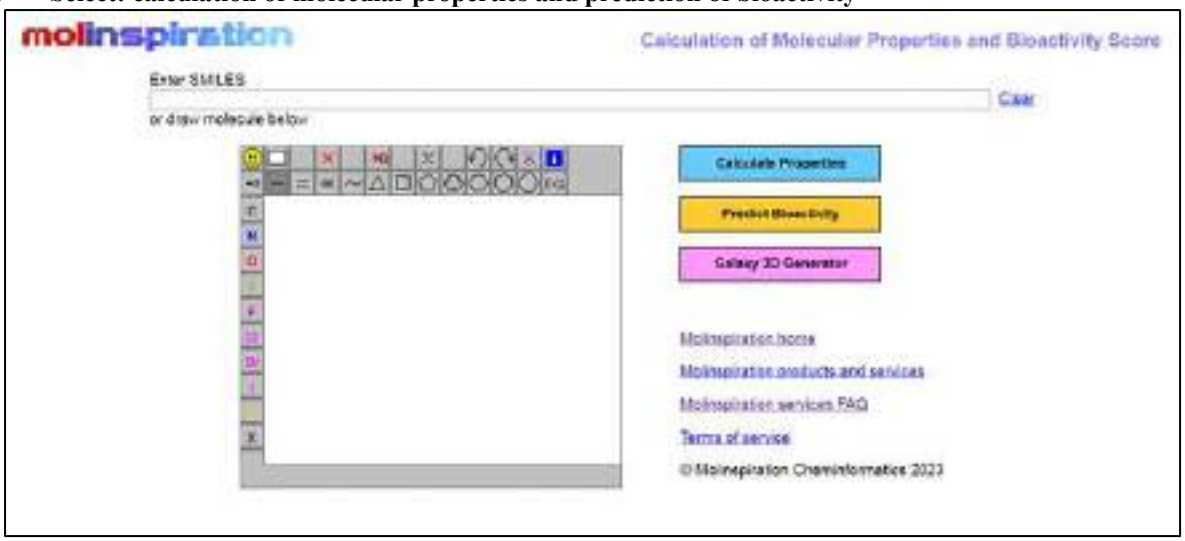
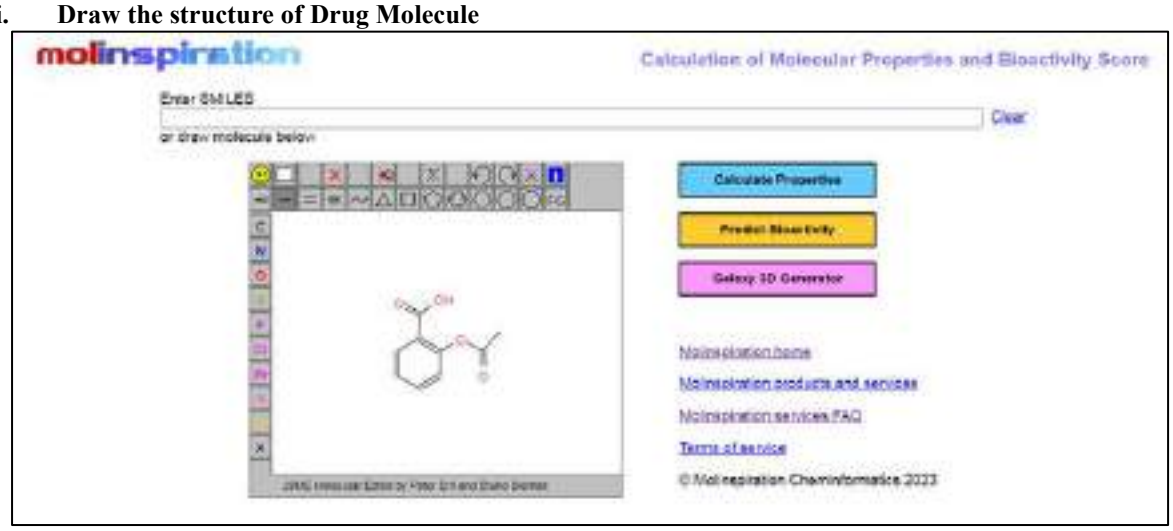
ii. Select: calculation of molecular properties and prediction of bioactivity



iii. Draw the structure of Drug Molecule



iv. Select: Calculate Properties

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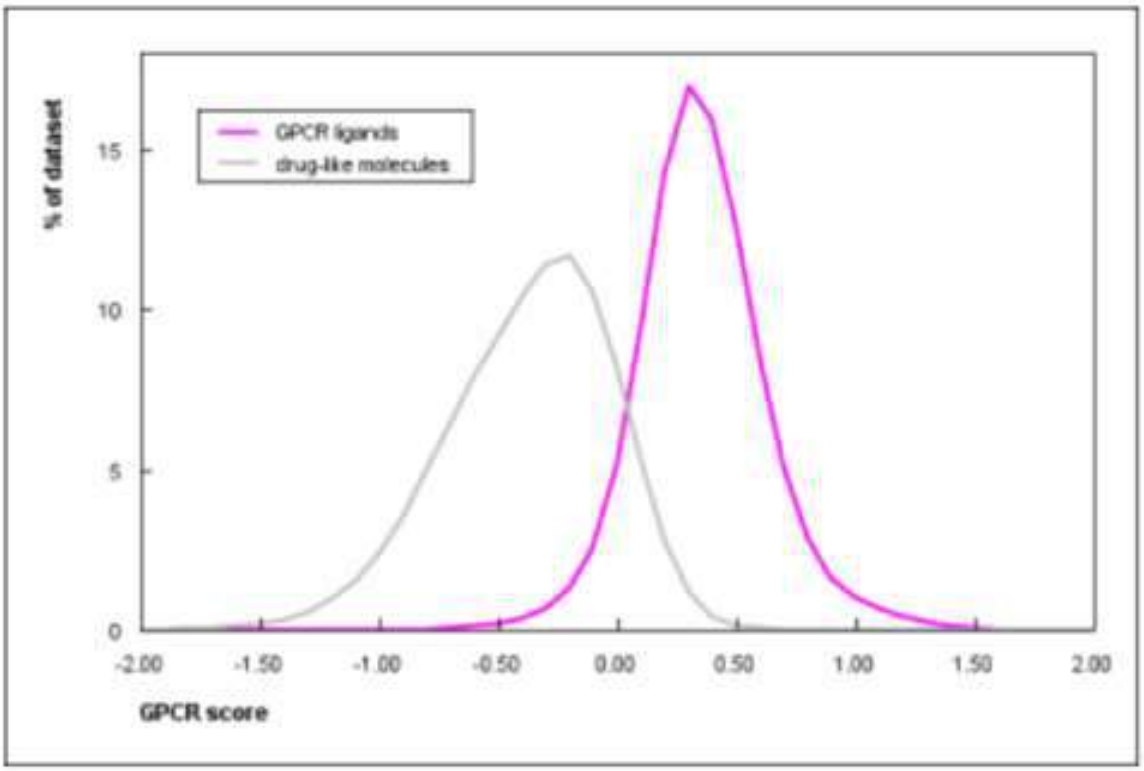
v. **Select: Predict Bioactivity**

6. DRUG LIKENESS

Drug likeliness is a qualitative means of analysis to check whether the given molecule is a drug or not and it is defined as a complex balance of various molecular properties and structural features which determine whether a particular molecule is similar to the known drugs. Activity of all test compounds and standard drug (Ampicillin) were analyzed under six criteria of known successful drug activity in areas of GPCR ligand, ion channel modulator, kinase inhibitor, nuclear receptor ligand, protease inhibitor and enzyme inhibitor by the molinspiration software.

i. GPCR Ligand

G Protein-Coupled Receptors (GPCRs) represent one of the largest and most important integral membrane protein families. These receptors serve as increasingly attractive drug targets due to their relevance in the treatment of various diseases, such as inflammatory disorders, metabolic imbalances, cardiac disorders, cancer, monogenic disorders, etc.



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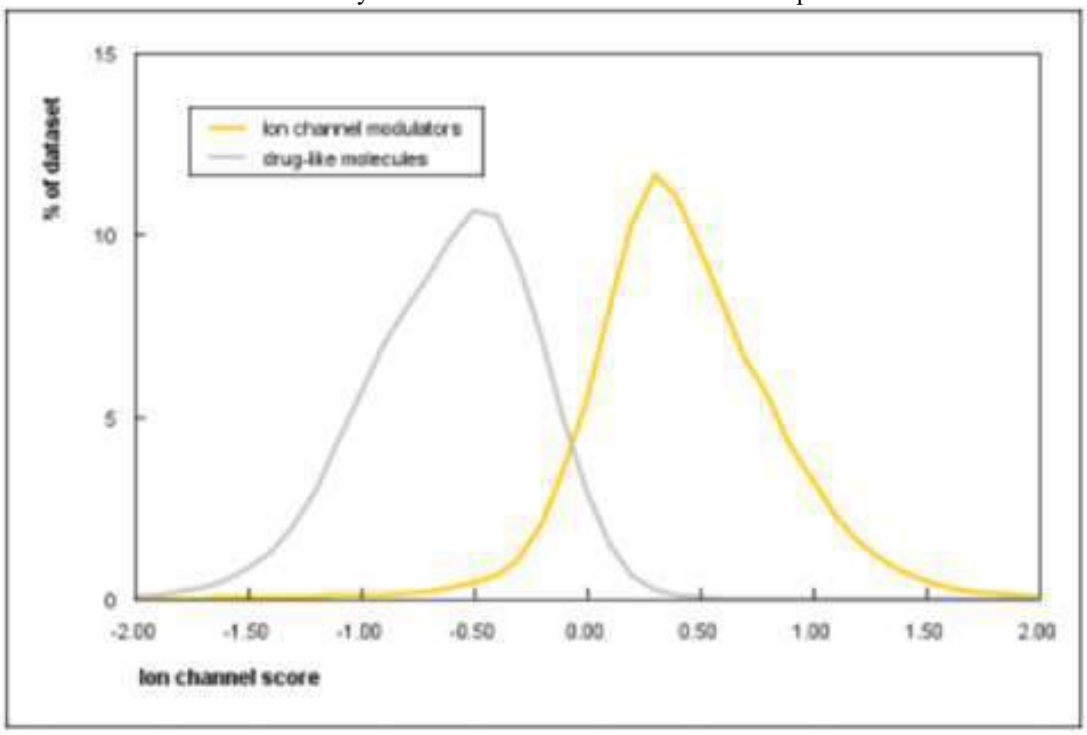
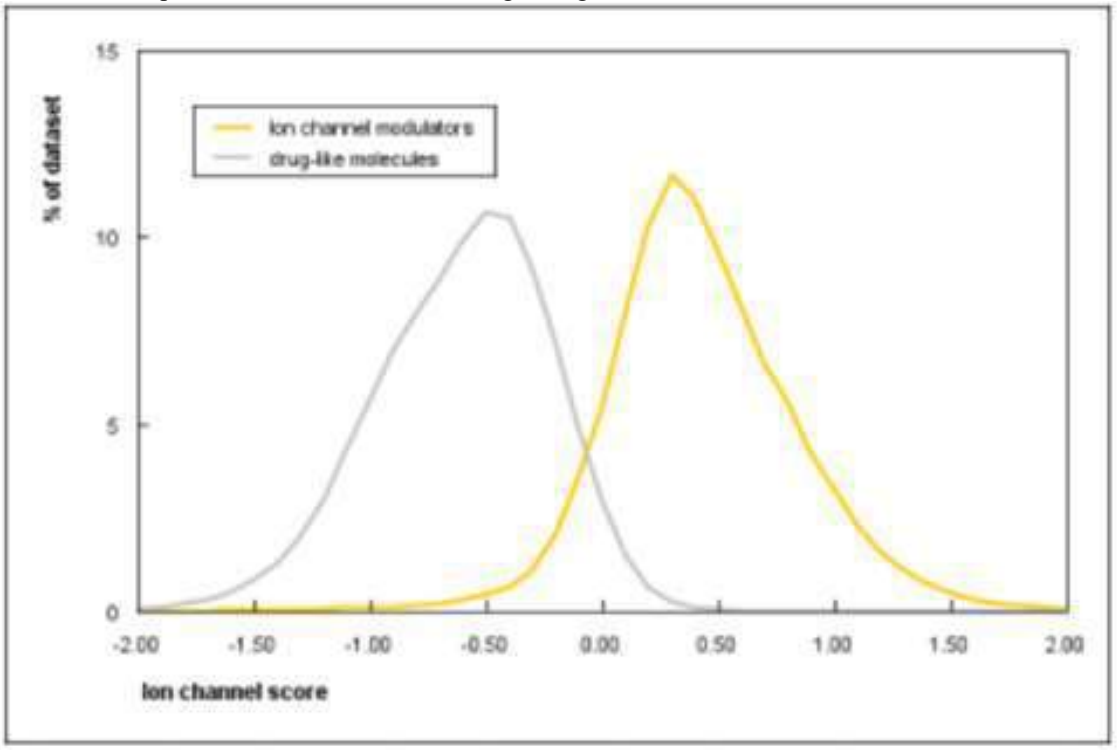
ii. Ion Channel Modulator

Ion channels are essentially pore-forming membrane proteins where some drugs may directly or indirectly interact leading to a change in action potentials and other electrical signals across the membrane. A channel modulator, or ion channel modulator, is a type of drug which modulates ion channels. They include channel blockers and channel openers.



iii. Kinase Inhibitor

A substance that blocks a type of enzyme called a kinase. Human cells have many different kinases, and they help control important functions, such as cell signalling, metabolism, division, and survival.



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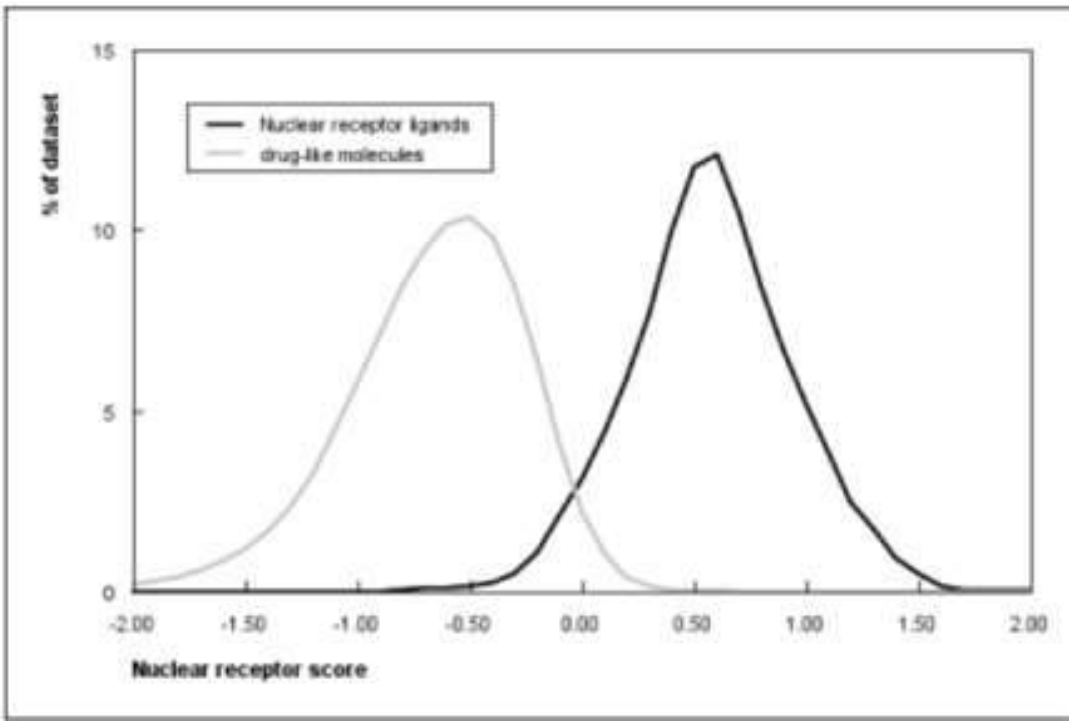
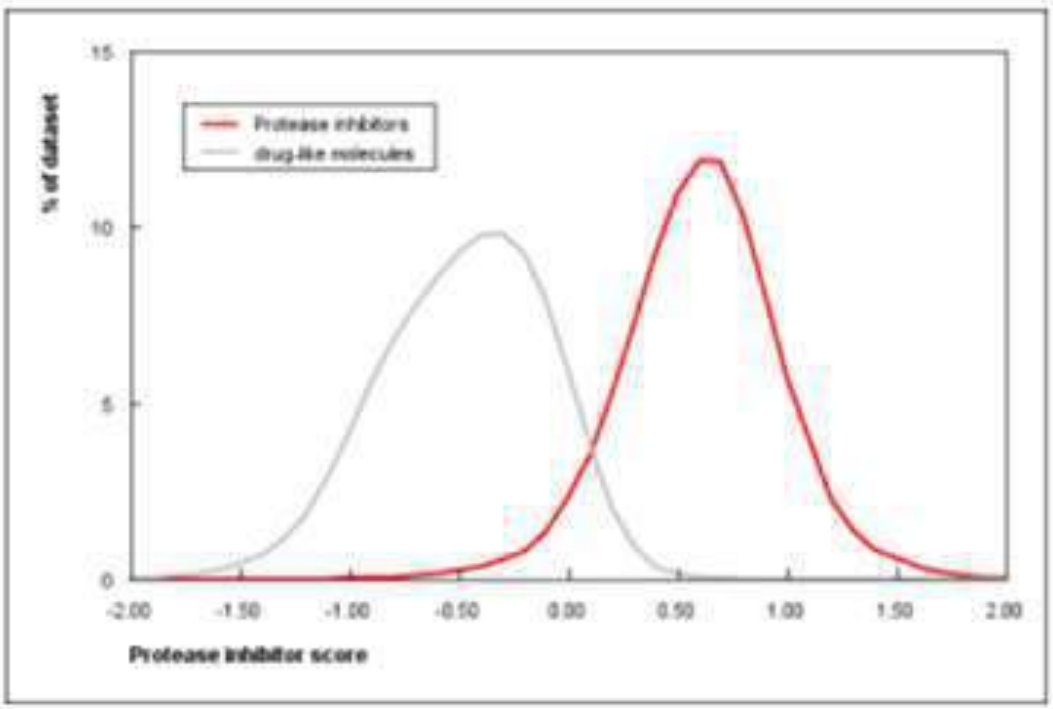
iv. Nuclear Receptor Ligand

Nuclear receptors are a family of ligand-regulated transcription factors that are activated by steroid hormones, such as estrogen and progesterone, and various other lipid-soluble signals, including retinoic acid, oxysterols, and thyroid hormone.



v. Protease Inhibitor

Medications that inhibit the cleavage of the polyprotein into functional proteins are called protease inhibitors. Protease is a protein-based enzyme that normally breaks the polyprotein into functional proteins, so blocking, or inhibiting, protease prevents this essential step of viral reproduction. Some protease inhibitors can keep a virus from making copies of itself (for example, AIDS virus protease inhibitors), and some can prevent cancer cells from spreading.



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7. PASS – A CRITICAL TOOL IN SEARCHING FOR 'MISSING INFORMATION'

New Definition of a post-authorisation safety study is "any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effective ness of risk management measures". However, previously, a post-authorisation safety study was defined as "a pharmaco epidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorization conducted with the aim of identifying or quantifying a safety hazard relating to an authorized medicinal product". One may therefore conclude that the amended definition of PASS aims to cover not only on-label, but also off-label studies, thus implying that any new safety information, based on the studies conducted outside the scope of the MA, ought to be communicated to the CAs and will be taken into account in the risk/benefit analysis of the product.

Depending on the type of the study, the medical objective and the size of the patient population to be observed, PASS can be conducted either as clinical trials of phase or as non-interventional (observational) studies. Unlike clinical trials, observational research provides data on how marketed products are actually being used in the real world without the restrictions of a controlled environment. In accordance with legal requirements, PASS may be requested by CAs either as a commitment at the time of authorisation or in the post-authorisation phase, for identifying previously unrecognized safety concerns. For certain medicinal products, applicants may receive a MA under the condition that they perform additional monitoring. In such cases the MA will be compulsorily varied to include the obligation as a condition of the MA and the risk management system has to be updated accordingly.

"Principally those non interventional post-authorisation safety studies where there is a known safety issue under investigation and/or when the numbers of patients to be included in the study will add significantly to the existing safety data for the product(s)", creating ambiguity in further defining of what does and what does not constitute PASS. Inconsistent interpretation of the PASS definition within and between companies resulted in various outcomes, varying from under- to over-reporting, including inadequate company oversight and tracking of PASS, non-inclusion of relevant study updates and reports in RMPs/Peri odic Safety Update Reports (PSURs) and the FDA annual reports, or the opposite - MAHs taking the conservative approach and including every post-marketing study in RMPs/ PSURs or generation/reporting of data irrelevant to safety. These misconceptions of PASS resulted in significant unnecessary work for MAH and CAs. In order to address the request of CAs in the most competent and efficient manner, careful analysis and definition of the study objectives, typically requiring a pharmacoepidemiology expertise, is of utmost importance.

8. ADVANTAGES AND DISADVANTAGES

❖ ADVANTAGES

- **Rapid Property Prediction:** Molinspiration allows for the quick and efficient prediction of various molecular properties, such as logP, logS, pKa, and more, which is essential in drug design and other chemistry-related applications.
- **User-Friendly Interface:** Its user-friendly interface is both intuitive and accessible to a broad spectrum of users, including those without extensive computational or programming knowledge.
- **Large Molecular Database:** Molinspiration is based on a comprehensive database of chemical compounds, enabling users to work with a broad range of chemical structures.
- **Versatility:** It can be used for a variety of tasks, including virtual screening, lead optimization, and ADMET (Absorption, Distribution, Metabolism, Excretion, and Toxicity) prediction.
- **Visualization Tools:** The software provides visualization tools for molecular structures and properties, making it easier for users to interpret and communicate their results.
- **Compatibility:** Molinspiration is compatible with various chemical file formats, facilitating data import and export.
- **Predictive Accuracy:** It has been widely used and validated in scientific research, demonstrating good predictive accuracy for many molecular properties.
- **Customization:** Users can customize and adapt the software to their specific needs and research goals.

❖ Disadvantages

- **Data Accuracy:** The accuracy of predictions heavily depends on the quality and relevance of the underlying data in its database. In some cases, the database may not include specific compounds or have limited representation for certain chemical classes.
- **Predictive Variability:** Prediction accuracy can vary for different properties and compounds. Some properties may be predicted with higher accuracy than others.
- **Sensitivity to Input Data:** The quality of input molecular structures and data can significantly impact the accuracy of predictions. Small errors or discrepancies in input data can lead to inaccurate results.

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- **Cost:** Molinspiration may require a paid license or subscription, which can be a disadvantage for users with budget constraints, especially in academic or small research settings.

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COMPLETE UTILIZATION OF FENUGREEK SEEDS CONSTITUENTS FOR CURING COMMON HUMAN PROBLEMS

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ABSTRACT
In Indian homes, herbs are highly valued for their medical properties. When their active ingredients are produced, they have been shown to arrest, diminish, and end the majority of diseases. Trigonella has been present on the continents of Asia, Europe, Africa, and Australia since prehistoric times. The species name "foenum-graecum" (meaning "Greek hay") suggests that it was once used as a feed crop. Traditionally, Trigonella foenum-graecum was used to cure a variety of illnesses. In addition to its medicinal properties, which include antidiabetic, anticarcinogenic, hypocholesterolemic, antioxidant, and immunological activities, fenugreek (Trigonella foenum-graecum) is a legume that has been used as a spice to improve the sensory quality of foods throughout the world. It is also used as an adhesive, emulsifying agent, and food stabilizer in the development of various food products, but most significantly, it is used to create wholesome and nourishing extruded and baked goods.Fenugreek (Trigonella foenum-graecum L.) is frequently used in Ayurvedic and Traditional Chinese medicine because of its many health advantages. Numerous substances, including alkaloids, amino acids, coumarins, flavonoids, saponins, polyphenols, carbohydrates, vitamins, and other bioactive substances, are found in its leaves and seeds.
KEYWORDS - *Fenugreek ,Trigonella foenum graceum,nutracuticals, Antioxidant, Antidiabetic, digestive stimulant, Anticancer, medicinal uses.*

REVIEW OF LITERATURE

1)Rashid R. Ahmad H. Ahmed Z et.al(2) -There are several uses for fenugreek as a spice, herb, food, and medication. Its active ingredients—galactomannan, trigonelle, diosgenin, and 4-hydroxyisoleucine—have a noticeable impact on diabetes management. In newly diagnosed type-2 diabetics, the impact of galactomannan derived from fenugreek on lipid profile, HbA1c, and fasting blood glucose was noted. Newly diagnosed type-2 diabetics (n = 64) were the subjects of a 12-week interventional randomized, single blind control research with a 4-week washout period. The group (n = 32) was given 1 gm/day of galactomannan following a rigorous randomization trial, whereas the control group (n = 32) was given a placebo. Three measurements of fasting blood glucose, HbA1c, and lipid profile were made: once at baseline, once after 12-weeks, and once following a 4-week washout period. Each variable's mean and SD were determined. Fasting blood glucose, HbA1c, total cholesterol, triglycerides, and low-density lipoprotein all significantly decreased in the study group. The high density lipoprotein did not increase considerably, although it did improve. The findings imply that low doses of galactomannan may be utilized as an alternate treatment for newly diagnosed type-2 diabetics to control their hyperglycemia and dyslipidemia.

2) Sajad Ahmad wani et.al(5) -Trigonella foenum-graecum, sometimes known as fenugreek, is a legume that has been used as a spice to improve the flavor of meals all over the world. It is well recognized for its therapeutic properties, which include immunological, antioxidant, hypocholesterolemic, anticarcinogenic, and antidiabetic effects. In addition to its therapeutic benefits, it is utilized as an emulsifying agent, food stabilizer, and adhesive in a variety of food product advancements. More significantly, it is employed in the creation of wholesome and nourishing extruded and baked goods. The current study examines the nutraceutical qualities of fenugreek and how it is used in different product development.

3)Uma maheshwari shrinivas et.al(15)- The seeds of fenugreek (Trigonella foenum-graecum L.) are used extensively in both traditional medicine and culinary dishes. The bioactive components of fenugreek, including diosgenin, 4-hydroxyisoleucine (4-HIL), trigonelline, galactomannan (GM), and polyphenols like quercetin, are typically responsible for its biomedical properties. Fenugreek seeds have been shown to have positive effects on a number of physiological markers associated with diabetes mellitus (DM). They also

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have a role as a dietary modulator on metabolism, physiology, and biological mechanisms of action that are pertinent to DM and other lifestyle diseases. Antioxidation, immunomodulation, inflammation, digestive stimulation, antibacterial activity, and galactagogue are further aspects of its nutraceutical qualities. Consequently, fenugreek seed is a miracle spice.

4)Nasim khorshidian et.al(14)- Native to southern Europe and Asia, fenugreek (Trigonella foenum graecum) is an annual herb with white flowers and firm, angular, yellowish brown seeds. In addition to its therapeutic benefits, fenugreek has long been valued for its nutritional content. Gum, fiber, alkaloids, flavonoids, saponins, and volatile content are all abundant in fenugreek seeds. Because of its high fiber content, fenugreek can be used as an adhesive, food stabilizer, and emulsifying agent to alter the texture of food for certain uses. Fenugreek may also be considered an antidiabetic, anticarcinogenic, antioxidant, antibacterial, antianorexic, and stomach stimulant, according to some data. It may also be used as a treatment for hypocholesterolemia and hypoglycemia. Reviewing fenugreek's possible uses as a nutraceutical and functional food is the goal of this essay.

INTRODUCTION

Fenugreek, or Trigonella foenum graecum, is a member of the Fabaceae family. This herb has medicinal properties and is used to treat a wide range of illnesses, including cancer, diabetes, inflammation, hypercholesterolemia, reproductive issues, and neurological diseases. Fenugreek seeds have been used as stomachic, expectorant, demulcent, carminative, and laxative for ages [1].Though it was first cultivated in Eastern Europe, it is now grown throughout. The phytochemicals that give it its pharmacological properties include flavonoids, alkaloids, coumarins, vitamins, carbohydrates (galactomannan), saponins, diosgenin, trigonelline, and soluble fibers. Its anti-diabetic, anti-sterility, and anti-fertility actions have been demonstrated in a number of clinical and pre-clinical investigations. Additionally, it controls the synthesis of enzymes that lower cholesterol and manage blood sugar levels[2].In order to lessen oxidative stress, it also controls detoxifying and antioxidant enzymes. Fenugreek's flavonoids and saponins stop the creation of carcinogen-DNA adducts, which in turn prevents the genesis of tumors[3].It is known by several names in several languages, including Fieno greco (Italian), Bockshorklee (German), Methi (Hindi), Fenugrec (French), Alholva (Spanish), Koroha (Japanese), Halba (Malaya), Hulba (Arabic), and Pazhitnik (Russian)[4].Fenugreek seed contains roughly 25% dietary fiber, which modifies food texture. Because of its high fiber, protein, and gum content, it is utilized as an emulsifying agent, glue, and food stabilizer these days. It is discovered that fenugreek protein is more soluble at alkaline pH levels[5].It has a wealth of minerals and other beneficial components, including steroidal saponins and protein, vitamin C, niacin, potassium, diosgenin, alkaloids, lysine, and L-tryptophan[6].Fenugreek has long been known to have health benefits when consumed as vegetables, food supplements, or medical treatments. Although it has been utilized by numerous cultures, Asia and the Mediterranean region have been its primary users[7].Diosgenin increases apoptosis, inhibits proliferation, and inhibits invasion brought on by tumor necrosis factor. Sperm cell count, motility, and total and free testosterone can all be increased by fenugreek seeds, which benefits both sexual and physical health[8].Fenugreek is a winter crop, so it can withstand cold temperatures and frost. It grows best in areas with moderate to low rainfall, and it performs best in loam and clayey loam soils with adequate drainage[9].

Nutritional Information

One tablespoon, or 11 grams (g), of whole fenugreek seeds contains 35 calories and several nutrients, including :

Nutritional Information	Percentage
Fiber	3g
Protein	3g
Carbs	6g
Fat	1g
Iron	21% of the Daily value (DV)
Manganese	6% of the DV
Magnesium	5% of the DV
Phosphorous	3% of the DV

Table no :1(Nutritional information about Fenugreek)

Fenugreek Seeds

Fenugreek seeds are used in relatively larger amounts to make soups and pan cakes, as well as a spice and flavoring agent. It works well as a stomach stimulant and against anorexia in India's traditional medical system[10].You can eat fenugreek seeds raw or cooked. They are aromatic, bitter, carminative, galactogogue, and antimicrobial. 50% of the seed is made up of inaccessible carbohydrates[11].Fenugreek seed has several therapeutic uses, including anticancer, hypocholesterolemia, lactation support,

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antimicrobial, stomach stimulant, anorexia treatment, antidiabetic agent, and galactogogue. Fenugreek's physiological benefits, such as its antidiabetic and hypocholesterolemic properties, are mostly attributed to its intrinsic dietary fiber content, which has shown promise as a nutraceutical[12].Each 100 grams (g) of fenugreek seeds comprises 60% carbohydrates, 25% dietary fiber, 23 g protein, 6 g lipids, and 9 g water. Fenugreek is particularly rich in potassium, phosphorus, magnesium, and calcium. Fresh fenugreek leaves contain about 86% water, 6% carbohydrates, 4% protein, and about 1% each of fiber and fat[13].Fenugreek seeds, which are available whole or ground, have a pleasant bitterness and subtle sweetness that is used to flavor a variety of meals, such as curry powders, spice blends, and teas. The seed has a core, hard, yellow embryo surrounded by a horny, comparatively large coating of white, semi-transparent endosperm [14].The firm seeds of fenugreek are brownish-yellow when grown up. They have a a unique, fragrant scent and are employed in cooking, food items, alcoholic beverages, and non-alcoholic drinks [15].

Fig no.1- Fenugreek seeds

Nutracutical Properties

a)Anticancer Effect

One of the major causes of death worldwide is cancer. Numerous published research employing cell lines or experimental animals have demonstrated the preventive effect of fenugreek seeds in cancer models[16].Fenugreek contains a bioactive compound, 'diosgenin,' which is an anti-cancer agent.Thymoquinone and diosgenin have anti-neoplastic properties because they inhibit Akt and JNK phosphorylations, promote the expression of apoptotic genes and caspase activity, and stop cell division. These two bioactive substances have anti-proliferative qualities as well as synergistic effects[17].The cytotoxic quality of fenugreek has been demonstrated to be helpful in the management and prevention of cancer[18].When rats were given 1,2-dimethylhydrazine, a diet containing fenugreek seed powder reduced the incidence of colon tumors and hepatic lipid peroxidation. It also enhanced the activities of catalase, superoxide dismutase, glutathione S-transferase, and glutathione peroxidase in the liver[19].

b)Antibacterial and Antifungal Effect

Fenugreek is a valuable source of physiologically active compounds that can be used to create more effective and innovative antifungal medications.Multiple studies have reported the efficacy of fenugreek extracts against Helicobacter pylori.According to a study, fenugreek pollens are more abundant in honey samples with the most antibacterial action against Staphylococcus aureus, Pseudomonas aeruginosa, and Escherichia coli than in flowers.The fenugreek can be used in the treatment of patients with calcic urolithiasis[5].Among other herbal extracts, fenugreek's antibacterial potential has gained popularity. Studies have been conducted on the efficacy of fenugreek against various microorganisms.Bioactive substances found in fenugreek leaves include glycosides, ascorbic acid, phenolic compounds, and flavonoids such as quercetin, vitexin, and kaempferol. These flavonoids also function as a bioactive source or reducing agent for the creation of silver nanoparticles[3].

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C)Gastroprotective Effects

Gastric ulcer treatment is one of the traditional uses of fenugreek. On rats with ethanol-induced stomach ulcers, the ulcer-preventive potential of fenugreek seeds was investigated in comparison to omeprazole.The presence of flavanoids in fenugreek may be responsible for its antiulcer properties, as they have been shown to shield the mucosa from the development of ulcerative lesions caused by a variety of necrotic agents[7]. Unhealthy eating habits and lifestyle choices cause peptic ulcers, gastric ulcers, nausea, vomiting, and discomfort in the abdomen. Numerous research have demonstrated fenugreek's protective properties against gastrointestinal disorders. It has anti-inflammatory, anti-ulcer, gastroprotective, antioxidant, and anti-secretory qualities[3].

d) Antidiabetic Effect

It has been observed that fenugreek's bioactive ingredients, such as galactomannan, saponins, trigonella, diosgenin, and 4-hydroxy-isoleucine, have beneficial benefits on diabetes. Numerous distinct components have been identified. Research has shown how they affect blood sugar[3].By restoring pancreatic B-cell function and blocking, among other many physiological mechanisms, fenugreek regulates diabetes. activity of alpha-amylase and sucrase. 4- Pancreatic B-cells secrete insulin in response to hydroxyisoleucine. The fenugreek saponin extract has demonstrated hepatoprotective, hypolipidemic, and anti-diabetic properties[20].The high fiber content found in fenugreek powder or seeds could also be beneficial for supporting blood sugar control, even in people without diabetes[21].

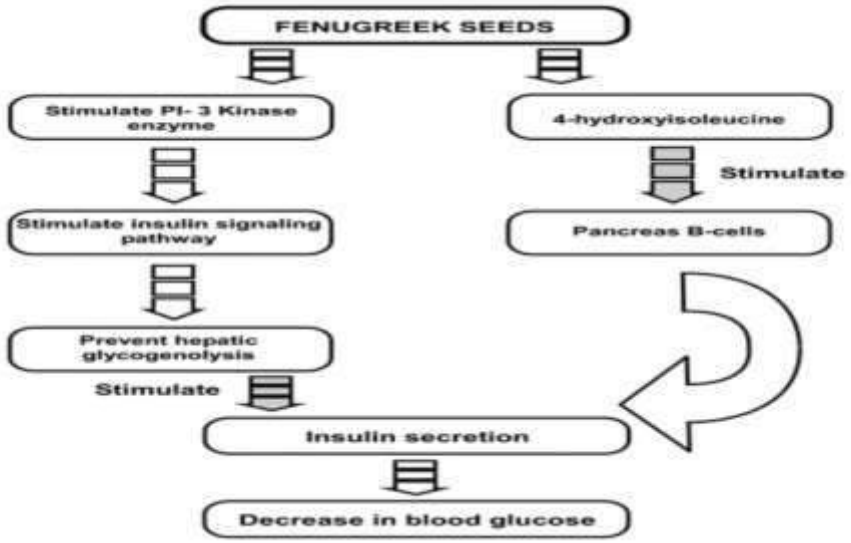

Fig no : 2 (Mechanism of action of Fenugreek in diabetes)

e) Antioxidant Effect

Nowadays, it is believed that oxidative damage at the cellular or subcellular level plays a significant role in the development of diseases such as diabetes, cancer, inflammatory diseases, coronary vascular disease, and aging. Both the mitochondria and the genetic material of cells are harmed by reactive oxygen radicals. They cause significant membrane damage and membrane-mediated chromosomal damage by inducing lipid peroxidation in cellular membranes[22]. By using a soxhelt extraction method and a variety of solvents, including ethanol, methanol, acetone, ethyl acetate, dichloromethane, and hexane, crude extracts of fenugreek were produced. The total phenolic content, chelating activity, flavonoid content, antioxidant/radical scavenging activity, reducing powder, and free radical scavenging activity of the extracts were measured using the Folin-Ciocalteu technique. The findings demonstrate the antioxidant activity of all fenugreek extracts[23].

f) Other Properties of Fenugreek

Fenugreek leaves and seeds were recommended due to their haematinic properties. High levels of iron have reportedly been found in the seeds, and fenugreek germination increases the amount of vitamins A, B, and C in the plant. Rich in vital amino acids, ascorbate, and folate, they provide restorative and nutritional qualities and have been shown to increase hemoglobin levels in the blood[24].Fenugreek has also been used to shield the liver from hepatotoxicity caused by ethanol[25].Additionally, fenugreek has been shown to be an effective adjuvant treatment for Parkinson's disease patients when used in conjunction with L-Dopa [26].In other investigations, fenugreek seed extract shown analgesic benefits, possibly through reducing inflammation[27].

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g) feenugreek Seeds for Hairs

Methi seeds work wonders to reverse baldness and hair thinning, as well as to combat dandruff and hair loss. Nicotinic acid and proteins included in fenugreek seeds, also known as methi, are excellent for hair development. Large quantities of lecithin, which moisturizes and strengthens hair, are present in it. It heals a range of scalp disorders, cures dandruff, conditions hair, keeps the scalp cool, and lessens dryness in the hair. It gives strength from the roots and is very helpful against hair loss. Methi's lecithin aids in repairing and regrowing dry, damaged hair. The natural tonic aids in hydrating hair and restoring its shine and bouncy texture. A common condition affecting hair, dandruff appears especially[28].It works well for treating dermatitis and dry scalps as well. The emulsifying agent lecithin is found in fenugreek seeds. The seeds release a slick material that gives hair a glossy appearance when soaked in water. Methi seeds are the best option for conditioning hair because of this feature. Fenugreek mucilage mimics that slick appearance. Reversing baldness is one of fenugreek's most well-liked hair applications. Hormone precursors found in fenugreek promote hair development and aid in fortifying and regenerating hair follicles[29].

h) Controlling Rheumatoid Arthritis

Rheumatoid arthritis is a joint condition characterized by tissue damage and synovial growth, resulting in persistent inflammation. A significant contributor to increased joint discomfort and pain is elevated energy expenditure as well as pro-inflammatory cytokines like interleukin (IL-6) and tumour necrosis factor-alpha (TNF-α)[30].As an autoimmune disease, rheumatoid arthritis has been linked to estrogen-like substances that have been shown to reduce tissue inflammation by binding to DNA and initiating pathways that mitigate the effects of autoimmune diseases[31].

Utilization of Fenugreek in Various Food Products

a) Fenugreek as food stabilizer, Food Adhesive, Food Emulsifier And Gum

The ability of the fenugreek protein to stabilize and emulsify the dietary ingredients depends on how it interacts with them.Due to its galactomannan composition, fenugreek's dietary fiber has the potential to be widely used in the food sector for its emulsifying and stabilizing qualities.Dietary fiber from fenugreek has been utilized to make baked items like cakes, bread, pizza, and muffins. The addition of fenugreek to flour enables the creation of nutritious meals that might be well-liked by people following western diets.

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b)Fenugreek in Bakery Products

A good source of dietary fiber and numerous essential minerals is the husk of fenugreek seeds. You may make high-fiber muffins using this fiber-rich functional ingredient.The bread retained the beneficial effect of fenugreek, which lowers insulin resistance. Consequently, this study clearly shows that fenugreek can be used in baked goods up to a reasonable amount, which can help treat diabetic patients and lower insulin resistance.Biscuits made with up to 10% fenugreek flour have been produced without sacrificing their overall quality. Overall, the most favorable composite fenugreek flour biscuits were those with 10% germinated fenugreek flour based on their physical, sensory, and nutritional qualities.The research verified that fenugreek seed—raw, soaking, and germinated—substantially decreased serum total cholesterol, LDL cholesterol, and total lipids; however, triglycerides and serum HDL cholesterol did not change significantly.Fenugreek leaves, seeds (both dry and germinated), and wheat flour added with 5-10% of the grain's dry and germinated fenugreek powder enhanced the amount of total proteins, fibers, iron, zinc, calcium, vitamin B, carotene, vitamin E, and vitamin C in basal diets. These dietary supplements have nutritional and restorative qualities since they also help anemic rats' blood image. It is safe and healthful to use fenugreek products as dietary supplements on a daily basis.

c)Fenugreek in Traditional Food

A common dish in Turkey is fenugreek paste, also known as "Cemen," which is made from mashed fenugreek seeds. The balls used to produce clarified butter are made from crushed fenugreek seed or coarse fenugreek powder[12].

d) Fenugreek gum as a stabilizer in Ice Cream

To determine the effects of various fenugreek gum concentrations as an ice cream stabilizer, a research named "Utilization and evaluation of fenugreek (Trigonella foenum graecum) gum as a stabilizer in ice cream" was conducted. After the mucilage from fenugreek (HM-57) seeds was removed, 20% of the gum could be produced. The gum was evaluated for its acceptability as a stabilizing agent in ice cream. Gum was incorporated into the ice cream at concentrations of 0.5%, 1.0%, 1.5%, and 2.0% before its physical and sensory qualities were evaluated.Furthermore, it was discovered that as fenugreek gum was added in greater amounts, the overrun and melting characteristics of the ice cream improved. Fenugreek gum is a good natural stabilizer that can be added to diabetic products. It has been demonstrated to be effective in ice cream[32].

CONCLUSION

This review discusses the benefits of fenugreek, including its anti-diabetic, anti-cancer, Antibacterial and antifungal, Gastroprotective effect, Antioxidant, controlling rhematoid arthritis, for hair, other properties of Fenugreek. Significant bioactive substances have been discovered in fenugreek.also discuss the Utilisation of Fenugreek seeds in various food products.This review revealed that fenugreek has been utilized as a gum, food emulsifier, food stabilizer, and food glue. Several kinds of baked goods and extruded products have been made with fenugreek. Given the numerous health benefits that have been reviewed in this article and the numerous previously published scientific studies supporting them, fenugreek is safe to use liberally and offers a host of health advantages. As such, it is suggested that we incorporate it into our daily diet.

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MOST MEDICINAL FRUIT- BAEL

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ABSTRACT

The Indian traditional medical system, Ayurveda, and diverse forms of folk medicine make considerable use of leaves, bark, roots, fruits, and seeds to treat a wide range of illnesses. Bael fruits are edible, and the pulp is used to make puddings, juice, and murabba, among other treats. Bael fruits are also utilised in many traditional treatments as a laxative, to cure respiratory ailments, and to treat gastric ulcers, diarrhoea, and dysentery. Numerous traditional medical practices have been confirmed by scientific research, and accounts suggest that the fruit has a wide variety of therapeutic benefits, such as antioxidant, prevention of free radical production, and scavenging of free radicals.[1] India is the world's largest producer of medicinal herbs, making it the botanical garden of the globe. Since Charak (1500 B.C.), Bael (Aegle marmelos) has been recognised as one of India's most significant medicinal plants. Bael, or Aegle marmelos, is a medium-sized deciduous tree in the Rutaceae family. It is sometimes referred to as golden apple or Bengal quince. This tree's entire range of parts, including the stem, bark, root, leaves, and fruit at all phases of development, have long been utilised in traditional medicine due to its medicinal qualities. When the fruit is just starting to ripen, it has significant medicinal benefit. Ripe fruit has laxative, cooling, astringent, and fragrant properties. The unripe or partially ripe fruit has digestive, anti-scorbutic, and stomachic properties. ripe[2]. Aegle marmelos, a member of the Rutaceae family, is well-known in traditional medicine as Bael and has a number of therapeutic uses, most notably as a cooling agent. It is indigenous to India and can be found all over South Asia. Bael is one of the most underappreciated and neglected fruit crops used for medicinal purposes. It is thought to contain a storehouse of nutrients and remedies. A variety of medical conditions can be treated with the various portions of the bael tree, including asthma, anaemia, fractures, wound healing, swollen joints, high blood pressure, jaundice, diarrhoea, good mental state, and brain typhoid problems during pregnancy. Bael is well known for its pyretic, analgesic, and anticancer properties. It also relieves constipation. Numerous phytochemicals have been identified and isolated from diverse[3] Aegle marmelos (Linn.) Correa ex Roxb., or Bael, is a medium-sized tree of Indian origin that can reach an elevation of 1200 meters. This adaptable tree species contains a wide range of coumarins, alkaloids, sterols, and essential oils in its leaves, roots, seed, bark, and fruit, among other parts. With the use of various post-harvest technologies, the fruits are also used to prepare a wide range of byproducts, including candy, panjiri, toffee, jam, and so on. This helps to reduce post-harvest losses and therefore increases the shelf life, which further aids in value addition and in generating a good income for[4]

KEYWORDS: *Beal,traditional plant,medicinal value,aegle marmelos, underutilized tree.*

INTRODUCTION

The majority of the tree's components, including the fruit, blossoms, roots, bark, leaves, and stem, have health benefits at every stage of development (Maity, 2009). This medium-sized tree can be found growing throughout India's jungles at an elevation of 1,200 meters. It can be found across the sub-Himalayan forests of Bengal, central, and southern India. The fruit's peel is composed of a tougher shell that ranges in colour from green[5]Bael is beneficial for treating a wide range of illnesses because it includes a variety of phytochemicals, including polysaccharides, gums, resins, essential oils, tannins, and alkaloids. Its nutritional value is far greater than that of other fruits. It is quite significant for the ecosystem as well. Compared to other trees, it releases a higher percentage of oxygen, acting as a climatic cleaner. Many important medicinal uses exist for it, including antifungal, analgesic, anti-inflammatory, antipyretic, hypoglycemic, anti-lipidemic, immune-modulatory, wound-healing, anti-fertility, and insecticidal properties.[6] therapeutic potential and it is belong to family Rutaceae, it is known by outside of the country (Sharma et al. 2007). In India, the plant is widely cultivated particularly in Uttar Pradesh and Bihar.[7] Fruits are considered to be protective since they are high in minerals, vitamins, and phytochemicals. Fruits are a great source of soluble dietary fibre, which lowers blood fat and cholesterol levels and facilitates easy bowel movements. In general, fruits have much higher antioxidant levels than vegetables, pulses, and cereals. Antioxidant qualities aid in the body's elimination of free radicals, protecting against a variety of infectious and chronic illnesses. In many ways, underutilised fruits are just as significant as economically developed fruit harvests. The word "underutilised" crop has been described in a variety of ways in international literature; the majority of these definitions have placed emphasis on characteristics such as connections to the cultural history of the[8]

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Traditional Uses of Bael Fruit

Bark

Fig1[11]

Chemical Component

coumarin, xanthotoxol, imperatorin, aegeline, and marmeline.

Use:-used to treat jaundice, diarrhoea, small pox and asthma. The decoction of root and bark is used in the treatment of fever.

Fruit

Fig.2[12]

Chemical Component

carotenoids, phenolics, alkaloids, pectins, tannins, coumarins, flavonoids, and terpenoids,

Uses

Bael fruits are also used in the treatment of chronic diarrhea, dysentery, and peptic ulcers, as a laxative and to recuperate from respiratory affections in various folk medicines.

Leaf

Fig3[13]

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Chemical Component
coumarin, xanthotoxol, imperatorin, aegeline, and marmeline.

Uses
constipation, diarrhea, diabetes, and other conditions.

Flower

Fig4[14]

Chemical Component:-coumarin, xanthotoxol, imperatorin, aegeline, and marmeline.

Uses: Skin care,diarrhoea, diabetes, constipation.

Pollination and Fruiting Pattern
According to Singh et al. (2014h and 2018d), the stem is short, thick, soft, and has spreading, occasionally spiky branches with the bottom ones drooping. The bark is peeling. Additionally, it has been noted that the bael germplasm occasionally contains 4- 8 leaflets rather than trifoliate leaflets (Singh et al., 2015b, 2019e, 2019f). Singh et al. There is a significant variance in the quantity, size, form, and orientation of thorns in[9]

Fig5[15]Cauliflorus flowering and fruiting pattern in bael under semi-arid conditions

The kinds having a longer flowering period may serve as a long-term resource which allows the existence of a consistent population of (Singh pollinatorset al. 2008). Some flowers may have petals that open all at once, while others may have petals that open one at a time,

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taking 45 to 60 minutes to fully open. The anthers and floral organs shrink and turn brick red following dehiscence as time goes on, and the petals' openings in individual flowers might differ from flower to flower within the same genotype (Singh et al. 2018a).

Fig.6[16]Different pollinating agents of bael flowers genetic resources and varietal wealth.

Bael Used for Diarrhoea:

This study aimed to review Aegle marmelos's anti-diarrheal properties. The Unit of Siddha Medicine library at the University of Jaffna is where the Siddha literatures were found. For the analysis, information was gathered from books and the internet and tallied. The Rutaceae family includes the Beal Fruit Tree (Aegle marmelos), also known by the Tamil names Vilvam, Kuvilam, and Sinhala name Belli. Because of all of its therapeutic benefits, it is the most valued medicinal plant in the Siddha medical system. It's a deciduous tree, modest to medium in size. It has a globose fruit that is grey or yellowish in colour, alternating leaf arrangement, greenish white blooms, and a large number of seeds. found in Sri Lanka. Fruit (both ripe and unripe), leaves, the peel of ripe fruit, roots, bark, and flowers are all utilised.

Unripe fruit contains astringent, stomachic, digestive, and slightly constipating properties. Siddha claims that Aegle marmelos reduces Vatha, Pitha, and Kapha doshas and has an astringent, bitter taste. It is also spicy and potent. Diarrhoeal illnesses rank among the most prevalent infectious diseases in the world, accounting for 3.2% of all fatalities annually, or the equivalent of 1.8 million deaths worldwide. This review makes it very clear that Aegle marmelos is a significant medicinal herb that is widely utilised in traditional medicine, Siddha, Ayurveda, and Unani. Aegle marmelos has served a variety of ethnobotanical functions throughout history. Based on the facts gathered, it appears that Aegle marmelos possesses anti-diarrheal properties.[16]

Flavonoids, coumarins, and tannins are some of the compounds found in bael. These compounds help to minimise swelling (inflammation). This may aid in the treatment of diarrhoea, asthma, and other ailments. Additionally, several of these substances aid in lowering blood sugar.[17]

CONCLUSION

1. We may conclude that modern technology should be considered for the highest grade bael production. Improved cultivars, dense planting, drip irrigation, plant growth regulators, canopy and nutrient control, and high planting density are some of the

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main horticultural treatments that affect plant health, flowering, and yield. Fruit quality—specifically, fruit size, pulp colour, and aroma with the ideal minimum residue limit—should be the primary focus for the export market. Bael is a fruit crop that may be grown sustainably on small holdings because of its adaptability to a variety of topographies and agroclimatic conditions. Furthermore, it offers plenty of possibilities for nutritional.

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SYZYGIUM CUMINI'S (JAMUN) PHARMACOLOGICAL CHARACTERISTICS AND THERAPEUTIC POTENTIAL

Ms. Vaishnavi M. Poul, Dr. Rani Mhetre, Dr. Vijay Sable

ABSTRACT

Commonly referred to as Java Plum, Blackberry, Black Plum, or Jambul, JAMUN (Syzygium cumini) is a huge, glabrous, evergreen tree that grows in Australia, Malaya, Sri Lanka, and India. The trees bear rectangular or ellipsoid berries every year. When fully ripe, they turn purple black, yet when raw, they are green. The ripe fruits taste rather tart and sweet. According to studies, the berries are rich in minerals, carbohydrates, and pharmacologically active phytochemicals such anthocyanins, terpenes, and flavonoids. Among the several compounds included in the plant are anthocyanins, glucoside, ellagic acid, isoquercetin, kaemferol, and myrecetin. The seeds are said to contain the glycoside jambolin or antimellin and the alkaloid jambosine, which prevent starch from being converted to sugar diasterately. The database's extensive collection of literatures shown that extracts from various jamun sections exhibited notable pharmacological effects. A plant noted for its ethnomedical applications is jamun. Numerous pharmacological properties, including antibacterial, antifungal, antiviral, antigenotoxic, anti-inflammatory, anti-ulcerogenic, cardioprotective, anti-allergic, anticancer, chemopreventive, radioprotective, free radical scavenging, antioxidant, hepatoprotective, anti-diarrheal, hypoglycemic, and antidiabetic effects, have been demonstrated by scientific studies to be present in the different extracts of jamun. Bark, seed, and leaf extracts are too helpful in the management of diabetes. The primary focus of this review is the medicinal value of jamun plants and how they can be used to treat a range of illnesses.

KEYWORDS: *JAMUN (Syzygium cumini) cardioprotective, cervical cell lines.*

INTRODUCTION

Since ancient times, people have utilized plants as medicine to treat a wide range of illnesses, making them extremely beneficial. The gift of nature that calms the mind and heals the body has long been sought after by man. In India, jamun is regarded as a native and significant minor crop. This tropical evergreen tree is indigenous to Bangladesh, India, Nepal, Pakistan, Sri Lanka, the Philippines, and Indonesia. This fruit crop is resilient. Its towering, evergreen tree becomes partially deciduous during droughts. India is where jamun originated. It can be found growing wild all around the nation. With a height of 2530 meters and a stem girth of 3–4 meters, Jamun is a huge evergreen tree.This tree has a lovely shape and is cultivated along the roadsides of Bunds Road for its mouthwatering fruits, shade, and windbreak. A crop that is cross-pollinated is jamun. Fruits are produced by this tree for as long as 60 to 70 years[1]. There have been reports of the medicinal benefits of several plant parts, including the leaves, seeds, and bark. It is particularly helpful in the treatment of diabetic mellitus, ulcer, antioxidant, antibacterial, anti fungal, nitric oxide scavenging, free radical scavenging, antimicrobial, anti HIV and radioprotective measures. In ancient times, ayurveda made use of seeds, barks, flowers, and leaves[2]. The plant's bark has antibacterial, digestive, anthelminthic, febrifuge, sweet, carminative, diuretic, astringent, and stomachic properties. Diabetes, ringworm infection, spleenopathy, pharyngitis, and urethrorrhea are all treated with the fruits and seeds. The leaves have been widely used to prevent blood discharges in the feces, cure diabetes, leucorrhea, and constipation. The plant's bark has antibacterial, digestive, anthelminthic, febrifuge, sweet, astringent, carminative, diuretic, and constipating properties. Diabetes, ringworm infection, spleenopathy, pharyngitis, and urethrorrhea are all treated with the fruits and seeds. The leaves have been widely used to prevent blood discharges in the feces, cure diabetes, leucorrhea, and constipation[3].

Morphological Characteristics of Syzygium Cumini (Jamun)

Jamun is a huge, highly foliaceous, evergreen tree with thick, greyish-brown bark that exfoliates in woody scales. The wood produces brown dyes and a form of gum called Kino. It is white, close-grained, and long-lasting. The leathery, oblong-ovate to elliptic or obovateelliptic leaves are 6 to 12 centimeters long, smooth, glossy, and have many nerves that unite within the edge. The tip is broad and less acuminate. The panicles, which are 4 to 6 cm long and frequently axillary or terminal, are borne mostly from the branchlets beneath the leaves. Round or rectangular in shape, the fragrant, greenish-white flowers are found in dichotomous paniculate cymes and can be found in clusters of only a few or 10 to 40.The calyx is serrated, funnel-shaped, and roughly 4 millimeters long. The petals fall as a single, tiny disk because they are cohesive. The stamens are roughly as long as the calyx and are quite numerous. Numerous varieties with varying fruit sizes and colors have been created, including some enhanced races with seedless fruits and flesh that is purple to violet

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or white in color. Typically rectangular, 1.5 to 3.5 cm long, dark-purple or almost black, delicious, juicy, and tasty, the berries have a single big seed[4].

Parts Are Used
(Leaves, Stem bark, Flowers, Fruit, Seeds)
Phytochemical constituents

Leaves

Diagram 1

After being extracted in methanol and water, the leaves of the jamun plant were examined for the presence of several phytochemicals. A variety of alkaloids, flavonoids, glycosides, steroids, phenols, tannins, saponins, and cardiac glycosides have been discovered in both aqueous and methanol extracts[5], Myricitin, myricetin 3-O-4-acetyl-L-rhamnopyranoside, quercetin, and myricetin[6].

Stem Bark

Diagram 2

The stem bark is abundant in betulinic acid, friedelin, β-sitosterol, eugenin, and fatty acid ester of myricetin, gallic acid, ellagic acid, quercetin, and kaempferol[7], bergenins, flavonoids and tannins[8].

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Flower

Diagram 3

Kaempferol, myricetin, isoquercetin (quercetin-3-glucoside), myricetin-3-L-arabinoside, quercetin-3-D-galactoside, dihydromyricetin, oleanolic acid, acetyl oleanolic acid, eugenol-triterpenoid A, and eugenol-triterpenoid B are abundant in the flowers[9].

Fruit

Diagram 4

Fruits contain malic acid as the major acid, a small quantity of oxalic acid is also reported to be present, Gallic acid and tannins account for astringency of the fruit. The fruit's purple hue results from the presence of cyaniding diglycosides. Fruits contain glucose, fructose, mannose, galactose, non-reducing sugar (9.26%), and sugar (8.09%). According to reports, there are the following mineral elements (mg/100g of edible pulp): Ca, Mg, Fe, Na, K, and Cu. Vitamin A (80 IU), thiamine (0.03 mg), riboflavin (0.01 mg), nicotinic acid (0.2 mg), vitamin C (18 mg), choline (7 mg), and folic acid (3 µg) are the vitamins found in 100g of edible pulp[10].

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Seed

Diagram 5

Hydrolyzable tannins, phenolic acids, flavonoids, other phenolics, terpenoids, phloroglucinol derivatives, and saponins[11]. Amino acids, alkaloids, flavonoids, phytosterols, phenols, saponins, and tannins [12]. Carbohydrates, vitamin, proteins[13].

Therapeutic use of Jamun

The entire jamun plant, including the seeds, fruit pulp, leaves, flowers, and bark, is well known for its therapeutic properties. Jamun is used in many traditional medical systems, including homeopathic, Siddha, Ayurvedic, and Unani. Charkha and Sushruta suggested jamun as a remedy for a variety of ailments, including diarrhea, obesity, vaginal discharge, menstrual disorders, hemorrhage, etc., marking the beginning of the plant's medicinal use[14]. Anti-diabetic, antioxidative, anti-hyperlipidemic, anti-ulcer, anti-allergic, anti-inflammatory, anti-arthritic, antibacterial, and radioprotective properties are just a few of the recognized pharmacological properties of S. cumini.These effects have been connected to the presence of several flavonoids and phenolics in the S. cumini tree.Ayurveda and other traditional Indian medical systems have referenced the therapeutic properties of S. cumini seeds, leaves, stem bark, and complete fruit [15].

Anti-Diabetic

Many medical systems recommend jamun seeds as a way to manage diabetes. Numerous pharmacological research have also confirmed jamun seed's anti-diabetic properties. According to research by Helmstadter and Kumar et al., giving jamun seed to mice with diabetes caused a significant drop in blood glucose levels[16,17]. Various scientists have investigated the extracts' efficacy using various solvents on various animal models[18].

Anti-Oxidant

Increased lipid peroxidation is thought to be linked to oxidative stress, which is a significant factor in the development of diabetic complications[19]. Reactive oxygen species production rises and antioxidant defense capacity falls, causing oxidative stress in cells and tissues[20]. Several solvents, including nhexane, chloroform, ethyl acetate, butanol, and water, were used to separate the methanolic extract of SC's leaves, bark, and seeds. These fractions' capacity to scavenge free radicals and behave as antioxidants was examined.The polar fractions, such as the water and ethyl acetate fractions, produced the best results out of all of them[21]. When evaluated using a variety of in vitro techniques, including the ferric reducing antioxidant power (FRAP) assay, 2,2-diphenyl-1-picrylhydrazyl (DPPH) scavenging assay, nitric oxide radical scavenging, ABTS assay, total reducing antioxidant potential, total antioxidant activity, reducing power, and hydroxyl radical scavenging activity, the SC leaf and seed extract demonstrated a notable level of antioxidant activity[22].

Anti-Hyperlipidimic

Abnormal lipid profiles are among the most prevalent consequences of diabetes mellitus. Alcoholic E. jambolana seed extract (0.1 g/kg body weight) was shown to have an anti-hyperlipidemic action in the liver, kidney, and plasma of streptozotocin-induced diabetic rats. Glibenclamide (0.6 x 10-3 g/kg) and E. jambolana seed extract were used to treat diabetic rats, bringing their elevated plasma lipid levels back to almost normal. Oral administration of E.jambolana seed extract lowered the levels of blood LDL and VLDL cholesterol and elevated HDL cholesterol in diabetic rats by regulating the hydrolysis of lipoproteins and their selective absorption and processing in

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liver and kidney[23]. Fat depots include insulin-sensitive lipases, which remain active or uncontrolled in the absence of insulin and result in lipolysis and the mobilisation of fatty acids from fat depots to plasma, which raises blood cholesterol levels[24].

Anti-Ulcer

A peptic ulcer occurs when the stomach and/or duodenum's mucosal integrity is disrupted, resulting in a local defect or excavation brought on by active inflammation. Impaired mucosal resistance (mucus, bicarbonate secretion, prostaglandins, blood flow, and the process of restitution and regeneration after cellular injury) and offensive factors (acid-pepsin secretion, H. pylori, bile, increased free radicals, and decreased antioxidants) are out of balance. There have been reports of negative side effects linked to the medications used to treat peptic ulcers[25]. Due to its impact on both defensive and offensive mucosal variables, diabetes has been shown to increase the risk of developing peptic ulcers. There have been reports of ulcer-preventive benefits from E. jambolana seeds[26].

Anti-Allergy

In Swiss mice weighing 20–25 g, S. cumini leaf extract at a dose of 0.1 g/kg prevented only 23% of allergic paw oedema, but 50% of paw oedema generated by compound 48/80, a potent mast cell degranulator. Treatment with S. cumini (SC) reduced the amount of oedema caused by histamine and 5-hydroxytryptamine (5-HT) by 58% and 52%, respectively. Paw oedema caused by platelet aggregating factor showed no change. These findings imply that the SC extract may be far more successful in preventing reactions whose mechanism relies on 5-HT and histamine production. Additionally, SC extract directly affected mast cell degranulation, preventing the histamine release that the mast cell degranulator C48/80 produced in vitro[27].

Anti-Bacterial

The study used extracts from several fruit pulp maturity indices (young, premature, mature, preripened, and ripened) and solvent systems (ethyl acetate, acetone, methanol, aqueous, and diethyl ether). Compared to Gramme negative bacteria, the extracts claimed greater efficacy against Gramme positive bacteria. Among the different maturity stages and solvents, the diethyl ether extract from preripened pulp showed the greatest promise as an antibacterial agent[28].

CONCLUSION

Although S. cumini, also referred to as "jamun," has a number of pharmacological properties, its anti-diabetic properties might be the most significant. The entire jamun, including the peel, pulp, and seed, is a rich source of phytochemicals, containing bioactives that are both phenolic and non-phenolic. The most extensively researched of them is the ameliorating activity against Type 1 and Type 2 diabetes. Pharmacological studies link the phytochemicals to a variety of therapeutic actions, including antioxidative, anti-cancer, antidiabetic, antibacterial, and radioprotective activities. To determine the primary functional component in charge of these functions, more research is necessary. Jamun is a seasonal, perishable, and underappreciated fruit with an appealing appearance, an astringent flavour, and a notable mineral and vitamin content. Traditional healers frequently utilise jamun to treat a variety of illnesses, particularly diabetes and its consequences. The majority of pharmacological research on diabetes was done on seeds, but further research is needed to fully understand the pharmacological potential of the other plant parts. Likewise, there aren't many studies on the pharmacological effects of jamun's phytochemical ingredients. With these facts in mind, the authors hope that this study will emphasise the significance of jamun in a variety of treatments and suggest that more clinical and phytochemical research be conducted on this traditional medicinal plant in order to develop safer medications. In addition to its primary purpose of providing nutrients, jamun has a great deal of promise for use as a raw material for post-harvest processing and the creation of functional foods with the ability to prevent disease. This review provides thorough details on the medicinal, nutritional, and processing aspects of jamun.

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THE REVIEW ON IMMUNOTHERAPY IN CANCER TREATMENT: CURRENT ADVANCES AND FUTURE DIRECTIONS

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ABSTRACT

One disease that arises from unchecked cell growth and proliferation is cancer. Many cancer types now have lower death rates as a result of early diagnosis techniques. Still, cancer is the second leading cause of mortality globally, after cardiovascular illnesses. Consequently, the major goal of cancer research has been to provide more potent therapies in order to lower the number of cancer-related deaths. Acquiring a deeper comprehension of the molecular pathways within cancer cells has led to changes and evolutions in the treatment of cancer. Developing therapy modalities with the highest response rate and the fewest adverse effects is the top objective for research. In this regard, immunotherapies have ushered in a new phase of cancer therapy. The future of next-generation therapeutic approaches is summarized in this article by presenting the most popular immunotherapy techniques.

According to recent research, biological therapies that target the tumor microenvironment specifically may engage the immune system. Clinical trials have demonstrated significant progress in the use of immune cells—particularly T cells, which are essential for cell-mediated immunity—for the treatment of malignant tumors. As a result, the treatment of cancer through therapeutic approaches and developmental strategies is the main subject of this article. The immunomodulatory response, the role of important tumor-infiltrating cells, the molecular elements, and prognostic biomarkers are highlighted in this review. Recent developments in treatment approaches are also covered.

KEYWORDS: *Cancer, immunotherapy, CAR-T-cell therapy, monoclonal antibody, mRNA vaccine, tumor microenvironment, combination therapy, checkpoint-inhibitors.*

INTRODUCTION

Cancer is a disease of unchecked cell proliferation. Certain characteristics set cancer cells apart from healthy ones: they continue to express proliferative signals, are immune-evading, resistant to cell death, insensitive to signals that suppress growth, have an infinite capacity for replication, encourage angiogenesis, promote invasion and metastasis, and rewire cellular and environmental metabolism(1). Cancer cells escape from apoptosis(2) and are not captured by cell cycle regulatory mechanisms as a result of their genetic abnormalities. Genetic changes and environmental variables have a crucial influence in the development of cancer. These include chemical carcinogens like alcohol intake, smoking, and asbestos exposure; physical carcinogens like ionizing and UV radiation; and food consumption of aflatoxin and arsenic. Biological carcinogens, such as infections from specific bacteria, viruses, or parasites, are responsible for one-third of cancer deaths. Other factors that contribute to cancer mortality include smoking, alcohol usage, having a high body mass index, eating an unhealthy diet, and not getting enough exercise(3, 4).

While many cancer types now have lower death rates because to good treatment options, the majority of cancer research is concentrated on creating more potent medicines to lower the death toll. A deeper comprehension of the molecular pathways behind cancer has led to changes and evolutions in cancer treatment. Globally, there are more and more cancer patients, which presents serious issues. But the hunt for the medication that has the best response rate and the fewest adverse effects is still going strong(5). Treatments for cancer that are employed in the clinic include surgery, hormone therapy, photodynamic therapy, targeted therapy, radiotherapy, chemotherapy, stem cell transplantation, and immunotherapy(6). Due to the resistance mechanisms these therapies have against cancer, they are frequently used in combination.

This paper discusses the elements that might be useful in establishing national and international roadmaps and forecasts the future of next-generation cancer therapies based on existing research.

IMMUNOTHERAPIES

A sophisticated approach to treating a variety of cancers, including solid and hematological tumors, immunotherapy has emerged as one of the available therapeutic alternatives.

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Immunotherapies aim to combat cancer by using the patient's own immune system, opening the door to more specialized and potent treatments. For patients with various malignancies, cancer immunotherapy is a viable treatment option because it has comparatively fewer side effects than chemotherapy[7]. Monoclonal antibodies (mAbs), mRNA vaccines, immune checkpoint inhibitors, and adoptive cell transfer in the form of chimeric antigen receptor (CAR)-T cell therapies are among the immunotherapy medications available today (Fig 1)[8].

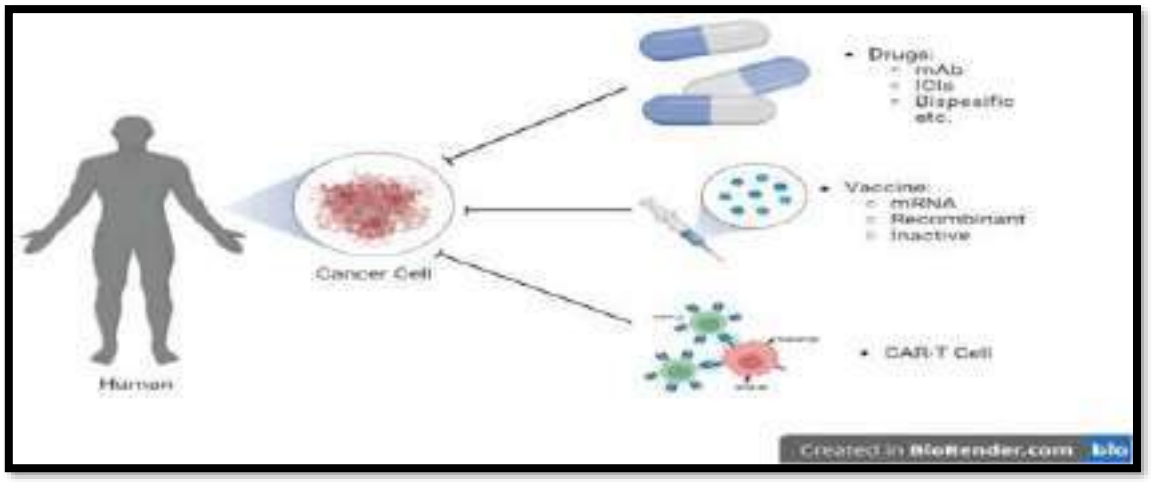

Fig. 1: Current advances and future prospects in cancer immunotherapies.

Depending on the immune response, cancer immunotherapy is categorized as either active or passive. Agents such as lymphocytes, cytokines, or mAbs that boost the body's natural anti-tumor response are used in passive immunotherapy. Vaccination, non-specific immunomodulation, and immune system activation by selective antigen receptor targeting to tumor cells are examples of active immunotherapy techniques[9]. T-cell immune checkpoint pathways are mostly linked to immune response resistance mechanisms. Therefore, reducing immune response evasion can be achieved by examining novel immunological checkpoints and molecular pathways. Finding tactics that will improve T-cell continuity and proliferation, decrease immunosuppression, and stop T-cell depletion is essential to improving the response to immunotherapeutics[10].

MONOCLONAL ANTIBODIES (mAbs) FOR CANCER THERAPY

mAbs are proteins that attach to a particular molecular target and are either synthesized or generated by B lymphocytes[8]. Humanized monoclonal antibodies have been designed targeting relevant targets to achieve anti-cancer effects in preclinical models and patient studies[11]. Because mAbs are significantly more selective and have fewer cytotoxic effects, they have recently become a highly favored cancer therapeutic[12].

Research has indicated that mAbs[13] may enhance cancer patients' overall survival. Based on these investigations, numerous anti-cancer mechanisms, including complement-dependent cytotoxicity (CDC), antibody-dependent cell-mediated cytotoxicity (ADCC), apoptosis promotion, and cell proliferation inhibition, have been linked to recovery[14]. Production within the purview of this technology is carried out employing immortal cancer B-cell myeloma cells and immunized mouse spleen cells capable of producing antibodies[15]. For oncological illnesses, the US Food and Drug Administration (FDA) has approved more than 22 immunotherapeutic medications; a few of these are included in Table 1.

Name	Target	Cancer (Year of First Approval)
Adagrasib	RAS GTPase family	Non small cell lung cancer (2002)
Bevacizumab	VEGF	Colorectal ,lung ,cervical, renal cell cancers.
Cemiplimab	PD-1	Cutaneous squamous -cell carcinoma (2018)
Durvalumab	PD-L1	Bladder cancer (2017)
Elacestrant	ER,HER2	Breast cancer (2023)
Teclistamsab-cqyv	CD-3	Multiple myeloma(2022)

Table 1: FDA-Approved Immunotherapeutic Drugs for Different Cancer Types.

IMMUNE CHECKPOINT INHIBITORS

Immunocheckpoint inhibitors (ICIs), which have recently been developed, have changed the treatment of cancer and increased patient lifespan. The therapy of many cancer forms, such as non-small cell lung cancer (NSCLC), melanoma, head and neck cancer, bladder cancer, and renal cell carcinoma, has been authorized for immune checkpoint inhibitors (ICIs) that target checkpoint proteins

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like CTLA-4 or PD-1.[16] Immune cells have "checkpoint" proteins that function as on/off switches to regulate immune responses. Checkpoint inhibitors prevent T cells from destroying tumor cells, which aids the immune system in its indirect attack on cancer cells.[17] By connecting to a programmed death ligand 1 (PD-L1) cell, T cells with PD-1 expression function as a kind of "off switch" that prevents T cells from attacking other cells in the body. T cells are instructed to leave the other cell alone when PD-1 binds to PD-L1. However, certain cancer cells express a lot of PD-L1 in order to evade the immune response.PD-1 and PD-L1 checkpoint inhibitors are the main immunotherapies used to treat advanced lung cancer, according to numerous studies conducted on a range of tumor types .

A variety of human malignancies have shown therapeutic benefit when treated with clinically licensed antibodies against PD-L1/PD-1 . Accordingly, increased tumor metastasis, improved drug efflux via multidrug resistance protein 1 (MDR-1), and activation of PD-L1 expression severely impede cis-platinum (Cis-Pt)-mediated treatment. Metformin-modified chitosan (Ch-Met) can accumulate selectively in mitochondria and cause disruptions to mitochondrial activity, ultimately leading to decreased tumor metastasis and inhibition of PD-L1 expression. Consequently, it was shown that Ch-Met could sensitize Cis-Pt's chemotherapeutic efficacy . Consequently, a variety of cancer types are being treated with antagonistic antibodies-mediated immunotherapeutic approaches that target PD-1 or its ligand, PD-L1, and can considerably increase patient survival. Therefore, certain small-molecule inhibitors are being developed, evaluated, and authorized in order to block the expression and/or activity of PD-L1 [109,112,113]. Table 2 presents a summary of small-molecule inhibitors that may block the processes governing PD-L1 expression.

Target	Drug	Cancer type	Modulated PD1
Histone methyltransferase EZH2	Tazemetostat and DZNep	Prostate cancer	Transcriptional upregulation of PD-L1
	Tazemetostat (Tazverik)	Epithelioid sarcoma (2020)	Transcriptional upregulation of PD-L1 via decreased H3K27me3, FDA approved
Histone deacetylase inhibitor	Vorinostat (Zolinza)	Cutaneous T cell lymphoma (2006)	Transcriptional upregulation of PD-L1, FDA approved
DNA methyltransferases	Decitabine (Dacogen)	Myelodysplastic syndrome (2006)	Transcriptional upregulation of PD-L1 via decreased DNA methylation in the PD-L1 promoter region, FDA approved
ZFP36 (Tristetraprolin)	Doxorubicin	NSCLC and breast cancers	Downregulates translation of PD-L1

Table 2: Small drugs with checkpoint inhibition capacity in cancer immunotherapy.

PERSONALIZED RECOMBINANT CANCER VACCINES

Cancer immunotherapy becomes a crucial component of the cancer treatment plan by concentrating on TAAs. It provides a number of therapeutic advantages and doesn't have any unanticipated side effects.

These developments therefore necessitate the creation of recombinant vaccines for cancer immunotherapy that are both extremely effective and less toxic. Remarkably, the number of mutations among tumor types is significant, with 10 s to 1000 s mutations . Greater immunogenicity and survival following checkpoint blockade treatments have been linked to higher mutational events in the tumor. For example, treatment with ipilimumab and tremelimumab, antibodies against cytotoxic T-lymphocyte antigen 4 (CTLA-4) has been shown to prolong overall survival in patients with melanoma . It's interesting to note that very few gene variations that express TAA-specific peptides spontaneously elicit an immunological response . Selective binding to MHC class II, which implies the function of CD4+ T cells rather than CD8+ T cells, is necessary for TAA-induced cytokine responses .Nonetheless, numerous investigations have exhibited the significance of CD4+ and CD8+ T cell reactions to TAA vaccinations in diverse forms of malignancy. Prediction algorithms are used to determine whether tumor-derived peptides may combine with the patient's MHC alleles to generate an acceptable TAA. [18]However, more investigation and technology advancements to comprehend the processes of antitumoral immune responses could lead to increased accuracy and efficacy. Numerous advancements in immunotherapeutic strategies are required to solve this issue.

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TUMOR MICROENVIRONMENT IN CANCER

Tumor microenvironment, or TME, has a vital role in the formation and progression of cancer, influencing the growth and metastasis of a tumor. The microenvironment of cancer cells is made up of blood arteries, immunosuppressive cells, and an abundance of fibrous matrix. These interactions allow the tumor tissue to be shielded from the immune system's grasp (Figure 1). The growth and spread of cancer cells are dependent on this interaction because it promotes the heterogeneity of cancer cells, clonal evolution, and increased multidrug resistance. Their clinicopathologic importance in predicting outcomes and therapeutic success has been clarified in a number of papers · Numerous investigations have demonstrated that the course of tumor growth is determined by a dynamic and mutualistic interaction between the surrounding stroma and tumor cells. It is commonly known that tumor-related structures and activated signaling pathways play a significant role in cancer cells and the tumor microenvironment. Patients with cancer have been found to have differences in the compositions of resident cell types within the TME, such as mesenchymal stem cells, resting fibroblasts, dendritic cells (DCs), cytotoxic T cells (CD8+T), helper T cells (CD4+T), tumor-associated macrophages (TAMs), and associated inflammatory pathways . TAMs are essential for the growth of tumors because they induce genetic instability, facilitate metastasis, nurture cancer stem cells, and suppress protective adaptive immunity. Typically, they express surface molecules that are distinctive of them, like the macrophage mannose receptor 1 (CD206) and the hemoglobin scavenger receptor (CD163) .

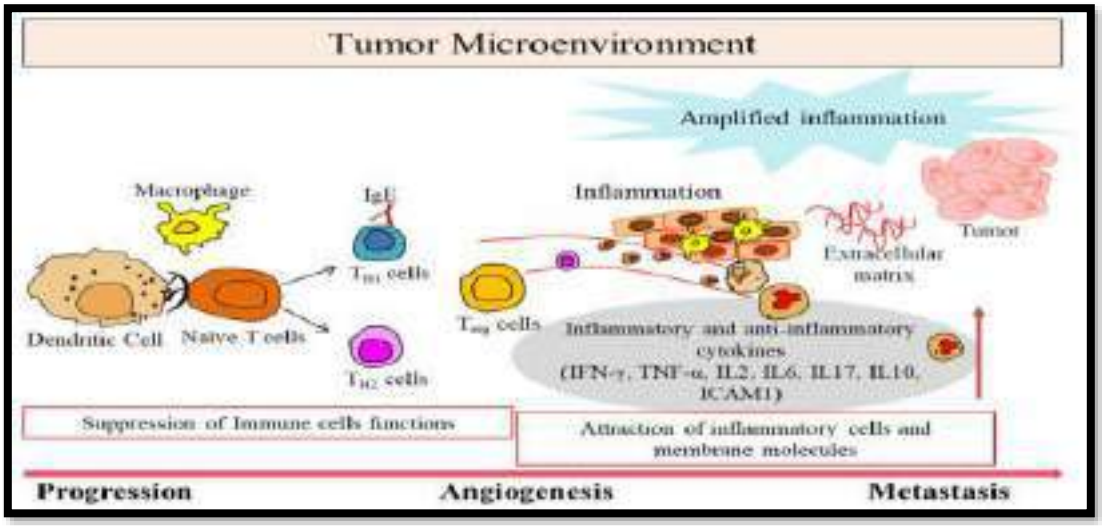

Fig.2: Tumor microenvironment in cancer. Schematic depicting progress of tumor involving suppression of immune function, tumor cells proliferation leading to metastasis.

CAR-T-CELL THERAPY

In CAR-T-cell therapy, autologous T-cells from patients are used to create a tumor antigen-specific CAR ex vivo, which is then injected back into the patient. More recent research has shown that leukemia regression may be induced in vivo by using nanocarriers containing CAR genes and gene editing instruments. At the moment, early phase investigations on B-cell malignancies comprise the majority of clinical trials employing CAR-T cells. The most often used target is CD19, which has been used more recently together with other antigen targets but mostly alone.[19]

Particularly in the case of B-cell acute lymphoblastic leukemia, CAR-T-cell treatment has demonstrated promising clinical outcomes. However, because of tumor histological characteristics, the absence of antigens specific to the tumor, the immunosuppressive tumor microenvironment, and possibly fatal tumor toxicity, its effects are restricted in solid tumors[43]. Scientists are working to get beyond some of these obstacles, though, especially by creating CAR-T agents. Alongside obstacles, encouraging outcomes will continue to emerge as research into CAR-T treatments continues.

CONCLUSION

Cancer immunotherapy is a way to use the body's immune system to combat cancer. It may be possible to modify the immune system to eradicate cancer by appropriately initiating the immune responses without causing unintended effects. Not just T cells, but also other immune cells including natural killer cells and antigen-presenting cells, can be involved in this. New optimism has emerged in the fight against cancer as a result of the effectiveness of immunotherapies and cancer vaccines in clinical studies. Despite having more immune-related side effects, these tactics are more tolerable than conventional chemotherapeutic drugs. Our confidence in treating cancer has increased with the development of novel biological therapy techniques. Clinical decision support systems powered by artificial intelligence may offer a quick fix for this issue in the near future.[20]

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AN OVERVIEW OF: ANTIFUNGAL DRUGS

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Author(1), Guide(2), Principal(3).

ABSTRACT
We evaluated the registered antifungal medications and outlined their methods of action, pharmacological characteristics, and susceptibility to certain fungus. Approved antimycotics can inhibit 1,3-β-d-glucan synthase, lanosterol 14-αdemethylase, protein and deoxyribonucleic acid production, or sequester ergosterol. Their most serious side effects are hepatotoxicity, nephrotoxicity, and myelotoxicity. Echinocandins have essentially no drug-drug interactions, while triazoles have the most. Antifungal resistance can be established in most infections by drug target overexpression, efflux pump activation, and amino acid substitution. Additionally reviewed are the investigational antifungal medications undergoing clinical studies. The most promising new antifungal treatments are siderophores used in the Trojan horse technique or siderophore production enzyme inhibitors.

KEYWORDS: *invasive fungal infections, resistance, siderophores, triazoles, echinocandins, flucytosine, amphotericin B, and antifungal medications.*

INTRODUCTION

When Antifungal medications are used to treat infections caused by fungi, which can affect various parts of the body, including the skin, nails, respiratory system, and internal organs. Fungal infections range from mild conditions like athlete's foot to more severe systemic infections, especially in immunocompromised individuals. of action of many antifungal agents. 2,3 Fungal infections pose a continuous and serious threat to human health and life.1 These fungal infections in humans can be classified into (a) Allergic reactions to fungal proteins,
(b) Toxic reactions to toxins present in certain fungi and (c) Infections (mycoses).

Healthy individuals are susceptible to a host of superficial, cutaneous, subcutaneous and in certain instances, systemic infections that cause a variety of conditions ranging from Athletes foot and nail infections to severe life-threatening disseminated disease (e.g., histoplasmosis). 5 Many fungal infections are caused by opportunistic pathogens that may be endogenous (Candida infections) or acquired from the environment (Cryptococcus, Aspergillus infections). 6 The incidence of mucormycosis may exceed 900,000 cases per year after the inclusion of Indian data estimates. 7 Furthermore, these infections are associated with high mortality rates. The epidemiology of invasive fungal infections usually focuses on specific areas. The lack of available global data leads to a broad range of mortality rates, 8 Typically a long period of 8 to 10 .10 Even though our modern healthcare is able to treat previously life-ending diseases, this often comes at the cost of immunosuppression. 9 Aspergillus and Candida spp. account for the majority of documented infections. The development of new antifungal drugs has been constantly required in the clinical therapy. 18

Aspergillus Niger
Aspergillus niger Van Tieghem causes a disease called black mould. The Aspergilli are a large and diverse genus. . The epidemiology of invasive aspergillosis indicates an increasing number of infections in immunosuppressed patients/individuals undergoing transplantation of bone marrow, hematopoietic stem cells, or organ transplantations, and those receiving intensive chemotherapy or other immunosuppressive treatment.

Mechanism of Action :- This review Describes the targets and mechanisms of action of all Classes of antifungal agents in clinical use or with Clinical potential. 13,14 Antifungal drugs target fungal infections by disrupting the structure or function of key components in fungal cells. Here is an overview of the main classes of antifungal drugs and their mechanisms of action:

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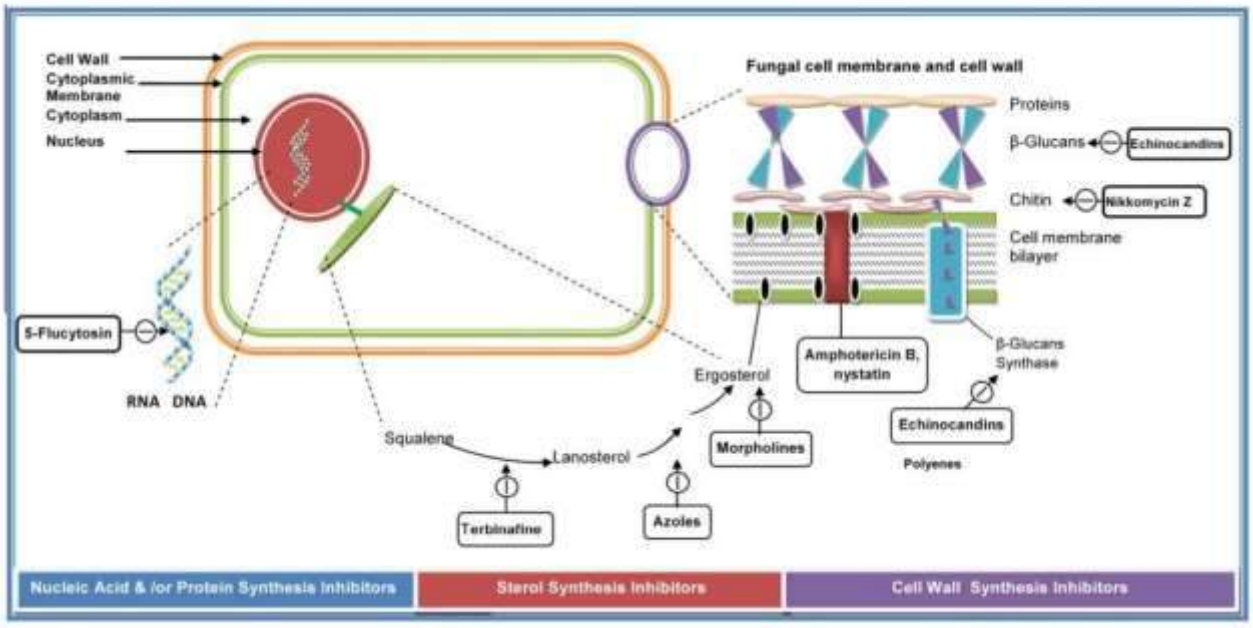

Fig. Targets for Antifungal Therapy

1. Polyenes (e.g., Amphotericin B, Nystatin)

Target: Ergosterol in fungal cell membranes.

Mechanism: These drugs bind to ergosterol, a key component of the fungal cell membrane, forming pores. This leads to leakage of essential ions (K^+, Na^+) and molecules, causing cell death.

2. Binding to Ergosterol

Target: Fungal cell membrane.

Drugs: Polyenes (e.g., amphotericin B, nystatin): Bind directly to ergosterol, forming pores in the membrane.

Effect: Leakage of intracellular ions and molecules, causing cell death.

Selective Toxicity: Humans have cholesterol instead of ergosterol, reducing drug effects on human cells.

3. Inhibition of Cell Wall Synthesis Target: Fungal cell wall.

Drugs: Echinocandins (e.g., caspofungin, micafungin): Inhibit β-1,3-glucan synthase, a critical enzyme for fungal cell wall glucan synthesis.

Effect: Weakening of the fungal cell wall, leading to osmotic instability and lysis

4. Inhibition of DNA/RNA Synthesis Target: Nucleic acid synthesis.

Drugs: Flucytosine (5-FC): A prodrug converted into 5-fluorouracil inside fungal cells, which inhibits thymidylate synthase and disrupts DNA and RNA synthesis.

Effect: Impaired fungal replication and protein synthesis.

5. Disruption of Microtubule Function Target: Fungal mitotic spindle.

Drugs: Griseofulvin: Binds to fungal tubulin, inhibiting mitosis.

Effect: Prevention of fungal cell division.

Tolnaftate: Mechanism: Inhibits squalene epoxidase, similar to allylamines.

Effect: Impaired ergosterol synthesis and membrane function.

Pharmacology and Toxicity of Antifungal Agents

Three lipidic formulations are commercially available: AMB lipid complex (ABLC), liposomal AMB (LAMB), and AMB colloidal dispersion (ABCD). 33

Generally, triazoles are well tolerated. The most common serious side effect, hepatotoxicity, occurs most often with VOR (in 31% cases). High protein binding and negligible metabolism by CYP450 are common among them; on the other hand, their half-life and degradation processes are different. Echinocandins have few known drug–drug interactions because of their reduced substrate potential to CYP450 enzymes. 20

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Here's an overview of the pharmacology and toxicity of antifungal agents:

Classes of Antifungal Agents

1. Polyenes: Amphotericin B, Nystatin
2. Azoles: Fluconazole, Itraconazole, Voriconazole, Posaconazole
3. Echinocandins: Caspofungin, Micafungin, Anidulafungin
4. Allylamines: Terbinafine
5. Flucytosine: 5-Fluorocytosine Pharmacology of Antifungal Agents*i

1. Mechanism of Action:
   - Azoles: Inhibit lanosterol 14α-demethylase, disrupting ergosterol synthesis.
   - Echinocandins: Inhibit β-glucan synthase, disrupting fungal cell wall synthesis.
   - Flucytosine: Converted to 5-fluorouracil, inhibiting DNA synthesis.
2. Pharmacokinetics:
   - Absorption: Variable, depending on agent and formulation.
   - Distribution: Generally distribute well into tissues, but may have limited penetration into certain sites (e.g., CSF).
   - Metabolism: Metabolized by liver enzymes, with some agents undergoing renal excretion.
   - Elimination: Half-lives vary, but generally range from several hours to several days.

Toxicity of Antifungal Agents

1. Common Toxicities:
   - Polyenes: Nephrotoxicity, infusion-related reactions.
   - Azoles: Hepatotoxicity, QT interval prolongation.
   - Echinocandins: Hepatotoxicity, infusion-related reactions.
   - Allylamines: Hepatotoxicity, gastrointestinal disturbances.
2. Less Common Toxicities:
   - Polyenes: Anaphylaxis, cardiac dysfunction.
   - Azoles: Seizures, Stevens-Johnson syndrome.
   - Echinocandins: Anaphylaxis, Stevens-Johnson syndrome.
   - Allylamines: Seizures, peripheral neuropathy.
   - Flucytosine: Pulmonary toxicity, neurological disturbances.

Monitoring and Management of Toxicity.

1. Monitoring:
   - Regular laboratory tests (e.g., liver function tests, complete blood counts).
   - Clinical monitoring for signs of toxicity (e.g., infusion-related reactions, hepatotoxicity).
2. Management:
   - Dose adjustment or discontinuation of the antifungal agent
   - Treatment of specific toxicities (e.g., hepatotoxicity with N-acetylcysteine).

It's essential to note that this is a general overview, and specific antifungal agents may have unique pharmacological and toxicological profiles. Always consult the latest clinical guidelines and prescribing information for specific agents.

Drugs :- Azoles

The azole drug These are synthetically derived antifungal agents, both used orally and topically. They are used for treating a large number of infections caused by dermatophytes, Candida, other fungi involved in deep mycosis, Nocardia, some gram-positive and anaerobic bacteria, e.g., Staphylococcus aureus, Enterococcus faecalis, Bacteroides fragilis and Leishmania.

Ketoconazole (KTZ) :- Ketoconazole is an antifungal drug that belongs to the imidazole class of azole antifungals. It has been widely used for systemic and topical fungal infections, though its systemic use has declined due to safety concerns. Here are the key aspects of ketoconazole. It can also be administered orally.

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Pharmacokinetics
The oral absorption of KTZ is improved by gastric acidity because it is more soluble at lower pH. The half-life is short and varies from 1.5-6 hours.
Side Effects : In females, menstrual irregularities may occur. Hepatotoxicity is also a side effect but is rarely fatal. 19,20

Antibiotics :- 1. Polyenes
Amphotericin B :-
Amphotericin B is an antifungal medication, not an antibiotic (which targets bacteria). However, I can provide you with some key information about Amphotericin.Amphotericin B was isolated from S. Adverse side effects associated with amphotericin B are infusional toxicity, nephrotoxicity and low blood potassium. 22
Mechanism of action
1. Binding to Ergosterol:
Amphotericin B has a high affinity for ergosterol, a key component of fungal cell membranes.
Ergosterol is essential for maintaining the structure and function of fungal cell membranes, making it a critical target.
2. Formation of Membrane Pores:
After binding to ergosterol, amphotericin B aggregates and forms pores or channels in the fungal cell membrane.
These pores create openings that disrupt the membrane's integrity.
3. Leakage of Cellular Contents:
The pores allow the uncontrolled leakage of:
Essential ions like potassium (K^+) and magnesium (Mg^{2+}). Metabolites and other small molecules.
4. Fungal cell death The loss of ions and critical molecules causes irreversible damage to the fungal cell, leading to cell death.

2. **Echinochandins**
Caspofungin
Caspofungin was approved by FDA for the treatment of patients with IA. Caspofungin has potent in vitro inhibitory activity against Aspergillus spp. and moderate activity against some other moulds such as H. capsulatum, C. immitis and B. dermatitidis. It is also active against P. carinii and moderately against dematiaceous fungi. But it has no activity against C. neoformans, Trichosporon spp., Fusarium spp., S. schenckii, zygomycetes and hyalohyphomycetes. 24,25 Caspofungin has few significant interactions as it is neither a substrate nor an inhibitor of the cytochrome P-450 system.

Side Effects
Caspofungin has few side effects, consisting mainly of headache, fever, nausea, rash, phlebitis at the site of infusion and reversible elevation of hepatic enzyme levels. 23

Heterocyclic Benzofuran
Griseofulvin
Griseofulvin is a narrow-spectrum antifungal agent isolated from cultures of Penicillium griseofulvum, and is active against dermatophytes, including Epidermophyton, Trichophyton, Microsporum, but not against fungi causing deep mycosis.

Mechanism of Action
Griseofulvin is an antifungal medication used to treat dermatophyte infections of the skin, hair, and nails. Its mechanism of action involves:

Inhibition of fungal mitosis: Griseofulvin disrupts fungal cell division by binding to microtubules, which are essential for mitotic spindle formation. This interference prevents the proper separation of chromosomes during mitosis, effectively halting fungal cell replication.

Deposition in keratinized tissues: Griseofulvin becomes concentrated in keratin precursor cells of the skin, hair, and nails. This keratin binding makes the tissue resistant to fungal invasion, helping eliminate the infection as the tissue regenerates and the infected keratin is replaced.

By targeting the fungal microtubules and localizing in keratin-rich areas, griseofulvin achieves both systemic and localized antifungal effects.

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Pharmacokinetics

1. Absorption

Griseofulvin is poorly water-soluble, and its absorption from the gastrointestinal (GI) tract is variable.

Enhanced absorption: Absorption is significantly improved when taken with highfat meals or in the micronized or ultramicronized formulations.

Peak plasma concentrations are reached approximately 4–6 hours after ingestion.

2. Distribution:

Griseofulvin is distributed widely throughout the body but accumulates primarily in keratinized tissues, such as skin, hair, and nails.

This selective deposition in keratinized tissues makes it effective against dermatophyte infections.

3. Metabolism:

Griseofulvin is metabolized in the liver, mainly via oxidation and demethylation.

The primary metabolite is 6-desmethylgriseofulvin, which has minimal antifungal activity. 4. Elimination:

The elimination half-life is approximately 9–24 hours, depending on the formulation and patient factors.

5. Bioavailability:

The bioavailability of griseofulvin is influenced by the particle size of the formulation:

Micronized formulation: About 25–70% bioavailability.

Ultramicronized formulation: Better bioavailability compared to micronized, requiring smaller doses for the same therapeutic effect.

Side Effects :-

Allergic reactions (rashes and fever) may occur. The drug is contraindicated in pregnant women. 26,27

3. Allylamines

Terbinafine

Terbinafine is an allylamine that has been available in the United States since May 1996. and other filamentous fungi but has variable activity against yeasts. Terbinafine has been shown to be fungicidal against dermatophytes, Sporothrix schenckii, dimorphic fungi, Scopulariopsis brevicaulis and Herdersonula and Acremonium species.49 Amorolfine can be used only for topical treatment of superficial mycoses, and neither of its targets has attracted recent research interest.

CONCLUSION

Fungal infections pose a continuous and serious threat to human health and life in recent years their has been an increased use of antifungal agents and has resulted in the development of resistance and toxicity, low efficacy rates. Antifungal drugs are essential for treating fungal infections, ranging from mild to life-threatening. Key drug classes like azoles, polyenes, echinocandins, and allylamines target fungal cells while minimizing harm to humans. Challenges include resistance, toxicity, and limited options. Advances in research aim to develop safer, more effective treatments and combat resistance. With rising fungal infections, improving antifungal therapies is crucial for global health.

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A REVIEW ON NOVEL DRUG DELIVERY SYSTEM

Mr. Rohit R. Jabhaye, Ms. Seema P. Rathod, Dr. Sunil S. Jaybhaye

ABSTRACT

The transdermalroute of administration has numerous advantages over more traditional routeof medicine.Recent development in novel drug system of herbal is theexternal subcaste ofthe skin,the stratum corneum. therefore, exploration to ameliorate transdermal medicine delivery(TDD) is worthwhile this subcaste is the areaof interest. This review composition is written to give content commentary recent advances in TDDS enhancement ways. ways that ameliorate the permeability ofthe skinhave been used developed to ameliorate bioavailability and increase the choice oftopical and transdermal medicines is a feasible option. This review describes improvement ways grounded on medicine/ vehicle optimization,e.g selection of medicines, prodrugs and ion dyads, supersaturated medicine results, eutectic systems, complexes, liposomes, vesicles and patches. Strengthening by changing the shell withmoisturizing chemical enhancers partitioning and solubility goods affecting crustal lipidand keratin structure bandied Medium of action of penetration enhancers and retardersand they're implicitfor clinical use operation is described.

KEYWORDS: *New drug delivery system, Phytosome, Nanoparticles, Microsphere, Transdermal Drug Delivery System Carriers, Colloidal drug carriers.*

INTRODUCTION

A novel drug delivery system is a new approach that utilizes new technologies, innovative ideas, and methodologies to deliver the active molecules in safe yet effective concentration to produce desired pharmacological action. It is a formulationor device that deliver as drug to a specific site in the body at a specific rate. Novel substances are novel, or new, substances not previously identified by drug experts andinclude illicit drugs and counter felt prescription medications. A novel drug delivery system plays important role to enhancing therapeutic efficacy, reducing toxicity,increasing patient compliance and enabling entirely new medical treatments.The various routes of NDDS include oral, parenteral (injected),sublingual, topical, transdermal, nasal, ocular, rectal, and vaginal, however drug delivery is notlimited tothese routes and there may be several ways to deliver medications through other routes. There are several different carriers with benefits over made on the basis typesin the novel drug delivery systems (NDDS). The traditional dosage forms display high dose and low availability, instability, first pass effect, fluctuation of plasma drug levels,and fast release of medicinal products. By-performance, protection, compliance with patients, and product shelf life. NDDS will mitigate the problems. Becoming aware of the potential effects on human health and environmental sustainability and due to thegrowled environmental performance of humanmade nanoparticles, nanoparticles are of current interest. In several different applications, nanoparticles are used and generated by various processes. Interesting theoretical problems are their calculationand characterization. Nanoparticles are classified as nanoparticles with a diameter between 10 and 100 nm. Their pharmacodynamics and pharmacokinetic properties aremodified as a targeted supply mechanism for the distribution of small and large molecules. They can be characterized as system containing dissolved active agent, encapsulated or adsorbed in the matrix material used to deliver the target tissue. Theeffect of medication on the target tissue has been shown to increase the retention stability by enzymes and intravascular solubilization of nanoparticles. During the designof nanoparticles, some controls need to be vigilant,including the release pattern, dimensions and surface characteristics, which decide the particular site action at optimum rates with a right dose scheme. The first nanoparticles documented were based on a polymeric non- biodegradable frame work (polyacrylamide, polymethylmethacrylate, polystyrene). The polymeric nanoparticles may holdpharmaceuticals or proteins. These bioactive are trapped as particulates or solid solutions in the polymer matrix, or they may be physically or chemically stuck to the surface of the particle. The medicine(s) may be applied to the previously prepared nanoparticles in the preparation of nanoparticles. This term does not reflect the morphological or structural organization of the system and is are suggestively general.Nano medicine is an innovative field of medicine.

ADVANTAGES OF NOVEL DRUG DELIVERY SYSTEM

1. Protection from physical and chemical degradation.
2. Sustained delivery.
3. Improved tissue macrophages distribution.
4. Enhancement of stability.

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5.Enhancement of pharmacological activity.
6.Protection from toxicity.
7. Increased bioavailability
8.Enhancement of solubility

RECENT DEVELOPMENTS IN NOVEL DRUG DELIVERY SYSTEM OF HERBALS

1.Phytosome
2.Liposome
3.Nanoparticles
4.Emulsions
5. Microsphere
6. Ethosome
7. Solid lipid nanopartical8.Niosomes 9.Proniosomes
10.Dendrimers 11.Liquid Crystals12.Hydrogels

1. Phytosome

Phytosomes are lipid compatible molecular complex which are composed of "phyto" which means plant and "some" meaning cell-like . Complexing the polyphenolic phytoconstituents in the molar ratio with phosphatidyl choline results in a new herbaldrug delivery system, known as "Phytosome". Phytosomes are advanced forms of herbal products that are better absorbed, utilized to produce better results than those produced by conventional herbal extracts. Phytosomes show better pharmacokineticand therapeutic profiles than conventional herbal extracts

- **Advantage of Phytosome**

1. Phytosome increases the absorption of active constituents, so its dose size requiredis small.
2. There is appreciable drug entrapment and improvement in the solubility of bile to herbal constituents, and it can target the liver.
3. In Phytosome, chemical bonds are formed between phosphatidylcholine molecules, so it shows good stability
4. Phytosome improves the percutaneous absorption of herbal phytoconstituents

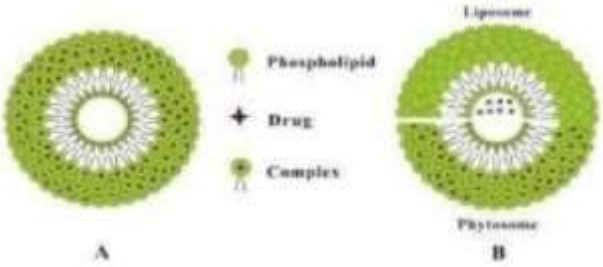

Figure. 3. liposome & Phytosome

2. Liposome

Tiny pouches made of lipids, or fat molecules surrounding a water core widely used forclinical cancer treatment. Several different kinds of liposomes are widely employed against infectious diseases and can deliver certain vaccines. During cancer treatment they encapsule drugs, shielding healthy cells from their toxicity, and prevent their concentration in vulnerable tissues such as those of patient kidneys and liver. Liposomescan also reduce or eliminate certain common side effects of cancer treatment such as nausea and hair loss.

They are form of vesicles that consist either of many, few or just one phospholipid bilayers.
The polar character of liposomal core enables polar drug molecules to be encapsulated.Amphiphilic and lipophilic molecules are solubilized within phospholipid bilayer according to their affinity towards phospholipids.

- **Advantages of liposome**

1. The high biocompatibility.
2. The easiness of preparation.

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3. The chemical versatility that allows the loading of hydrophilic, amphiphilic, and lipophilic compounds. The simple modulation of their pharmacokinetic properties bychanging the chemical composition of the bilayer components

Uses of Liposome

Another major and important advancement in the novel drug delivery systems is the use of liposomes for carrying the drugs to the site of action. Liposomes in both modified and unmodified forms are able to change the course of pharmacokinetic parameters of the drugs. These are widely used in delivering the cytotoxic agents to the tumour tissue and preventing side effects like myelosuppression. These are also used in targeting through receptor-mediated endocytosis. Modified liposomes also have huge applications in targeting various drugs to the organs like heart, liver, kidney,lungs and bones

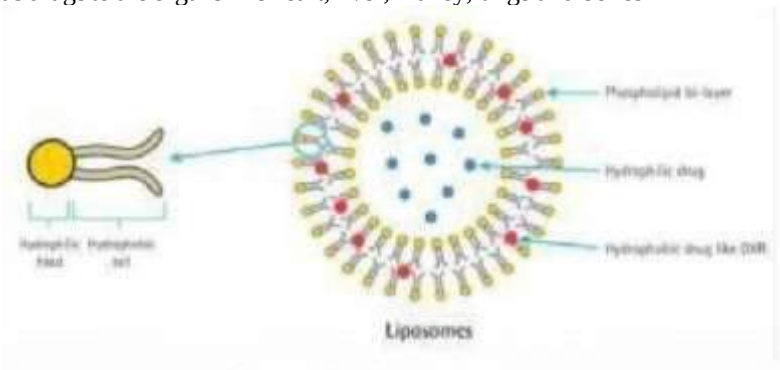
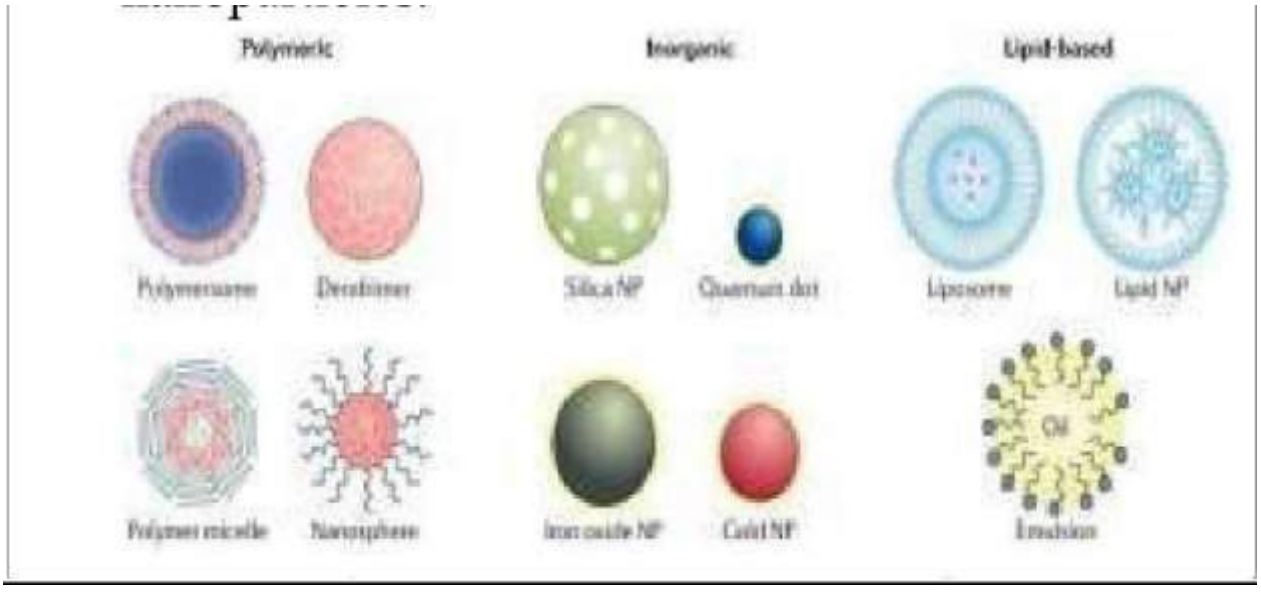


Figure 4. Liposomes

3. Nanoparticals

Nanoparticles (including nanospheres and nanocapsules of size 10-200 nm) are in the solid state and are either amorphous or crystalline. They are able to adsorb and/or encapsulate a drug, thus protecting it against chemical and enzymatic degradation. In recent years, biodegradable polymeric nanoparticles have attracted considerable attention as potential drug delivery devices in view of their applications in the controlled release of drugs, in targeting particular organs / tissues, as carriers of DNAin gene therapy, and in their ability to deliver proteins, peptides and genes through theperoralroute.



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- **Advantages of Herbal Nanoparticle Delivery System**

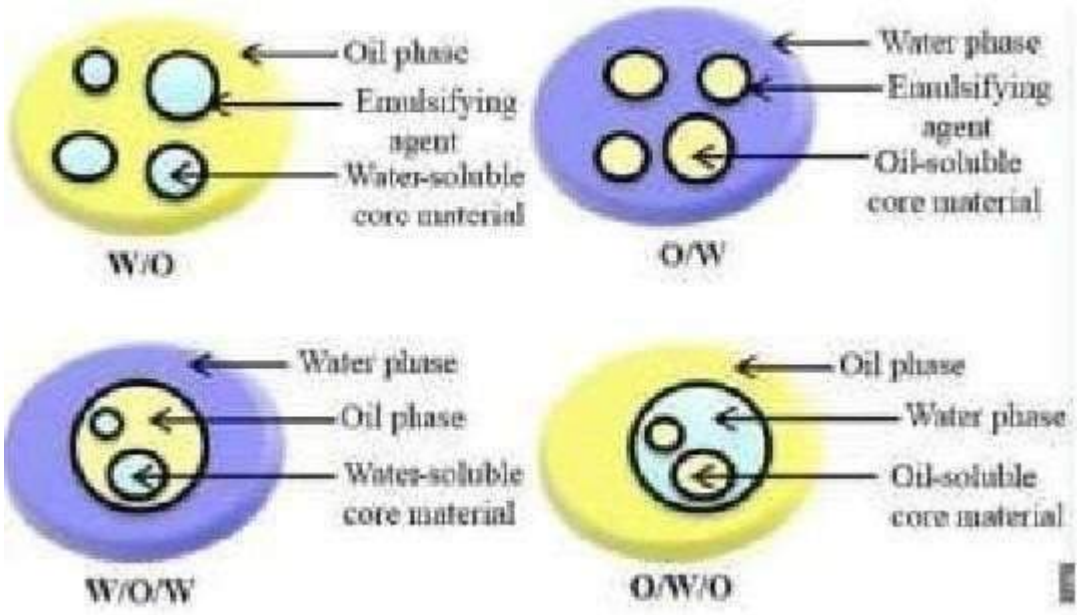
1.Nanoparticulate system delivers the herbal formulation directly to the site of action.2.Increased efficacy and therapeutic index.
3.Increased stability via encapsulation.4.Improved pharmacokinetic effect.
5.Producible with various sizes, compound surface properties.

4. Emulsion

Emulsion is a biphasic system in which one page intimately disperse in other page in form of minute droplet in ranking in diameter from 0.1um to 100um. In emulsion,one page is always water or aqueous page and the other page is oily liquid,that is non aqueous. Among them, the micro emulsion is also called Nano emulsion, and sab microemulsion is called liquid emulsion. Micro emulsion is a clear, the thermodynamically, stable, frequency in combination with a cosurfactant.

- **Advantages of Emulsion-Based Formulations**

1. It can release the drug for a long time because it is packed in the inner phase and makes direct.
2. contact with the body and other tissues.
3. As a result of the lipophilic drugs being made into o/w/o emulsion, the droplets of oil are phagocytosised by macrophages and increase its concentration in liver, spleenand kidney.
4. As the emulsion contains herbal formulation, it will increase the stability of hydrolyzed formulated material and improve the penetrability of drug into skin and mucous.
5. The new type, viz., Elemenum emulsion, is used as an anti-cancer drug and causes no harm to the heart and liver



5. Microshpere

Microsphere comprises of small spherical particles, with diameters in the micrometer range, typically 1 μm to 1000 μm (1 mm). Microspheres are sometimes referred to as micro- particles. Microspheres can be manufactured from various natural and synthetic materials. Glass microspheres, polymer microspheres and ceramic microspheres are commercially available. Microspheres are classified as biodegradable ornonbiodegradable. Biodegradable microspheres include albumin microspheres, modified starch microspheres, gelatin microspheres, polypropylene dextranmicrospheres, polylactic acid microspheres, etc. According to the current literature reports on nonbiodegradable microspheres, polylactic acid is the onlypolymer approved to be used by people, and it is used as a controlled-release agent. Solid and hollow microspheres vary widely in density and therefore are used for different applications.

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6. Ethosome

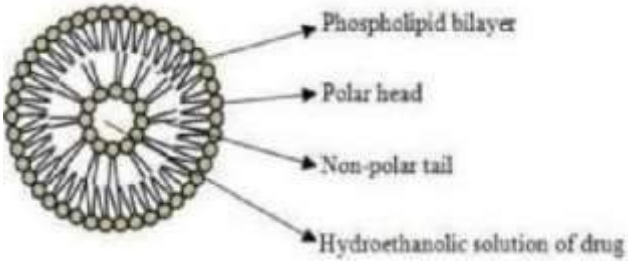
Ethosomes are developed by mixture of phospholipids and high concentration of ethanol. This carrier can penetrate through the skin deeply lead to improve drug delivery into deeper layer of skin and in blood circulation. These formulations are useful for topical delivery of alkaloids in form of gel and cream for patients comfort. They show increase in their permeability through the skin by fluidizing the lipid domainof the skin. Unstable nature and poor skin penetration are limits for Ethanosomes tropical delivery. The Ethosomes was developed and examined for their ability the topical absorption of Tetrandine through dermal delivery, and the relation of formulations to the pharmacological activity of Tetrandrine loaded in the formulationwas also accessed. Result of the drug levels in rat plasma showed that when Tetrandrineloded Ethosomes were topically administered in rats the drug level was lowto be detected in rat plasmaIn conclusion, Ethosomes were demonstrated to be promising carrier for improving topical delivery of Tentrandrine via skin

- **Advantages of Ethosomal Drug Delivery**

1. Ethosomes are a platform for the delivery of large amounts of diverse groups ofdrugs.
2. Ethosomaldrud is administered in semisolid form resulting in Improvement in patientscompliance

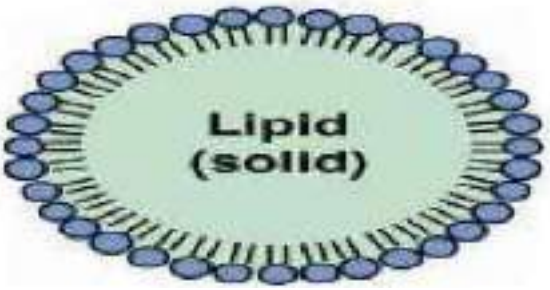
7. Solid Lipid Nanoparticles

(SLNs) are a new pharmaceutical delivery system or pharmaceutical formulation.



The conventional approaches such as use of permeation enhancers, surface modification, prodrug synthesis, complex formation and colloidal lipid carrier based strategies have been developed for the delivery of drugs to intestinal lymphatics. In addition, polymeric nanoparticles, self-emulsifying delivery systems, liposomes, microemulsions, micellar solutions and recently solid lipid nanoparticles (SLN) have been exploited as probable possibilities as carriers for oral intestinal lymphatic delivery.

A solid lipid nanoparticle is typically spherical with an average diameter between 10 and 1000 nanometers. Solid lipid nanoparticles possess a solid lipid core matrix that can solubilize lipophilic molecules. The lipid core is stabilized by surfactants (emulsifiers). The term lipid is used here in a broader sense and includes triglycerides (e.g. tristearin), diglycerides (e.g.glycerolbahenate), monoglycerides (e.g. glycerol monostearate), fatty acids (e.g. stearic acid), steroids (e.g. cholesterol), and waxes (e.g. cetyl palmitate). All classes of emulsifiers (with respect to charge and molecularweight) have been used to stabilize the lipid dispersion. It has been found that the combination of emulsifiers might prevent particle agglomeration more efficiently.



8. Ninosome

Niosomes are multilamellar vesicles formed from non-ionic surfactants of the alkyl or dialkyl polyglycerol ether class and cholesterol. Earlier studies, in association with L'Oreal have shown that, in general, niosomes have properties as potential drug carriers

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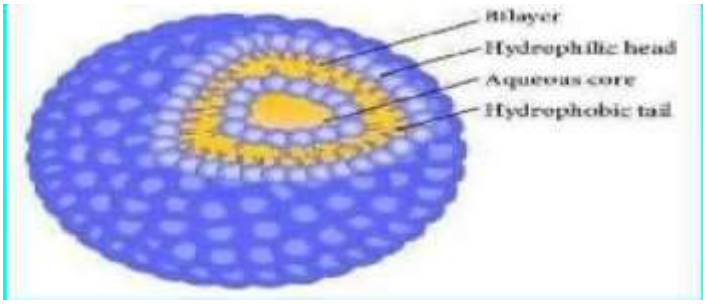
similar to liposomes. Niosomes are different from liposomes in that they offer certainadvantages over liposomes

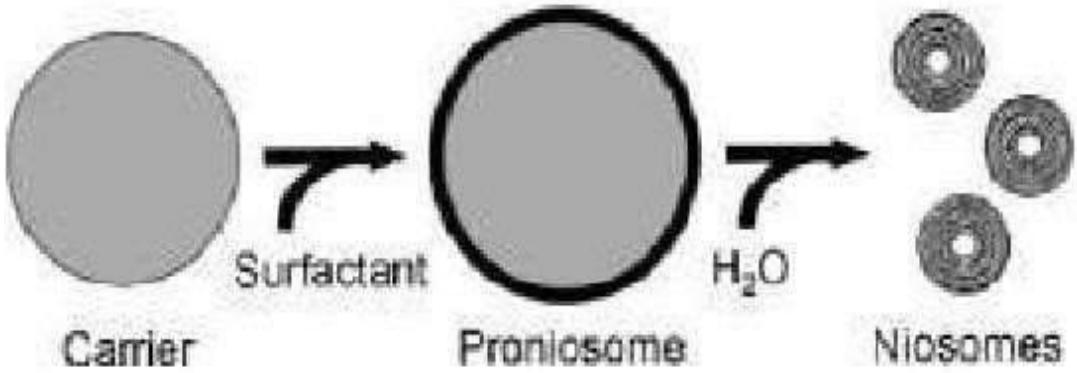
Types of Niosomes

1. Niosomes are classified based on number of bilayers,
2. Size and method of preparation.
3. Multilamellar-0.5µmto10µmindiameter.
4. LargerUnilamellar-0.1µmto1µmindiameter
5. Small Unilamellar–25-500nm in diameter.



9. Proniosomes

Pronanosome gel system is step forward to ninosome, which can be utilized for various applications in delivery of actives at desire site. Proniosomal gels are theformulations, which on in situ hydration with water from the skin are converted into niosomes .



10. Dendrimers

are precisely defined, synthetic nanoparticles that are approximately 5–10 nm in diameter. They are made up of layers of polymer surrounding a control core. The dendrimers surface contains many different sites to which drugs may be attach and also attachment sites for materials such as PEG which can be used to modified the way of dendrimer which interacts with body. PEG can be attached to dendrimer to 'disguise' it and prevent the body's defense mechanism for detecting it, there by slowing the process of break down. This fascinating particle holds significant promisefor cancer treatment. Its many branches allow other molecules to easily attach to itssurface. Researchers have fashioned dendrimers into sophisticated anticancer machines carrying five chemical tools–a molecule designed to bind to cancer cells, a second that fluorescence upon locating genetic mutations, a third to assist in imagingtumor shape using x–rays, a fourth carrying drugs released on demand, and a fifth thatwould send a signal when cancerous cells are finally dead. The creators of these dendrimers had successful tests with cancer cells in culture and plan to try them in living animals soon

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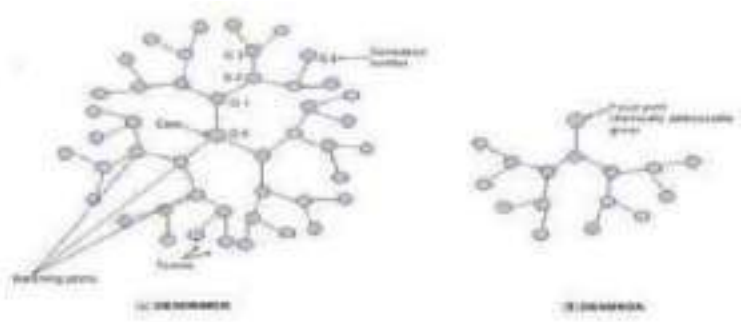

11. Liquid Crystal

Liquid Crystals combine the properties of both liquid and solid states. They can be made to from different geometries, with alternative polar and non-polar layers (i.e., a lamellar phase) where aqueous drug solutions can be included

12. Hydrogels

Hydrogels are three-dimensional, hydrophilic, polymeric networks capable ofimbibing large amounts of water or biological fluids. They are used to regulate drug release in reservoir-based, controlled release systems or as carriers in swellable and swelling-controlled release devices.

OBJECTIVE

1. Provide an exhaustive overview of existing conventional drug deliver systems.
2. Focus on advancements in nanotechnologybased drug delivery systems.
3. Assess the impact of these innovations on drug stability, solubility, and bioavailability.
4. Examine the applications of novel drug delivery systems in specific therapeuticareas, such as oncology, neurology, and infectious diseases.
5. Assess the significance of biodegradable and sustained release drug delivery systems.
6. Analyze the impact of novel drug delivery systems on patient convenience andcompliance.

CONCLUSION

Novel Drug delivery System (NDDS) is a combination of advance techniques and newly designed dosage forms which are much better than conventional dosage forms. Advantages of Novel Drug Delivery System are Optimum dose at the right time and right location, Efficient use of expensive drugs, excipients and reductionin production cost, Beneficial to patients, better therapy, improved comfort and standard of living. Basic modes of novel drug delivery systems are: Targeted Drug Delivery System, Controlled Drug Delivery System etc. Novel Drug delivery & drug targeting is new techniques which is used in pharmaceutical science. Like targeting drug molecules, vaccine delivery, Gene therapy, commercial development of novelcarries (liposomes). Pharmaceutical innovations like the Novel Drug Delivery Systems presents health professionals with a broad range of arsenals to treat diseases with never before efficacy, safety and precision. Clinically the NDDS not only smoothens the saw-tooth pattern of drug levels in blood, but also affords targeting the drugs to their site of action and thus reduces dose-related side effects. Smaller quantity of drug and fewer numbers of dosing could be used to treat a disease with increased success. It is hoped that with more and more research endeavors being focused into this arena, in near future, a large portion ofthe conventional dosage forms would be replaced by these NDDS and an overall betterment of health care delivery is expected with that change over. Pharmaceutical companies are interested to conduct research on NDDS to get edgeover the big pharmaceutical companies to capture the regulated market through ANDA in regulated market. Moreover, development and implementation of new branches like Pharmacovigilance will ensure availability of safer medicines to our people.

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REVIEW OF MEDICINAL VALUES IN BAMBUSA VULGARIS

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Lokmangal College of Pharmacy, Wadala, Solapur, MH

ABSTRACT

The building construction industry is one of the largest consumers of energy derived from fossil fuels in various forms. As the world's population grows, so does the demand for housing, infrastructure, and development. Building materials have a high embodied energy due to chemical processes and other variables, notwithstanding advancements in technology. This study emphasizes the importance of using natural materials like bamboo, which are energy-efficient, have lower embodied energy, and are environmentally friendly. The study used a Universal Testing Machine (UTM) to assess the tensile and compressive strength of treated and untreated bamboo, comparing them to concrete and steel. Bamboo has the potential to be a sustainable building material for both small and large buildings, reducing the carbon footprint. It can be cultivated in numerous areas with no effort and is quickly refilled.

Plants are a valuable source of herbal remedies for treating specific diseases and disorders. Indigenous medicinal plants are increasingly being used in complementary and alternative medicine (CAM) due to their considerable contribution to pharmaceuticals. Bambusoideae is a big Poaceae grass family with 119 genera and 1482 species. Approximately 70% of Asia's bamboo woods are covered. This study will provide an overview of the ethnobotanical relevance and traditional knowledge of therapeutic plants in the Bambusoideae. This review provides valuable information on medicinal plants, their applications, and parts used by indigenous people and societies in Asian locations. Bamboo has made major contributions to the ethnobotanical area, particularly as medicines for various ailments, as reviewed here. Ethnobotanical data has successfully contributed to the CAM. This review on ethnobotany and traditional knowledge of bamboo has numerous benefits and can serve as a foundation for future study in the pharmaceutical area, both locally and worldwide. Herbal medications are commonly utilized in medical systems to treat and manage various disorders. Gold bamboo shoots (Bambusa vulgaris) have significant nutritional value, making them a viable food source. Gold bamboo plants have been traditionally utilized to heal human ailments. The phytochemical composition of this plant includes carbohydrates, glycosides, saponins, alkaloids, flavonoids, phenolics, tannins, phytosterols, triterpenoids, oils, and lipids. Gold bamboo has traditionally been used to treat malaria and diabetes. This plant has several pharmacological properties, including analgesic, antipyretic, antidiabetic, anti-inflammatory, antimicrobial, antioxidant, antiviral, antikidney stone, hepatoprotective, diuretic, abortifacient, anti-anxiety, and renal disease actions.

KEYWORDS: *Asia, Bambusoideae, Complementary and Alternative Medicine, Ethnobotany, and Traditional Knowledge.*

REVIEW OF LITERATURE

1. **Antony Kumar Boity**
   The building construction industry is a big consumer of energy derived from fossil fuels in various forms. As the global population grows, so does the demand for housing, infrastructure, and other forms of construction. With modern technology and innovation, a wide choice of building materials are accessible, but they have a high embodied energy due to several chemical processes and other considerations. The current research emphasizes the importance of using materials like bamboo, which are abundant in nature and can be easily used without requiring a lot of energy, have low embodied energy, and are environmentally sustainable.
2. **T. Vijaya Gowri**
   The Indian population is rapidly growing, and it is critical to meet their fundamental necessities such as food and shelter. It necessitates the use of additional construction materials and contributes to resource depletion. To ensure resource sustainability, it is vital to develop novel alternatives to conventional materials. Bamboo is a green, renewable, quick growing, and environmentally beneficial material that can be used as an alternative to steel reinforcement. This study discusses the various varieties of bamboos available, testing procedures, their use as reinforcement, testing methods for mechanical qualities, and a comparison between steel reinforcement and various forms of bamboo reinforcement.

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3. **Wei Zhang**
   Bamboo fiber is a novel type of natural fiber derived from bamboo using machine technology, and it is at the forefront of bamboo timber processing, innovative composite and textile research. The combing method is mostly used for processing bamboo fiber. Bamboo fiber had to be plastic and strong in order to be processed by machine. The purpose of this study is to investigate changes in mechanical properties - lengthways tensile qualities of bamboo following alkali treatment, with an emphasis on the relationship between lengthways tensile properties of alkali treated bamboo and moisture content. This research first identified the mechanism of bamboo plastic deformation.
4. **L. Y. Lee**
   Bamboo is one of the most rapidly growing natural building materials, and it is widely available in most developing countries, including South America, Africa, and Asia. Bamboo is a "green gold" plant in the tropical rainforest. It is a fast-growing monocotyledon plant from the Gramineae family (Bambusoideae) that requires little time to reproduce. Bamboo's physical strength has allowed builders throughout history to employ bamboo as a natural and sustainable construction material for houses and constructions. Because of its capacity to bend, bamboo is the most chosen material in vernacular construction, especially recently in Southeast Asian countries, which has birthed a new trend in architectural design.

INTRODUCTION

The building industry is the world's greatest energy consumer, accounting for over one-third of global energy consumption. Since the turn of the 20th century, the amount of energy consumed has increased alarmingly, and this trend is expected to continue in the years to come due to the growing population and all the energy-intensive industries—power plants, factories, transportation, and buildings that are expanding. According to a number of earlier studies, in order for developed and developing countries to evaluate and rank energy-saving initiatives in the world's biggest energy-consuming countries, a thorough analysis of energy use in the building sector is necessary. It has been discovered that choosing sustainable building materials and using them in construction has a number of advantages, including lowering the embodied energy of the materials, lowering the toxic emissions they produce, and affecting the building's environmental impact [3]. This highlights how important it is to use sustainable materials that have lower embodied energy and lifecycle carbon emissions. Doing so will minimize energy consumption and emissions and pave the path for a sustainable environment [4].

As a result of increased usage of new and innovative materials in building due to advancements in technology, the environment is being negatively impacted, mountains are being destroyed in the process of extracting minerals, and the limited supply of natural resources is being depleted. To maintain both the sustainability of building construction and the availability of natural resources such as land, water, and air for our future generations, we need to search for substitute materials. Globally, bamboo products are becoming more and more well-liked as an affordable, environmentally friendly, and sustainable alternative to traditional building materials [5]. It grows three times faster than most plants and is regarded as one of the fastest-growing grasses due to its rapidly expanding root system. "The Green Gold" is as sturdy as most of the wood on the market and is more affordable than timber [6]. This cutting-edge architectural building material will support sustainable development in the construction sector in addition to green development. Over 1200 species of bamboo belonging to more than 70 genera can be found throughout the world's more than 14 million hectares of natural forests, which have not received enough research attention [7]. Interestingly, about seven million hectares of bamboo forest, or South and Southeast Asia, are home to 80% of these species [8]. This includes China, India, and Myanmar. Bamboos are found growing practically everywhere in India, and they show good physical strength performance due to their high stiffness, high growth rate, high intensity, and superior thermal stability [9]. Additionally, this renewable resource is "one of the fastest growing plants."

Bambusa vulgaris, often known as common bamboo or golden bamboo, is a type of open bamboo cluster, according to Wikipedia [1]. Although it is native to southern China's Yunnan Province and Indochina, golden bamboo has been widely grown and has naturalized in several locations. Bamboo gold is one of the most prevalent and recognizable species of bamboo. The clumps that Bambusa vulgaris develops are loose and thornless. Its leaves are a dark green color, while its stems are lemon yellow with green stripes. The stems have thick walls, are initially robust, are not straight, are difficult to split, and are not flexible. Densely tufted stems are 4–10 cm thick and can reach heights of up to 10–20 m (30–70 ft). The trunk is either flexible or straight, drooping at the ends and curved in various directions. The walls of trunks are quite thick. Nodes somewhat increased. It is 20–45 cm (7.9–17.7 in) in length. From the center trunk node to the top, certain branches grow. The leaf blade is lanceolate and thin.

Large gramineous plants, bamboo can reach heights of 40 m and diameters of up to 20 cm on woody stalks (Scurlock et al., 2000). It is found all over the world, with 1707 species in 128 genera (Nayak and Mishra, 2016; Sawarkar et al., 2020; Vorontsova et al., 2016). Bambusa oldhamii Munro, which grows around 4 feet per day, is one of the fastest growing bamboo species on the planet, with a growth

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rate of up to 1 m per day (Wu et al., 2011). 36 million hectares (MH) of bamboo forest span the world; 16 MH are in India, 6.5 MH are in China, and 4 MH are in Brazil (Forest Survey of India (FSI), 2019; INBAR, 2019).

Picture: Bamboo Plant

MATERIAL AND METHOD

The mature bamboo specimen used in this study is between three and four years old. A green solution called Borax was applied to certain bamboo specimens to prevent fungal and insect assaults. The course of treatment lasted for three days. Sections of bamboo, both treated and untreated, were utilized and put through testing using a Universal Testing Machine (UTM). The compressive strength, tensile strength, and shear strength tests were performed.

PROPERTIES OF BAMBOO AS BUILDING MATERIAL

Fascinating findings were observed when comparing the mechanical characteristics of bamboo with several regularly used materials, like steel and concrete (Fig. 1). It is discovered that bamboo has compressive strength comparable to the grade of concrete that is frequently used in residential buildings. These days, M25 or M30 grade concrete is used for most building projects; this indicates that the concrete can support up to 30N loads per millimeter of area. Table 4 displays the capabilities of treated bamboo.

APPPLICATION OF BAMBOO IN THE BUILDING

Bamboo undergoes modifications and treatments to enable them to grow into the desired shape and structural form. All it takes to create a squared cross-section is to push the bamboo's tail inside. Bamboo can be bent into the desired shape by compacting it into the desired shape. This would be less expensive than using timber for a similar building. Bamboo can be given any required length, curvature, or shape in order to be used as a structural material, depending on the structural

BACKGROUND OF BAMBOOS IN ASIAN REGIONS

Bamboo is renowned for their hardiness, rapid growth, and brief harvest seasons. Additionally, they are affordable, offer a steady supply, and sustain people's livelihoods throughout history. Because of these characteristics, bamboo is a dependable resource for supplying the demands of a growing market, population, and growth.23–24 As a result, it has been deeply entwined with Asian culture, embodying the continent's bamboo civilization.25 Although these grasses are widespread throughout Africa, Latin America, and Asia, they

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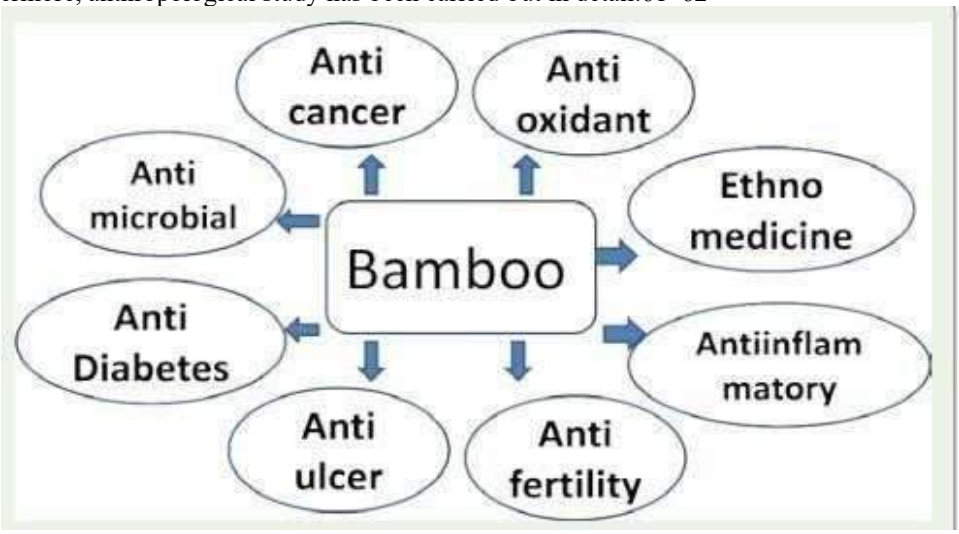
originated in Southeast Asia. Climates mostly dictate the geographic distribution of bamboo.26 It can quickly adapt to a wide range of climatic and soil conditions, which allows it to be extensively dispersed in the tropical and subtropical zones between 46° N and 47° S latitude. It can reach elevations of up to 4000 m in the Himalayas and portions of China.27– 28 While 8.8 to 36°C is the ideal temperature range for bamboo to grow in, several species can withstand temperatures as low as -20°C.30 Because bamboo grows best in regions with heavy rainfall—roughly 1270 mm to 6350 mm or more— rainfall has a major influence on the distribution and growth of these species, as evidenced by studies 31– 32.

ETHNOBOTANT AND TRADITIONAL KNOWLEDGE OF BAMBOOS IN ASIA

"The study of plants used by humans" is the definition of ethnobotany, which was first used in 1896 by American botanist John Harshberger.55 Ethnobotany is a subfield of botany that studies goods made from natural sources, including food, building materials, fiber plants, coloring agents, fertilizers, taboos, avoidance, and poisonous and useful plants as well as magical or religious beliefs.56–58 Stated differently, ethnobotany is the study of the uses of native plants by humans in particular areas and civilizations.59 Nowadays, it is often accepted that ethnobotany and the organic, customary relationship between plants and people in a dynamic ecosystem are intimately related. .. Ethnic people largely depend on plants for nearly all of their daily wants and requirements, and they strongly believe that native folklore medicine is a part of the system. Indigenous societies' religious activities and beliefs are closely linked to the practical techniques that make up traditional medicine. Knowledge of medicinal plants plays a major role in traditional medicine. Six billion people, or around 80% of the world's population, rely mostly on traditional medicines, according to the World Health Organization.60 Furthermore, anthropological study has been carried out in detail.61–62



Picture: Bamboo Medicinal Properties

• **ANTICANCER ACTIVITY**

Since the test endpoint of mammalian cell transformation systems is the neoplastic conversion of target cells, they are especially helpful among the several short-term evaluation systems for the detection of environmental carcinogens/mutagens. For hundreds of years, people in Eastern Asia have utilized Sasa sentanensis leaves as a possible source of natural medicine. The alkaline extract made from the leaves is referred to as "Sasa health."

Using the BALB/c 3T3 A31-1-1 cell transformation system, the carcinogenic and tumor- promoting potential of Chikusaku-eki, a bamboo charcoal by-product used as a folk treatment, was assessed for carcinogenic/co-carcinogenic activity in BALB/c 3T3 cells. The findings demonstrated that Chikusakueki did not increase tumor growth [21]. Immune function inhibition is one of the unintentional causes of tumor growth. It has been demonstrated that polysaccharides derived from microbial cell walls or mushrooms are effective immunostimulant agents. Traditional Japanese medicine uses kumaizasa bamboo leaf extracts as an anti-inflammatory. The anticancer activity and immunopotentiating efficacy of bamboo (Sasa senanensis) leaf extracts prepared under "vigorous conditions" were assessed in a study on immunostimulus- mediated anti-tumor activity. The extracts activated natural killer cells and macrophages, indicating that they might be the main immunostimulant element that is crucial for preventing cancer. [22]

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• **ANTIOXIDANT ACTIVITY**

In many South-East Asian nations, bamboo shoots are the most widely consumed traditional food item, typically in the form of fresh, fermented, or canned goods. [26] conducted a study on overcoming cyanogenic toxicity and navigating high altitude for safe edible bamboo shoots with abundant nutritional qualities. In Asia, it was noted that eating bamboo species with high levels of total cyanogenic content (TCC) led to a high incidence of food illness. According to the study, edible bamboo species with large, strong bamboo shoot textures that have undergone morphological and genetic evolution and grow at low elevations have high levels of TCC, low antioxidant qualities, and low levels of advantageous macronutrients and micronutrients. Crucially, it is revealed that Dendrocalamus species have a high level of TCC regardless of the increasing altitude, but Bambusa species have a moderate amount of TCC. The results unequivocally showed that the high-altitude Chimonobambusa callosa species is a safe, nutrient-dense eating bamboo [26]. According to a prior study, antioxidant phytochemicals including phenolic compounds found in bamboo leaf extracts are responsible for their therapeutic benefits [27]. Studies on the antioxidant activity of "Moso" (Phyllostachys edulis), a plant grown in China, revealed notable inhibitory effects on ferrous metal-chelating abilities, superoxide radical, hydroxyl radical, and DPPH radical [28].

• **ANTIMICROBIAL ACTIVITY**

Bamboos are utilized as bioactive agents in many different products, such as the Chinese food's utilization of tender shoots, vinegar, juice, beer, salt, and bamboo charcoal (bintochan). Since ancient times, Chinese herbal medicine and Indian Ayurvedic medicine have utilized a variety of traditional medications linked to bamboos for the treatment of fever and detoxification. One common vegetative, monopodial bamboo species found in China's subtropics is Moso bamboo, which belongs to the Bambusoideae (Poaceae) family. Bamboos have long been employed as therapeutic agents in ethnomedicine to reduce inflammation and boost natural immunity, and many funguses related to bamboo have both medicinal and culinary uses.

Investigated the Antimicrobial Activity and Diversity of Cultivable Endophytic Fungi Derived from Moso Bamboo Seeds. During submerged fermentation, the crude extracts of isolates B09, B34, B35, B38, and 816 also showed varying degrees of bioactivities against pathogenic fungi that are bambusicolous. The antibacterial activity of endophytic fungus linked to Moso bamboo seeds was initially documented in this work, and the findings indicated that they might be used as a possible source of bioactive chemicals and activators of plant defense. They also concluded that, in contrast to the other strains reported, strains of Shiraia sp. that were isolated and cultivated from moso bamboo seeds could produce hypocrellin A at a high yield [33].

• **ANTI-DIABETIC ACTIVITY**

Reduced pancreatic output of insulin and resistance to its effects in several tissues, including muscle, liver, and adipose, result in type 2 diabetes, which impairs glucose absorption.

Obesity prevalence has increased in tandem with one of the main risk factors for type 2 diabetes. Managing type 2 diabetes often entails dietary and activity modifications, and the majority of patients eventually need pharmacotherapy, such as an oral anti-diabetic medication. 50 diabetic rats were used to test an extract from Moso bamboo leaves,which showed a hypoglycemic effect.
When Sasa borealis leaf extract was used in place of meat in a patty, plasma glucose levels dramatically decreased, suggesting that the extract had anti-diabetic properties [37].

Pseudosasa japonica leaves were tested for their ability to prevent obesity and diabetes in C57BL/6J mice fed a high-fat diet. Despite the fact that the mice given bamboo extract had a marginally larger food intake than the control group, their weight increase was still limited [37]. When streptozotocininduced, diabetic rats were used to test the petroleum extract of Bambusa vulgaris leaves for antidiabetic effects, it was discovered that oral administration of the extract When compared to the common medication glibenclamide, the oral administration of the petroleum extract of Bambusa vulgaris leaf for 15 days was found to be effective in significantly lowering the blood glucose level in a dosedependent manner, demonstrating the extract's anti-diabetic activity in streptozotocin-induced diabetic rats [38].

• **ANTI-ULCER ACTIVITY**

Rats' incidence of water immersion and restraint stress, ethanol-induced, and indomethacin-induced stomach ulcers was considerably decreased when a hot-water extract (Folin) of bamboo grass (Sasa albomarginata) was administered orally [40]. Through histological analysis of the rats' gastric mucosa treated with Folin, these researchers assessed the antiulcer effect of bamboo

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grass in rats. They found that microscopic blood clots covered the superficial epithelium, maintaining the cellular integrity of the gastric mucosa, particularly against stress ulcers.

Folin was observed to inhibit the release of histamine from rat mast cells, stabilize erythrocytes, and speed up their agglutination in acidic environments. It also reduced the incidence of hyperemia and a decrease in acid mucopolysaccharides in the ethanol-induced ulcer. According to their findings, the prevention of stomach lesions may be due to the microscopic hemostatic action of folate strengthened by a membrane-stabilizing effect.

- **ANTI-INFLAMMATORY ACTIVITY**

Indian traditional medicine has utilized Bambusa arundinacea preparations to treat a range of inflammatory diseases. The extract's anti-inflammatory properties are believed to be highly beneficial in the management of inflammatory diseases [42] sought to comprehend Bambusa arundinacea's antiinflammatory and anti-ulcer properties.

The majority of anti-inflammatory medications on the market are known to cause ulcers. When compared to conventional medications, the methanol extract of Bambusa arundinacea leaves has been shown to have a considerable anti-inflammatory effect against both immunologically and carcinogeninduced paw oedema, as well as antiulcer activity in albino rats. The most effective anti-inflammatory activity trial with the least harmful (no ulcerogenic) activity was discovered to be the combination of methanol extract and phenylbutazone (a non-steroidal anti-inflammatory agent, or NSAIA). Therefore, the best anti-inflammatory medication was found to be produced by combining a herbal product (methanol extract of Bambusa arundinacea) with modern medicine (NSAIAs). This combination can be helpful for the long-term treatment of chronic inflammatory conditions like rheumatoid arthritis with peptic ulcers, which are frequently observed.

- **ANTI-FERTILITY ACTIVITY**

Male rats' fecundity was decreased by an ethanolic extract of Bambusa arundinacea. Seven days of BASE treatment reduced fertility. Only eight days after BASE removal did mating behavior fully restore. There were fewer spermatozoa in the caput and cauda epididymis. Additionally, spermatozoa extracted from the cauda epididymis of experimental mice showed a concurrent decrease in motility [20]. Bamboo leaves are frequently used as animal feed, and some of the compounds found in them have been linked to miscarriages in pregnant animals [47]. This suggests that teratogenic active compounds, such as alkaloids, flavonoids, and triterpenoids, can kill a fetus in the uterus and then cause spontaneous abortion or resorption. However, it was shown that eating bamboo leaves, which contain antifertility chemicals, decreased the motility of sperm in male mice. The sperm mobility of cow spermatozoa was able to be decreased by the addition of bamboo leaf infusion, and the pace at which sperm motility declined increased with concentration.

- **ANTI-HYPERTENSIVE ACTIVITY**

A variety of proteins, carbohydrates, amino acids, minerals, fat, sugar, fiber, and inorganic salts are all present in bamboo stalks. Freshly picked bamboo shoots contain cyanogenic glycosides in high concentrations, which can lead to major issues. About 57–67% of the total amino acid content is made up of tyrosine. The aqueous extract of bamboo shoots contains fractions of angiotensin converting enzyme inhibitory peptide, often known as bamboo shoot peptide [BSP]. Because the phenolic ingredient in BSP has a vasodilatory effect that lowers hypertension, the proportion that was found indicated that Asp-Tyr was the essential compound and that it lowers systolic blood pressure medicinal uses of Bambusa vuigaris include-

- Managing intestinal parasites, discomfort, and stomach issues
- Managing skin issues
- Managing menstruation discomfort
- Addressing fever and diabetes

There is possible medical use for every part of the bamboo plant, including the rhizome, culm shavings, leaves, roots, shoots, and seeds.

CONCLUSION

An alternative material for inexpensive constructions is bamboo. When compared to other bamboo varieties such as Nola, Jewa, and Yngoon, Barak bamboo is showing greater strength.

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Bamboo fibers do not demonstrate the strength for which they were intended. Nonetheless, the hybrid concrete made by combining bamboo and steel shows comparable strengths to steel-reinforced concrete.

Because the experimental ultimate moment is greater than the intended moment, the bamboo reinforced slab can be designed using the working stress approach. It is advised to use bamboo instead of stee reinforcement.

Digital image analysis can be used to determine the fiber distribution in bamboo, allowing for a somewhat accurate calculation of the modulus of elasticity. Twin-mesh bamcrete offers excellent resistance to bullet fire. However, RCC panels are not demonstrating strong enough defense against gunfire.

Bamboo is a little-studied plant with a lot of therapeutic potential. In addition to its usage in food and crafts, bamboo requires further research. For bamboo to be widely used in a variety of therapeutic applications, its ethnopharmacological uses must be supported by solid scientific research.

In addition to providing millions of people with shelter, bamboo has long been used as a substitute for food and energy. Its natural abundance of amino acids, minerals, vitamins, and fibers makes it a promising raw material for nutritional products and medicines. Every part of bamboo contains beneficial Phytoconstituents that are good for human health, and it also contributes significantly to environmental maintenance due to its high capacity to sequester carbon and its 35% higher oxygen release than an equivalent stand of trees.

Globally, people are currently dealing with several health issues, such as obesity, cancer, and cardiovascular illnesses; bamboo may be a useful treatment for most of these conditions. Bamboo and their products were primarily utilized in traditional forms or as traditional medicine in the past, but in the last ten years, their high-quality nutritional components which are outlined below have led to their conversion and consumption as an advanced medicinal product.

- Anti-inflammatory qualities: Bamboo includes substances that have anti-inflammatory qualities, which could help cure ailments including asthma and arthritis.
- Antioxidant qualities: Packed with antioxidants, bamboo shoots can lower the risk of chronic illnesses like cancer and heart disease and shield cells from harm brought on by free radicals.
- Wound treatment: Because of its antibacterial qualities and capacity to accelerate the healing process, bamboo sap has long been used to treat burns, wounds, and other skin injuries.
- Respiratory health: In traditional medicine, bamboo leaves are used to treat ailments like bronchitis and coughs because they are thought to offer respiratory advantages. Digestive health: Rich in dietary fiber, bamboo shoots can help to regulate bowel motions and enhance digestive health.

Strong scientific research is required to support bamboo's ethnopharmacological application in a variety of therapeutic contexts. Carbohydrates, glycosides, saponins, alkaloids, flavonoids, phenolics and tannins, phytosterols, triterpenoids, oils, and fats were all detected in the methanol extract of the leaves of the plant, according to qualitative chemical tests, while phytosterols and triterpenoids were detected in the other extracts.

Analgesic, antipyretic, antidiabetic, anti-inflammatory, antibacterial, antioxidant, antiviral, anti-kidney stone, diuretic, hepatoprotective, abortifacient, anti-anxiety, and renal impairment medications are among Bambusa vulgaris's pharmacological properties.

The plants of the Bambusoideae family have made significant contributions to the realms of pharmacology and ethnobotany. The bamboo plants utilized by local communities and indigenous people in Asian countries, particularly to treat various illnesses and disorders, were compiled in this review article. It's interesting to note that these known plant species and their therapeutic benefits may serve as a solid foundation for further CAM research. Accurately identifying plant resources and materials for appropriate harvesting, as well as the compounds extracted, is essential to preventing their damage.

To help preserve and use native medicinal plants in the future, it is very important to make sure the right raw materials are being gathered and supplied for pharmaceutical use. In other words, people respect and are cognizant of indigenous tradition and wisdom. Therefore, it has been demonstrated that ethnobotanical research, particularly in Asian countries, may be one of the helpful methods for cataloging and documenting possible therapeutic plants, such as Bambusoideae.

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Bamboo is a resource that is widely available and should be investigated because its potential is not being fully realized. Utilizing bamboo in construction will lower carbon emissions and advance environmental preservation. More research is required to describe the development of bamboo materials, support the market industry's focus on bamboo materials, and efficiently reveal the possible benefits of bamboo-based building materials.

The authors affirm that none of the work described in this publication may have been influenced by any known conflicting financial interests or personal ties.

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MEDICINAL PURPOSE OF GARLIC (ALLIUM SATIVUM)

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ABSTRACT
This review aims to update and evaluate garlic's medicinal properties, which include anti-inflammatory, antifungal, antibacterial, antioxidant, detoxifying, preventing platelet aggregation, lowering blood pressure, lowering cholesterol and triglycerides, preventing arteriosclerosis, antithrombotic, and anticancer effects. According to scientific studies, the sulfur compounds found in or extracted from garlic are responsible for the vast range of dietary and therapeutic benefits of garlic . Garlic's biological active component, allicin and its derivatives, are organic sulfur compounds that have powerful pharmacological effects. The most significant components of this plant, according to studies on its chemical makeup, are organosulfur compounds including allicin, diallyl disulphide, S-allylcysteine, and diallyl trisulfide, which are essential for its nutraceutical uses. One of the most significant bulb vegetables, garlic is used to flavor and spice cuisine. Numerous beneficial minerals, vitamins, and other compounds for human health can be found in garlic. In addition, it contains high levels of calcium, potassium, phosphorus, sulfur, iodine fiber, silica, sugar, protein, and fat.
KEYWORDS: *Allium Sativum, Antiviral,Antimicrobial,Antifungal, Antiviral,Anticancer, Antidiabetic, Antioxidant*

INTRODUCTION

For thousands of years, humans have utilized pure or unrefined natural compounds from plants, animals, and microorganisms to treat a wide range of illnesses. One of the herbs that has been extensively studied throughout the years and utilized for centuries to combat infectious infections is garlic (Allium sativum L.). For many years, there has been debate concerning the taxonomic status of garlic and allied taxa. The most recent classification scheme for garlic, which was based mostly on nuclear ribosomal DNA sequences, was class Liliopsida, subclass Liliidae, superorder Liliianae, order Amaryllidales, family Alliaceae, subfamily Allioideae, tribe Allieae, and genus Allium [3].

Garlic contains a lot of biologically active ingredients that help with its medicinal uses. Around the world, people have used garlic to treat a variety of illnesses, such as high blood pressure, infections, and snake bites. Some cultures have also employed it to fend off evil spirits. Garlic is also used to lower cholesterol and cardiovascular risk, as well as for its antibacterial and antineoplastic properties[2].Garlic was suggested by traditional Chinese and Indian medicine to treat leprosy and parasitic infestations, as well as to help with digestion and breathing.Garlic has significant epidemiologic evidence supporting its medicinal and preventative uses. Numerous clinical and experimental studies indicate that garlic and its compounds have numerous beneficial effects[4]. The complex sulfurcontaining molecules that are quickly absorbed, changed, and digested make up the active ingredients. Garlic reduces total cholesterol levels by about 10% and improves HDL/LDL ratios, according to pooled data from many randomized trials. Garlic is also a mild antihypertensive that decreases blood pressure by 5–7%, according to randomized research. Additionally, garlic increases fibrinolytic activity and suppresses platelet aggregation, which lessens clots on injured endothelium[5]. Hippocrates, the Father of Medicine, once stated, "Let food be thy medicine and let medicine be thy food. Hippocrates recommended garlic to treat a number of ailments, which lends credence to this claim. In many cultures, garlic was used to give workers vigor and improve their ability to perform their jobs. It was administered to the first Olympic competitors in Greece as possibly one of the first "performance enhancing" substances[6].

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Fig-1

According to reports, ginger is one of the most widely utilized herbs in traditional medicine across many nations. Ginger has long been used by the Chinese to treat conditions including rheumatism and bleeding, as well as to aid with digestion and relieve nausea. It has reportedly been used to cure respiratory disorders, toothaches, snakebite, and baldness. In Arabian medicine, ginger is used as an aphrodisiac.However, some Africans think that eating ginger on a daily basis may help keep mosquitoes away[7].

Botanical Description – Garlic is a perennial plant with fine leaves and a compound bulb made up of 10–50 tiny bulb-lets, or cloves, encased in a thin, pinkish or white sheath and with short, embedded roots. With the exception of those close to the center, the cloves are asymmetrical in shape. Garlic can reach a height of 1.2 m (4 ft) and has hermaphrodite blooms. The plant yields bulblets as well as seeds. Since ancient times, the health advantages of garlic and other Allium species have been recognized. The herb garlic, which is grown practically everywhere, seems to have come from central Asia and then moved to China, the Near East, and the Mediterranean region before heading west to Mexico, Central and Southern Europe, and Northern Africa (Egypt)[8].
The stem's lower half is heated by the long, flat, pointed leaves; the scape is slender, smooth, and shiny, with long, beaked spathes that enclose heads that contain firm bulbils. The tiny, white flowers extend into leafy tips[9].

Chemical Composition -The vacuolar enzyme alliinase quickly lyses the cytosolic cysteine sulfoxides (alliin) in garlic when it is crushed, sliced, chewed, dehydrated, ground up, or otherwise harmed by bacteria. Seventy to eighty percent of the thiosulfinates are allicin, a transiently produced chemical. Usually, alliinase transforms alliin into allicin. Diallyl sulfide (DAS), diallyl disulfide (DADS), ajoene, and dithiins are among the compounds that allicin rapidly decomposes into. Concurrently, g-glutamyl cysteine is transformed into S-allylcysteine (SAC) through a mechanism distinct from the alliin–allicin pathway .

1. There are at least 33 sulfur compounds in garlic, including: S-allylcysteine (SAC), vinyldithiins, allylpropyl disulfide, diallyl trisulfide (DATS), alliin, allicin, ajoene, and others.
2. A number of enzymes (superoxide dismutases, catalases, myrosinase, peroxidase, and allinase,catalases, myrosinase, arginases, lipases, peroxidase, and superoxide dismutases),
3. Amino Acids: Threonine, Methionine, Asparagic Acid, Glutamic Acid, and Arginine.
4. Glutamyl peptides, or proteins
5. B1, B2, B6, C, and E vitamins
6. Trace minerals such as Se, Ge, and Te 7. Prostaglandins, lipids, biotin, nicotinic acid, fructan, pectin, and adenosine[1].

Traditional Use -: According to Velisek et al. (1997), garlic is one of the most significant bulb vegetables and is used as a seasoning and spice in meals. Due to its strong flavor, it is frequently used as a seasoning or condiment all over the world. Additionally, Edwards et al. (1997) observed that garlic is employed in food preparation, especially in stews and in the production of preserved goods. The chemicals that give garlic its pungency, lachrymatory qualities, and spicy aroma include diallyldisulfid, allicin, and other organic sulfur compounds.Garlic enhances the flavor and facilitates digestion of food. It is a key component in many of the world's most popular

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cuisines. In the food sector, garlic is used as a spice in both fresh and dehydrated forms. According to Ahmad (1996), it is dehydrated into various products like flakes, slices, and powders. Garlic not only enhances food flavor but also contains a variety of beneficial minerals, vitamins, and other compounds that are beneficial to human health. In addition to vitamins, it's high in sugar, protein, fat, calcium, potassium, phosphorus, sulfur, iodine fiber, and silicon. It has a high nutritional content. Due to its strong flavor, it is mostly used as a spice, seasoning, and flavoring for foods that contain both green[2].

Medicinal Properties – Antiviral Effect –

Antiviral action against coxsackievirus species, herpes simplex virus types 1 and 2, influenza B, para-influenza virus type 3, vaccinia virus, vesicular stomatitis virus, human immunodeficiency virus type 1, and human rhinovirus type 2 has been confirmed by garlic and its sulfur compounds. Ajoene, allicin, allyl methyl thiosulfanate, and methyl allyl thiosulfanate were the chemicals in garlic that had the most virucidal activity; the polar fractions of alliin, deoxyalliin, diallyl disulfide, and diallyl trisulfide showed little activity. Garlic is an effective treatment for the influenza B virus and the herpes simplex virus, according to several scientific investigations[3].When administered with influenza vaccine, it increases the formation of neutralizing antibodies and protects mice from infection with the intranasally implanted influenza virus, demonstrating its antibacterial properties in vivo[8].

Anti-Microbial Effect

Since Pasteur originally reported garlic's antibacterial qualities in 1958, other studies have shown how efficient and broad-spectrum its antimicrobial activity is against a variety of bacteria, viruses, parasites, protozoa, and fungi (Jaber and AlMossawi, 2007). Commercial antibiotics are used as an alternate treatment for a variety of diseases because garlic is more effective and has fewer side effects[3].Due to its extensive use as a topical and systemic antibacterial agent, garlic is known as Russian penicillin [10].

Anti-Fungal Effect

Against a variety of fungus, such as Candida, Torulopsis, Trichophyton, Cryptococcus, Aspergillus, Trichosporon, and Rhodotorula species, garlic extracts shown a broad spectrum fungicidal action. Garlic extract has recently been shown to prevent Rhodotorula mucilaginosa and Meyerozyma guilliermondii from germinating and growing[11].Pure allicin was found to have antifungal properties. The antifungal activity was reduced when the allicin was extracted from the process using a solvent.Schmidt and Marquardt initially demonstrated antifingal action in 1936 while dealing with epidermophyte cultures[3].

Antioxidant Effect

Both whole garlic and aged garlic extract have direct antioxidant properties and raise the levels of the antioxidant enzymes glutathione peroxidase and catalase in the blood. Allicin, an extract from garlic, effectively scavenges exogenously produced hydroxyl radicals in a dose-dependent manner; however, heating to 100°C for 20 minutes decreased their efficacy by around 10%[3].Both the 10% homogenate of garlic in physiological saline solution and its supernatant were effective in lowering the levels of free radicals in cigarette smoke. Additionally, smashed garlic produces allicin, another substance that is plentiful in dried garlic. Recent research indicates that allicin breaks down into the powerful antioxidant sulfenic acid[6].

Antidiabetic Activity

Garlic contains allicin, which has a strong hypoglycemic impact. This effect is believed to be caused by enhanced hepatic metabolism, increased insulin release, and an insulinsparing effect[9].In diabetic mice, but not in normal mice, oral administration of garlic extract resulted in a significant drop in serum glucose, total cholesterol, triglycerides, urea, uric acid, aspartate amino transferase, and alanine amino transferase levels, as well as a rise in serum insulin. An investigation comparing the effects of glibenclamide and garlic extract revealed that the latter had a less potent antidiabetic impact than the former[8].

Cardiovascular Effect

It was found through statistical analysis that people with lower blood pressure are more likely to eat more garlic. Numerous epidemiologic studies have shown a negative relationship between the development of cardiovascular disease and garlic use. The authors believe that whereas d-penicillamine is ineffective in treating mean systolic blood pressure[12].Garlic's involvement in coronary heart disease was studied in rabbits, and it was discovered that regular garlic consumption could really erase pre-existing atherosclerotic plaques and lesions[3].

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Anti-Cancer Effect

Garlic plays an important role in preventing cancer, particularly tumors of the digestive system, according to numerous epidemiological, clinical, and laboratory research investigations. A cohort study conducted in the Netherlands discovered that eating garlic significantly reduced the risk of developing stomach cancer. In a human population research, regular garlic consumption decreased the incidence of stomach, colon, and esophageal cancer[7].The strongest radical scavenging action was exhibited by Sallylcysteine and S-allylmercapto-L-cysteine, the two main compounds found in old garlic. Furthermore, in a number of animal models, it has been discovered that some organosulfur compounds obtained from garlic, such as S-allylcysteine, slow the growth of chemically produced and transplantable cancers. Garlic consumption may therefore offer some protection against the development of cancer.[5]

CONCLUSION

Since ancient times, garlic (Allium sativum L.) has been linked to a variety of biological functions. The biologically active components found in the plant play a crucial part in its nutraceutical use. It is widely used as a spice or condiment in continental cuisine and is known to contain important minerals, vitamins, and protein. In addition, the plant may have a number of pharmacological properties.Many pharmacological qualities, including antioxidant, anti-inflammatory, rheumatologic, blood circulation booster, anti-cramp, antiulcer, anticholinergic, analgesic, antimicrobial, anti-stress, anti-cancer, immune system booster, and anti-diabetic, have been documented for them.

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IMPROVED & OPTIMIZED MEDIA FOR BUTTONMUSHROOM

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Author, Guide, Principle

ABSTRACT

A total of 294 single spores were isolated from eleven-button mushroom strain and 132 were evaluated for their fertility of which 24 were found non-fruiting whereas eleven single spore isolates started fruiting after second flush of cropping and remaining were fertile. button mushrooms (Agaricus bisporus) were coated by dissolving four different organic coating materialviz. apple peel powder), carboxymethyl cellulose, tartaric acid, and glycerol monostearate in distilled water and dipping the mushroom in coating solution for 45 to 75 experiments were conducted using response surface methodology and the coated as well as uncoated samples were stored at ambient and refrigerated conditions. Various quality parameters of button mushroom were measured. During the last decade several major breakthroughs have been achieved in mushroom biotechnology, which greatly enhanced classical mushroom breeding. Other hand efficacy of developed organic coating powder tested on button mushroom (Agaricus bisporus) shows some prominent practical application for fresh produce. From analysis and interpretation ofthe experimental result it was found that organic coating powder was effectively increase the shelflife of button mushroom also maintained its quality.

INTRODUCTION

Indian agriculture will continue to be a main strength of Indian economy. With the variety of agricultural crops grown today, we have achieved food security by producing over 200 million tons of food grain. However, our struggle to achieve nutritional security is still on. Though we have significant achievements in milk, vegetables and fruit production still we have to do more. Infuture, the ever-increasing population, depleting agricultural land, changes in environment, watershortage and need for quality food products at competitive rates are going to be important issues.To meet these challenges and to provide food and nutritional security to our people, it is importantto diversify the agricultural activities in areas like horticulture. Diversification in any farming system imparts sustainability. Mushrooms are one such component that not only impart diversification but also help in addressing the problems of quality food, health and environment related issues. One of the major areas that can contribute towards goal of conservation of natural resources as well as increased productivity is recycling of agro-wastes including agro-industrial waste. Utilizing these wastes for growing mushrooms can enhance income and impart higher levelof sustainability. Commercial production of edible mushrooms bio converts the agricultural, industrial, forestry and household wastes into nutritious food (mushrooms). Indoor cultivation of mushrooms utilizes the vertical space and is regarded as the highest protein producer per unit areaand time-almost 100 times more than the conventional agriculture and animal husbandry.

This hi-tech horticulture venture has a promising scope to meet the food shortages without unduepressure on land. Mushroom farming today is being practiced in more than 100 countries and its production is increasing at an annual rate of 6-7%. In some developed countries of Europe and America, mushroom farming has attained the status of a high-tech industry with very high levels of mechanization and automation. Present world production of mushrooms is around 3.5 million tones as per FAO Stat and is over 25 million tones (estimated) as per claims of Chinese Associationof Edible Fungi. The wide variation in world production data in FAO Stat and CAEF is partly dueto the fact that in FAO Stat, mushroom means butt on mushroom (Agaricus spp.) along with the boletes, morels and tuber, whereas CAEF data covers all types of Mushroom .China alone is reported to grow more than 20 different types of mushrooms at commercial scale and mushroom cultivation has become China's sixth largest industry.

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Furthermore, the production and consumption of the Agaricus Bosporus mushroom increased in the past years and production occupied the first rank and constitute by 40% of the production by the rest of the fungi known internationally (Nasiri et al 2013). It became a desirable food instead of meat because of its high nutritional value, as it contains 20-40% of protein on a dry weight basis,and its proteins are similar to animal meat proteins in terms of quality, while it ranked the third after meat and eggs in terms of quantity as well as, it's content of mineral salts, essential amino acids and vitamins (A, D, B1, B2, and B3), which earned it high medical importance, so doctors advise to give it food for patients with heart disease, atherosclerosis, and high blood pressure as well as containing some inhibiting materials for cancer tumors growth,

Therefore, the growing need for this in Iraq as it is characterized by its high nutritional value. A bisporus had highly nutritious qualities with a rich source bisporus . A cancer, and antioxidant, reduction as antifungal activity, strain were diabetic-inflationary, anti-blood pressure and cholesterol, liver protective, antifibrotic, anti contents have a high moisture sample bisporus . A Depending on harvest and growth. It has both medicinal and nutritional Due to their excellent digestibility, protein. In addition to being a great source of protein, mushrooms are also a meat tivefor alternant free, and -Erol, gluten, and minerals, and are low in calories, fat, cholesteric source of vitamin.

To improving the production and quality of mushroom by adding biochar and ash to the casing layer, two different media are needed for the cultivation of mushrooms, commercial Agaricus bisporus strain available to meet specific demands for fresh and processed products is very limited.Despite an enormous on the part of mushroom scientists, conventional breeding techniques have resulted in few novel strains. Two different media are needed for the cultivation of mushrooms togrow fruiting bodies, one of them A .bisporus(the material utilized to cover the mushroom compostto induce the transition from asexual to (Pardo reproductive growth after complete colonization This casing layer had the effect to promotes an ecological change and improving the quality of thecompost also had an impact on the management of cultivation conditions, depended on the geneticcapacity of the mycelium induction rather depended on physical, chemical and microbiological factors as pH, particle size and electrical conductivity.

The casing layer has an alkaline pH of 7-8 this rate has important to grow this mushroom and another hand help control the presence of competitors such as Trichoderma, which grows better at acidic, sometime could adding some supplement to improve character casing layer, also could adding biochar and ash.

To improve and increase the shelf life of button mushroom use of coating is essential, the past fewyears, research has been focused on the development of new sustainable coatings, based on biodegradable polymers. The type of coating to be used is based on the biological property of theproduct to be coated. In postharvest processing, many researchers have used different types of edible coating material such as Natural Seal TM 1020, cellulose-based edible coating on cut appleand other fruits and vegetables crop, which have proven increase in their shelf life.

It is evident from the above that the yields of major market crops of the world will have to be morethan doubled, simply to maintain the current consumption pattern .In case of mushrooms, for whichvast markets (like India) still remain to be trapped, the production at global level may have to be more than doubled in the next 18-20 years.

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It is possible to cultivate mushrooms under varied climatic conditions. Some of the important mushrooms for temperate, sub-tropical and tropical conditions are briefly described below:

A.TEMPERATURE MUSHROOM

The button mushroom is most popular variety both for domestic and export market At global levelit ranks first. The major production is from Hitech projects .However, Hitech projects faced several problems in successful production resulting in high cost of production. The main problemsare quality of raw materials particularly, wheat/paddy straw, chicken manure and some times gypsum resulting Button mushroom6 Mushrooms: Cultivation, Marketing and Consumption in poor quality of compost and poor yield. Besides, high cost of imported cultures/spawn, machineries and casing material are other impediments.

In recent years evenincreasing cost of electricity has given severe blow to the mushroom industry.Several medium scale projects have started growing mushroom targeting big city markets utilizingindigenous machinery and equipment. However, during winter season hundreds of seasonal growers undertake button mushroom production particularly in Northern States targeting big citieslike Delhi, Chandigarh, etc.

ADVANTAGES

There are good opportunities in India both for domestic and export market for buttonmushroom .

- Seasonal production is possible in big way in Jammu and Kashmir, HimachalPradesh, Punjab, Haryana, Uttar Pradesh, Uttaranchal, Bihar, West Bengal, NorthEastern Region, Madhya Pradesh and other areas where temperature remainsbelow 200C during winter season. In this situation cost of production is low.
- Raw materials are easily and cheaply available for compost and casing material
- Awareness about food and medicinal values is increasing in the country thuscreating betterdomestic market.
- Transport facilities are available both by land and air
- There is increasing market for postharvest products like pickle and soup powder.

LIMITATION

- High cost of energy for year round production.
- Un-organized production and sale particularly by seasonal farmers.
- Lack of facilities to produce quality compost, casing material, spawn and processed products.

PRESERVATION TECHNIQUES

1. Vegetative mycelium culture (Tissue culture)
   Under aseptic conditions using laminar flow, young basidiocarp is cleaned withsterilized distilled water and dipped into 0.1% mercuric chloride or 2.5% sodiumhypochlorite solution for 1 min. In case of button mushroom, the basidiocarp is air driedand split open longitudinally from centre and vegetative mycelial bits are cut from thecollar region (junction of pileus and stipe). Whereas, in black ear mushroom, the ear iscut along the edgewith a sterilized scissor and inner tissues are scrapped and smallbits of tissues are taken. These bits are then washed in sterilized water to remove HgCl2and placed in oven sterilized petriplates having culture media. Inoculated plates areincubated at 250 ± 20C in a BOD incubator. In general, tissue from inside the fruiting bodyof mushroom is taken from the region of active growth.Within 4-5 days the new mycelium growing

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over the media is observed. The purecultures are made by carefully transferring young mycelium from growing edge of thecolony from petriplate to test tubes and again incubating at 250 ± 20Cfor 10-14 days (350Cfor Volvariella spp.

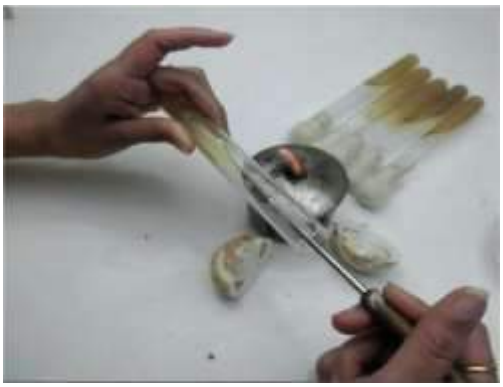

FIG 2 : Tissue Culture

Fig 3 : Tissue Culture In Tube

2. MULTISPORE CULTURE

Under aseptic conditions, spore mass is scraped from a fresh spore print orbasidiocarp andsuspended in 100 ml of sterilized distilled water in flasks and shaked toobtain uniform spore suspension. A few drops of this suspension is added to lukewarmculture medium and poured intooven sterilized petriplates. Petriplates are rotated tohomogenize the spore suspension into culturemedium. The culture medium is allowedto solidify and then petriplates are incubated at 250°± 20Cfor 3-4 days (350C for Volvariellavolvacea). The spore germination is observed under microscopeand germinating sporesare transferred carefully to culture tubes along with a piece of agar containing a culturemedium recommended for the mushroom species isolated. The culture tubes are thenincubated at 250C for 10-14 days in case of Agaricus bisporus and A.bitorquis and at320Cfor Volvariella volvacea for 7 to 10 days.

RESULT AND DISCUSSION

Optimization of process parameters to enhance the shelf life of coated button mushroom :

Numerical optimization of the processing parameters, that is, APP concentration (% wt/vol), CMCconcentration (% wt/vol), and dipping time (s) was carried out using Design-Expert 10.0.1 statistical software. All the responses, that is, weight loss (%), shrinkage ratio, Aw, color variation(ΔE*), microbial load [log (cfu/g)], % FRSA, and shelf life were considered for optimization. Optimization of the samples was done on the basis of data (except shelf life) taken on the 2nd dayof storage for coated button mushroom. The goal set up for optimization of processing parameters and response variables for shelf life enhancement of coated button mushrooms.Based on abovementioned criteria, the optimization was carried out . Out of the 48 solutions obtained, the one with highest desirability (0.853) was selected. The most optimum point obtained ,. It shows that after coating of freshly harvested button mushroom, the coated button mushroom can be safelyconsumed for 5 days.

CONCLUSION

Succesfull inhibition from the microbial attack on coated button mushroom samples were found by the application of developed organic coating powder and The practice of added casing layer isan important technique for improving yield in the industrial production of A. bisporus. Waste conversion such as biochar and ash can be selected as quality supplements. These wastes were suggested to enhance properties of the physical and chemical of casing layer thus had effect for the development and growth of the fruiting bodies

Concluded that the biochar added to casing layer when applied properly has significant benefits, including an increase in yield and biological efficiency and the most important one is reduction infruit formation cycle when combined with ash. On the other hand, the application of biochar, ash and interaction added increase protein fruit body content.

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Mushrooms Agaricus bisporus(White Iraqi Strain),

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5. *Alqaisi, Tikrit Journal for Agricultural Sciences (2024) 24 (1): ISSN:1813-1646 (Print); 2664-0597 (Online)Tikrit Journal for Agricultural Sciences Journal Homepage: http://www.tjas.org, improving the production and quality of white button mushroom (Agaricus bisporus) by adding biochar and ash to the casing layer,*
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A REVIEW OF ANALYSIS ON MPOX (MONKEY POX VIRUS) A GLOBAL PANDEMIC

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ABSTRACT

Mpox, previously known as monkeypox, is a zoonotic viral disease caused by the monkeypox virus, which is a member of the Ortho poxvirus genus.

Although historically endemic to Central and West Africa, recent outbreaks have highlighted its potential to spread more widely.

Mpox is characterized by symptoms similar to smallpox, including fever, rash, and lymphadenopathy, with a progression from flu-like symptoms to a distinctive rash that evolves from macules to pustules.

Transmission occurs through direct contact with infectious bodily fluids, lesions, or contaminated materials, and can also be zoonotic, involving animals such as rodents.

Recent global outbreaks have prompted increased surveillance, public health responses, and vaccination efforts. Research continues to focus on improving diagnostic methods, understanding the virus's epidemiology, and developing effective treatments and vaccines.

Given its potential for widespread dissemination, continued vigilance and preparedness are essential to managing and mitigating future outbreaks. [1]

KEYWORDS: *MPOX , Vaccination , DROC , Orthopoxviruses , Chickenpox , Clade I , Clade II .*

INTRODUCTION

Although mpox is uncommon among children in the United States, pediatrics cases have been identified during the 2022 global mpox outbreak. Vaccines and antiviral drugs established for other Ortho poxviruses are now extensively used to prevent and treat mpox in both children and adults in the United States. Although the scientific literature on mpox in children and adolescents is limited, previous case reports can provide important information about the clinical characteristics and potential sequel of untreated clade II mpox in these age groups. [2]

In this review, we summaries the epidemiology and clinical aspects of mpox in children and adolescents, In May 2022, an unprecedented global outbreak of mpox(previously known as monkey pox) was recognized. Since then, over 80,000 cases have been identified in nonendemic nations, including over 29,000 in the United States. Although the current global outbreak has predominantly affected adults, over 500 laboratory confirmed cases in children and adolescents have been reported worldwide, with many more children and adolescents being exposed to the mpoxvirus (MPXV). [1]

There are two well-defined MPXV clades with distinct clinical characteristics: clade I (previously known as the Congo Basin Clade) and clade II (formerly known as the West African Clade). The vast majority of published research, including mostpediatric case reports, covers infection with clade I MPXV, which has been linked to greater severity and higher-class fatality rate than clade II . Because of their relevance to the current outbreak, this review focuses on outbreak and pediatric case reports of clade II MPOXV infection. As the outbreak progress, pediatricians and other health care practitioners who care for children and adolescents should be prepared to recognise, diagnose, and treat mpox and it's consequences, as well as contribute to preventive efforts, [2]

Epidemiology

The Ortho poxviruses MPXV is endemic to West and Central Africa and is capable of infecting both people and animals. Despite the fact that the virus was first identified in caged monkeys and given the moniker "monkey pox," the most likely reservoir species is small ground rats. Close skin-to-skin contact or mucosal contact with lesions are the most prevalent ways that MPXV is transferred. Respiratory secretions and transplacenta transmission are thought to occur less frequently. The most typical way for humans to become infected is by contact with other sick people or animals; fomite-facilitated transmission through towels, linens, or other household items can also happen. the MPXV format requires 3 to 17 days to incubate. Depending on how the condition was acquired, there can be differences in its severity and clinical presentation the Congo reported the first known human case of mpox. instances total—five involving children—were documented in three West African countries in 1970 and 1971. In the 1970s

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and 1980s, more cases of mpox were documented in Central Africa once it was discovered to be a zoonosis that can infect humans. The majority of cases were in youngsters, and most were sporadic or happened in small clusters after a common animal exposure. Initially, it was believed that there was not much room for prolonged person-to-person transmissions or recently, during a 2003 outbreak of clade II MPXV in the United States, children and adolescents accounted for 26% of confirmed or probable cases sickness was linked to contact with pet prairie dogs co-housed with imported small animals from Africa.[3]

Cross-protection against mpox is provided by the smallpox immunisation. Adults
are becoming more vulnerable to MPXV as decades have passed since the standard smallpox immunisation program ceased in 1972; the median age of cases that have been reported has risen from 4 years in the 1970s to 21 years in the 2010s. Whether age-related physiological changes in MPXV sensitivity exist independently of vaccination status is unknown. Unlike previous outbreaks, the ongoing 2022 outbreak in the United States has resulted in 0.3% of cases to date being caused by children and teenagers under the age of the comparatively low number of MPXV infections among children in 2022 is probably due to a significant change in transmission, in addition to the absence of immunity among the majority of adults: mpox is now mostly (though not exclusively) disseminated through close, intimate human-to-human contact. It has spread especially among gay, bisexual, and other males who have sex with men in their social networks as a result, it is critical that pediatricians stay vigilant for the risk of mpox when caring for adolescent or young adult males who have sex with male partners, even though mpox can afflict people of various ages, gender identities, and sexual orient [4]

Mpox, previously known as monkeypox, is a zoonotic viral disease caused by the monkeypox virus, which is a member of the Ortho poxvirus genus.
Although historically endemic to Central and West Africa, recent outbreaks have highlighted its potential to spread more widely.
Mpox is characterized by symptoms similar to smallpox, including fever, rash, and lymphadenopathy, with a progression from flu-like symptoms to a distinctive rash that evolves from macules to pustules.

Transmission occurs through direct contact with infectious bodily fluids, lesions, or contaminated materials, and can also be zoonotic, involving animals such as rodents.

Recent global outbreaks have prompted increased surveillance, public health responses, and vaccination efforts. Research continues to focus on improving diagnostic methods, understanding the virus's epidemiology, and developing effective treatments and vaccines. Given its potential for widespread dissemination, continued vigilance and preparedness are essential to managing and mitigating future outbreaks.[2]

Clinical Trials
The hallmark of mpox is a rash with well-circumscribed, deep-seated, solid or rubbery lesions that, in later stages, are frequently umbilicated. Macular, popular, vesicular, and pustular phases of the rash are followed by scabbing over and desquamation (Fig 1). The rash may appear in different parts of the body at different frequently hurt or itch. During the disease, fever, chills, myalgia's, or malaise can strike at any point. Additionally, lymphadenopathy is frequently seen.

Mpox photographs. Clinical images show an early vesicle (1A), an umbilicated pustule (1B), an ulcerated lesion (1C), and a generalised pustular rash (1D). 1A, 1B, and 1C images are credited to the UK Health Security Agency. 1D image credit: NHS England's High Consequence Infectious Diseases Network. The severity, complications, and case fatality ratios (CFR) of mpox may differ in children and adults. Other Ortho poxviruses, such as variola and vaccinia, have been shown to put children at risk for serious consequences.1Historical accounts of the severity of clade I mpox in children and adolescents indicate increased severity in children [5]

linked to greater severity and a higher case fatality rate than clade II.Because of their relevance to the current outbreak, this review focusses on outbreak and pediatric case reports of clade II MPXV infection. As the outbreak progresses, pediatricians and other healthcare practitioners who care for children and adolescents should be prepared to recognize, diagnose, and treat mpox and its consequences, as well as contribute to preventative efforts. [2]

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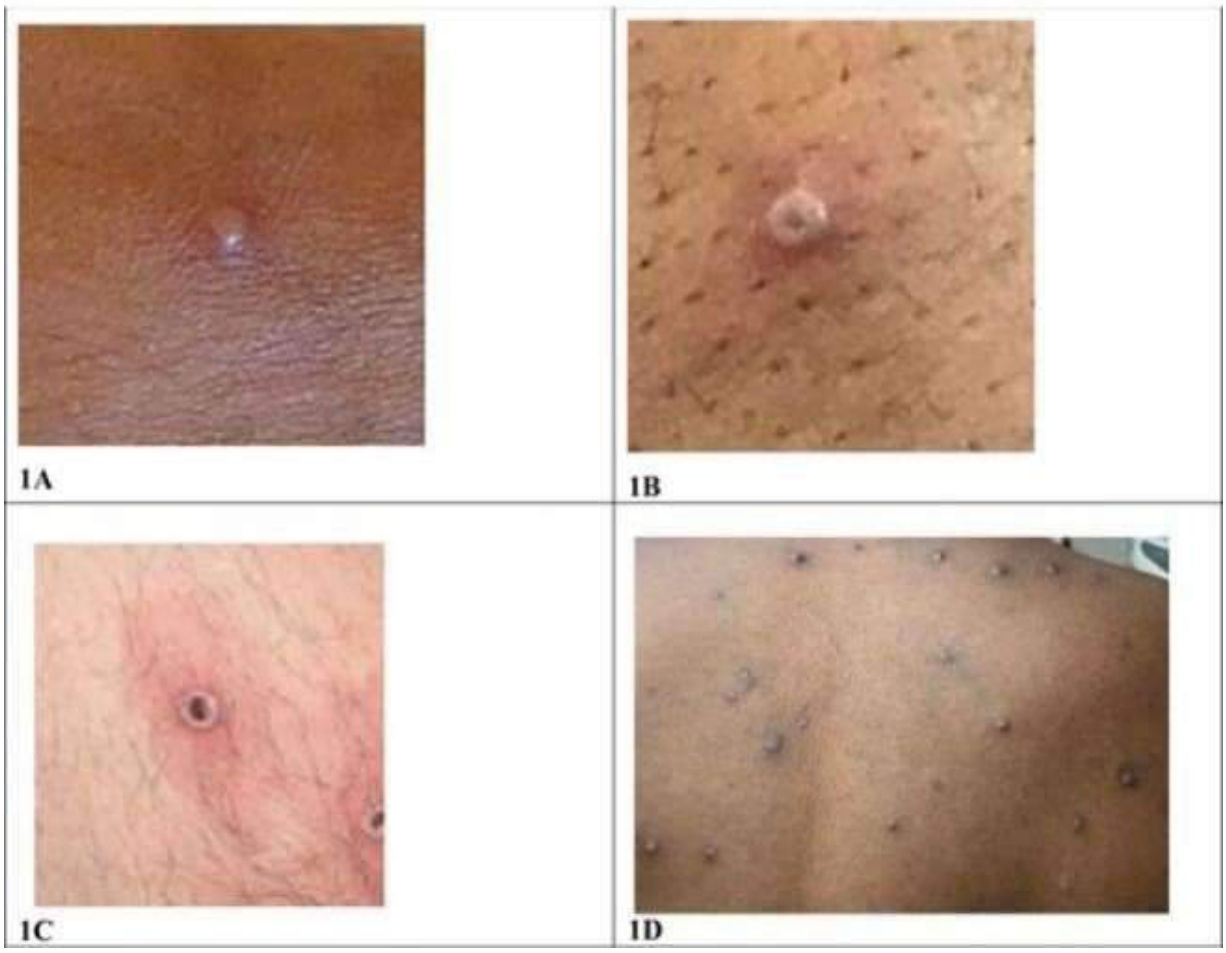
Figure No. 1



Congo from 1980 to 1985 found that children under 8 years old, especially those under 4 years old, had a higher CFR of up to 15%. However, a further analysis revealed that the mortality rate attributable to clade I mpox in the Democratic Republic of Congo is lower than previously reported due to possible underreporting of cases and misattribution of death from mpox. Finally, of the 92 potential instances included in the latter study, three deaths were linked to mpox, and all three occurred in patients under the age of three. [5]

Clinical Descriptions of Clade II Mpox Before 2022 Outbreak

Here are few detailed accounts of clade II mpox, including its consequences and severity in children and teenagers. For this review of clade II mpox prior to the current outbreak, we searched multiple databases for articles in English that included a pediatric age-related term (e.g., "NICU," "preschool," or "teenager") and a term related to mpox or mpox vaccines or therapeutics (e.g., "monkey pox," "MPXV," "JYNNEOS," or "tecovirimat"). We summarised papers presenting individual case level data for patients under 18 years old with confirmed or probable mpox.

Cases were limited to those caused by clade II MPXV, which was identified through molecular genotyping or inferred from location in West Africa. We included cases from outbreaks in Nigeria, Sierra Leone, Ivory Coast, and Liberia from 1970 to 1979, as well as the 2003 outbreak in the United States, a 2017 outbreak in Nigeria, and one additional 2019 case from Sierra Leone. These findings are complemented with previously unreported case data from the 2003 US outbreak provided by the US. Centres for Disease Control and Prevention (CDC). [5]

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Table No.1

	1970-1990	1991-1999	2000-2009	2010-2018
Democratic Republic of Congo (former Zaire)	386 (confirmed) [27] + 2–5 [28, 29]	511 [28, 30]	Not fully enumerable [3, 11, 24]	Not fully enumerable [16, 31–34]
Central African Republic	6 (confirmed) [35]	N/A*	4 [19]	At least 68 (at least 29 confirmed) [19, 34, 36–38]
Cameroon	2 (confirmed) [27, 39]	4 (1 confirmed) [28, 29, 40, 41]	N/A*	16 (1 confirmed) [34]
Nigeria	10 (3 confirmed) [42–44]	N/A*	N/A*	244 (101 confirmed) [34]
Ivory Coast	2 (confirmed) [43, 45]	N/A*	N/A*	N/A*
Liberia	4 (confirmed) [42, 46]	N/A*	N/A*	2 (confirmed) [19]
Sierra Leone	1 (confirmed) [42, 46]	N/A*	N/A*	At least 2 (2 confirmed) [19, 46, 47]
Gabon	1–10 (one confirmed) [28, 29, 40, 48]	N/A*	N/A*	N/A*
USA	N/A*	N/A*	47 (37 confirmed, 10 probable) [49, 50]	N/A*
Republic of Congo	N/A*	N/A*	12 (3 confirmed, 8 probable) [51, 52]	88 (2 confirmed) [53, 54]
South Sudan	N/A*	N/A*	49 (10 confirmed, 9 probable) [55]	N/A*

Confirmation status mentioned between brackets if known. * No information available

Table No.1 Confirms Cases According To Country

Every patient acquired a rash. Of the 22 patients, 17 (77%) had more clinical information available. The rash was described as papular, vesicular, pustular, or umbilicated, which is consistent with descriptions of clade II MPXV infections in adults Lesions were most commonly recorded on the trunk, palms or soles, arms or hands, back, and legs or feet. All cases in whom rash distribution was characterised had a generalised rash. Fever, chills, or sweats were present in 12 (71%) of 17 cases, lymphadenopathy in 8 (47%) (with cervical lymphadenopathy being the most prevalent), sore throat in 7 (41%), headache in 7 (41%), and myalgias in 4 (24%). As postexposure prophylaxis (PEP), a 12-year-old child who had mpox had recently gotten the live vaccine known as Dryvax. Seven days following the vaccination, symptoms appeared. He didn't need to stay at a hospital. It's unclear how the immunisation helped this patient's symptoms lessen. Neither vaccinations nor MPXV-directed treatments were given to anyone else [5].

Clinical Description During 2022

In 2022, cases of mpox in children and adolescents have been reported from several different nations. Compared to earlier clade II mpox epidemics, the severity and rate of complications appear to be lower, which could be due to early diagnosis, easy access to healthcare, the availability of antiviral medication, or other factors. An overview of pediatric cases in the US in 2022 included 83 cases: Conjunctivitis, discomfort, and secondary skin infections were among the problems that occurred; 22% of patients received antiviral therapy, 11% were hospitalised, none needed intensive care unit care, and no deaths were reported. An investigation on instances in Spain, with ages ranging from 7 months to 17 years, found that none of the patients got antiviral therapy, one developed a small secondary skin infection, and none necessitated hospitalisation.

In 2022, a number of clinical case reports of newborns with clade II mpox were reported. An MPXV and adenovirus-infected newborn was reported to have a generalised rash and respiratory failure in a UK publication. According to a Florida report, a baby under two months old was admitted to the hospital due to possible secondary skin infections and mpox lesions around the eyes. The baby was treated with tecovirimat, intravenous vaccine (VIGIV), and preventive ocular trifluridine, and eventually made a good recovery. Finally, a 7-month-old baby in Spain recovered totally without therapy after a brief episode of illness.

Adult cases of mpox in the current outbreak have been characterised by relatively localised disease, most commonly involving the genitals, though a variety of dermatologic and other symptoms have been documented. In the present outbreak.

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Reported complications of mpox in adults include proctitis, urethritis, phimosis, balanitis, secondary bacterial skin infections, conjunctivitis, and other visual problems, as well as encephalomyelitis. Children and adolescents who contract mpox during the current outbreak may be at risk for these problems. Sexually active teenagers with anogenital lesions are especially susceptible to anal or genitourinary problems. [6]

Diagnosis

When considering mpox in children and adolescents, other conditions that cause rashes are likely to be considered, such as varicella (chickenpox), herpes zoster (shingles), hand, foot, and mouth disease, scabies, molluscum, contagiosum, impetigo, measles, herpes simplex virus, syphilis, allergic skin rashes, drug eruptions, and a variety of congenital infections in neonates. Unlike varicella lesions, which exhibit regional pleomorphism, mpox lesions in a single location of the body are usually at the same stage of evolution. Although the mpox rash takes around 2 to 4 weeks to develop, many other rash disorders, such as varicella, progress much faster. He specific characteristics of lesions, slow progression, and painful or pruritic nature can help distinguish the mpox rash from other systemic rashes. Other sexually transmitted infections (STIs) to consider in sexually active adolescents with genital lesions include syphilis, chancroid, herpes simplex virus, and lymphogranuloma venereum. [2]

MPXV testing should be undertaken if epidemiologic criteria are met or if clinical characteristics provide a strong suspicion. The ideal method for testing Ortho poxviruses is polymerase chain reaction (PCR), which is currently accessible in public health and certain private laboratories. Sample collection should include thorough swabbing, although unroofing or aspirating the lesion is neither necessary nor advised. Testing the crust is also an option. Single laboratory test results should be interpreted with caution in patients with a low risk of mpox.32 Serologic testing for MPXV may be considered as an adjuvant in patients who have not been immunised against Ortho poxviruses if there is a risk of false positive testing or if testing the rash is impossible.

MPOXV Treatment

As of this writing, the US Food and Drug Administration (FDA) has not approved any drugs to treat mpox, and there is no clinical trial data to guide therapeutic decisions. Investigational drugs can be considered to treat children and adolescents with severe illness (e.g., sepsis, encephalitis); those with involvement of anatomic areas that may result in serious sequelae, such as scarring or strictures; and those who may be at increased risk for severe illness, such as children under the age of one year, those with immunocompromising conditions, and those with eczema or any other condition that causes a break in the skin. [6]

Tecovirimat is an antiviral medicine that was originally intended to fight smallpox.
It is now used as the first-line treatment for mpox in the United States under an Expanded Access Investigational New Drug protocol. Tecovirimat appears to be well tolerated in adults, while its efficacy is unknown; outcome data from the present outbreak are being gathered, including data from randomised controlled trials. Tecovirimat has been administered to infants, children, and adolescents in at least 18 cases in the United States, including 8 children under the age of five, and a newborn as young as ten days old in the United Kingdom. Dosing for infants and children under 13 kg has not yet been determined, and the difficulty of attaining precise dosing and adequate absorption with enteral tecovirimat must be balanced against the risk of nephrotoxicity from intravenous tecovirimat. Other therapies may be considered as adjuncts or alternatives to tecovirimat after consulting with doctors and public health authorities. VIGIV is licensed for the treatment of vaccinia virus vaccine problems and has already been used for this purpose; it has also been administered to small infants during the present outbreak with no documented adverse events. Other antiviral drugs, notably cidofovir and its prodrug, brincidofovir, have shown in vitro effectiveness against Ortho poxviruses, but their usage is limited by possible renal and hepatic damage. The examples shown in Table 1 illustrate clade II mpox problems that have been reported in pediatric patients. In children with mpox, treatment teams should be on the lookout for indications of encephalitis. To reduce the danger of a secondary skin infection, lesions should be cleaned and covered. It's also important to make sure kids don't contact their eyes after touching lesions or pick at them. MPXV infections in the eyes have the potential to be blinding and leave a lasting corneal scar. Given the potential of autoinoculation, topical trifluridine can be used in conjunction with ophthalmology to treat mpox's ocular symptoms as well as a preventive measure for lesions on the eyelid or near the eye.

Prevention

Pediatric healthcare professionals are crucial in the fight against mpox. Importantly, adolescents with a history of sexual activity, especially men who engage in sexual activity with other men, may benefit from more extensive counselling for multiple sclerosis (mpox), including behavioral preventive techniques, identification of mpox symptoms, and vaccination as preexposure prophylaxis (PrEP).Adolescents and young adults who are determined to be at increased risk for mpox, such as gay, bisexual, or other MSM, transgender, or nonbinary people with more than one sexual partner in the last six months, or those diagnosed with a STI in the last six months, as well as those who anticipate experiencing the above risks, should be offered mpox PrEP where minor consent laws allow or with parental consent [8]

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According to current US guidelines, individuals who have mpox should stay away from other people during the whole period of their illness, from the moment symptoms start to appear until lesions have healed, scabs have come off, and a new layer of skin has grown. Individuals who have mpox should refrain from touching, tending to others, including kids, or sharing a bed with others who do not have the virus. The present outbreak has also shown that there may be significant surface contamination in the home, indicating the potential for transmission through termites. Homes where mpox patients have resided should be cleaned from the surfaces, and clothes and other linens worn by mpox patients should be washed. [8]

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FORMULATION AND EVALUATION ON HERBAL ANTI ACNE FACE WASH

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ABSTRACT

Natural remedies are more acceptable in the belief that they are safer with fewer side effects than the synthetic ones. Herbal formulations have growing demand in the world market. The present work deals with the development & evaluation of the herbal anti-acne face wash containing aqueous extract of neem leaves (Azadirachta indica), turmeric (Curcuma longa), liquorice root, shahi jeera, orange peel & hydro alcoholic extract of fruit of nutmeg (Myristicafragrance). Although various topical herbal formulations for acne are available in the market, we propose to make pure herbal formulation without using any synthetic ingredient. The plantshave been reported in literature having good anti-microbial, anti-oxidant & anti-inflammatoryactivity. Various formulation batches i.e., F1 to F5 were prepared using xanthum gum in variedconcentrations. Prepared formulations (F1 to F5) were evaluated for various parameters like colour, appearance, consistency, washability, pH & spreadability. Optimized batch of formulation was compared with the marketed preparation. Amongst all the formulation studiesbatch F2 was found optimum for all the parameter. It was very good attempt to establish the herbal anti-acne face wash containing aqueous extract of neem leaves, turmeric rhizomes & fruits of nutmeg.

KEYWORDS: *Neem, Xanthan gum, herbal ingredients, anti-acne face wash.*

INTRODUCTION

Acne vulgaris is a common skin disorder that affects almost everyone at least once in their lifetime. It is classified into five types: comedonal, papular, pustular, cystic, and nodular acne. Comedonal acne is non-inflammatory and consists of two types: whiteheads and blackheads. Whiteheads appear as white-colored, raised bumps, while blackheads appear as open pores containing dark-colored skin debris made up of melanin, sebum, and follicular cells.Papules are red, solid, elevated lesions that are usually less than 5mm in diameter. Pustules areskin elevations containing purulent material. Cysts and nodules are solid, elevated lesions thatinvolve deeper dermal and subcutaneous tissues. Cysts are less than 5mm in diameter, while nodules exceed 5mm.

The pathogenesis of acne involves multiple physiological factors such as follicular hyper-proliferation, increased sebum production due to higher androgen levels, and colonization of organisms like Propionibacterium acnes and Staphylococcus epidermidis. Recent research hasshed light on various other factors like variation in target cell sensitivity, biological markers, neuro-endocrine, genetic, and environmental factors, which play a role in the pathogenesis of acne.

There are several herbal and synthetic ingredients that have shown remarkable beneficial effects on acne vulgaris. These ingredients may act through various mechanisms such as controlling sebum secretion, inhibiting Propionibacterium acne and Staphylococcus epidermidis, removing the keratin layer, and preventing inflammation or redness. Manyformulations are available in the market with a variety of active pharmaceutical ingredients forthe treatment of acne. Topical formulations such as gels, creams, and lotions are commonly used for treating acne.

- **TYPES OF ACNE**

➢ **Acne Vulgaris**

Acne vulgaris is the medical name for common acne -- the presence of blackheads, whiteheads, and other types of pimples on the skin. The most common spots for breakouts arethe face, chest, shoulders, and back. Although mild acne may improve with over-the-counter treatments, more severe forms should be treated by a dermatologist.

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- **Nodules**

Nodules are large, inflamed bumps that feel firm to the touch. They develop deep within the skin and are often painful. Nodules should be treated by a dermatologist since they can scar.Over-the-counter treatments may not be powerful enough to clear them up, but prescription drugs can be effective.

- **Mild Acne**

Acne falls into the "mild" category if you have fewer than 20 whiteheads or blackheads, fewer than 15 inflamed bumps, or fewer than 30 total lesions. Mild acne is usually treated withover-the-counter topical medicine. It may take up to eight weeks to see a significant improvement

- **Cysts**

Cysts are large, pus-filled lesions that look similar to boils. Like nodules, cysts can be painfuland should be treated by a dermatologist since they also can scar. People who develop nodulesand cysts are usually considered to have a more severe form of acne.

- **Pustules**

Pustules are another kind of inflamed pimple. They resemble a whitehead with a red ring around the bump. The bump is typically filled with white or yellow pus. Avoid picking or squeezing pustules. Picking can cause scars or dark spots to develop on the skin.

❖ **BENEFITS**

1. Cleanses the face. Cleansing is the first step on the ladder of CTM.
2. Hydrates the skin.
3. Slows down signs of premature aging.
4. Treats acne.
5. Stimulates blood circulation.
6. Helps other product to penetrate properly into the skin.
7. Deals with multiple skin issues.

AIM

The Aim of formulation is to formulate, evaluate the herbal anti-acne facewash.

- **OBJECTIVES**

1. To develop a purely herbal formulation for acne treatment that does not contain any syntheticingredients.
2. To evaluate the efficacy of the herbal formulation in treating acne and reducinginflammation.
3. To identify the optimal concentrations of natural ingredients that provide the best anti-acneeffect.
4. To assess the safety of the herbal formulation by conducting toxicity studies and ensuringthat it does not cause any adverse effects.
5. To compare the efficacy of the herbal formulation with that of the commercially availablesynthetic products for treating acne.
6. To establish the herbal formulation as a safe, effective, and affordable alternative to syntheticproducts in the market.
7. To provide a natural skincare solution that is accessible to a wide range of people, includingthose who prefer using natural remedies or are sensitive to synthetic products.

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PLAN OF WORK

- **Literature Survey/Review**

1. Review of literature for selection of topic.
2. Searching of ingredients for project work

Procurement Of Ingredients.(Physical Characterisation)

Formula Selection

Formulation/Preparation of Herbal Facewash

Evaluation

Outcome/Conclusion

Report Writing and Submission

METHODOLOGY

A) Selected ingredient for formulation of Herbal Facewash:

1. Ashwagandha
2. Turmeric
3. Nutmeg Seed
4. Liquorice Root
5. Honey
6. Shahi Jeera
7. Lemon Juice
8. Xanthan Gum
9. Orange Peel Extract
10. Rose Water

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1) Ashwagandha

1. Ashwagandha is an evergreen shrub that grows in Asia and Africa. It is commonly usedfor stress. There is little evidence for its use as an "adaptogen."
2. Ashwagandha contains chemicals that might help calm the brain, reduce swelling, lower blood pressure, and alter the immune system.
3. Since ashwagandha is traditionally used as an adaptogen, it is used for many conditionsrelated to stress. Adaptogens are believed to help the body resist physical and mental stress. Some of the conditions it is used for include insomnia, aging, anxiety and manyothers, but there is no good scientific evidence to support most of these uses. There is also no good evidence to support using ashwagandha for COVID-19.

- **Uses**

1. One of the most noticeable benefits of Ashwagandha for skin include its ability to reduce acne, since it is anti-bacterial and anti-inflammatory in nature.
2. Ashwagandha deeply cleanses the skin tissue of its impurities and removes residual dirtand grime from the face.

2) Turmeric

1. Turmeric is a common spice that comes from the root of Curcuma longa. It contains a chemical called curcumin, which might reduce swelling.
2. Turmeric has a warm, bitter taste and is frequently used to flavor or color curry powders, mustards, butters, and cheeses. Because curcumin and other chemicals in turmeric might decrease swelling, it is often used to treat conditions that involve pain and inflammation.

- **Uses**

1. It helps you fight pimples and blemishes and keeps your skin clear, glowing and pimple- free.
2. The turmeric's anti-inflammatory properties can help to avoid pore clogging and soothe your skin

3) Nutmeg Seed

a. NUTMEG Botanical name - Myristica Fragrans
b. Part used - Dried Kernels of seeds
c. Family - Myristicaceae
2. THE IMPORTANT CONSTITUENTS IN NUTMEGS ARE:

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a. Myristicin b. Elemicin c. Eugenol d. P-cymene e. Phytosterin f. Amyolodextrin

- **Uses**

1. Helps in fading blemishes, gives a radiant spotless skin.
2. Reduces the wrinkes, fine lines and calms the skin

4) Liquorice Root

1. Synonyms:-Glycyrrhiza; Liquorice root; Glycyrrhizae radix.
2. Biological Sources:- Liquorice is the dried, peeled or unpeeled, roots, rhizome or stolonof Glycyrrhiza glabra Linn.
3. Family:-Leguminosae.
4. Geographical Source: Liquorice is grown in the sub-Himalayan tracts and Baluchistan.It is cultivated on a large scale in Spain, Sicily and Yorkshire (England)

- **Uses**

1. Licorice is said to have a soothing effect on skin and helps to ease inflammation.
2. The glycyrrhizin found in licorice can reduce redness, irritation and swelling, and isused to treat skin conditions like atopic dermatitis and eczema.

5) Honey

1. Synonyms: Madhu,
2. Biological Source: Honey is a sugar secretion deposited in honey comb by the bees.
3. Family Apdae, order Hymenoptera.
4. Geographical Source: Honey is produced in Africa, Australia, New Zealand, Californiaand India.
5. Colour: pale yellow to yellowish brown
6. Odour: Characteristic, pleasant
7. Chemical Constituents: • Honey is aqueous solution of glucose 35%, fructose 45%, andsucrose about 2%

6) Shahi Jeera (Cumin)

1. The cumin includes antibacterial, antimicrobial, and anti-inflammatory properties that canhelp calm the skin and keep it free of blemishes.
2. Cumin's essential oils can help tone the skin and increase blood flow and circulation. Thisnatural ingredient can also be used as a great exfoliator, so it's a win-win.

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7) Lemon Juice Extract

Lemons contain antibacterial properties (which is why the juice is a great cleanser), helpingfight the bacteria agents causing your breakouts. It also acts as a natural exfoliator — removing dead skin cells that can clog your pores — as well as a great oil-eliminator.

- **Uses**

1. Lemon juice naturally contains vitamin C, an antioxidant that may help reduce skin damage and premature aging.
2. Due to its high pH levels, lemon can decrease oil on the skin and reduce inflammation.
3. Antifungal.
4. Skin lightening.

8) Xanthan Gum

1. It works to efficiently thicken the foam without jeopardizing it.
2. Xanthan gum is a substance used in making some foods and medications. It has different effects in these products: It can add thickness, keep textures from changing, and hold ingredients in place

- **Uses**

It is used as an emulsifier too.

9) Orange Peel Extract

1. Vitamin C in the peels helps cleanse your skin deeply and unclogs pores by removingexcess oil and grime.
2. Regularly using orange peel powder can help you prevent unpleasant skin breakouts,blackheads, acne, and even reduce existing blackheads or acne

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10) Rose Water

1. Cool and refreshing, rose water for skin contains anti-inflammatory and antibacterialproperties that help reduce redness and acne.
2. It is also known to help soothe major skin care issues like eczema or rosacea.

- **Uses:**

1. Rose water has been used as a beauty product for thousands of years, so it's no surprisethat it can improve your complexion and reduce skin redness.
2. The antibacterial properties may help reduce acne.
3. The anti-inflammatory properties can reduce skin redness and puffiness.

B]FORMULA

Sr.no	Ingredients	Quantity taken for 10g gel				
		F^1	F^2	F^3	F^4	F^5
1	Ashwagandha Extract	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
2	Turmeric Extract	0.2 ml	0.25 ml	0.5 ml	0.25ml	0.2 ml
3	Nutmeg Extract	0.5 ml	0.5 ml	0.25ml	0.2 ml	0.25ml
4	Orange Peel Extract	0.2 ml	0.2 ml	0.25ml	0.2 ml	0.2 ml
5	Liquorice Extract	0.2 ml	0.25ml	0.25ml	0.2 ml	0.25ml
6	Shahi Jeera Extract	0.2 ml	0.2 ml	0.2 ml	0.2 ml	0.2 ml
7	Lemon Juice Extract	0.2 ml	0.2 ml	0.25ml	0.2 ml	0.2 ml
8	Honey	0.5 ml	0.5 ml	0.5 ml	0.5 ml	0.5 ml
9	Xanthan Gum	0.1 mg	0.15ml	0.2 ml	0.2 ml	0.15ml
10	Rose Water	q.s	q.s	q.s	q.s	q.s

C] PROCEDURE

1. Herbal extracts maceration. Method by be prepared by maceration method.
2. All extracts are Filtered clearly & stored in suitable containers.
3. Desired quantity of gelling agent i.e. xanthan gum weighed accurately.
4. Transfer this xanthan gum powder in a beaker &allow to mix in water with continuousstirring. (completely gel mixture were formed)
5. The desired quantity of ashwagandha &turmeric extract dissolved in lemon juice andhoney.
6. Desired quantity of other herbal extracts were added in mixture of xanthan gum withcontinuous stirring.

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7. Add rose water in that formulation in sufficient quantity.
8. The prepared formulation were filled in a suitable container & label accordingly.

EVALUATION TEST FOR FACE WASH

1. **Physical evaluation:** Physical characteristics like colour, look, and uniformity werevisually assessed.
   Colour: yellowish.
2. **Determination of pH:** A calibrated digital pH meter was used to measure the pHof the formulation's 1% aqueous solution at a fixed temperature.
   PH: 4.8
3. **Grittiness:** The product was checked for the presence of any gritty particles by applying it on the skin.
4. **Spreadability:** On the wooden block a ground glass slide was mounted. On this ground slide, 2 gram of the prepared gel was put. Thereafter, a second glass slide with the same dimensions as the fixed ground slide was sandwiched between this slide and the gel preparation. The hook is provided on the second glass slide. For five minutes, aweight of 500 mg was placed on top of the two slides to remove air and produce a homogenous gel film between them. A specified amount of weight was added to the pan, which was connected to the pulley. The top slide's time (in sec) needed to travel adistance of 5 cm was recorded [25].
   Spreadability was calculated by using the following formula,$S=M\times L/T$
   Were, S- Spreadability
   M- Weight tied to the upper slide (20gm).L- Length of the glasss (6.5cm).
   T- Time in sec.
5. **Washability:** The product will be painted by hand and was observed under runningwater [25

RESULT AND DISCUSSION

The findings from the evaluation are presented in Table 2. The prepared formulation had an orange color while the marketed formulation had a green color. Formulations F1, F2, F3, and F4 were observed to have a semi-solid consistency. All the formulations were found to be uniform and easily washable. Moreover, all formulations had a slightly alkaline pH which wasfound to be compatible with the normal physiology of the skin.

Formulation/ Batch(Code)	Colour	Consistency	Washability	pH	Spreadability (gm-cm/sec)	Viscosity (cP)
Marketed	Green	Semi-Solid	Good	5.8	5.909	1475
F^1	Yellow	Semi-Solid	Good	4.9	4.193	1490
F^2	Yellow	Semi-Solid	Good	5.3	2.6	1535
F^3	Yellow	Semi-Solid	Good	5.4	5.416	1620
F^4	Yellow	Semi-Solid	Good	4.9	2.826	1412
F^5	Yellow	Liquid	Good	4.6	4.642	1540

CONCLUSION

The use of natural remedies is gaining popularity due to the belief that they are safer and have fewer side effects than synthetic ones. Herbal formulations, in particular, have a growingdemand in the world market. The development of a herbal face wash containing aqueous extracts of Ashwagandha leaves, turmeric rhizomes, liquorice root, and nutmeg seeds is a commendable effort. The study showed that batch F3 of the developed herbal formulation wassuperior to the other formulations.

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