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FORMULATION AND EVALUATION OF TOOTHPASTE

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ABSTRACT
The aimed of current research to formulate herbal toothpaste utilizing plant extract like Neem leaves, Guava leaves, Cinnamon bark other ingredient are Camphor, Honey. The plant extract ingredient posses the anti bacterial. The herbal toothpaste formulated which can satisfy all the required condition to keep the mouth fresh and prevent tooth decay by bacteria. The formulated herbal toothpaste compared with marketed preparation. Physical examination: Colour-greenish brown, smooth in nature, relative density-10.2, pH-8.2,Extrudability- 90.37, spredability- Good and stable formulation. The anti-microbial evaluation against Staphylococcusaureus reveal that formulated herbal tooth paste exhibited notable activity with ZOI of 19.7 mm at MIC of 25µg/mL the outcome of this research herbal toothpaste shows equal patronizing and engrossing passion over the marketed preparation it was consider after the comparing the marketed preparation(Colgate, Dabour Red, Dantkanti) with formulated herbal toothpaste. It has been good scope in future dental research and dental health of public.

1) INTRODUCTION

The chemical agent that could supplant patient dependent mechanical plaque control and it reduce and prevent oral disease. Self performed mechanical plaque removal is one of most accepted method of controlling plaque and gingivitis. The mechanical plaque control is time consuming and some are may lack motivation for these procedures.The therapeutic effect showing plants has been beneficial to the oral health from the thousands of year throughout the world. The traditional medicine has advantage more than the side effect like allergies. Neem is one of the most widely researched tropical trees for the development therapeutic action. 20 year ago the component of neem extract was analyzed.

The chewing 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. Hence, there is an urgent need to promote traditional preventive measured that are acceptable, easily available and cost effective.

The neem has been antibacterial activity is has 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. The leaf extract of neem showed superior antiviral and antihyperglycemic activity in vitro and in vivo on animals. It showed good in vitro broad range antibacterial activity.

Nanotechnology may defined as the creation of material, drug and devices that are used to manipulate matter that in specific size and increase the drug targeting. While the using various herbal be use to developed the nano-materials to enhances the action.

It is an two group comparative study. Food debris are white small particles on teeth, can be easily rinsed off. The dental plaque is thin film of bacteria that sticks to teeth and yellow colour can't be rinsed off. There has been closer relationship between tartar, calculus and periodontal disease. The extract are use in various category like NeemAntibacterial, Guava-Anti-inflammatory, BabulAstringent, Kalmi-Flavoring agent and other ingredient are Camphor-Antisetic, HoneySweetening agent, Glycerine-Humectant, Cal Carbonate- Abrasive, SLS-Detergent and also use the sodium chloride and distilled water. This led to paing increased attention on using natural ingredients in herbal dentrifrices. The aimed of current research to formulate herbal toothpaste utilizing plant extract like Neem leaves, Guava leaves, Cinnamon bark other ingredient are Camphor, Honey. The plant extract ingredient posses the anti-bacterial. The herbal toothpaste formulated which can satisfy all the required condition to keep the mouth fresh and prevent tooth decay by bacteria. The formulated herbal toothpaste compared with marketed preparation. Physical examination: Colour-greenish brown, smooth in nature, relative density-10.2, pH-8.2, Extrudabil-ity-90.37, spredability-Good and stable formulation. The anti-microbial evaluation against Staphylococcus aureus reveal that formulated herbal tooth paste exhibited notable activity with ZOI of 19.7 mm at MIC of 25µg/mL. the outcome of this research herbal toothpaste shows equal patronizing and engrossing passion over the marketed preparation it was consider after the comparing the marketed preparation(Colgate, Dabour Red, Dant-kanti) with formulated herbal toothpaste. It has been good scope in future dental research and det-al health of public. The

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chemical agent that could supplant patient dependent mechanical plaque control and it reduce and prevent oral disease. Self performed mechanical plaque removal is one of most accepted method of controlling plaque and gingivitis. The mechanical plaque control is time consuming, and some are may lack motivation for these procedures. The therapeutic effect showing plants has been beneficial to the oral health from the thousands of years throughout the world. The traditional medicine has advantage more than the side effect like allergies. Neem is one of the most widely researched tropical trees for the development therapeutic action. 20 year ago the component of neem extract was analyzed. The chewing 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. Hence, there is an urgent need to promote traditional preventive measured that are acceptable, easily available and cost effective. The neem has been antibacterial activity is has evaluated from the ancient times. It has been used for the various activities like as astringent, antiseptic, insecticidal, anti ulcer and for cleaning the teeth in pyorrhoea and other dental disease. The leaf extract of neem showed superior antiviral and antihyperglycemic activity in vitro and in vivo on animals. It showed good vitro broad range antibacterial activity. Nanotechnology may defined as the creation of material, drug and devices that are used to manipulate matter that in specific size and increase the drug targeting.

Oral hygiene is an important key to maintain good appearance, impression of an individual and gives confidence. The tooth consists of two parts, crown and the root. The crown of the tooth is covered by outer surface called enamel and it is the hardest tissue in the tooth. The major composition of enamel is hydroxyl apatite other than that it consists of water and keratin1.Dentine is the beneath part of the enamel, which is a composite of hydroxylapatite. It also consists of 70% of the collagen water. Fluorine is the major component of dentine. Oral consists of not only tooth but also saliva for easy to swallow the food. Saliva is the major element which intended for lubricating the food and to maintain proper environment in the mouth. Saliva is produced by various glands such as Labial, lingual, buccal and palatal are the larger and smaller glands which produce saliva continuously to keep the tooth environment in the dynamic state. Proteins, enzymes, bacteria and muccopolysaccharide are present in the saliva and the inorganic materials like calcium, sodium, potassium,chloride, phosphate ions The main aim of this iinvestigation to evaluate the Herbal toothpaste formulations and comparing with three popular commercial toothpastes.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.

Ideal Properties

- Non irritant
- Impart no stain in tooth
- Keep the mouth fresh and Clean
- Prolonged effect
- Cheap and easily

2) LITERATURE SURVEY

1) Siswomihardjon W et al. (2007): The difference of antibacterial effect of nee leaves and stick extract. In this paper study determined the antibacterial effect of ethanolic seem leaves and stick extract in inhibiting the growth of streptococcus mutants.
2) Prashant GM et al (2007): The effect of mange and neem extract on four organisans cansing dental caries: Streptococcus mutant, streptococcus salivavivus, streptococcus mitis, and streptococcus sanguis: An in vitro study. In this paper, study was conducted to evaluate the antimicrobial effects of these chewing sticks on the microorganisms Streptococcus mutant, Streptococcus salivavives, Streptococcus mitis, and Streptococcus sanguis which are involved in the development of dental cares
3) N. Yigit, et al. (2008): Antifungal activity of toothpastes against oral Candida isolate. In this paper formulated antimicrobial compounds with the aim of preventing or reducing plaque, calculus, gingival inflammation or dental caries. The herbal toothpaste exhibited good motifungal activity against all Candida species.
4) Shah S et al (2016): Evaluation of antimicrobial effect of azadirachtin plante tract (Soluneem TM) on commonly found root canal pathogenic microorganisers (viz. Enter coccus faecalis) in primary teeth. The aim of this study is to evaluate the antimicrobial activity of Solueem when used as an intrigating solution along with other commonly uned imigating solution sodium hypochlorite (NaOCT) against Enterococcus faecalis
5) George J et al. (2009): The efficacy of a herbal based toothpaste in the control of plaque and gingivitis. The present study was conducted a double-blinded controlled clinical trial with parallel groups was designed to investigate the effectiveness of a herbal-based toothpaste in the control of plaque and gingivitis as compared with a conventional dentifice. The efficacy of Colgate Herbal over Colgate toothpaste was assessed in this study
6) Martinis J. Verkalli, et al. (2011): Efficacy of natural antimicrobials in toothpaste formulations against oral biofilms in vitro. This paper explain about biofilm formation is a natural process in the oral environment but needs to be controlled

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through regular brushing in order to prevent the development of caries and periodontal diseases.

7) Telrandhe R et al (2016): Nanotechnology for cancer therapy. This paper is an overview of advances and prospects in applications of nanotechnology for cancer treatment. Nanotechnology is an use for prevention, diagnosis, and treatment. nanotechnology offers a promise for the targeted delivery of drags, genes and protein to tumer tissue and therefore alleviating the toxicity of anticancer agent in healthy tissues
8) Meng-long Hu, et al. (2018): Effect of desensitizing toothpastes on dentine hypersensitivity: A systematic review and meta-analysis. This paper explain study about Randomized Controlled Trials (RCTs) comparing desetizing toothpastes with a toothpaste without desensitizing component in achit patients that suffer from DH were included..
9) Shishir Ram Shetty, et al. (2019): Herbal medicine as adjunct in periodontal therapies. A review of clinical trials in past decade. The aim of this paper was to malyse the literature published in the research related to herbal medicine as adjunct in periodontal therapies.
10) Nagehan Yilmaz, et al. (2021): Comparison of the abrasive effects of children's toothpaste on glass ionomer cement. This paper evaluates the effect of two different children's toothpaste on the surface property of the conventional class ionomer cement which is used in atraumatic restorative treatment method.
11) Marcin oleks, et al. (2921): Advantages of using toothpaste containing propolis and plant oils for gingivith prevention and oral cavity hygiene in cleft palate patients The aim of paper focus on prevention of dental caries and periodontal disease through elimination of these factors as well as recommending oral hygiene preparation and providing motivation is a one of the basic tasks of dental team

3) AIM AND OBJECTIVE

Aim

Formulation And Evaluation of Herbal Toothpaste.

Objective of the Study

- The objective of study is to formulate herbal base product and compare the efficacy with conventionally marketed formulated toothpaste and evaluated the various parameter like colour, spredabilty, foamabilityand anti-bacterial activity. However, there is approach to provide the formulation for commercial production of herbal dental product with environmental friendly attributes.
- The herbal toothpaste formulated which can satisfy all the required condition to keep the mouth fresh andprevent tooth decay by bacteria.
- In the formulation of herbal toothpaste various natural ingredients are used which are more effective andthey does not have any side effect.
- By using natural ingredients the cost of the product will get decreased and the product will get effectiveand of less cost by which the demand of this product will get increase.

4) PLAN OF WORK

1) Selection of Material

- Identify the materials required for the project. This involves researching and choosing materials that are suitable for the project's objectives and constraints.
- Consider factors such as cost, availability, durability, and environmental impact when selecting materials.
- Create a detailed list of the chosen materials, including specifications and quantities needed for the project.

2) Selection of Method

- Determine the most appropriate methods or techniques to be used in the project. This could involve manufacturing processes, research methodologies, or problem-solving approaches.
- Evaluate different methods based on factors like efficiency, feasibility, and resource requirements.
- Justify the selection of the chosen method and explain how it aligns with the project goals.

3) Formulation

- Develop a detailed plan or formulation for the project. This involves outlining the steps, tasks, and milestones that need to be accomplished to achieve the project objectives.
- Break down the project into smaller, manageable components and assign responsibilities to team members if applicable.
- Create a timeline or schedule for the project, taking into account deadlines and dependencies between tasks.

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4) Evaluation

- Establish criteria for evaluating the success of the project. This could include performance metrics, quality standards, or customer satisfaction measures.
- Implement regular evaluations throughout the project lifecycle to monitor progress and identify potential issues.
- Adjust the project plan as needed based on the evaluation results, ensuring that the project stays on track and meets its goals.

5) Literature Survey

- Conduct a comprehensive review of existing literature and research relevant to the project. This includes academic papers, books, articles, and other sources of information.
- Summarize key findings from the literature survey and highlight any gaps or areas where the project can contribute new knowledge.
- Use the literature survey to inform the project design, methodology, and overall approach.

5) MATERIAL AND METHOD

Ingredients that used in formulation of herbal toothpaste

Table 1 Plant Etract

SR.NO	INGREDIENT	QUANTITY (g)
1)	Neem stem and bark	**0.5**
2)	Babul Leaves	**0.5**
3)	Guava Leaves	**0.5**
4)	Kalmi Bark	**0.5**

Table 2 Composition of Chemicals

SR.NO	INGREDIENT	QUANTITY (g)
1)	Camphor	**0.5**
2)	Honey	**0.5**
3)	Calcium Carbonate	**3.5**
4)	Glycerine	**2.0**
5)	Para Hydroxyl Benzoic Acid	**0.3**
6)	Sodium Lauryl Sulfate	**0.5**
7)	Sodium Chloride	**0.2**
8)	Distilled Water	**q.s.**

Name : Neem
Family': Meliaceae

- **Botanical Name:** Azadirachta indica
- Neem bark is used as an active ingredient in a number of toothpastes and toothpowders. Neem bark has anti-bacterial properties, it is quite useful in dentistry for curing gingival problems and maintaining oral health in a natural way. Neem twigs are used as oral deodorant, toothache reliever and for cleaning of teeth.



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Name: Babul
Family: Fabaceae
Botanical Name: Acacia nilotica

- Leaves dried and mixed with mustard oil are used as toothpaste. This paste is very good for maintaining the overall dental health, countering bad breath and massaging the gums. The paste is also useful in treating pyorrhea (gum disease) and other tooth disorders



Name: Guava
Family: Myrtaceae
Botanical Name: Psidium guajava

- The leaf extract of guava has traditionally been used for its health benefits. Toothpaste is a dentifrice used clean, maintain and improve the health of teeth. Guava leaves were washed with distilled water and shade dried for three days and then powdered for extraction



Name: Kalmi Bark
Family:Lauraceae
Botanical Name: Cinnamomum verum

- Kalmi bark is used in herbal toothpaste because besides protecting teeth from various types of dental problems, kalmi bark is also effective in sensitive teeth, reducing gingivitis and teeth stains and eliminates bad breathing.



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Name: Honey
Family: Apidae
Scientific Name: Apis mellifera

- Honey is generally used in toothpaste not only for stops the growth of dental plaque bacteria, but also reduces the amount of acid produced, which stops the bacteria from producing dextran that is a component of dental plaque.



6) FORMULATION

1. Preparation of Herbal Ingredients:

a Objective:
Gather and process the herbal ingredients for use in the formulation.

b Activities:
Neem leaves, neem bark, kalmi bark, guava leaves, and babul leaves are collected.
These herbal ingredients are dried to remove moisture.
The dried herbs are ground into a fine powder using a domestic mixer.

2. Weighing and Mixing in Mortar:

a Objective:
Measure and combine the required quantities of herbal ingredients in a mortar.

b Activities:
Weigh the necessary quantity of each dried and ground herbal ingredient.
Place the measured herbal ingredients into a mortar.

3. Preparation of Solution:

a Objective:
Create a solution containing additional ingredients for the formulation.

b Activities:
Calcium carbonate, sodium lauryl sulfate, methyl cellulose, honey, and glycerine are selected as additional ingredients.
These ingredients are mixed in water to form a solution.
Acacia is added to the solution, presumably as part of the binding or thickening process.

4. Incorporating Solution into Mortar:

a Objective:
Combine the herbal ingredients with the prepared solution to form a paste.

b Activities:
The solution containing additional ingredients is added drop by drop into the mortar containing herbal ingredients.
The mixture is triturated (ground or crushed) thoroughly until a paste consistency is achieved.

5. Transfer and Storage:

a Objective:
Transfer the obtained paste into a suitable container for storage.

b Activities:
Once the desired paste consistency is achieved, transfer the paste into a suitable storage container.
The container should be appropriate for the type of paste being produced.

7) EVALUATION

Physical Examination (Colour, Odour, Taste, Smoothness, Relative Density) Formulated tooth gel was evaluated for its colour. The visually colour was checked. Odour was found by smelling the product. Taste was checked manually by tasting the formulation. The Smoothness was tested by rubbing the gel formulation between the fingers. Relative density was determine by weight in gram taken in 10 ml formulation and 10 mldistilled water using RD bottle in 10 ml formulation and 10 ml distilled water using RD bottle.

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Transparency Approximately 5 ml of formulated gel was taken in the 10 ml test tube and its transparencywas checked visual.

pH pH of the formulated gel was determined by using pH meter. In this method, 1 g gel was dispersed in 100ml purified water. The electrode was washed with double distilled water, dried by tissue paper and calibratedbefore use with standard buffer solution at 4.0, 7.0 and 9.0. The pH measurements were done in triplicate andaverage values were calculated.

Homogeneity The tooth gel shall extrude a homogeneous mass from the transparent collapsible tube or any sutible container by applying of normal force at 27±20C. In addition bulk of contents shall extrude from the crimp of container and then rolled it is a gradually.

Determination of sharp and edge abrasive particles Extrude the content 15-20 cm long on the butter paper,repeat the same process for at least ten collapsible tubes. Press with the contents of the entire length with fingertip for the presence of sharp and hard edged abrasive particles. Tooth gel shall not contain such particles.

Viscosity It was determined by using viscometer (Brookfield) with 2 number spindles**.**

Microbial Growth In this method nutrient agar media was used. The blank and sample petriplates were usedand formulated gel sample were aseptically transferred on the sample plate in cross pattern. The growth of microbial was check continuously upto 15 days**.**

Foamability The foamability of formulated tooth gel evaluated by taking small amount of formulation with water in measuring cylinder initial volume was noted and then shaken for 10 times. Final volume of foam wasnoted**.**

Determination of moisture and volatile matter 5 g of formulation placed in a porcelain dish containing 6-8cm in diameter and 2 -4 cm depth in it. Dry the sample in oven at 1050C.

Extrudability In this method, The formulated gel were filled in standard capped collapsible aluminium tubeand sealed by crimping to the end. The weights of the tubes were recorded. The tubes were placed between two glass slides and were clamped. 500 g was placed over the slides and then cap was removed. The amountof the extruded gel was collected and weighed. The percent of the extruded gel was calculated.

Spreadability In this method, slip and drag characteristic of gel involve. Formulated gel (2g) placed on theground slide under study. The formulated gel placed (Sandwich like) between this slide and another glass slides for 5 min to expel air and to provide a uniform film of the gel between slides. Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 80 g with the help of string attachedto the hook and the time (Sec) required by the top slide to cover a distance of 7.5 cm was noted. A short interval indicated better spreadability.

Formula was used to calculate spreadability:

$S=M \times L/T$

Where,

S= Spreadability

M= Weight in the pan (tied to the upper slide)L= Length moved by the glass slide

T= Time (Sec) taken to separate the upper slide from the ground slide**.**

Stability Study The stability study was performed as per ICH guidelines. The formulated gel was filled incollapsible tubes and stored at different temperature and humidity conditions, 25ºC±2ºC / 60% ± 5% RH, 30ºC±2ºC / 65% ± 5% RH, 40ºC±2ºC / 75%±5% RH for the period of three months and studied for appearance, pH and spreadability.

Anti-Microbial Activity The in-vitro anti-microbial study of formulated tooth gel was performed by disc diffusion method in triplicate maner by using Muller Hinton Agar medium against a pathogenic bacterial strain Staphylococcus aureus (S. aureus, MTCC 3160). S. aureus was initially cultured in nutrient broth and incubated at 37ºC for 24 Hrs. and then cultured cells were tend tomultiply in the Muller Hinton agar plates. Then the formulated tooth gel containing discs were placed over the bacterial plates and incubated at 37ºC forthe 24 Hrs, comparing ciprofloxacin as the positive control. The diameter of zone of inhibition (ZOI) was measured in millimetres (mm). The minimum inhibitory concentration (MIC) is the smallest concentration in which the compound displays no visible microbial growth. It was determined by agar streak dilution method in triplicate manner. The protocol involve formation of microbial suspension (~105 CFU/mL), application to the petridish with serial dilution and incubation of petridish at 37±1ºC. The MIC value was determined and the average was taken.

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Reading of Plate and Interpretation After 14 to 16 Hrs. of incubation, each plate was examined. If the platesatisfactorily streaked and the inoculum was correct the result of ZOI should be uniformly circular and confluent lawn of growth. After measured the diameter of ZOI the data was noted and interpreting the result.

8) RESULTS AND DISCUSSION

The herbal tooth paste formulation was prepared from Neem leaves, Guava leaves, cinnamon bark, natural ingredient and small amount of synthetic ingredient.The formulated herbal toothpaste greenish brown in colourand showed the good homogeneity with absence of lumps and good anti-microbial activity.

9) CONCLUSION

The research concluded that Herbal toothpaste an emphasizing and more acceptable in dental research and they are safer with minimum side effect than synthetic preparation.The formulated toot paste capable to the tooth and oral hygine and show the anti-microbial activity against pathogen. The formulation compared with market prepar tion. Therefore it shows the equal patronizing and engrossing passion over the marketed formultions . The fomulated herbal toothpaste has been good scope in future in nature remedies research and Dental health of public

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