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Formulation and physicochemical evaluation of toothpaste formulated with Bay leaf extract and compared with Commercial Herbal Toothpastes

Kunwarsingh Sastiya*, Kirti Malviya, Sangeeta Dwivedi, Sapna Malviya, Anil Kharia

Modern institute of pharmaceutical sciences Gram Alwasa, behind revati range, Indore

*Corresponding Author's E mail: sastiyakunwarsingh@gmail.com

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ABSTRACT

The main aim of the present work is to prepare, evaluate and compare Lab Made Herbal toothpaste with commercial Herbal toothpastes. In the present study, commercial Herbal toothpastes such as Himalayaand Dant kanti have been evaluated for their quality. All the marketed Herbal tooth pastes and Lab Made Herbal toothpaste which had been evaluated complied with the standards specified by the Bureau of Indian Standards. The formulations were subjected to various evaluation tests like pH, Spreadability, abrasiveness, foaming ability, cleaning ability, fineness, moisture and volatile content, tube inertness, and stability studies. All the Results of evaluating parameters showed that Labmade formulation is comparatively equal and rarely better in terms of results than marketed formulation. Hence the selected Labmade formulation was found to be of good quality.

K**eywords:** Commercial Herbal toothpastes, Bureau of Indian standards, Toothpaste Ingredients.

INTRODUCTION

Toothpaste is a gel or paste formulation product and is used to clean and maintain oral hygiene with the aid of toothbrush. It is a common product used by the community for dental care. Although it is recommended by most dentist to brush the teeth twice daily and it is highly effective for plaque removal but it is not possible for bacterial infection. By removing the plaque, it will help in decrease the chances of periodontal inflammation which mainly caused by bacteria or oral flora. To overcome this problem, it is recommended for the patient to use toothpaste with better antibacterial activity. [1] Most of the toothpaste available in the market nowadays contains two types of ingredient which are the active and non-active toothpaste ingredient or the excipient. One of the active toothpaste ingredients is abrasive which helps in removing the plaque. It constitutes at least 50% from the total preparation of the toothpaste. It really helps in minimized periodontal disease. The commonly used abrasives are sodium bicarbonate, calcium carbonate and aluminium hydroxide. Whitening agents helps to remove stain on the teeth but the effect is temporary. The commonly used whitening agents for toothpastes in the market are peroxide and bleach. Fluoride and its derivatives are used to strengthen the enamel and prevent cavities. The most common used fluorides are sodium fluoride, sodium monofluorophosphate, olaflur and stannous fluoride. Between them, stannous fluoride shows effective controls of gingivitis. [2] The problem now is most people do not

know the long term consequence of using the commercial toothpastes. This is because the marketed toothpastes contain substance which consider as unhealthy and could harm the body in the future. Recently there is some issues arise on the harmful effect of fluoride when being used for a longer period of time. [3] The bleach and peroxide used as whitening agent in the toothpaste is consider as hazardous as they may cause irritation to the mouth and skin in small amount and chemical burn in large amount. The flavouring agents used are synthetically and chemically produced and commonly derived from petrochemicals. [4] After studying the drawbacks of commercial toothpastes, people are now more inclined toward the use of herbal formulations. Herbal toothpaste does not contain the artificial colors, flavors or fluoride that many, when compare the contents of artificial products.

This study is selected to overcome the problems associated with the usage of unhealthy ingredient used in commercial toothpastes which widely used around the world. In addition, to reduce the cases of periodontal cases which mainly caused by dental pathogen. Hence, in the present study we are interested to formulate and evaluate new herbal toothpaste and to study its antimicrobial potency.

MATERIALS AND METHOD

Plant Collection:

The weight of each ingredient was decided by review previous study formulation of Herbal toothpaste. The combination of percentage by weight of all the ingredients of this is 100%, which means the sum of quantity of toothpaste will formulate 100gm of toothpaste formulation. The ingredients of all toothpaste formulations are given in table 1 and Marketed Herbal tooth pastes Himalaya. And Dantkanti are used.

METHODS:

Preparation of Extract:

The bay leaf leaves (200 grams) were extracted by two methods.

Maceration extraction Process is performed with absolute alcohol

The leaf samples were washed, dried and blended into powder. Increasing polarity solvents such as ethanol (>99.5%) is used in the maceration extraction process. The leaf powder was incorporated in solvent to prepare 20% concentration. The mixture was mixed in conical flask, wrapped the flask with aluminium foil to avoid solvent evaporation and then expose it to light for three consequent days at room temperature. The contents were shaken with platform shaker at 70 rpm. The mixture was soaked for 3 days; the contents were transferred to 50 ml test tube and again centrifuged for 10 min with the revolutions of 4000rpm at room temperature. Finally, the supernatant liquid was separated and stored in refrigerator at 40C until it becomes useful in the procedure.[5]

Antibacterial Activity:

The well-diffusion method was used to identify the antibacterial activity of toothpaste as per the standard of the National Committee for Clinical Laboratory Standards. The antibacterial activity of plant extracts was carried out using Mueller Hinton II plates. Initially, plates were streaked with bacteria; punches were made with 5mm diameter into the medium using a sterile cork borer. The test bacterium was inoculated into all places; a sterile cotton swab dipped using sterile forceps into the suspension, rotated multiple times and excess inoculums removed by pressing the swab firmly above the fluid level inside the tube. The surface of the agar plate was rotated to ensure an equal distribution of inoculums present around the rim. Fifty test extract aliquots were dispensed into each well present in the plates after inoculation with bacteria. The plates are dried for 3 to 5 min to remove excess moisture present in it. Triangle shaped wells were prepared with a distance of 2 inches apart. The same extract was incorporated into three plates for each selected bacterial strain. Controls were prepared with pure solvents for each bacterium. The plates are wrapped with parafilm, labelled, and stored in an incubator at 37^{o}C. Each plate was examined after incubation for 24 hrs, identified inhibition zones measured (in millimeters) with a ruler. Experimental results were noted in parallel, and took the average results of three independent experimental results. Initially, the binder is mixed with solid abrasive, and then it is added to liquid phase, contains sweetener, humectants and preservative into a mixer. As a result, homogeneous paste was formed, then added the detergent and flavor, mixed vigorously, finally deairated and tubed.[6]

Table 1. Herbal Toothpaste Formulation Ingredients

S NO	INGREDIENTS	QUANTITY USED (%)	USES	MANUFACTURER
1	Bay leaf	9	Antibacterial and Whitening agent	Powder extract from plant of bay leaf
2	Orange powder	5	Antibacterial and Whitening agent	Crude drug local market
3	Calcium carbonate	35	Abrasive	MIPS Indore
4	Sodium lauryl sulphate	1.50	Foaming agent	MIPS Indore
5	glycerin	30.00	Preserving agent	MIPS Indore
6	Methyl cellulose	01.00	Thickening agent	MIPS Indore
7	Sodium saccharine	00.30	Sweetening agent	MIPS Indore
8	Methyl paraben	00.10	Preservative	MIPS Indore
9	Propyl paraben	00.02	Preservative	MIPS Indore
10	Titanium dioxide	00.50	Antioxidant	MIPS Indore
11	Menthol	1.50	Co solvent	MIPS Indore
12	Purified water	Q.s	Solvent	MIPS Indore

EVALUATION PARAMETERS:

According to the guidelines, the standards were prescribed for each evaluation test of non-fluorinated (type I) or fluorinated (type II) toothpastes.

Organoleptic Evaluation

Organoleptic evaluation (colour, taste, odour) were done by sensory and visual inspection.

Composition

Toothpaste is not composed of mono or disaccharides such as sucrose or fermentable carbohydrates. All ingredients should comply with the Indian standards.

Homogenecity

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.[7]

Tube Inertness

The toothpaste container shall not produce any corrosion or deterioration in normal storage conditions like heating temperature at 45±20C for ten days. Tube inertness can be examined by cutting the internal surface, open and observing whether any sign of deterioration or chemical attack occurred in the container.

Determination of Sharp and Edge Abrasive Particles

Extrude the contents 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.

Determination of Spreadability

One gram of toothpaste placed on a glass slide (10 x 10 cm), cover with another glass slide. Then carefully place two kg weight of on covered glass slide (sliding, shall not take place). Measure the spreading (in cm) of the toothpaste after 3 minutes. Repeating the experiment and note the average value of three readings.

Determination of Fineness

Weigh accurately about 10 gm of toothpaste placed in a 100 ml beaker. Allow 50 ml of water; stand for 30 min with stirring until the paste gets completely dispersed. Transfer the solution to 150 micron IS sieve and wash with a slow stream of tap water. Allow running tap water drained the on sieve and dry (at 105±20˚C) the sieve by place it in an oven. Transfer any residue particle is present on the sieve to a watch glass and weigh it.

Calculation:

Material on the sieve % by (Retained mass / Material taken) x 100 ii. Weigh accurately about 10 gm of toothpaste placed in a 100 ml beaker. Allow 50 ml of water; stand for 30 min with stirring until the paste gets completely dispersed. Transfer the solution to 75 micron IS sieve and wash with a slow stream of tap water. Allow running tap water drained on the sieve and dry (at 105±20˚C) the sieve by placing it in an oven. Transfer any residue particle is present on the sieve to a watch glass and weigh it.

pH Determination

Weigh 10 g of toothpaste placed in 150 ml beaker. Allow 10 ml of boiled and then cooled water. Stir vigorously to make a suspension. Measure the pH of the suspension using pH meter.

Foaming Power

Take a suspension of the material in measuring cylinder and shake the suspension for 12 times. And measure the volume of the foam produced after shaking for 5 minutes. Procedure: weigh 5 g of toothpaste in a 100 ml glass beaker. Add 10 ml of water, cover the glass beaker with a watch glass and stand for 30 minutes. Heat the suspension gently to dissolve the detergent if present in it. Stir the suspension with glass rods and transfer it to 250 ml measuring cylinder. Examine if no foam is produced (more than 2 ml). Transfer the residue retained in the beaker to measuring cylinder by adding of 5- 6 ml of water. Then make up the cylinder with 50ml of water. Stir the contents with up-down movements to get uniform suspension at 300C. After shaking, keep the cylinder stand for 5 minutes. And final note the volume obtained with foam + water.

Stability

The toothpaste shall be stable, but not to be deteriorating, ferment and segregate during normal storage conditions and usage. Stability of toothpaste can be tested when it exposes to 45±20C for a period of 28 days. After storage, no phase separation, fermentation and gassing can be observed. Also exposed to cool conditions such as 50˚C for 1 hour, no obstruction of extrudables form from the container is observed.[8]

Moisture Determination and Volatile Matter

Weigh 5 g of sample placed in a porcelain dish containing 6-8 cm in diameter and 2- 4 cm depth in it. Dry the sample in an oven at 105˚C.

% by mass =100 M1 / M M1 - Loss of mass (in grams) on drying

M - Mass (in grams) of the material taken for the test.

Microbial Testing:

The antibacterial activities of different formulations were determined by agar well diffusion method. In this method, nutrient agar plates were seeded with 24 h broth culture of S. aureus, (collected from

Nandani Medical Laboratories Pvt. Ltd. Kanadia Indore.). The agar plates were allowed to solidify. A sterile 8 mm borer was used to cut wells of equidistance in each of the plates solution of 0.2 ml of prepared formulations and marketed herbal toothpaste were introduced into the wells. The plates were incubated at 37ºC for 48 hours. The antibacterial activities were evaluated by measuring the zones of inhibition (in mm).

RESULTS AND DISCUSSION

Use of fluorides has been the foundation of caries counteractive action and the use of fluoridated toothpaste is the most widely recognized types of caries control being used today. Many commercial toothpastes claim to have abrasive, spreadability, foaming ability and have caries counteractive action, very little research has been conducted to compare these properties in Lab made dental product. Hence the purpose of this study was to evaluate and compare the efficacy of commercial toothpastes with Lab made toothpaste. Evaluation tests of toothpastes were carried out according to the standards specified by the Bureau of Indian standards IS 6356-1993 for Herbal tooth pastes samples (Himalaya and Dant kanti) and Lab made toothpaste sample. All the samples were complied with BIS and they found to be of good quality. Evaluation tests were carried out to view the different properties of Lab made and commercial toothpastes. All the Results of evaluating parameters were given in table 2. In the present study, comparatively equal and rarely better results have been observed with Lab made formulation than marketed formulations. Both preparations have shown equal efficacy in terms of foaming ability and pH. But increased activity in terms of abrasiveness and spreadability was appeared in Lab made formulation. Comparison of the abrasiveness of marketing pastes with Lab made formulation suggests that Lab made formulation has more abrasiveness than marketed pastes. And also, given significant result for cleaning ability which is similar to the results obtained in the commercial formulations. All the toothpastes were having good consistency and smooth texture. Also shown no symptoms for deterioration such as phase separation, gassing, fermentation when all the samples were placed at a temperature of 45±20˚C for a period of 28 days. We found extrudables from the all tubes after placing it in cool temperatures (50˚C) for 1 hour. So it confirmed that all toothpastes have good stability. The internal part of all collapsible tubes have given no sign of corrosion or damage during normal storage conditions at a temperature of 45±20˚C for 10 days except for Himalaya Herbal toothpaste tube has slightly affected by corrosion. So it was confirmed that the containers of Lab made, and Dant kanti have shown good tube inertness. The preferable amount of residue has retained on sieve for Lab made formulation which is better than the residue obtained by Himalaya Herbal but little less to the residue of Dant kanti toothpaste. So it was found that Lab made preparation has shown reasonably good % of fineness. The moisture and volatile matter present in Himalaya Herbal was significantly more than the rest of the formulations. The percent

of moisture and volatile content in Lab made formulation is given the same value as that of Dant kanti and Meswak got the least value. These results explaining all the formulations have good moisture and volatile content. The color produced with hydrogen sulfide in test solution is less than obtained with standard solution that indicates all the samples have limited amount of lead impurities. Stain produced by Himalaya Herbal sample is more than standard stain that indicates Himalaya Herbal toothpaste is having a little more amount of arsenic impurities. All the remaining formulations passed the limit test of arsenic. Fluoride ions present in the sample were potentiometrically determined by fluoride ion sensitive electrodes. The concentration (ppm) of fluoride ion in Lab made formulations is less than the standard values mentioned in table 2.

Table 2. Evaluation taste for lab made and commercial herbal toothpastes

SNO	PROPERTIES	LAB MADE	HIMALAYA	DANT KANTI
1	Hard and sharp edged abrasive particles	absent	Present	Absent
2	Abrasiveness	3	2	3
3	Spreadability(cm)	5.2	5.0	4.0
4	PH of 10% aq.susp.	8.5	7.5	8.0
5	Foaming ability	76	68	76
6	Cleaning ability	good	Good	Satisfactory
7	Stability(45±2°C28days&at 5°Cfor 1 hour)	Good	Good	Good
8	Tube inertness(at45±2°Cfor 10 days)	No corrosion	Slight corrosion	No corrosion
9	Fineness(%by mass)	0.41	0.39	0.42
10	Moisture and volatile Metter(%by mass)	1.8	2.0	1.8

Table 3: Microbial Testing

Formulation	Zone of inhibition (mm)
Formulation 1	19
Control	25

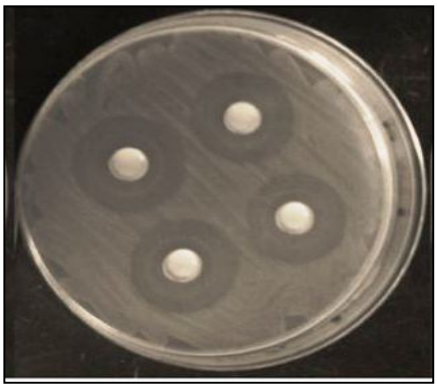

Figure 1. Showing Zone of Inhibition

CONCLUSION

Herbal-based products have growing demand in the market. People believed using product made up of natural sources ingredient are safer with fewer side effects than the synthetic one. It is a good attempt to establish such herbal toothpaste containing Bay leaf extract and orange peel extract which helps in reducing bacterial growth in the mouth. Further studies are warranted to improve the stability of the formulation, prove the efficacy and safety of the formulated toothpaste and to improve the antimicrobial activity of the toothpaste.

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