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Comparative Evaluation of Toothpastes Available in Indian Market as Per Regulatory Standards

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ABSTRACT

The aim of the present study is to evaluate and compare a formulated toothpaste with various commercially available toothpastes, including medicated types, herbal variants, and herbal sticks. Toothpaste plays an essential role in oral care by helping to remove plaque and food debris from teeth, control bad breath, and prevent issues like tooth decay (dental caries) and gum diseases (such as gingivitis), thereby promoting good oral hygiene. Today, a wide range of toothpaste options are available in the market, containing ingredients aimed at managing gingivitis, controlling tartar buildup, and whitening teeth. Among these, tooth whitening remains a key concern for many individuals. Toothpaste formulations often include abrasive particles that assist in removing stains and plaque, contributing to the whitening effect. With the advancement in formulation technologies and the inclusion of specialized ingredients, modern toothpaste offers enhanced clinical benefits. In the current study, ten different marketed toothpaste brands were examined for various parameters such as appearance, pH, spreadability, homogeneity, moisture content, presence of heavy metals, and antimicrobial activity. The findings were assessed in accordance with BIS (Bureau of Indian Standards) specifications and found to be compliant.

Introduction

1.1 TOOTHPASTE INDUSTRY: AN OVERVIEW

The toothpaste history in India can be tracked back from 1975 with 1200 tonnes of toothpaste produced by the toothpaste industry. Prior to the toothpastes Oral Hygiene was the domain of local home made powders and ayurvedh practitioners. With the entry of Colgate in Indian marketplace the awareness about Oral care and the importance of oral care. In recent years the Industry has shown impressive growth rate of 18.6% (this growth is calculated in terms of value growth in Rs.)

The growth in the Urban market has been largely by the Gel Segment. Presently, a large chunk of the Market is still held by Colgate. The major players in the toothpaste Industry being Colgate Palmolive and Hindustan Unilever Limited and several minor players like Balsara hygiene, Dabur etc.

Presently Colgate Dental Cream holds 52% of market share. HILL's Close up lies far behind with 23% of the existing market share. The third player in the marketplace in terms of market share is Colgate Gel with 10.5% of the marketshare. That leaves 14.5% marketshare for other Brands like Pepsodent, Pepsodent G, Promise, Babool, Sensofoam, Forhans, Cibaca, Neem, Vicco etc. The toothpaste market is presently valued at Rs. 750 croresout of which the Gel segment has already bagged 1/3rd portion of it. The Gel segment presently stands at Rs. 248 crores and is growing at a rate much faster than Cream. In India toothpaste usage as compared to other countries is very low which signifies about the potential of the market. In Urban India the usage of toothpaste per person per year is just 190gms. Where as it is 200gms of toothpaste per person per year in developing countries as Indonesia and Thailand. In developed countries as USA and other European countries the toothpaste usage is 375 gms per person year. In India the toothpastes companies are going in for advertising on a heavy note, on an average the companies managing this FMCG category are spending 6.15% of their sales on development. Colgate Palmolive had shelled out 15% of their sales on ads in the year 1994.

1.2 What are toothpaste

Toothpaste is an essential product for maintaining oral cleanliness. It assists in eliminating plaque and food particles from the teeth, controlling bad breath (halitosis), and preventing common dental problems such as cavities (dental caries) and gum infections like gingivitis. Today, a wide range of toothpaste options are available, each formulated to address specific concerns such as gum protection, tartar removal, and teeth whitening.

Among these functions, tooth whitening is particularly valued by many users. This effect is often achieved through the inclusion of abrasive agents that help remove surface stains and discoloration.

Advances in formulation technology have allowed manufacturers to enhance toothpaste effectiveness by incorporating beneficial ingredients and additives, offering improved clinical outcomes.

In this study, ten commercially available toothpaste brands were selected and evaluated based on various characteristics, including visual appearance, pH level, ease of spread (spreadability), uniformity (homogeneity), moisture content, presence of heavy metals, and antimicrobial activity. The findings from these evaluations were compared against the quality standards set by the Bureau of Indian Standards (BIS). [1]

Toothpaste, whether in paste or gel form, is applied to the teeth using a toothbrush. It supports both aesthetic and health-related dental needs by removing buildup, controlling odor, and delivering active agents like fluoride to help prevent tooth decay and gum disease.

Toothpaste is a vital product in the field of oral care, with its use dating back to ancient times. Historical records indicate that early toothpaste formulations were developed in India and China between 300 and 500 BC. The primary causes of dental caries and gum diseases, such as periodontitis, are often linked to the accumulation of dental plaque. Thus, maintaining proper oral hygiene using products like toothpaste, toothbrushes, mouth rinses, and antimicrobial preparations is essential for preventing such conditions.

1.3 Why Toothpastes Are Preferred Over Other Dental Preparations

Toothpaste is one of the most widely used oral hygiene products around the world. Compared to other dental preparations such as tooth powders, gels, mouthwashes, and herbal sticks, toothpaste offers several practical and therapeutic advantages. [2] The preference for toothpaste is attributed to the following reasons:

1. Convenient and Easy to Use

- Toothpastes are user-friendly and can be easily applied to a toothbrush without any mess or spillage.
- They are portable and hygienic, usually packed in tubes that prevent contamination.
- The paste consistency allows for quick application and even distribution across tooth surfaces.

2. Effective Plaque and Stain Removal

The mild abrasive agents in toothpaste help in removing food debris, surface stains, and dental plaque.

These abrasives are carefully formulated to clean without damaging tooth enamel.

3. Delivery of Active Ingredients

- Toothpastes are excellent carriers of active agents such as:
- **Fluoride** for preventing dental caries
- **Triclosan or Zinc** for anti-plaque and anti-gingivitis action
- **Whitening agents** for cosmetic benefits
- **Herbal extracts** for natural oral care

These ingredients are retained in the mouth longer during brushing, enhancing their effectiveness.

4. Combined Mechanical and Therapeutic Action

Toothpaste allows the mechanical action of brushing to work in tandem with chemical or therapeutic agents.

This dual action improves cleaning efficiency compared to mouthwashes or gels alone.

5. Better Taste and Acceptability

Toothpastes are available in a wide variety of flavors (mint, herbal, cinnamon, etc.) that mask the taste of active chemicals and make brushing a pleasant experience.

This encourages regular oral hygiene practices among both adults and children.

6. Wide Range of Formulations

Toothpastes cater to diverse oral needs, including:

- **Sensitivity relief**
- **Tartar control**
- **Whitening**
- **Medicated types for gum infections**

Consumers can choose based on their personal oral health requirements.

7. Improved Oral Health Compliance

- Because of their routine use in daily life, toothpaste ensures better compliance with oral health regimens.
- Unlike dental powders or rinses, which some users may find outdated or inconvenient, toothpaste fits seamlessly into modern oral care habits.

8. Hygienic Packaging and Longer Shelf Life

Toothpastes come in sealed, tamper-proof tubes or pumps, reducing the risk of contamination.

Most have a longer shelf life compared to homemade or natural preparations like tooth powders.

9. Safe for Daily Use

Modern toothpaste formulations are dermatologically tested, pH-balanced, and adhere to national and international safety standards (e.g., BIS, FDA).

Their regular use does not cause damage to teeth or gums when used as directed.

10. Widely Available and Affordable

Toothpaste is readily available across pharmacies, supermarkets, and even rural outlets.

They come in various price ranges and sizes, making them accessible to a broad population.

Ideal Properties of Toothpaste

1. Good abrasive effect
2. Non irritant and non-toxic
3. Impart no stain in tooth
4. Keep the mouth fresh and clean
5. Prolonged effect
6. Cheap and easily available

2. OBJECTIVES AND PLAN OF WORK

Objectives of the Study

2.1 To Identify and Collect Popular Toothpaste Brands in India (Medicated and Herbal):

The first step of the research involves a thorough market survey to identify the top-selling and most widely used brands of toothpaste in India. This includes products categorized under medicated, herbal, and conventional oral hygiene formulations. The selection will be based on popularity, market presence, consumer reviews, and availability in both urban and rural areas. This ensures that the study encompasses a wide spectrum of products currently being used by the general population.

2.2 To Evaluate the Selected Brands as per Indian Regulatory Standards (I.P./BIS):

After collection, each toothpaste brand will undergo a detailed evaluation based on parameters set by Indian regulatory authorities, such as the Indian Pharmacopoeia (IP) and the Bureau of Indian Standards (BIS). These standards ensure the safety, efficacy, and quality of dental products. Parameters to be analyzed include appearance, pH, spreadability, moisture content, heavy metal content, homogeneity, and antimicrobial activity.

2.3 To Analyze and Report on the Evaluation Outcome:

Following laboratory testing and parameter evaluation, a comprehensive comparative analysis will be conducted. The findings will be statistically interpreted to identify strengths and weaknesses of each formulation. This step aims to understand the relationship between the composition of toothpaste (especially herbal vs. synthetic ingredients) and their physical or chemical behavior and efficacy. The final report will highlight which products meet or exceed standard expectations and which may require reformulation or improvement. [3]

3. Plan of Work

3.1 Survey and Selection of Toothpaste Brands:

Conduct a comprehensive survey of local pharmacies, supermarkets, and e-commerce platforms to identify the most frequently purchased toothpaste brands across various price segments.

Select a diverse set of formulations, including medicated toothpaste (containing chemical agents for specific oral conditions), herbal toothpaste (comprising natural plant-based ingredients), and general oral hygiene toothpastes (commonly used for daily cleaning and freshness).

Procure 10–12 brands, ensuring they represent a variety of formulations and claims (whitening, anti-sensitivity, anti-cavity, etc.).

3.2 Preliminary Analysis and Label Review:

Document the list of ingredients and claims made by each brand.
Categorize ingredients into active and inactive, natural and synthetic.
Identify any ingredients flagged for causing sensitivity, allergic reactions, or long-term safety concerns.

3.3 Physicochemical Evaluation as per BIS/IP Standards:

Each sample will be tested under standardized conditions for the following parameters:
Appearance and Consistency: Visual inspection for color, phase separation, and texture.
pH Measurement: Using a calibrated pH meter, the pH of each sample will be recorded to assess acidity or alkalinity.
Spreadability: Measured by applying a fixed amount between glass slides and determining the diameter of spread.
Homogeneity: Ensuring uniformity of composition without granules or separation.
Moisture Content: Estimation by drying and weighing methods to determine the percentage of water content.
Heavy Metal Analysis: Detection of harmful elements like lead, arsenic, or mercury using chemical assays.
Antimicrobial Activity: **Test Method**: IS 14648:2011 – This is the **Indian Standard** method used for microbiological testing of toothpaste and similar products. [3]

3.4 Comparative Analysis and Interpretation of Data:

Results from each parameter will be recorded and tabulated.
Comparative graphs and charts will be created to visualize the performance of each toothpaste brand.
Statistical analysis will be conducted (e.g., standard deviation, ANOVA) to identify significant differences between formulations.

3.5 Formulation and Testing of Poly-Herbal Toothpaste:

Based on literature and traditional knowledge, a poly-herbal toothpaste will be formulated using ingredients such as neem, clove, babul, guava leaves, jamun seeds, vidanga, vajradanti, and others known for their antimicrobial and anti-inflammatory properties. [4]

The same set of tests will be conducted on the formulated herbal toothpaste to compare its performance with that of commercial products.

4. Materials and Methods

4.1 Overview of Formulation Strategy

The formulation of herbal toothpaste was designed with the primary aim of creating a safe, effective, and natural alternative to conventional commercial products. The strategy employed focused on selecting ingredients with well-documented roles in oral hygiene and health, ensuring compatibility among components, and maintaining physical and chemical stability. A blend of herbal and pharmaceutical-grade excipients was utilized to create a toothpaste that could match or exceed the performance of existing products in terms of antimicrobial activity, spreadability, pH, and sensory characteristics.[6]

4.2 Selection of Ingredients

Each ingredient in the formulation was carefully selected based on its functionality, safety profile, and compatibility with other components. The composition consists of the following:

- **Ginger Oil**: Used as the main active herbal ingredient, known for its **anti-inflammatory, antimicrobial**, and **antioxidant** properties. Ginger has traditionally been used in oral care for treating gingivitis and toothaches.
- **Calcium Carbonate**: A mild abrasive that assists in **mechanical plaque removal** without damaging the enamel. It also acts as a bulking agent.
- **Glycerin**: Functions as a **humectant**, preventing the paste from drying out and helping to maintain the smooth consistency of the product.
- **Sodium Lauryl Sulphate (SLS)**: A **surfactant and foaming agent**, it aids in the distribution of toothpaste across the mouth and enhances the cleansing effect by reducing surface tension.
- **Sodium Benzoate**: Acts as a **preservative** to inhibit microbial growth during storage.
- **Sodium Saccharin**: A **non-nutritive sweetener** used to improve palatability without the cariogenic effects of sugar.
- **Peppermint Oil**: Provides a **pleasant flavor and cooling sensation**, enhancing user acceptability and masking the taste of certain medicinal ingredients.

All ingredients were pharmaceutical grade and procured from reputed suppliers. The formulation was designed to total 100 g, with all ingredients expressed in weight/weight percentages.

4.3 Formulation Method

The herbal toothpaste was formulated using the **dry gum method**, a conventional pharmaceutical technique ideal for preparing semi-solid formulations such as pastes and gels. The method was selected for its ability to produce a consistent and uniform base. [5]

Step-by-Step Procedure:

Step 1: Preparation of Base

1. The solid excipients — **calcium carbonate, sodium lauryl sulphate, sodium benzoate**, and **sodium saccharin** — were accurately weighed according to the formulation table.
2. Each solid was **passed through sieve number 80** to ensure uniform particle size and remove any agglomerates.
3. These ingredients were blended uniformly in a **clean, dry mortar**, followed by **trituration with glycerin**, added gradually, until a **smooth, homogenous paste** was formed. [7]

Step 2: Addition of Herbal Extract *4. A pre-weighed amount of ginger oil was slowly incorporated into the base, ensuring thorough mixing to evenly distribute the active ingredient.*

Step 3: Flavoring *5. Finally, peppermint oil was added in a quantity sufficient (q.s.) to achieve the desired taste and aroma. The mixture was continuously stirred until a uniform consistency was achieved.*

4.4 Final Composition of Herbal Toothpaste

S. No.	Ingredient	Quantity (w/w %)	Purpose
1	Ginger Oil	2 ml	Anti-inflammatory and antimicrobial agent
2	Sodium Lauryl Sulphate	1.5 g	Surfactant, detergent, and foaming agent
3	Sodium Benzoate	0.1 g	Preservative to prevent microbial growth
4	Sodium Saccharin	0.2 g	Non-cariogenic sweetener
5	Glycerin	40 ml	Humectant and consistency enhancer
6	Calcium Carbonate	44 g	Mild abrasive for plaque removal
7	Peppermint Oil	Q.S.	Flavoring agent

All ingredients collectively made up **100 g** of the final herbal toothpaste formulation.

4.5 Evaluation Parameters

After formulation, the toothpaste was subjected to a preliminary **physical evaluation** to ensure it met desirable sensory and aesthetic standards.[8] The following parameters were assessed:

1. **Color**: Observed visually for uniformity and aesthetic appeal.
2. **Odour**: Smelled to assess the presence of a pleasant, herbal-minty aroma.
3. **Taste**: Tasted in small quantities to evaluate sweetness and flavor.
4. **Consistency**: Manually tested by rubbing the paste on the skin to assess spreadability and texture.
5. **State**: Inspected visually to ensure the formulation retained a semisolid, paste-like state suitable for application on a toothbrush.

4.6 Formulation of Toothpaste

Ingredients Used in the Formulation of Herbal Toothpaste

1 Ginger Oil – Natural Anti-Inflammatory Agent

- Use in toothpaste: Reduces gum inflammation and supports oral healing.

Figure 1: Ginger Oil – Used as Anti-inflammatory Agent

2 Sodium Lauryl Sulphate – Foaming and Cleaning Agent

- Use: Acts as a surfactant to create foam and enhance cleaning.

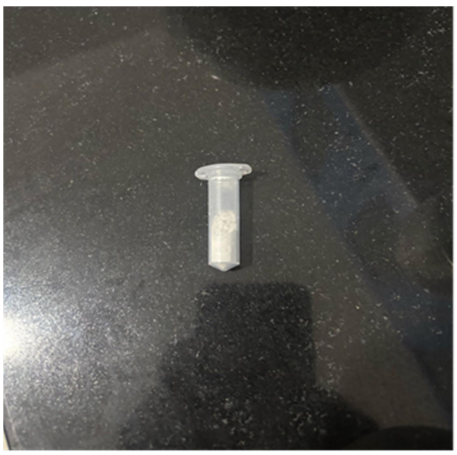

Figure 2: Sodium Lauryl Sulphate – Detergent and Foaming Agent

3 Sodium Benzoate – Preservative for Shelf Life

- Use: Prevents microbial growth, increasing product stability.

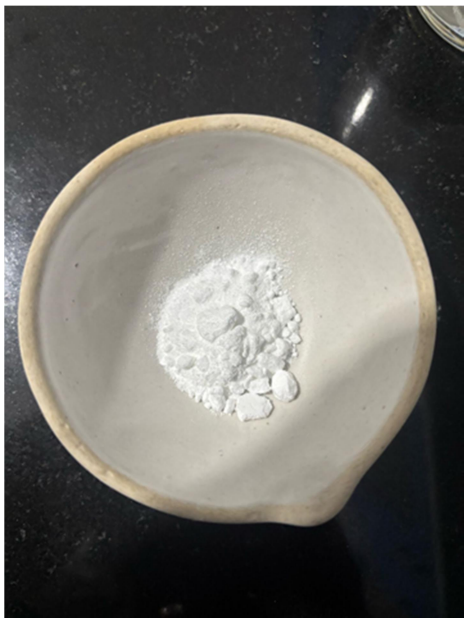

Figure 3: Sodium Benzoate – Used as Preservative

4 Sodium Saccharin – Non-Cariogenic Sweetener

- Use: Provides sweetness without promoting tooth decay.

5 Glycerin – Humectant for Moisture Retention

Use: Prevents drying, gives smooth consistency.

Figure 4: Glycerin – Used as Humectant

6 Calcium Carbonate – Mild Abrasive and Cleaning Agent

- Use: Helps remove plaque and stains without damaging enamel.

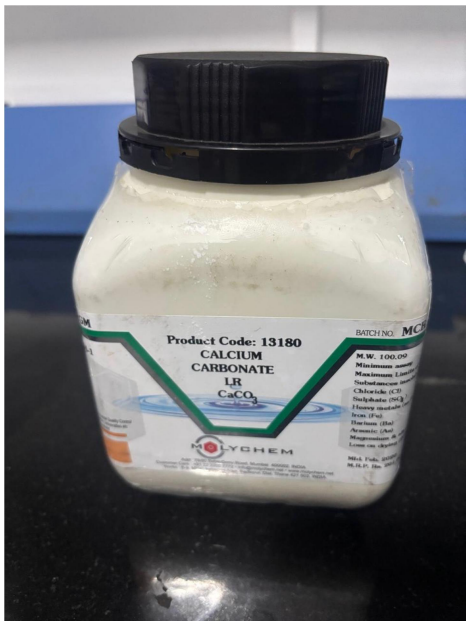

Figure 5: Calcium Carbonate – Used as Abrasive

7 Peppermint Oil – Flavoring and Cooling Agent

- Use: Provides a refreshing flavor and mild antiseptic properties.

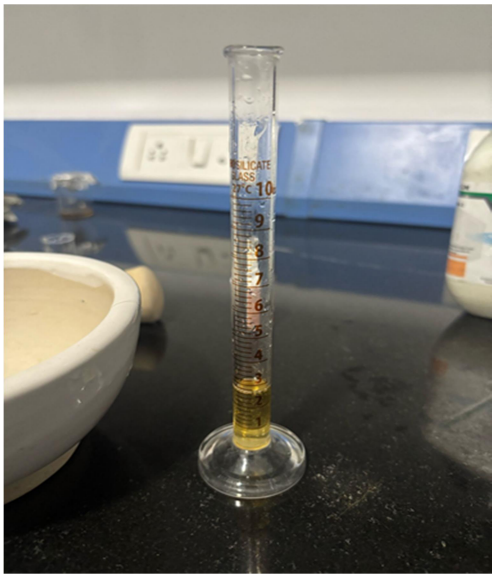

Figure 6: Peppermint Oil – Used as Flavoring Agent

4.7 Final Formulation of Herbal Toothpaste

Figure 7: Final Herbal Toothpaste Formulation Prepared by Homogenization Method (The image shows the freshly prepared herbal toothpaste with uniform consistency and creamy texture, ready for further evaluation and packaging.)

5. RESULTS AND DISCUSSIONS

Table 1 : Results of Appearance, pH, Spreadability of different brands of toothpastes

S.no	Brands	Classification	Appearence	pH	Spreadability
1	Sample A	Oral hygiene	White	7.23	8.5
2	Sample B	Oral hygiene	Red	6.73	9.2
3	Sample C	Oral hygiene	Pale pink	7.41	9.1
4	Sample D	Medicated	White	7.85	9.8
5	Sample E	Herbal	Green	8.5	9.4
6	Sample F	Herbal	Brown	7.64	8.5
7	Sample G	Herbal	Gray	6.92	10.5
8	Sample H	Herbal	Brownish	8.32	8.4
9	Sample I	Herbal	White	8.15	8.5
10	Formulation	Herbal	White	8.1	8.7

Note: From the above table values the pH and Spreadability were found to be limits.

Table 2 : Results of Homogeneity, Moisture content of different brands of toothpastes

S.no	Brands	Classification	Homogeneity	Moisture content
1	Sample A	Oral hygiene	Pass	1.6
2	Sample B	Oral hygiene	Pass	1.4
3	Sample C	Oral hygiene	Pass	1.5
4	Sample D	Medicated	Pass	1.8
5	Sample E	Herbal	Pass	1.3
6	Sample F	Herbal	Pass	1.8
7	Sample G	Herbal	Pass	2.0

8	Sample H	Herbal	Pass	1.9
9	Sample I	Herbal	Pass	1.8
10	Formulation	Herbal	Pass	1.7

Note: From the above table all the brands of toothpastes passed the tests for homogeneity.

Table 3 : Results of fineness, foaming power

S.no	Brands	Classification	Fineness	Foaming power(ml)
1	Sample A	Oral hygiene	Good	50
2	Sample B	Oral hygiene	Good	55
3	Sample C	Oral hygiene	Good	52
4	Sample D	Medicated	Good	56
5	Sample E	Herbal	Good	53
6	Sample F	Herbal	Good	51
7	Sample G	Herbal	Good	53
8	Sample H	Herbal	Good	54
9	Sample I	Herbal	Good	51
10	Formulation	Herbal	Good	49

Table 4 : Results of sharp,edge and abrasive particles of different brands of toothpastes

S.no	Brands	Classification	Determination Of Sharp & Edge	Determination Of Abrasive Particles
1	Sample A	Oral hygiene	Absent	Absent

2	Sample B	Oral hygiene	Absent	Absent
3	Sample C	Oral hygiene	Absent	Absent
4	Sample D	Medicated	Absent	Absent
5	Sample E	Herbal	Absent	Absent
6	Sample F	Herbal	Absent	Absent
7	Sample G	Herbal	Absent	Absent
8	Sample H	Herbal	Absent	Absent
9	Sample I	Herbal	Absent	Absent
10.	Formulation	Herbal	Absent	Absent

Table 5: Result of Heavy Metal Content (As & Pb)

S.no	Brands	Classification	Classification	Heavy metals Arsenic & Lead
1	Sample A	Oral hygiene	Oral hygiene	Within limits
2	Sample B	Oral hygiene	Oral hygiene	Within limits
3	Sample C	Oral hygiene	Oral hygiene	Within limits
4	Sample D	Medicated	Medicated	Within limits
5	Sample E	Herbal	Herbal	Within limits
6	Sample F	Herbal	Herbal	Within limits
7	Sample G	Herbal	Herbal	Within limits

8	Sample H	Herbal	Herbal	Within limits
9	Sample I	Herbal	Herbal	Within limits
10	Formulation	Herbal	Herbal	Within limits

Table 6: Result of Antimicrobial Activity (TVC)

S.no	Brands	Classification	Anti – microbial activity
1	Sample A	Oral hygiene	< 10
2	Sample B	Oral hygiene	< 10
3	Sample C	Oral hygiene	< 10
4	Sample D	Medicated	< 10
5	Sample E	Herbal	< 10
6	Sample F	Herbal	< 10
7	Sample G	Herbal	< 10
8	Sample H	Herbal	< 10
9	Sample I	Herbal	< 10
10	Formulation	Herbal	< 10

Total Viable Count (TVC):

- This measures the number of viable (living) microorganisms (like bacteria or fungi) in the sample.

- Result: **<10 cfu/gm** means less than 10 colony-forming units per gram — a **very low microbial load**, indicating excellent microbiological quality.

Test Method: IS 14648:2011 – This is the **Indian Standard** method used for microbiological testing of toothpaste and similar products

A **TVC of <10 cfu/gm** confirms the product is **safe from microbial contamination** and suitable for use from a biological standpoint.

RESULTS: The present comparative study demonstrated that both commercial and lab-made herbal toothpastes are compliant with BIS standards. All products showed acceptable physical properties and microbial safety. The formulated herbal toothpaste containing ginger oil exhibited favorable pH, spreadability, and microbial load, making it a potential candidate for commercialization. It stood at par with established brands in terms of performance and safety, highlighting the efficacy of traditional ingredients when combined with scientific formulation techniques.

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