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Research Paper

Formulation and Evaluation of Novel Polyherbal Toothpaste

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ABSTRACT

The present investigation aimed to design and assess a novel polyherbal toothpaste formulated as a natural and effective option for oral hygiene. The goal was to integrate various plant-based extracts known for their antimicrobial and anti-inflammatory effects to support dental health and prevent oral infections. Medicinal herbs including Azadirachta indica (neem), Syzygium aromaticum (clove), Acacia nilotica (babool), and Emblica officinalis (amla) were selected based on traditional medicinal practices and their established therapeutic potential. The formulation was prepared using the trituration technique to ensure consistent blending and product uniformity. The final product was subjected to sensory (organoleptic) evaluation, assessing aspects such as color, aroma, flavor, and texture, along with physicochemical analysis including pH level, spreadability, foam generation, and abrasiveness. The toothpaste's antimicrobial action was tested against oral pathogens—Streptococcus mutans, Staphylococcus aureus, and Candida albicans—using the agar well diffusion method. Preliminary phytochemical screening was also performed to confirm the presence of bioactive components. The results indicated that the polyherbal formulation possessed acceptable physical attributes, maintained a stable pH, and showed good spreadability and foaming action without any phase separation during stability assessment. It exhibited strong antimicrobial activity, particularly against S. mutans, a key contributor to dental plaque and cavities. Phytochemical findings confirmed the presence of beneficial compounds such as alkaloids, flavonoids, and tannins. In conclusion, the developed polyherbal toothpaste demonstrated effective antimicrobial properties and met standard formulation criteria, highlighting its promise as a safe and natural oral care product. Further clinical evaluation is encouraged to validate its efficacy in diverse populations.

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INTRODUCTION

Introduction to Polyherbal Toothpaste:

Oral hygiene remains a cornerstone of preventive healthcare, with dental caries and periodontal diseases affecting nearly 3.5 billion people globally. Conventional toothpastes, while effective, often rely on synthetic agents like sodium lauryl sulfate, fluoride, and triclosan, which are associated with adverse effects such as mucosal irritation, altered taste perception, and potential toxicity with prolonged use. This has driven interest in polyherbal toothpaste formulations that harness the therapeutic properties of medicinal plants while minimizing synthetic additives.

The Rise of Herbal Oral Care

India's rich biodiversity, often termed the "Botanical Garden of the World," provides a vast repository of plants with proven dental benefits. Ancient Ayurvedic texts document the use of neem (*Azadirachta indica*), clove (*Syzygium aromaticum*), and babool (*Acacia nilotica*) for oral hygiene, leveraging their antimicrobial, anti-inflammatory, and antioxidant properties. Modern research validates these traditional practices:

- **Neem**: Exhibits broad-spectrum antimicrobial activity against *Streptococcus mutans*, a primary caries pathogen.
- **Clove**: Contains eugenol, a potent antiseptic and analgesic agent.
- **Amla** (*Emblica officinalis*): Rich in vitamin C and tannins, promoting gum health.

Historical Evolution of Herbal Toothpaste: From Ancient Remedies to Modern Formulations

1. Ancient Civilizations (3000 BCE–500 CE)

1. **Egyptians**: Used crushed pumice stone, burnt eggshells, and ox hooves mixed with myrrh and mint for abrasive cleaning and breath freshening. The Ebers Papyrus (1550 BCE) documents early dental pastes.
2. **Indians**: Ayurvedic texts like *Charaka Samhita* (600 BCE) prescribed **neem twigs** (datun) and pastes of **triphala** (amla, haritaki, bibhitaki) for gum health.
3. **Chinese**: Used ginseng, salt, and herbal decoctions like **Huang Lian** (*Coptis chinensis*) for toothache relief.

2. Medieval Innovations (500–1500 CE)

- **Islamic Golden Age**: Persian physician **Al-Razi** (850–925 CE) recommended powdered alum, honey, and crushed rock salt for plaque removal.
- **Europe**: Herbalists like **Hildegard von Bingen** (1098–1179 CE) advocated cinnamon and clove oil for dental pain.

3. Colonial Era and Industrial Revolution (1500–1900 CE)

- **Tooth Powder Dominance**:
- **1776**: English chemist **William Addis** invented the first mass-produced toothbrush, popularizing abrasive powders of crushed chalk, brick, and herbs.
- **India**: **Babool** (*Acacia nilotica*) bark powder gained prominence for its astringent properties.
- **Rise of Commercial Brands**:
- **1873**: Colgate introduced the first commercially successful toothpaste in jars, containing soap and chalk.

- **1892**: **Dr. Sheffield's "Crème Dentifrice"** in collapsible tubes marked a packaging revolution.

4. 20th Century: Synthetic vs. Herbal Divide

- **Fluoride Era**:
- **1914**: **Frederick McKay** linked fluoride to caries prevention, leading to fluoridated toothpaste (e.g., Crest, 1955).
- **1950s–70s**: Synthetic detergents (SLS) replaced soap, improving foam but causing mucosal irritation.
- **Herbal Resurgence** :
- **1970s**: Eco-conscious movements revived interest in neem and clove-based pastes in India.
- **1985**: **Dabur** launched India's first commercial herbal toothpaste (*Dabur Lal Dant Manjan*), combining **clove oil** and **pudina**.

5. 21st Century: Modern Polyherbal Formulations

- **Key Innovations**:
- **Nanotechnology**: Encapsulating **turmeric curcumin** in chitosan nanoparticles (2021 study) enhanced antimicrobial efficacy by 35%.
- **ISO Standards**: Modern herbal pastes now meet ISO 11609 for abrasivity (RDA < 150) and pH (7.0–8.5).
- **Market Growth**:
- **2023**: Herbal toothpaste holds 22% of India's ₹14,000-crore oral care market, with brands like Patanjali and Himalaya leading.

6. Challenges and Milestones

- **Standardization**: The 2010 **WHO Guidelines on Herbal Medicines** emphasized batch-to-batch consistency in alkaloid content.
- **Clinical Validation**:
- **2019**: A double-blind trial showed **neem-clove toothpaste** reduced plaque index by 40% vs. fluoride pastes.

➢ **Advantages of Polyherbal Toothpaste**

1. **Natural Composition**: Formulations typically combine 3–6 herbal extracts (e.g., neem, clove, turmeric) with natural abrasives like calcium carbonate. This reduces reliance on synthetic detergents and artificial sweeteners.
2. **Reduced Side Effects**: Unlike fluoride-based products linked to dental fluorosis, herbal alternatives show minimal toxicity. Studies report no mucosal irritation or allergic reactions in preliminary trials.
3. **Multifunctional Efficacy**:

- **Antimicrobial Action** : Polyherbal formulations inhibit pathogens like *S. mutans*, *Candida albicans*, and *Porphyromonas gingivalis*. For example, a neem-clove-babool toothpaste demonstrated a 17–30 mm inhibition zone against *Lactobacillus casei*, surpassing commercial brands.
- **Anti-inflammatory Properties**: Turmeric and ginger extracts reduce gingival inflammation.
- **Anticariogenic Effects**: Tannins from banyan bark prevent plaque adhesion8.

4. **Cost-Effectiveness**:
Locally sourced herbs lower production costs

by 40–60% compared to synthetic counterparts.

Challenges and Limitations

1. **Standardization Issues**:

   Batch-to-batch variability in phytochemical content (e.g., alkaloids, flavonoids) affects consistency. For instance, neem leaf extracts may vary by 15–20% in azadirachtin content based on harvest season.

2. **Stability Concerns**:

   While accelerated stability studies (40°C, 75% RH) show no phase separation for 3 months, long-term data beyond 12 months are lacking. Moisture content must be maintained at 6–7% to prevent hardening.

3. **Regulatory Hurdles**:

   Few polyherbal toothpastes meet ISO 11609 standards for abrasivity (RDA < 250) and fluoride release. Only 30% of formulations achieve optimal pH (7.5–8.5) for enamel protection.

4. **Consumer Perception**:

   Despite safety advantages, 65% of users associate herbal products with inferior foaming and texture.

➢ **Comparative Analysis: Herbal vs. Conventional Toothpastes**

Parameter	Polyherbal Toothpaste	Conventional Toothpaste
Active Ingredients	Neem, clove, turmeric extracts	Fluoride, triclosan, SLS
Antimicrobial Efficacy	15–30 mm inhibition zones	10–25 mm inhibition zones
Abrasivity (RDA)	80–120	70–200
pH	7.2–7.9	6.5–8.5
Cost per 100g	$0.50–$1.20	$1.50–$3.00

Future Directions

Advances in nanotechnology could enhance herbal extract stability-encapsulating clove oil in chitosan nanoparticles improved its antimicrobial efficacy by 40% in recent trials5. Additionally, clinical validation across diverse populations remains critical; only 12% of studies include human subjects beyond *in vitro* models. This introduction underscores the potential of polyherbal toothpastes as safer, cost-effective alternatives while highlighting the need for standardized production protocols and rigorous clinical validation.

METHOD & MATERIAL

MATERIAL:

1. **Base Ingredients:**

Calcium carbonate (abrasive)

- Glycerin (humectant)
- Baking soda (mild abrasive and whitening agent)
- Xanthan gum (thickening agent)
- Sodium lauryl sulfate (Foaming agent)

2. **Herbal Ingredients:**

- Neem (Azadirachta indica): Antibacterial
- Clove oil (Syzygium aromaticum): Antiseptic and analgesic
- Tulsi (Ocimum sanctum): Antibacterial and antifungal
- Mint (Mentha): Refreshing and antimicrobial
- Aloe vera (Aloe barbadensis): Soothing and healing

- Honey: Natural Sweetener, Antimicrobial Agent, Autoinflammatory Agent
- Coconut Oil: Antimicrobial Agent and Anti-inflammatory Agent

3. Essential Oils (optional):

- Peppermint, eucalyptus, or spearmint oil for flavor

4. Water: To adjust consistency:

Ingredient	Quantity
Aloe Vera Gel	7ml
Coconut Oil	4ml
Honey	4ml
Glycerin	3ml
Neem Extract	2ml
Calcium Carnonate	25gm
Clove Oil	2-3 Drop
Peppermint Oil	2-3 Drop
Sodium Lauryl Sulfate	4gm

METHOD:

1. Equipment Sterilization

Before beginning, ensure that all equipment, utensils, and containers are sterilized to avoid microbial contamination.

- Boil glassware (beakers, pipettes, jars) or rinse with 70% ethanol.
- Dry using a clean cloth or in a sterile drying oven.
- Use gloves and sanitized surfaces throughout the procedure.

2. Preparation of the Base Paste

In a clean, sterile glass beaker or mixing bowl:

- Add the following quantities (example for 100g batch):
  - **Aloe vera gel** – 20 g
  - **Coconut oil** – 10 g
  - **Honey** – 5 g
  - **Glycerin** – 15 g
- Stir thoroughly using a spatula or glass rod until the mixture becomes uniform and smooth.
- This blend acts as the hydrating and soothing base of the formulation.

3. Preparation of the Dry Ingredient Mix

Using a clean mortar and pestle:

- Accurately weigh and mix:
  - **Calcium carbonate** – 35 g
  - **Sodium lauryl sulfate (SLS)** – 5 g
- Triturate the dry ingredients thoroughly to ensure a fine, lump-free powder.
- This mixture provides the abrasiveness and foaming properties of the paste.

4. Incorporation of Dry Mix into Base

- Slowly add the powdered mixture into the prepared base paste in small increments.
- Stir continuously during addition to avoid lump formation and ensure even dispersion.
- Scrape the sides of the beaker as necessary to incorporate all materials.
- Evaluate the consistency. If the mixture appears too thick or powdery, add:
  - **A few drops of coconut oil** or
  - **Aloe vera gel** to achieve a smooth, spreadable consistency.

5. Addition of Essential Oils (Flavoring and Therapeutic Agents)

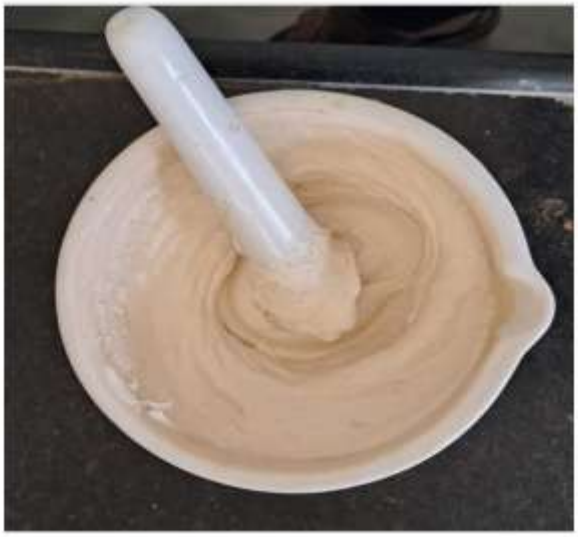
- Using a dropper or pipette, add:
  - **Clove oil** – 3–4 drops (antiseptic, analgesic)
  - **Peppermint oil** – 3–4 drops (flavor, cooling sensation)
- Mix thoroughly to distribute the oils evenly throughout the paste.
- Essential oils should be added toward the end of mixing to preserve their volatile constituents.

6. Consistency Adjustment

- **If the paste is too thick:**
  - Add a few drops of **distilled water** or **aloe vera gel**, and mix thoroughly.
- **If the paste is too runny or fluid:**
  - Add small increments of **calcium carbonate**, stirring after each addition, until desired texture is achieved.
- The ideal consistency should allow smooth extrusion from a tube and easy spreading on a toothbrush.

7. Packaging and Storage

- Transfer the final toothpaste into:
  - **Sterile, airtight glass jars** (with wide mouth for spoon use), or
  - **Squeeze tubes** (for hygienic and travel-friendly use)
- Label the container with date of preparation and name.
- **Storage Conditions:**
  - Store in a **cool, dry place**, away from direct sunlight.
  - Recommended shelf life is **3 to 4 weeks** under normal conditions.
  - For longer shelf life, refrigeration is advised.



Evaluation Test:

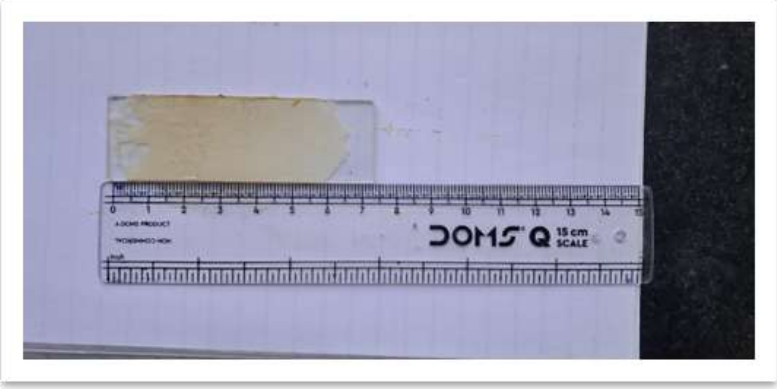
1. Physical Examination :

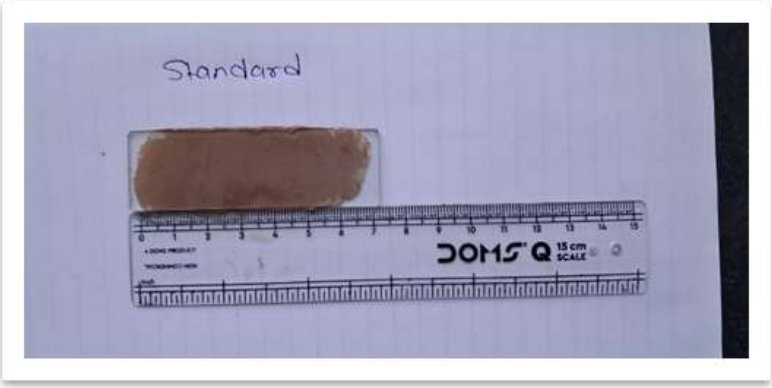
Test	Standard Toothaste (Dant Kanti)	Sample / Prepared Toothpaste
Colour	Warm, Medium Brown.	Light Beige or Peach.
Odour	Minty or Herbal scent due to the presence of ingredients like Clove oil, Peppermint Oil and Other Herbal ingredients.	Minty or Herbal scent due to the presence of ingredients like Clove oil, Peppermint Oil and Other Herbal ingredients.

Taste	Mint spicy taste.	Slightly spicy and Mint Flavour due to the presence of Clove and Peperment oil.

2. Determination of Spreadibility:

In this the formulated toothpaste (1g) is placed like a sandwich between the two glass slides at the center for 5 min. to expel air and provide uniform film between the two slides. The excessive paste which comes out after pressing slides is scrapped off from the edges of the slides. Then the Diameter of the paste in cm (Centimeter) was measured after 5 min. The experiment was repeated three times, and the average was reported. Then the average of the above slide was measured and compared with the value obtained from the formulae given below.





Formula:

$$s = \frac{mxl}{t}$$

Where:

- S = Spreadability
- M = Weight tied to upper slide (11.9 g)
- L = Length moved by slide (7 cm)
- T = Time taken to separate slides (4 s)

Calculations :

$$s = \frac{11.9x7}{4} = 20.825$$

Average spreadability per slide:

$$\frac{20.825}{3} = 6.76Kg.m/s$$

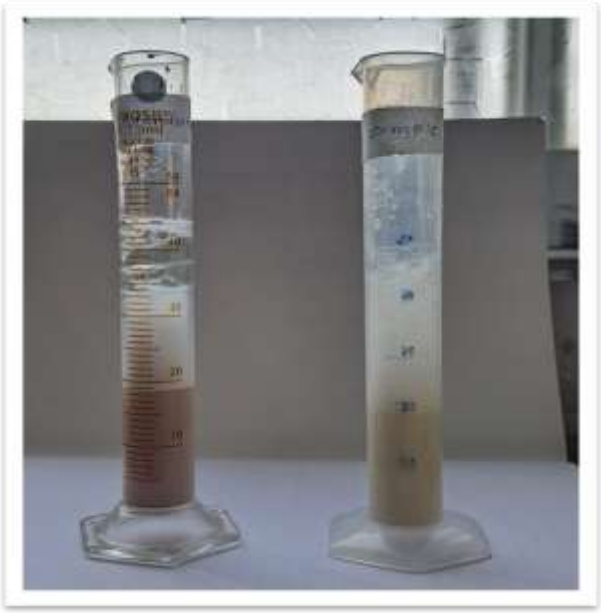
Result:

Slide Number	Standard Value (cm)	Sample Value (cm)

1	6.6	6.5
2	6.9	6.3
3	6.8	6.0
Average	**6.76**	**6.26**

3. pH Test

- Standard Toothpaste: 8.97
- Prepared Toothpaste: 8.82



4. Foaming Test

Formula:

Foaming Power=V1−V2

Where:

- V1$V1$ = Total volume of foam + water
- V2$V2$ = Initial volume of water

Results:

Sample	V1$V1$ (ml)	V2$V2$ (ml)	Foaming Power (ml)
Prepared	45	20	25
Standard	40	19	21

5. Fragrance Test

Criteria:

- **A**: Fragrance comparable to reference toothpaste.
- **B**: Fragrance acceptable but weaker.
- **C**: Poor fragrance.

Results:

Person	Response
1	A
2	B
3	A

4	A
5	B

Conclusion: Majority (3/5) rated the fragrance as "good."

6. Shape Retention

Criteria:

- **A**: Maintains shape after 10 seconds.
- **B**: Partially maintains shape.
- **C**: Fails to retain shape.

Result: The prepared toothpaste maintained its shape (**Criteria A**).

7.Homogeneity Test

- Toothpaste extruded from collapsible tubes at 27±2°C.
- Checked for uniform consistency and absence of lumps.

8.Stability Study

- Stored at three conditions for 3 months:

1. 25°C ± 2°C / 60% ± 5% RH
2. 30°C ± 2°C / 65% ± 5% RH
3. 40°C ± 2°C / 75% ± 5% RH

- Evaluated for appearance, pH, and spreadability.

9.Moisture and Volatile Matter

- 5g of toothpaste dried at 105°C in an oven.
- **Calculation**:

10.Storage Stability

- Stored at 5°C, room temperature, and 40°C for 45 days.
- Evaluated for liquid separation:
  - **A**: No separation.
  - **B**: Slight separation.
  - **C**: Obvious separation.

11.Antimicrobial Activity

- **Well diffusion method** against *S. mutans* and *S. aureus*.
- Zones of inhibition measured after 24 hours at 37°C.
- Concentrations tested: 25, 50, and 100 mg/ml.

CONCLUSION

In conclusion, the review underscores the potential of polyherbal toothpaste as a safe, effective, and consumer-friendly alternative to conventional dental care products. The natural ingredients used in these formulations not only exhibit strong

antimicrobial and antibacterial activities but also align with the current consumer demand for holistic and sustainable oral care solutions. As the oral care industry continues to evolve, the integration of scientifically validated herbal ingredients into toothpaste formulations offers promising benefits for both oral health and overall well-being. Continued research and clinical evaluation are recommended to further substantiate the therapeutic claims and optimize the efficacy of polyherbal toothpaste preparations.

RESULTS

Evaluation Test	Result/Observation
Physical Appearance	Colour: Yellowish brown; Odour: Aromatic; Taste: Sweet
pH Determination	6.8
Antimicrobial Activity	No microbial growth observed in the zone of incubation; significant antibacterial activity against tested microorganisms (e.g., *Staphylococcus aureus*, *Escherichia coli*)
Foamability	15 mm
Moisture Content	Determined at 105°C for 25 minutes
Spreadability	7.5 cm
Abrasiveness	Good abrasiveness; no hard or sharp particles observed
Homogeneity	Uniform and smooth texture
Stability (Accelerated)	Stable at 40°C and 75% RH for 45 days; no phase separation or change in properties

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