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FORMULATIONS AND EVALUATION OF HERBAL TOOTHPASTE

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ABSTRACT

Toothpaste is a widely used product for oral hygiene, commonly employed for teeth and mouth cleaning, as well as for treating various dental disorders. Dentists often recommend toothpaste for addressing issues like sensitivity and chronic gingivitis. Herbal toothpastes harness the antibacterial and antimicrobial properties of different herbal extracts from crude drugs. These formulations utilize a variety of herbs and bark, among others. Evaluation of herbal toothpastes involves multiple tests including physical examination, relative density, abrasiveness, spreadability determination, pH determination, homogeneity, foaming, stability, moisture and volatile matter determination, moisture content, foaming character, and organoleptic evaluation, among others. This research aims to consolidate on herbal toothpaste, covering its introduction, various formulations, and evaluation parameters, facilitating researchers interested in exploring this area further.

KEYWORDS: *Neem, Toothpaste, Clove, Herbal Toothpaste etc.*

INTRODUCTION

Toothpaste is the most common preventive measure in oral health care, serving as a vital component in maintaining oral hygiene. Many commercially available dentifrices claim to have antimicrobial properties, but there is limited research to validate these claims. This study aimed to evaluate the efficacy of different toothpaste formulations in reducing oral microbial load. The findings indicated that the selected toothpaste formulations were effective in controlling microbial load, thereby contributing to good oral hygiene. However, practicing appropriate oral hygiene measures and brushing techniques is crucial for maintaining oral health, potentially more so than the specific ingredients in the toothpaste.

Chronic gingivitis, one of the most prevalent oral diseases globally, is primarily caused by dental plaque. While mechanical methods, such as brushing and flossing, are essential for plaque removal, their limitations necessitate supplementary measures. The inclusion of safe and effective antimicrobial agents in toothpaste is considered a beneficial adjunct to mechanical plaque control. Research has demonstrated that certain chemicals, such as chlorhexidine and triclosan, can be added to toothpaste to inhibit plaque formation directly.

Various chemical agents have been incorporated into toothpastes and mouth rinses, with some showing efficacy in reducing dental plaque formation. With increasing awareness of indigenous medical practices, there has been a growing interest in herbal medicine and alternative therapies for health care promotion. Herbal toothpastes, which do not contain synthetic agents like triclosan or fluoride, often use natural ingredients such as mineral salts (e.g., sodium fluoride and sodium chloride) and plant extracts like lemon, eucalyptus, rosemary, chamomile, sage, and myrrh.

The primary purpose of toothpaste is to reduce oral bacterial flora and deliver fluoride to the teeth, as fluoride is proven to protect teeth against bacterial attacks. Fluoride occurs naturally in many foods and drinking water. Effective toothpastes that reduce oral bacterial flora significantly contribute to dental health. For instance, triclosan is frequently used in toothpaste for its antibacterial properties to prevent gum disease, while sodium fluoride also possesses antibacterial qualities.

Natural toothpastes, which exclude synthetic ingredients like triclosan and fluoride, aim to offer similar benefits through natural compounds. They typically contain minerals and plant extracts that have antibacterial and anti-inflammatory properties.

Despite the benefits of chemical agents, self-performed mechanical plaque removal remains the most widely accepted method of controlling plaque and gingivitis. Mechanical plaque control is time-consuming, and many individuals may lack the motivation for these procedures. Therefore, integrating effective chemical agents in toothpastes can enhance plaque control and support overall oral health.

Plants with therapeutic effects have been beneficial to oral health for thousands of years across the world. Traditional medicine often has more advantages and fewer side effects, such as allergies, compared to modern treatments. Neem is one of the most widely researched tropical trees for its therapeutic properties. Approximately 20 years ago, the components of

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neem extract were analyzed for their medicinal value. Chewing sticks, including those made from neem, have been used in the Indian subcontinent, the Middle East, and Africa since ancient times.

Dental caries is steadily increasing in underdeveloped and developing countries, creating an urgent need to promote traditional preventive measures that are accessible, readily available, and cost-effective. Neem has been recognized for its antibacterial activity since ancient times. It has been used for various purposes, including as an astringent, antiseptic, insecticidal agent, anti-ulcer treatment, and for cleaning teeth affected by pyorrhea and other dental diseases. Neem leaf extract has demonstrated superior antiviral and antihyperglycemic activity in vitro and in vivo on animals. It also shows broad-spectrum antibacterial activity in vitro.
Nanotechnology, which involves creating materials, drugs, and devices that manipulate matter at specific sizes to enhance drug targeting, is being explored to improve the efficacy of herbal medicines. Developing nano-materials from herbal extracts can enhance their action and benefits.

In this comparative study, the focus is on the difference between food debris and dental plaque. Food debris consists of small white particles on teeth that can be easily rinsed off, while dental plaque is a thin, yellowish film of bacteria that adheres to teeth and cannot be rinsed off. There is a close relationship between tartar, calculus, and periodontal disease. Various natural extracts are used in different categories, such as neem for antibacterial purposes, guava for anti-inflammatory effects, babul as an astringent, kalmi as a flavoring agent, and other ingredients like camphor (antiseptic), honey (sweetening agent), glycerine (humectant), calcium carbonate (abrasive), SLS (detergent), sodium chloride, and distilled water. This has led to increased attention on using natural ingredients in herbal dentifrices.

Toothpaste is the most common preventive approach in oral health care. Many commercially available dentifrices claim to have antimicrobial properties, but little research has been conducted to investigate these claims. It is well understood that more than 2000 years ago, dentifrices were used for cleaning teeth, and the use of toothpicks and brushes dates back even further. Today's dentifrices follow many of the same concepts developed centuries ago. The use of natural or Ayurvedic medicines for general and oral health is an integral part of Indian tradition. Many Ayurvedic toothpastes available in the market claim to have excellent antimicrobial properties.

While toothpastes are used almost universally in the developed world, some groups and cultures still practice traditional tooth brushing without dentifrice, using items like miswak or salt. Although dentifrices have been used since antiquity, recent formulations aim to deliver active compounds that prevent and/or treat oral diseases. The history of toothpastes is extensively reviewed elsewhere.
Neem possesses antibacterial, anti-inflammatory, and anti-caries properties. Its antimicrobial effects have been reported against Streptococcus mutans and Streptococcus faecalis. Dried neem chewing sticks show significant antibacterial activity against S. mutans. However, limited research is available regarding the efficacy of natural dentifrices. Therefore, this study was undertaken to evaluate their impact on oral hygiene and gingival bleeding.

Toothpaste not only protects, cleans, and polishes teeth but also enhances oral hygiene efficiency. It has a pleasant flavor and smell and freshens breath. Brushing twice a day with toothpaste is crucial for maintaining a healthy mouth. The major goal of this research is to formulate and evaluate herbal toothpaste. Toothpaste is typically used by all individuals for cleaning teeth and mouth and is also used to treat many dental issues.

IDEAL PROPERTIES OF TOOTHPASTE

Non-Harmful to Oral Tissues
The toothpaste should be gentle on the gums, tongue, and other oral tissues, preventing irritation or damage.

Non-Staining
It should not cause any discoloration of the teeth, ensuring the natural whiteness is maintained.

Non-Abrasive to Enamel
The formulation should be non-scratching and safe for the enamel surface of the teeth, preventing erosion and sensitivity.

Safe if Ingested
If accidentally swallowed, the toothpaste should not cause harm to the gastrointestinal tract (GIT).

Pleasant Odor and Taste

- It should have a pleasant flavor and smell, making the brushing experience enjoyable.
- Free from Unnatural Chemicals
- Ideally, the toothpaste should not contain artificial chemicals, dyes, flavors, or preservatives, reducing the risk of adverse reactions.

Natural Ingredients Only
The formulation should be made exclusively with natural ingredients to ensure safety and environmental friendliness.

No Growth Hormones, Chemicals, or Pesticides
Ingredients should be free from growth hormones, chemicals, or pesticides to ensure purity and health safety.

Benefits of Toothpaste
Combat Dental Issues
Toothpaste helps prevent dental caries, gum disease, bad breath, calculus buildup, erosion, and dentin hypersensitivity.

Abrasives for Cleaning and Whitening
Contains mild abrasives to effectively clean teeth and remove surface stains, resulting in whiter teeth.

Flavour for Fresh Breath
Includes flavors that help freshen breath, providing a pleasant aftertaste.

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Visual Appeal

- Dyes are used to give the toothpaste a visually appealing color, enhancing user experience.
- Enamel Strengthening.
- Helps to remineralize and strengthen enamel that has been weakened by acids, protecting against decay.

Germ-Killing Properties
Contains antibacterial agents to kill germs and prevent infections, promoting overall oral health.

Active Ingredient Delivery
Delivers active ingredients effectively to help prevent various dental diseases, ensuring targeted oral care.

Relieves Toothache
Certain formulations can provide relief from toothache, reducing discomfort.

Cavity Prevention and Fresh Breath

- Fights against cavities and maintains fresh breath, essential for daily oral hygiene.
- Intrinsic Stain Removal
- Helps in removing intrinsic stains from teeth, restoring natural color.

Bacteria Removal
Effective in removing harmful bacteria from the oral cavity, reducing the risk of infections.

Anti-Inflammatory Effects
Shows anti-inflammatory effects on gums, reducing swelling and redness.

Advantages of Using Toothpaste
Ensures Safe Teeth Cleaning
Provides effective cleaning of teeth without causing harm to the oral tissues or enamel, ensuring a thorough yet gentle cleaning experience.

Calms Throbbing Pain in Gums
Contains soothing agents that can alleviate gum pain and inflammation, providing relief from discomfort.

Removes Stains Without Damaging Enamel
Formulated with mild abrasives that effectively remove surface stains while preserving the integrity of the enamel, helping to maintain a bright smile.

Freshens Your Breath
Includes ingredients that neutralize bad odors, leaving the mouth feeling fresh and clean.

Safe for Children
Specially designed to be safe if ingested, making it an excellent choice for young children who might accidentally swallow toothpaste.

Stronger Enamel and Better Protection Against Tooth Decay
Enriched with fluoride and other minerals that strengthen enamel, providing enhanced protection against cavities and tooth decay.

No Risk to Children's Health if Swallowed
Represents a safe alternative to ordinary toothpaste for children, reducing concerns about accidental ingestion.

Disadvantages of Using Toothpaste

- Ineffective at Removing Major Stains
- While it can handle minor discoloration, toothpaste alone is not sufficient for major stains; professional whitening services may be required for more significant results.

Increased Salivation
Some formulations may stimulate increased salivation, which can be uncomfortable for some users.

Potential Enamel Erosion
Overuse of certain abrasive toothpastes can gradually wear down the enamel, leading to enamel erosion over time.

Dentin Abrasion and Increased Tooth Sensitivity
If the toothpaste is too abrasive, it can cause dentin abrasion, which exposes the sensitive inner layers of the teeth, leading to increased sensitivity and discomfort.

Applications of Toothpaste
Perfume Your Palms
Eliminate Strong Odors: Cutting onions, cleaning fish, or handling garlic can leave strong odors on your hands. Wash them with toothpaste to effectively remove these smells.

Clean you're Jewellery
Polish Metal Jewellery: Use a soft toothbrush with a small amount of toothpaste to brush dull metal jewellery. Rinse and polish it with a soft cloth to restore its shine. For more tarnished pieces, soak the metal in a cup of water with dissolved toothpaste.

Caution for Pearls: Avoid using toothpaste on pearls as it can damage their delicate surface.

Remove Crayon Marks from Painted Walls
Wipe with Toothpaste: Put a dab of toothpaste on a damp sponge and gently wipe crayon marks off painted walls without damaging the paint.

Defog Goggles
Prevent Fogging: The mild abrasives in toothpaste can help prevent goggles and masks from fogging up. Lightly rub toothpaste inside a diving mask, motorcycle goggles, or a hockey helmet face guard. Wipe and rinse the surface clean.

Caution for Coatings: Be aware that toothpaste may remove special coatings like anti-glare treatments, so use it cautiously.

Clear Pimples
Overnight Treatment: Dab a small amount of toothpaste on pimples before bed. In the morning, wash your face clean. This

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method can also work for bug bites and bee stings—just ensure you remove the stinger first. The toothpaste will dry out and reduce the size of the blemishes.

MATERIAL AND METHODS

The materials utilized in the experiment were of pharmaceutical grade or the highest quality laboratory reagents, directly obtained from the manufacturer. Throughout the experiment, double-distilled water served as the solvent. The list of materials used included various substances categorized according to their respective functions. Firstly, Neem, recognized as the active ingredient, played a pivotal role in the experiment's formulation. Clove, serving as a flavouring agent, added a distinct taste to the final product. Dicalcium phosphate functioned as a leavening agent, contributing to the texture and consistency of the formulation. Calcium carbonate acted as an oxidation agent, influencing the chemical reactions within the experiment. Glycerine served as a moisturizing agent, ensuring the product's smooth and hydrating properties. Gum Tragacanth was utilized as an emulsifier, aiding in the uniform distribution of ingredients. Saccharin, a sweetening agent, provided a pleasant taste without adding calories. Finally, sodium lauryl sulphate functioned as an additional emulsifier, enhancing the stability and consistency of the formulation throughout the experiment. Each material played a crucial role in achieving the desired characteristics and properties of the final product.

Neem and Clove were acquired from the local market for the experiment. Additionally, a range of chemical reagents were employed in the study, including Dicalcium Phosphate, Calcium Carbonate, Glycerine, Gum Tragacanth, Saccharin, and Sodium Lauryl Sulphate.

DRUG PROFILES

Neem Powder *(Azadirachta indica)*

Neem's health-promoting effects are largely attributed to its rich antioxidant content, making it a valuable resource in traditional medicinal practices such as Chinese, Ayurvedic, and Unani medicine, particularly prevalent in the Indian subcontinent. Neem has been extensively utilized for the treatment and prevention of various diseases. Previous research has confirmed that both Neem and its constituents play a crucial role in scavenging free radicals and inhibiting disease pathogens.

Studies conducted on animal models have further demonstrated the pivotal role of Neem and its primary constituents in anticancer management. Through the modulation of various molecular pathways, Neem exhibits promising potential in combating cancer. Importantly, Neem is considered a safe medicinal plant that modulates numerous biological processes without adverse effects.

Furthermore, Neem showcases a wide array of biological and pharmacological activities, including antibacterial, antifungal, and anti-inflammatory properties. Its versatility in targeting multiple biological pathways underscores its significance as a therapeutic agent in traditional medicine systems and highlights its potential for modern medical applications.

On the other hand, Neem powder, derived from the Azadirachta indica tree, offers remarkable benefits for oral health. Despite its bitter taste, Neem is highly regarded for its antibacterial and anti-inflammatory properties. These properties make it an excellent aid in oral hygiene, as it can effectively clean teeth and reduce plaque buildup over time. By targeting harmful bacteria and reducing inflammation in the oral cavity, Neem powder contributes to maintaining overall dental health. Its natural composition makes it a preferred choice for individuals seeking alternative and holistic approaches to oral care.

Clove oil *(SyzygiumAromaticum)*

Clove oil, derived from the *Syzygium aromaticum* plant, holds significant pharmacological importance beyond its culinary and aromatic applications. This essential oil contains eugenol, a potent phytochemical renowned for its analgesic properties. In South Korea and India, eugenol extracted from clove oil is traditionally utilized to alleviate toothaches. When applied topically to a cavity in a decayed tooth or a post-extraction socket, clove oil or eugenol can provide temporary relief from dental pain. However, in the United States, the FDA (Food and Drug Administration) has questioned the effectiveness of eugenol in treating dental pain, leading to the downgrading of clove oil's status as an analgesic due to insufficient evidence supporting its efficacy.

Clove oil contains several important phytochemicals, with eugenyl acetate, eugenol, and β-caryophyllene being the most significant. These compounds are not only responsible for the distinct aroma and flavor of clove oil but also possess notable pharmacological properties. Pharmacologically, Syzygium aromaticum, the plant from which clove oil is derived, has been extensively studied for its effects on various pathogenic parasites and microorganisms. These include pathogenic bacteria, Plasmodium, Babesia, and Theileria parasites, as well as viruses such as Herpes simplex and hepatitis C.

Eugenyl acetate, eugenol, and β-caryophyllene exhibit diverse pharmacological activities, including antimicrobial, antiparasitic, and antiviral effects. They have been investigated for their potential therapeutic applications in combating infectious diseases caused by bacteria, parasites, and viruses. Additionally, studies have explored their mechanisms of action and interactions with target pathogens.

Moreover, the physicochemical properties of clove oil, such as color, specific gravity, refractive index, optical rotation, and solubility in ethanol, are also important considerations in pharmacological research. Understanding these properties aids in the characterization and standardization of clove oil formulations for medicinal use. Specifically, the concentrations of eugenol and β-caryophyllene in clove oil are crucial factors determining its pharmacological potency and effectiveness against various pathogens.

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Figure 1: Clove

Dicalcium phosphate (DCP)

Dicalcium phosphate (DCP) is a widely used calcium supplement in the food and pharmaceutical sectors, boasting a range of properties and applications. Comprised of calcium ions and phosphate ions, DCP is minimally soluble in water and typically displays a neutral to slightly basic pH. Its appearance as a fine white powder underscores its versatility in various formulations. Serving as a concentrated calcium source, DCP offers high bioavailability, supporting bone health and other physiological functions. Its stability and compatibility with other ingredients make it suitable for diverse applications, including as a food additive to fortify dairy, baked goods, and beverages, as well as a pharmaceutical excipient in tablet formulations. Additionally, DCP is integral to dietary supplements, animal feed for livestock and poultry, and industrial processes such as water treatment and ceramics manufacturing, showcasing its multifaceted role in promoting nutrition, health, and industrial efficiency.

Calcium carbonate ($CaCO_3$)

Calcium carbonate ($CaCO_3$) is a compound comprising calcium, carbon, and oxygen. It appears as a white powder or colourless crystals and is sparingly soluble in water. With a pH greater than 7, it is basic in nature. Calcium carbonate serves as a significant source of calcium ions, crucial for various physiological functions. Its applications span across multiple industries: in pharmaceuticals, it acts as an antacid; in food and beverages, it fortifies products and serves as a colouring agent; in construction, it enhances the strength of materials; in papermaking, it improves paper quality; in cosmetics, it functions as a bulking agent; and in agriculture, it amends soil and promotes plant growth. Overall, calcium carbonate's versatility and broad applications make it indispensable across numerous sectors.

Sodium lauryl sulfate (SLS)

Sodium lauryl sulfate (SLS) is a versatile synthetic detergent and surfactant widely employed in personal care and household products for its multifaceted properties. It acts as a surfactant, reducing liquid surface tension, making it efficient in removing dirt and grease. With its foaming capabilities, it's a common ingredient in soaps and shampoos, aiding in ingredient dispersion. SLS's emulsifying function stabilizes water and oil mixtures in cosmetic products. Additionally, it serves as a penetration enhancer in skincare items, allowing active ingredients to penetrate the skin more effectively. Its mild antimicrobial properties extend the shelf life of personal care products. SLS is utilized in various sectors, from personal care products to household cleaners and industrial processes, owing to its versatility. However, it's crucial to be mindful of potential skin irritation, particularly in high concentrations. Therefore, moderation is advised, especially in sensitive areas.

Gum Tragacanth

Gum Tragacanth, derived from the dried sap of Astragalus species, is a complex polysaccharide mixture, primarily composed of tragacanthin and bassorin. Its hydrocolloid nature enables it to absorb and retain water, forming a gel-like consistency, while its high viscosity and thixotropic behavior make it an effective thickening agent. With good stability across temperatures and pH levels, Gum Tragacanth is used in diverse formulations. It also exhibits film-forming and emulsifying properties, making it valuable in industries ranging from food and pharmaceuticals to cosmetics and textiles. Recognized as safe for consumption and biodegradable, it finds applications in art conservation, veterinary medicine, and traditional medicine for gastrointestinal discomfort relief. Overall, Gum Tragacanth's versatility enhances the texture, stability, and performance of various products across industries.

Method of Formulation for Toothpaste

Dry Gum Method:

Preparation of Base:

- Solid ingredients such as dicalcium phosphate, calcium carbonate, SLS (Sodium Lauryl Sulfate), sodium saccharine and Gum Tragacanth are accurately weighed as per the formula requirements.
- These ingredients are then sieved with a No. 80 sieve to ensure uniform particle size.
- The sieved chemicals are mixed in a mortar and pestle, and triturated with accurately weighed sorbitol until a semisolid mass is formed.

Addition of Herbal Ingredients

- Herbal extracts in powdered form, accurately weighed, are sieved and added to the base mixture.
- Neem known for their therapeutic properties, are incorporated into the formulation.
- Clove is added at the end to provide flavouring, enhancing the overall sensory experience of the toothpaste.

Wet Gum Method

Preparation of Base

- In this method, the solid ingredients are mixed with water or glycerin to form a paste-like consistency.
- The mixture is then heated and stirred until a smooth base is obtained.

Addition of Herbal Ingredients

- Similar to the dry gum method, accurately weighed herbal extracts and essential oils are added to the base mixture.

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- The formulation is thoroughly mixed to ensure uniform distribution of all ingredients.

Adjustment of Consistency

- The consistency of the toothpaste is adjusted by adding additional water or glycerin if necessary.
- The final product is then homogenized to achieve a smooth texture before packaging.

Both methods have their advantages and are used based on the specific requirements of the formulation and manufacturing process. The choice between the dry gum method and the wet gum method depends on factors such as the desired texture, stability, and compatibility of the ingredients.

EVALUATION OF TOOTHPASTE

Physical Examination

Colour: The formulated toothpaste is evaluated for its color through visual inspection.

Odour: The odour of the toothpaste is determined by smelling the product.

Taste: The taste of the toothpaste is manually checked by tasting the formulation.

Relative Density

The relative density of the toothpaste is determined by weighing the formulation in grams taken in 10 ml of the formulation and 10 ml of distilled water using a relative density (RD) bottle.

Abrasiveness

Toothpaste samples are extruded onto butter paper, and the presence of sharp or hard-edged abrasive particles is examined by pressing the contents with fingertips. Toothpaste should not contain such particles.

Spreadability Determination

The slip and drag characteristics of the toothpaste are evaluated. A specified amount of formulated paste is placed between glass slides, and the time taken for the upper slide to cover a distance of 7.5 cm under a specified weight is noted. Spreadability is calculated using a formula.

pH Determination

- The pH of the formulated herbal toothpaste is determined using a pH meter. Toothpaste is suspended in water, and the pH is measured.

Homogeneity

The toothpaste's homogeneity is assessed by extruding a homogeneous mass from the collapsible tube or container and rolling it gradually to ensure bulk extrusion from the crimp.

Foaming

The foamability of the toothpaste is evaluated by measuring the initial and final volumes of foam formed after shaking the formulation with water in a measuring cylinder. The foaming power is determined by the difference in volumes.

Stability

Stability studies are conducted according to ICH guidelines. The formulated paste is stored under different temperature and humidity conditions for three months and examined for appearance, pH, and spreadability.

Determination of Moisture and Volatile Matter

Moisture and volatile matter content of the toothpaste are determined by drying a specified amount of formulation in an oven and calculating the loss of mass.

Moisture Content

Toothpaste is weighed before and after drying in an oven at 105°C to determine the percentage moisture content.

Foaming Character

Two methods are employed to assess the foaming character of the toothpaste using stoppered test tubes and graduated cylinders.

Organoleptic Evaluation

Colour and taste of the toothpaste are evaluated through sensory and visual inspection.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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