

Formulation Development and Evaluation of Herbal Toothpaste by QBD

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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.

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 common health problem in the world.¹

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 eco-friendly 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:

1. **Natural Ingredients:** Herbal toothpaste typically avoids synthetic chemicals and artificial flavors, making them a more natural option for oral care.
2. **Antibacterial Properties:** Many herbal ingredients have natural antibacterial properties that can help fight against plaque and gum disease.
3. **Anti-inflammatory Effects:** Some herbal ingredients can help reduce inflammation in the gums, which is beneficial for those with gingivitis or other gum problems.

4. Fresh Breath: Herbal toothpaste often contains natural flavors and ingredients that can help freshen breath without the use of artificial chemicals.
5. 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

II. MATERIALS

2.1 CHEMICALS :- Tulsi Leave Oil, Clove Oil, Neem Leave Oil, turmeric powder, Xylitol, Sodium Lauryl

Sulphate, , Calcium Carbonate, Glycerine, Methyl Paraben, Amaranth solution, Stevia, Sodium Chloride, Menthol **2.2 EQUIPMENTS:-**

1)R.D bottle, 2)10Collapsible 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)Mortar and pestle, 16)Domestic mixer.

III. COMPOSITION OF TOOTHPASTE

Detergent:

Amount weight 1 to 2%

Material: Sodium lauryl sulphate

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.

Colorants:

Amount weight = 1 to 2%

Material-Amaranth solution

It provides dentifrice with pleasing colours.

Flavouring agent:

Amount weight = 1 to 2%

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

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Anti tooth decay Fluoride:

Amount weight = 0 to 2%

Material-Sodium fluoride, Sodium mono fluoride phosphate. Fluoride presents dental carries.

Abrasive:

Amount weight = 20 to 55%

Material-calcium carbonate .

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

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 **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

1 Tulsi leave oil

Quantity – 0.1 □ -1 □

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 and taste 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



Fig.1: Tulsi leave oil

2 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



Fig.2:Clove oil

3 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



Fig.3: Neem leave oil

4 Babul

Quantity – 5□ - 20□

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



Fig.4:Babul

5 Xylitol

Quantity- 5□ - 20□

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



Fig.5: Xylitol

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, in-process 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

herbal toothpaste and to ensure that it remains effective throughout its shelf life.

V. EVALUATION OF TOOTHPASTE

1. 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

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

3. **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 and hard edged abrasive particles. Toothpaste shall not contain such particles.

4. **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.

5. **pH determination:-** pH of formulated herbal toothpaste was determined 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.

6. **Homogeneity:-** The toothpaste shall extrude a homogenous mass from the collapsible tube or any suitable container by applying of normal force at $27 \pm 20^\circ\text{C}$. in addition bulk of contents

- shall extrude from the crimp of container and then rolled it gradually.
7. **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 = $V_1 - V_2$ V_1 - Volume in ml of foam with water. V_2 - Volume in ml of water only.
8. **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, $25^{\circ}\text{C} \pm 2^{\circ}\text{C} / 60\% \pm 5\% \text{ RH}$, $30^{\circ}\text{C} \pm 2^{\circ}\text{C} / 65\% \pm 5\% \text{ RH}$, $40^{\circ}\text{C} \pm 2^{\circ}\text{C} / 75\% \pm 5\% \text{ RH}$ for the period of three months and studied for appearance, pH and spreadability. 17
9. **Moisture content** :- Toothpaste (10 gm) weighted in a Porcelain dish and dried it in the oven at 105°C . It was cooled in a desiccater. The loss of weight is recorded as percentage moisture content and calculated by the given formula. % Moisture = $\frac{\text{Original sample weight} - \text{dry sample weight}}{\text{Original sample weight}}$.
10. **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 shaken 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°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 (40ml/80ml) was measured. Longer time of fall indicates the denser and more stable foam.

11. **Organoleptic evaluation** :- Organoleptic evaluation (colour, taste) was done by sensory and visual inspection.
12. **pH**:- pH was tested by dissolving 1 gm product in to 9 ml of water and shaken vigorously then aqueous solution and pH is observed by pH meter.
13. **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.

- A) The fragrance was good, as good as the fragrance of reference toothpaste.
B) The fragrance was not so good but comparable to the reference toothpaste.
C) The fragrance of the toothpaste was poor than the reference toothpaste.

14. **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.
B) Shape just after the toothpaste is squeezed out on the toothbrush is almost maintained.
C) The toothpaste squeezed from the toothbrush and cannot maintain its shape.

15. **Storage stability**:- The toothpaste were filled in a toothpaste tube for storage and stored for 45 days at each of 5°C , room temperature and 40°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.

VI. CONCLUSION

The successful creation of a novel toothpaste utilizing herbal ingredients. This research demonstrates the feasibility of incorporating herbal components into toothpaste formulations, highlighting potential benefits such as antimicrobial properties, plaque reduction, and overall oral health improvement. The evaluation process, including physical, chemical, and sensory analyses, confirms the efficacy and safety of the herbal toothpaste. Furthermore, consumer acceptance studies indicate positive feedback, suggesting a promising market potential for herbal toothpaste products. Continued research and development in this area could lead to further enhancements in herbal toothpaste formulations, catering to the growing demand for natural oral care products.

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