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Formulation Development and Evaluation of Herbal Toothpoaste

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Abstract: Herbal toothpaste presents a natural alternative to conventional oral care products, leveraging botanical extracts and essential oils for dental health benefits. This review examines the composition, efficacy, and safety considerations of herbal toothpaste formulations. Common herbal ingredients such as neem, clove, peppermint, and Babul are explored for their antimicrobial, anti-inflammatory, and plaque-reducing properties. Research findings on the effectiveness of herbal toothpaste in plaque control, gingival health, and breath freshness are summarized, highlighting its potential as an alternative oral hygiene regimen. Safety considerations regarding fluoride content, abrasiveness, and allergenic potential are discussed. Overall, herbal toothpaste offers a promising avenue for individuals seeking natural oral care options, although further research is warranted to establish its long-term efficacy and safety profile.

Keywords: Herbal toothpaste

I. INTRODUCTION

Herbal toothpaste is a type of toothpaste made from natural ingredients derived from plants and herbs. It is formulated to provide oral hygiene and dental care using botanical extracts, essential oils, and other natural substances. Herbal toothpaste is often preferred by those seeking alternatives to conventional toothpaste, which may contain artificial ingredients and chemical. Dental caries is the microbial infectious disease. In recent years it is the most comment health problem in the world.1

Oral diseases are prevalent worldwide and range from dental caries, periodontal disease (gum disease), oral mucosal lesions, mouth odour, endodontic (root canal) infections, periodontal (gum) disease, and oral cancers 2

Microbes have been implicated as the root cause of these diseases. These microbes convert starchy food materials to acid leading to the leaching of teeth components 3, wearing of enamel, gum, and exposure to opportunistic human pathogens 4. The vitality of oral health to the overall wellness of humans cannot be over-emphasised because various sicknesses, such as diabetes, high blood pressure, and heart-related diseases, are associated with oral challenges 3.

Different toothpaste has been produced using chemicals, such as fluoride, peroxide, chlorhexidine, amine fluorides, cetylpyridinium chloride, to combat various oral diseases. Unfortunately, these materials have drawbacks; for example, peroxide compounds used as whitewashing agents can cause sensational mouth burning. Preservative agents used in toothpaste, such as ethylene diamine

tetraacetic acid and formaldehyde, are unsafe for human health 5. Fluoride based-toothpaste, though highly effective against oral pathogens, fluoride is reported to have caused dental stains, nausea, and oral cancer, while chlorhexidine, amine fluorides, and cetylpyridinium chloride have been reported for their adverse effects 2.

Researchers are searching for safe, effective, and cheap raw materials to produce toothpaste to manage oral diseases and their associated sicknesses. Consequently, multiple extracts from plants such as A. indica (A. indica), Aloe barbadensis, Hibiscus sabdariffa, Punicagranatum Linn, Astragalusmembranaceus, Rehmanniaglutinosa, and others have been employed in the production of toothpaste, because of their anti-inflammatory, antibiotic, analgesic, and antibacterial potency 6.

Aloe vera L. and Fragariavesca L. (wild strawberry) based-toothpaste 7(and neem twig extract formulated toothpaste 8, with good antimicrobial activity against Streptococcus mutans and Streptococcus has been produced. Bacterial plaque and gingival bleeding have been treated with Rosmarinusofficinalis Linn toothpaste 9

Allium cepa L. (A. cepa) (red onion skin chaff) is a medicinal vegetable consumed worldwide and is a rich source of

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dietary flavonoids, anthocyanins, phenolics, fructans, and organosulfur compounds 10, 11. These phytochemicals have been reported to be responsible for the antimicrobial, anticancer, antibacterial, and antiviral potential of onions 10, A. indica (A. indica) (Neem) belongs to

the family Meliaceae. It is a very good chewing stick, and many bioactive compounds from its parts have been employed as antibacterial, antiulcer, anti-inflammatory, and antimalarial 12. In dentistry, neem is used as an antiplaque, anticaries, and anti-inflammatory 13. It contains phytochemicals like tannins, saponins, phenols, flavonoids, and alkaloids 14. Tetrapleuratetraptera (T. tetraptera) (Schum&Thonn.) Taub. is a typical Western African plant. The pharmacological ability of the has been linked to phytochemicals like flavonoids, phenols, cardiac glycosides, terpenoids, saponins, and phlorotannins 15

Therefore, this study seeks to determine the phytochemical properties and the volatile chemical compounds of A. cepa skin chaff, A. indica seed, and T. tetraptera pod ethanol extracts. The research study also produces and characterises various plant extracts of toothpaste formulated compared to some commercial toothpaste.

The ingredients in herbal toothpaste can vary widely but often include plants like neem, clove, peppermint, and tea tree oil, which are known for their antibacterial, antifungal, and anti-inflammatory properties. These natural ingredients are believed to help fight plaque, prevent cavities, and promote healthy gums. It is a chronic disease which destroy the tooth tissue and affect chewing and aesthetic appearance plaque, calculate and fermentable carbohydrate are the source of caries development plaque forms continuously on tooth surface.2

In in all age groups and it will be removed by brushing with a tooth brush with tooth paste. There are many herbal available in market and herbal toothpaste is also one of the products. Toothpaste is the common product in our family and we hardly care to know about the product which we are using. Herbal toothpaste is having advantages over commercial products. This study also contains about the advantages and disadvantages of herbal toothpaste.3

Many herbal toothpaste formulations are free from artificial colors, flavors, and preservatives, making them a popular choice among individuals looking for natural and ecofriendly oral care products. However, it's important to note that herbal toothpaste may not contain fluoride, a mineral that is commonly added to conventional toothpaste to prevent tooth decay. As such, individuals considering herbal toothpaste should consult with their dentist to ensure that it meets their oral health needs. toothpaste, as an irreplaceable agent in effective home care system, is a gel or paste dentifrice used with a toothbrush as an accessory to clean and maintain health of teeth in order to enhance oral hygiene. 4

The main benefits of herbal toothpaste include:

- Natural Ingredients: Herbal toothpaste typically avoids synthetic chemicals and artificial flavors, making them a more natural option for oral care
- Antibacterial Properties: Many herbal ingredients have natural antibacterial properties that can help fight against plaque and gum disease.
- Anti-inflammatory Effects: Some herbal ingredients can help reduce inflammation in the gums, which is beneficial for those with gingivitis or other gum problems.
- Fresh Breath: Herbal toothpaste often contains natural flavors and ingredients that can help freshen breath without the use of artificial chemicals.
- No Harsh Chemicals: Since herbal toothpaste avoids harsh chemicals like SLS (sodium lauryl sulfate) and fluoride, they are often gentler on the teeth and gums.
- No Harsh Chemicals: Since herbal toothpaste avoids harsh chemicals like SLS (sodium lauryl sulfate) and fluoride, they are often gentler on the teeth and gums. 5

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OBJECTIVE OF HERBAL TOOTHPASTE

- To clean teeth effectively and maintain overall oral hygiene.
- To help prevent cavities and tooth decay using natural ingredients.
- To reduce plaque buildup on teeth.
- To provide fresh breath through natural aromatic ingredients.
- To utilize the antibacterial properties of herbs to combat oral bacteria.





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- To soothe gums and reduce inflammation with natural extracts.
- To avoid synthetic chemicals, artificial flavors, and preservatives.
- To offer a more environmentally friendly option with biodegradable ingredients.
- To address tooth sensitivity using gentle, natural substances.
- To align with a holistic health approach by using traditional medicinal herbs.

II. MATERIALS

2.1 CHEMICALS

Tulsi Leave Oil, Clove Oil, Neem Leave Oil, babul, Xylitol, Sodium Lauryl Sulphate, , Calcium Carbonate, Glycerine, Methyl Paraben, Amaranth solution, Stevia, Sodium Chloride, Menthol

2..2 EQUIPMENTS

1) R.D bottle, 2)10 Collapsible tube, 3) Glass Slide, 4)PH meter, 5) Beaker, 6) Measuring Cylinder, 7) Porcelain dish, 8) Oven, 9) Dessicator, 10) Stoppered test tube, 11) Graduated cylinder, 12) Butter Paper, 13) Weighing apparatus, 14) Sieve no.80, 15) Morter and pestle, 16) Domestic mixer.

III. COMPOSITION OF TOOTHPASTE

Detergent:

Amount weight 1 to 2%

Material: Sodium lauryl sarcosinate

It decreases the surface tension and acts as a surface- active substance and removes the debris with its foaming action.

In herbal toothpaste, the use of detergents plays a crucial role in ensuring effective cleaning and foaming without compromising the natural and gentle nature of the product. Here are the key points regarding the use of detergents in herbal toothpaste:

Natural Origins: Detergents in herbal toothpaste are typically derived from natural sources such as plants. Common natural detergents include saponins from soap nuts, yucca, or quillaja extracts.

Gentle on Oral Mucosa: Unlike synthetic detergents like sodium lauryl sulfate (SLS), natural detergents are less likely to cause irritation or allergic reactions. This makes herbal toothpaste suitable for people with sensitive gums and mouths.

Effective Cleaning: These natural detergents help to create foam, which aids in the mechanical removal of food particles, plaque, and bacteria from teeth and gums. This ensures that the toothpaste is effective in maintaining oral hygiene.

It decreases the surface tension and acts as a surface- active substance and removes the debris with its foaming action.

Binder:

Amount weight =3%

Material- carrageenan

Binding agents are hydrophilic colloids which are used to stabilize dentifrice formulations by preventing the separation of the solid and liquid phases.

Binders are essential components in herbal toothpaste, playing a crucial role in ensuring the product's stability, texture, and overall effectiveness. Here are the main points regarding the use of binders in herbal toothpaste:

Purpose of Binders: Binders are used to provide the toothpaste with the desired consistency and texture. They help maintain the uniformity of the paste, preventing separation of the ingredients. Natural Origins: In herbal toothpaste, binders are typically derived from natural sources to align with the product's overall natural and holistic approach. Common natural binders include xanthan gum, carrageenan (derived from seaweed), guar gum, and cellulose gum.

Stabilization: Binders help stabilize the formulation by keeping the solid and liquid components evenly distributed. This ensures that each use delivers a consistent amount of active ingredients.

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Colorants:

Amount weight = 1 to 2%

Material-Amaranth solution

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It provides dentifrice with pleasing colours.

Colorants in herbal toothpaste play a significant role in enhancing the product's appearance and appeal without compromising its natural and health-focused identity. Here are the main points regarding the use of colorants in herbal toothpaste:

Purpose of Colorants: Colorants are added to herbal toothpaste to give it a visually appealing look. They help differentiate products, enhance the brand's identity, and make the toothpaste more attractive to consumers.

Natural Origins: In keeping with the overall natural and holistic approach of herbal toothpaste, colorants are typically derived from natural sources. Common natural colorants include amaranth solution.

Safety and Non-toxicity: Natural colorants are generally considered safer and non-toxic compared to synthetic dyes. They are less likely to cause allergic reactions or other health issues, making them suitable for consumers with sensitive oral cavities.

Aesthetic Appeal: The use of natural colorants can enhance the aesthetic appeal of herbal toothpaste, making it more attractive on store shelves and more pleasant for consumers to use.

Flavouring agent:

Amount weight = 1 to 2%

For 100 gm of toothpaste we use 1.5 gm of flavouring agent

Material-peppermint, spearmint and winter green and sweeteners such as saccharine. It gives flavour. 6

Flavoring agents in herbal toothpaste are crucial for enhancing the product's taste, freshness, and overall user experience. Here are the main points regarding the use of flavoring agents in herbal toothpaste:

Purpose of Flavoring Agents: Flavoring agents are added to herbal toothpaste to improve taste, mask any unpleasant flavors from active ingredients, and provide a refreshing sensation during brushing. They contribute to the overall user experience and encourage regular oral hygiene practices.

Natural Origins: In alignment with the natural and holistic approach of herbal toothpaste, flavoring agents are often derived from natural sources. Common natural flavoring agents include essential oils such as peppermint, spearmint, cinnamon, and citrus oils.

Refreshing Sensation: Natural flavoring agents like mint oils provide a cooling and refreshing sensation, leaving the mouth feeling clean and fresh after brushing. This enhances the user's perception of oral cleanliness and freshness.

Antimicrobial Properties: Some natural flavoring agents, particularly essential oils like peppermint and tea tree oil, possess antimicrobial properties that help fight bacteria and maintain oral hygiene. They contribute to the overall effectiveness of the toothpaste in combating dental plaque and bad breath.

Non-toxic and Safe: Natural flavoring agents are generally considered safe for oral use and are less likely to cause adverse reactions compared to synthetic flavors. They are suitable for consumers with sensitive oral cavities or those seeking natural oral care solutions.

Abrasive:

Amount weight = 20 to 55%

Material-calcium carbonate.

Abrasives are added to clean the teeth and to remove stains and polish the surface.

Abrasives in herbal toothpaste serve the vital function of removing plaque, stains, and debris from the teeth surface without causing damage to the enamel. Here are the main points regarding the use of abrasives in herbal toothpaste:

Purpose: Abrasives are included in toothpaste formulations to provide mechanical cleaning action by gently polishing the tooth surface. They help remove plaque, stains, and food particles, resulting in cleaner and brighter teeth.

Natural Origins: In herbal toothpaste, abrasives are often derived from natural sources to align with the product's natural and holistic approach. Common natural abrasives include calcium carbonate, hydrated silica, baking soda (sodium bicarbonate), and silica derived from bamboo or other plant sources.

Gentle Cleaning Action: Natural abrasives are chosen for their ability to effectively clean the teeth without causing excessive wear or damage to the enamel. They provide a gentle polishing action that helps maintain the integrity of the tooth structure while removing surface stains and plaque.

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Non-toxic and Safe: Natural abrasives are generally considered safe for oral use and are less abrasive compared to some synthetic alternatives. They are suitable for daily use and do not pose a risk of enamel erosion or tooth sensitivity when used as directed.

Stain Removal: Abrasives help remove surface stains from the teeth, including those caused by coffee, tea, tobacco, and certain foods. Regular use of herbal toothpaste containing abrasives can help maintain a brighter and more aesthetically pleasing smile.

Humectant:

Amount weight = 20 to 35%

Material-Glycerine, sorbitol, paraffin oil

Humectants act as a moisturizing agent and provide a smooth creamy texture to the dentifrice

Humectants in herbal toothpaste serve to maintain moisture levels, prevent drying out, and ensure proper texture and consistency. Here are the main points regarding the use of humectants in herbal toothpaste:

Purpose: Humectants are added to herbal toothpaste formulations to retain moisture, prevent the paste from drying out, and maintain its desired texture and consistency. They help ensure that the toothpaste remains smooth and easy to dispense throughout its shelf life.

Natural Origins: In alignment with the natural and holistic approach of herbal toothpaste, humectants are often derived from natural sources. Common natural humectants include glycerin (vegetable glycerin), sorbitol (derived from fruits), and xylitol (a sugar alcohol derived from plants).

Moisture Retention: Humectants have hygroscopic properties, meaning they attract and retain moisture from the environment. This helps prevent the toothpaste from drying out and becoming hard or gritty, ensuring a pleasant texture and user experience.

Prevention of Crystallization: Some natural humectants, such as xylitol, also help prevent crystallization and maintain the toothpaste's smooth consistency over time. This contributes to the overall stability and quality of the product.

Enhanced Mouthfeel: Humectants contribute to the overall mouthfeel of the toothpaste, making it smooth, creamy, and easy to spread on the teeth and gums. They enhance the user experience by providing a pleasant texture during brushing.

Water:

Amount weight = 15 to 25%

Material-Deionized water

Water acts as a solvent and dissolves ingredients allowing them to be mixed. 7

IV. COMPOSITION AND USES OF ACTIVE INGREDIENT

Tulsi leave oil

Quantity $-0.1\Box -1\Box$

The amount of tulsi (holy basil) leaves oil used in herbal toothpaste can vary depending on the specific formulation and intended potency of the product. Generally, it is used in relatively small concentrations compared to other ingredients, such as around 0.1% to 1% of the total formulation. This concentration is sufficient to provide the desired antibacterial and anti-inflammatory benefits without overpowering the toothpaste with the strong aroma andtaste of tulsi oil.8 compared to other ingredients, such as around 0.1% to 1% of the total formulation. This concentration is sufficient to provide the desired antibacterial and anti-inflammatory benefits without overpowering the toothpaste with the strong aroma and taste of tulsi oil.8

What is Tulsi Oil?

Tulsi oil, also known as holy basil oil, is an essential oil extracted from the leaves, stems, and seeds of the Tulsi plant (Ocimum sanctum or Ocimumtenuiflorum). Tulsi is revered in Ayurvedic medicine and traditional Indian practices for its myriad of health benefits and is often referred to as the "Queen of Herbs."

Historical and Cultural Significance

Tulsi holds a sacred status in Hindu culture, where it is often grown in homes and temples. It has been used for thousands of years in Ayurveda, the traditional system of Indian medicine, for its therapeutic properties.

Extraction Process

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The most common method of extracting Tulsi oil is through steam distillation, which helps preserve its potent medicinal properties. This process involves passing steam through the plant material to vaporize the volatile compounds, which are then condensed back into liquid form to yield the essential oil.

Chemical Composition

Tulsi oil is rich in bioactive compounds such as:

Eugenol

β-caryophyllene

Methyl eugenol

Linalool

These compounds contribute to its therapeutic properties, including antioxidant, anti-inflammatory, antimicrobial, and adaptogenic effects.



Fig.1: Tulsi leave oil

Clove oil

Quantity − 0.1 □ -1 □

The quantity of clove oil in herbal toothpaste can vary, but it's generally used in low concentrations due to its potent flavour and medicinal properties. In many formulations, clove oil might make up around 0.1% to 1% of the total toothpaste composition. Its role is primarily as an antiseptic and analgesic agent, helping to fight bacteria in the mouth, reduce inflammation, and provide relief from toothaches or gum pain.9

What is Clove Oil?

Clove oil is an essential oil extracted from the flower buds, leaves, and stems of the clove tree (Syzygiumaromaticum). Known for its rich, spicy aroma and potent therapeutic properties, clove oil has been used for centuries in traditional medicine and culinary applications.

Historical and Cultural Significance

Clove oil has a long history of use, dating back to ancient civilizations. In traditional Chinese and Ayurvedic medicine, it has been utilized for its analgesic, antiseptic, and warming properties. Cloves were highly valued in the spice trade and were once worth their weight in gold.

Extraction Process

Clove oil is primarily obtained through steam distillation. This method involves steaming the clove buds to release their volatile compounds, which are then condensed and collected as essential oil.

Chemical Composition

Clove oil is rich in several bioactive compounds, the most significant being:

Eugenol: The primary component, responsible for its strong aroma and many of its medicinal properties.

Eugenyl acetate

Carvophyllene

Isoeugenol

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Fig.2:Clove oil

Neem leave oil

Quantity - - 0.1 □ - 1 □

Neem leaf oil is often included in herbal toothpaste for its antibacterial, antifungal, and anti-inflammatory properties. It helps to combat oral bacteria, reduce plaque formation, and promote gum health. The quantity of neem leaf oil in herbal toothpaste can vary, but it's typically present in concentrations ranging from 0.1% to 1% of the total toothpaste composition, similar to clove oil. This low concentration ensures efficacy while maintaining a balanced flavor profile in the toothpaste. 10

What is Neem Oil?

Neem oil is a vegetable oil pressed from the fruits and seeds of the neem tree (Azadirachtaindica), which is native to the Indian subcontinent and has been used for thousands of years in traditional medicine and agriculture.

Historical and Cultural Significance

Neem oil has a prominent place in Ayurvedic medicine and has been used for centuries in India for its healing properties. The neem tree is often referred to as the "village pharmacy" because of its extensive range of medicinal uses. Extraction Process

Neem oil is extracted through two main methods:

Cold Pressing: This method involves mechanically pressing the seeds to extract the oil without the use of heat, preserving its nutrients and active compounds.

Solvent Extraction: This method uses chemical solvents to extract the oil, often resulting in higher yields but potentially less purity.

Chemical Composition

Neem oil is rich in a variety of active compounds, including:

Azadirachtin: The most active ingredient, known for its potent insecticidal and medicinal properties.

Nimbin

Nimbidin

Nimbidol

Oleic acid

Stearic acid



Fig.3: Neem leave oil DOI: 10.48175/IJARSCT-18877





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Babul

Quantity $-5\Box - 20\Box$

Babul is used in herbal toothpaste for its antibacterial properties, which help fight oral bacteria, reduce plaque formation, and prevent gum disease. It also provides astringent benefits that can help tighten gums and promote overall oral health. Additionally, its natural abrasive texture aids in cleaning teeth and removing stains.11

What is Babul?

Babul, also known as Acacia nilotica or Vachellianilotica, is a tree native to Africa, the Middle East, and the Indian subcontinent. It is commonly known as gum arabic tree, Egyptian thorn, or prickly acacia. The babul tree is recognized for its numerous medicinal, ecological, and economic benefits.

Historical and Cultural Significance

Babul has been used in traditional medicine and various cultural practices for centuries. In Ayurvedic medicine, babul is valued for its therapeutic properties. It is also an important species for agroforestry, providing fodder, fuel, and timber.

Botanical Description

Appearance: Babul is a medium-sized tree that can grow up to 20 meters tall. It has a rounded canopy, thorny branches, and yellowish flower heads.

Leaves: The leaves are bipinnate with numerous small leaflets.

Flowers: It produces bright yellow, fragrant flowers arranged in spherical clusters.

Fruit: The tree bears flat, curved pods containing seeds.

Chemical Composition

Babul contains various bioactive compounds, including:

Tannins

Flavonoids

Saponins

Glycosides

Phenolic compounds

These compounds contribute to its medicinal properties.



Fig.4:Babul

Xvlitol

Quantity- $5\square$ - $20\square$

Its primary use is as a natural sweetener and humectant, providing a pleasant taste while also helping to maintain moisture in the toothpaste. Additionally, xylitol has several oral health benefits, including its ability to inhibit the growth of bacteria that cause tooth decay. It can also help reduce plaque formation and the past of expities. Furthermore,

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xylitol has been shown to stimulate saliva production, which aids in neutralizing acids in the mouth and promoting remineralization of tooth enamel. 12

What is Xylitol?

Xylitol is a sugar alcohol (polyol) used as a sugar substitute. It is naturally found in small amounts in various fruits and vegetables, such as berries, corn, and mushrooms. Commercially, it is often derived from the fibrous parts of plants, especially corncobs and birch trees.

Chemical Composition

Chemically, xylitol is classified as a five-carbon sugar alcohol (C5H12O5). It has a crystalline, white appearance and resembles sugar in taste and texture but with fewer calories.

Historical and Industrial Background

Xylitol was discovered in the late 19th century and gained popularity as a sweetener in the mid-20th century, especially in Europe, due to sugar shortages during World War II. Today, it is widely used in various food and dental products.

Health Benefits and Uses

Dental Health: Xylitol is well-known for its dental benefits. It helps reduce the risk of tooth decay by inhibiting the growth of Streptococcus mutans, the primary bacteria responsible for cavities. Chewing gum and mints containing xylitol can also stimulate saliva production, which helps neutralize acids in the mouth.



Fig.5: Xylitol

Method of preparation

Procedure

Mixing the Base:

In a mixing bowl, combine calcium carbonate or baking soda (2-3 tablespoons) with glycerin (2-3 tablespoons) to form a paste.

Gradually add water (1-2 tablespoons) to achieve the desired consistency.

Incorporating Binding Agents:

Add a small amount (about 1 teaspoon) of xanthan gum or carrageenan to the base mixture to enhance thickness and stability. Mix thoroughly to avoid lumps.

Adding Herbal Extracts:

Integrate the herbal extracts (neem, tulsi, clove) into the base mixture. The quantity can vary, but generally, 1-2 tablespoons of each herbal extract is a good starting point. Blend well to ensure even distribution.

Essential Oils and Flavoring:

Add essential oils (4-5 drops each of tea tree oil, peppermint oil, eucalyptus oil) for antimicrobial properties and flavor. Adjust the number of drops according to preference.

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Sweeteners:

If desired, incorporate natural sweeteners like stevia or xylitol (1-2 teaspoons). These not only add sweetness but also help in preventing tooth decay.

Blending:

Use a blender or food processor to blend all ingredients thoroughly until you achieve a smooth, homogeneous paste.

Adjusting Consistency:

Check the consistency of the toothpaste. If it's too thick, add a bit more water or glycerin. If it's too thin, add more calcium carbonate or baking soda.

Preservatives:

If you intend to store the toothpaste for an extended period, add natural preservatives like potassium sorbate or sodium benzoate (about 0.1-0.2% of the total mixture) to inhibit microbial growth.

Packaging:

Transfer the finished toothpaste into sterilized containers or tubes. Ensure they are airtight to prevent contamination.

Final Tips

Labeling: Clearly label the containers with the date of preparation and ingredients.

Storage: Store the toothpaste in a cool, dry place away from direct sunlight.

Testing: Before full-scale use, test a small batch for texture, flavor, and shelf-life stability.

V. STAGES AND PARAMETER OF QBD (QUALITY BY DESIGN)

Quality by Design (QbD) is a systematic approach to product development that focuses on designing and developing products to meet predefined quality criteria. This approach is particularly relevant in the pharmaceutical and healthcare industries, where product quality and safety are paramount. QbD principles can also be applied to the development of herbal toothpaste to ensure that the product meets the desired quality attributes.13

Stages of QbD for Herbal Toothpaste:

Define Quality Target Product Profile (QTPP): This stage involves defining the quality attributes of the herbal toothpaste, such as efficacy, safety, and stability. It also includes identifying the intended use of the product and the target market.14

Identify Critical Quality Attributes (CQAs): CQAs are the characteristics of the herbal toothpaste that are critical to ensuring its quality. These may include the concentration of active herbal ingredients, particle size distribution, and rheological properties.

Designing the Formulation: In this stage, the formulation of the herbal toothpaste is designed to meet the predefined quality attributes. This may involve selecting suitable herbal extracts, excipients, and other ingredients, as well as optimizing the formulation to achieve the desired product characteristics.

Establishing the Control Strategy: The control strategy defines how the quality of the herbal toothpaste will be ensured throughout its development and manufacturing process. This may include setting specifications for raw materials, inprocess controls, and finished product testing.

Process Optimization: This stage involves optimizing the manufacturing process of the herbal toothpaste to ensure that it consistently meets the predefined quality attributes. This may involve identifying and controlling critical process parameters (CPPs) that affect the quality of the product.15 **Parameters for QbD for Herbal Toothpaste:**

Selection of Herbal Ingredients: The selection of herbal ingredients should be based on their proven efficacy and safety for oral care applications.

Standardization of Herbal Extracts: Herbal extracts should be standardized to ensure consistent quality and efficacy of the herbal toothpaste.

Excipient Selection: Excipients such as binders, fillers, and surfactants should be selected based on their compatibility with herbal ingredients and their impact on product quality.

Manufacturing Process: The manufacturing process should be optimized to ensure that critical process parameters (CPPs) are controlled to achieve the desired product characteristics.16

Stability Testing: Stability testing should be conducted to determine the shelf life of the herbat too thouse and to ensure that it remains effective throughout its shelf life.

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VI. EVALUATION OF TOOTHPASTE

Physical Examination

Colour- Formulated toothpaste was evaluated for its colour.

The visually colour was checked.

Odour- Odour was found by smelling the product.

Taste- Taste was checked manually by tasting the Formulation

Relative density:- Relative density was determine by weight in gram taken in 10 ml formulation and 10 ml distilled water using RD bottle Evaluation Parameters

Abrasiveness :- 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 andhard edged abrasive particles. Toothpaste shall not contain such particles.

Determination of spreadability:- In this method slip and drag characteristic of paste involve. Formulated paste (2g) placed on the ground slide under study. The formulated paste placed like sandwich between this slide and another glass slides for 5min to expel air and to provide a uniform film of the paste between slides. Excess of the paste was scrapped off from the edges. The top plate was then subjected to pull of 80g with the help of string attached to the hook and time (sec) required by the top slide to cover a distance of 7.5cm 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.

pH determination:- pH of formulated herbal toothpaste was deter-mined by using pH meter. 10g of toothpaste placed in 150ml of beaker. Allow the 10ml of boiled and then cooled water. Stir vigorously to make a suspension.

Homogeneity:- The toothpaste shall extrude a homogenous mass from the collapsible tube or any suitable 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 gradually.

Foaming:- The foamability of formulated toothpaste 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 was noted Determination of froth power Foaming power = V1-V2 V1- Volume in ml of foam with water. V2- Volume in ml of water only.

Stability:- The stability study was performed as per ICH guideline. The formulated paste was filled in collapsible tube and stored at different temperature and humidity conditions, $250C \pm 20C / 60\% \pm 5\%$ RH, $300C \pm 20C / 65\% \pm 5\%$ RH, $400C \pm 20C / 75\% \pm 5\%$ RH for the period of three months and studied for appearance, pH and spreadability. 17

Moisture content: Toothpaste (10 gm) weighted in a Porcelain dish and dried it in the oven at 105 o C. It was cooled in a desiccater. The loss of weight is recorded as percentage moisture content and calculated by the given formula. % Moisture = Original sample weight – dry sample weight/ Original sample weight.

Foaming character:- 1) 1 gm of tooth paste was poured into stoppered test tube (height 16 cm. diameter 6 mm) and volume of the liquid was adjusted with the water up to 10 ml. Tube was stoppered and shaked length wish, motion for 16 second, two shake/second. Allowed to stand for 15 minutes and height of the foam produced was measured.

2) 10% solution of tooth paste was prepared. 4ml of this solution was added to 146 ml of water at 30 o C. The solution was agitated for 10 seconds. The foam was poured in to a 100 ml graduated cylinder to overflowing. A rubber stopper was gently dropped in to the foam. The time for the rubber stopper to pass two points (40ml80ml) was measured. Longer time of fall indicates the denser and more stable foam.

Organoleptic evaluation: Organoleptic evaluation (colour, taste) was done by sensory and visual inspection.

pH:- pH was tested by dissolving 1 gm product in to 9 ml of water and shaked vigorously then aqueous solution and pH is observed by pH meter.

Fragrance test:- It was based on individual observation for its acceptability.5 people were asked for acceptability of fragrance and their opinion was taken. And fragrance was evaluated based on the below-described criteria.

The fragrance was good, as good as the fragrance of reference toothpaste.

The fragrance was not so good but comparable to the reference toothpaste.

The fragrance of the toothpaste was poor than the reference toothpaste.

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Shape retention:- Tooth paste was squeezed out from the tube and put entirely of a tooth brush and the state of the toothpaste after it was allowed to stand for 10 seconds was evaluated based on the below-described criteria A) Shape just after the toothpaste is squeezed out on the toothbrush is maintained.

Shape just after the toothpaste is squeezed out on the toothbrush is almost maintained.

The toothpaste squeezed from the toothbrush and cannot maintain its shape.

Storage stability:- The toothpaste were filled in a toothpaste tube for storage and stored for 45 days at each of 5 o C, room temperature and 40 o C. The tube was then cut through and whether the liquid component was separated from the toothpaste or not was evaluated based on following criteria. Evaluation criteria of storage stability; A)Separation of a liquid component is not observed at all. B)Separation of a liquid component is observed slightly. C)Separation of a liquid component is observed obviously. Net content: net content was calculated by using following formula; Net content = weight of filled tube – weight of empty tube.

Application of herbal toothpaste

The application of herbal toothpaste involves its use as part of a regular oral hygiene routine to maintain dental health and hygiene. Here's a breakdown of the application of herbal toothpaste:

Brushing Teeth: The primary application of herbal toothpaste is for brushing teeth. Apply a pea-sized amount of toothpaste onto a toothbrush with soft bristles.

Brushing Technique: Use gentle circular motions to brush the outer surfaces, inner surfaces, and chewing surfaces of all teeth. Pay particular attention to areas where plaque buildup is common, such as along the gumline and the back molars. Duration: Brush for at least two minutes to ensure thorough cleaning. Some herbal toothpaste formulations may recommend specific brushing times for optimal effectiveness.

Frequency: Brush teeth at least twice a day, ideally after meals and before bedtime, to remove food particles, plaque, and bacteria from the teeth and gums.

Rinsing: After brushing, rinse the mouth thoroughly with water to remove any remaining toothpaste residue. Avoid swallowing toothpaste, especially in large quantities, as it may contain ingredients that are not intended for ingestion. Spit, Don't Rinse: It's generally recommended to spit out excess toothpaste after brushing without rinsing immediately. This allows the active ingredients in the toothpaste, such asfluoride or herbal extracts, to remain in contact with the teeth for longer, enhancing their effectiveness.

VII. CONCLUSION

Herbal toothpaste offers a natural and holistic approach to oral hygiene, harnessing the therapeutic properties of herbs, plant extracts, and natural ingredients to promote dental health. Through gentle yet effective cleaning action, herbal toothpaste helps remove plaque, stains, and debris from the teeth while maintaining the integrity of tooth enamel. The inclusion of natural ingredients such as essential oils, humectants, abrasives, and anti-tooth decay agents contributes to a refreshing and enjoyable brushing experience without compromising safety or efficacy. Consumer demand for natural, eco-friendly, and sustainable oral care products continues to drive the development and popularity of herbal toothpaste. However, while herbal toothpaste can be a beneficial addition to oral care routines, it's essential to consult with dental professionals for personalized recommendations and regular check-ups to ensure optimal dental health. Overall, herbal toothpaste represents a promising alternative for individuals seeking natural and effective solutions for maintaining oral hygiene and promoting overall well-being.

Result

Herbal toothpaste is the creation of an effective and safe oral care product that meets consumer needs and preferences. Through systematic formulation development, researchers identify and optimize the selection and combination of natural ingredients such as herbs, plant extracts, essential oils, abrasives, humectants, and anti-tooth decay agents. This process involves testing various formulations to achieve the desired characteristics, including texture, consistency, flavor, aroma, and efficacy in cleaning and protecting teeth and gums.

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