

FORMULATION & EVALUATION OF POLYHERBAL TOOTHPASTE WHICH IS MORE EFFECTIVE, ECONOMICAL AND POTENTIAL TO ALL DENTAL PROBLEM IN COMPARISON TO ALL MARKETED TOOTHPASTE.

Dr. Satendra Kumar*

India.

*Corresponding Author: Dr. Satendra Kumar

India.

Article Received on 13/01/2023

Article Revised on 02/02/2023

Article Accepted on 23/02/2023

ABSTRACT

The aim of the present research work is to be formulated herbal toothpaste containing natural ingredients like Guava leaves, Neem stem and bark Kalmi bark, Babul leaves etc. which were traditionally used for tooth cleaning. Formulation containing natural ingredients is more acceptable in the belief that they are safer than synthetic drugs. In present study formulated herbal toothpaste was evaluated for its Organoleptic and physical properties such as color, odor, taste, pH, spread ability, moisture content, fineness, foam ability etc. as per standards specified by Bureau of Indian Standards and compare with commercially marketed toothpaste formulations. The results of the evaluating parameters shows the promising results as compare to marketed formulations. Hence the lab made herbal toothpaste was found to be of good quality. The plant extract ingredient posses the anti-bacterial. The herbal toothpaste formulated which can satisfy all the required condition to keep the mouth fresh and prevent tooth decay by bacteria. The formulated herbal tooth- paste compared with marketed preparation. It has been good scope in future dental research and dental health of public.

KEYWORDS: Herbal ingredient, toothpaste, antibacterial, dental, ZOI, Comparative study.

INTRODUCTION

Toothpastes are the most common preventive means in oral health care. Many commercially available dentifrices claim to have antimicrobial properties, but little research has been conducted to investigate these claims. Therefore, this study was conducted to evaluate the efficacy of different toothpaste formulations in reducing the oral microbial load. The selected tooth paste formulations were effective in controlling the microbial load and therefore contributing to maintain good oral hygiene. However, practicing appropriate oral hygiene measures & brushing technique is of utmost importance in maintaining good oral health than the effectiveness of various ingredients in the toothpastes used.^[1]

The therapeutic effect showing plants has been beneficial to the oral health from the thousands of year throughout the world. The traditional medicine has advantage more than the side effect like allergies. Neem is one of the most widely researched tropical trees for the development therapeutic action. 20 year ago the component of neem extract was analyzed.^[2]

The neem has been antibacterial activity is evaluated from the ancient times. It has been use for the various activities like as astringent, antiseptic, insecticidal, anti

ulcer and for cleaning the teeth in pyorrhea and other dental disease. The leaf extract of neem showed superior antiviral and antihyper-glycemic activity in vitro and in vivo on animals. It showed good in vitro broad range antibacterial activity.^[3]

Chronic gingivitis is one of the most common oral diseases with high prevalence around the world. Dental plaque is the major etiological and initiating factor for the development of gingivitis. However, due to the limitation of mechanical methods, the addition of some safe and effective drugs to prevent gingivitis in toothpaste is also considered to be a good supplementary to the control of mechanical plaque. Studies have shown that certain chemicals, such as chlorhexidine or triclosan, are added to the toothpaste to directly inhibit the formation of plaque.^[4]

Various chemical agents have been used in toothpastes and mouth rinses and a few have been shown to reduce dental plaque formation. Due to an increased awareness of indigenous medical practices in various parts of the world, the use of "herbal" medicine has engendered interest. And facilitated the growth of complementary and alternative therapies in health care promotion.^[5]

It is an two group comparative study. Food debris are white small particles on teeth, can be easily rinsed off. The dental plaque is thin film of bacteria that sticks to teeth and yellow color can't be rinsed off. There has been closer relationship between tartar, calculus and periodontal disease. The extract are use in various category like Neem- Antibacterial, Guava-Anti-inflammatory, Babul- Astringent, Kalmi-Flavoring agent and other ingredient are Camphor-Antiseptic, Honey-Sweetening agent, Glycerine-Humectant, Cal Carbonate-Abrasive, SLS-Detergent and also use the sodium chloride and distilled water. This led to paying increased attention on using natural ingredients in herbal dentifrices.^[6] The aim of study was to formulate herbal base product was compare the efficacy with conventionally marketed formulated toothpaste and evaluated the various parameter like color, spread ability, foam ability, extrudability and anti-bacterial activity. However, there is approach to provide the formulation for commercial production of herbal dental product with environmental friendly attributes.

The main purpose of toothpaste is to reduce oral bacterial flora and deliver fluoride to the teeth. This is because fluoride has been proven to protect teeth against attack from bacteria and can be found naturally in many everyday things including food and drinking water. Toothpaste that efficiently reduces oral bacterial flora should contribute to dental health.

Formulation and composition of Toothpaste

Table -1

Sr. No	Ingredients	Quantity(gm)
1	Sodium chloride	0.2
2	Sodium lauryl sulfate	0.5
3	Para hydroxyl benzoic acid	0.3
4	Glycerin	0.2
5	Calcium carbonate	3.5
6	Honey	0.5
7	Camphor	0.5

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

Formulation

All herbal ingredients were dried and grounded using domestic mixer. The required quantity of ingredients

Table-2

Sr. NO	Ingredients	Quantity (gm)
1.	Gauva leaves	0.5
2.	Kalmi bark	0.5
3.	Neem stem & bark	0.5
4.	Babul leaves	0.5

MATERIALS AND METHODS

Chemicals

Calcium carbonate (Balaji Chemicals), Para hydroxyl benzoic acid (Loba Chemicals), Sodium lauryl sulfate (Loba Chemicals), Sodium chloride (Balaji Chemicals), Camphor (Local market), Honey and glycerin were purchased from local market.

Collection

The various part of the plants like Babul, Kalmi, Guava and Neem, etc were collected from the plant present in our medicinal garden in the campus of L.N Pharmacy College situated in the Baitalpur Deoria located in Utter Pradesh state of India. The plants were identified and authenticated by BHU Department of Botany, Banaras Hindu University, and Varanasi U.P. India.

Preparation of base

(1)The solid ingredients calcium carbonate, sodium lauryl sulphate, glycerin, sodium benzoate, sodium saccharine were weighed accurately as mentioned in the formula and sieved with sieve no.80 so as to maintain the particle size.

(2)These ingredients were also mixed in a mortar and pestle, and then triturated with precisely weighed glycerin until a semisolid substance was created.

(3)Addition of herbal ingredients-

(4)Add accurately weighed herbal extract.

were weighed and taken in mortar. Calcium carbonate, Sodium lauryl sulfate, methyl cellulose, honey and glycerin were mixed in water. Acacia were added into the above mixture. This solution was added drop wise into mortar containing herbal ingredients and triturated well until a paste consistency is formed.^[7]

Evaluation of Toothpaste (Formulated)**(1) Physical Examination of herbal toothpaste**

[1] **Color-** The formulated toothpaste was examined for its color and checked color visually.

[2] **Odor-** The odor was checked by smelling the product.

[3] **Smoothness-** The Smoothness was tested by rubbing the formulation paste between the fingers

[4] **Taste-** Taste was checked manually by tasting the formulation

(2) Relative density

The relative density was determined by weight in gram taken in 10 ml formulation container and add 10 ml distilled water by using in RD bottle

(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) 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.

(5) Foaming and its Foaming character

The foam ability 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.

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

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.

(6) PH

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.

(7) Determination of moisture and volatile matter

5 g of formulation 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 .

Calculation; by mass = $100\text{MI}/\text{M MI-Loss of mass (g)}$

On drying M- Mass (g) of the material taken for the test^[8]

(8) Stability study

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 periods of three months and studied of appearance, pH and spread ability.

(9) Moisture content

Toothpaste (10 gm) weighted in a Porcelain dish and dried it in the oven at 105°C . It was cooled in desiccators. 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) Reading of plate and interpretation

After 15 to 16 hours of incubation, each plate was examined. If the plate satisfactory streaked, the inoculums were correct the result of ZOI should be uniformly circular and a confluent lawn of growth. After measure the diameter of ZOI the data was noted and interpreting the result.

(11) Anti-bacterial activity

In-vitro anti-bacterial study of formulated paste was performed by disc diffusion method in triplicate manner by using Mukker Hinton Agar medium against a pathogenic bacteria strain *Staphylococcus aureus* (*S. aureus*, MTCC 3160). *S. aureus* was initially cultured cells were tend to multiple in the Muller Hinton agar plates. Then the formulated paste containing discs were placed over the bacterial plates and incubated at 37°C for the 24 hour, comparing ciprofloxacin as the positive control. The diameter of zone of inhibition (ZOI) was measured in millimeters (mm).

The minimum inhibitory concentrations (MIC) are the smallest concentration in which the compound displays no visible microbial growth. It had been determined by agar streak dilution method in triplicate manner. The protocol involves formulation of microbial suspension ($\sim 10^5$ CFU/mL), application to the Petridis with serial dilution and incubation of Petridis at $37 \pm 1^\circ\text{C}$. the MIC value was determined and average was taken.^[9]

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

(13) Spread ability

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 spread ability.

Formula was used to calculate spread ability:

$$S = M \times L / T$$

Where,

S= Spread ability

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

14) 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

(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

Comparison between formulated Herbal toothpaste with marketed preparation.^[10]

The formulated herbal toothpaste was compared with marketed preparation follows Anti-microbial activity, Spread ability, Foam ability, H determination, % Moisture content.

RESULTS AND DISCUSSION

The herbal tooth paste formulation was prepared from Neem leaves, Guava leaves, cinnamon bark, natural ingredient and small amount of synthetic ingredient. At the trial phase of formulation three batches were performed due to the problem like homogeneity, spread ability, and foam ability the two batches discarded permanently and only single batch was selected for next steps. The formulated herbal toothpaste greenish brown in color and showed the good homogeneity with absence of lumps and good anti-microbial activity.

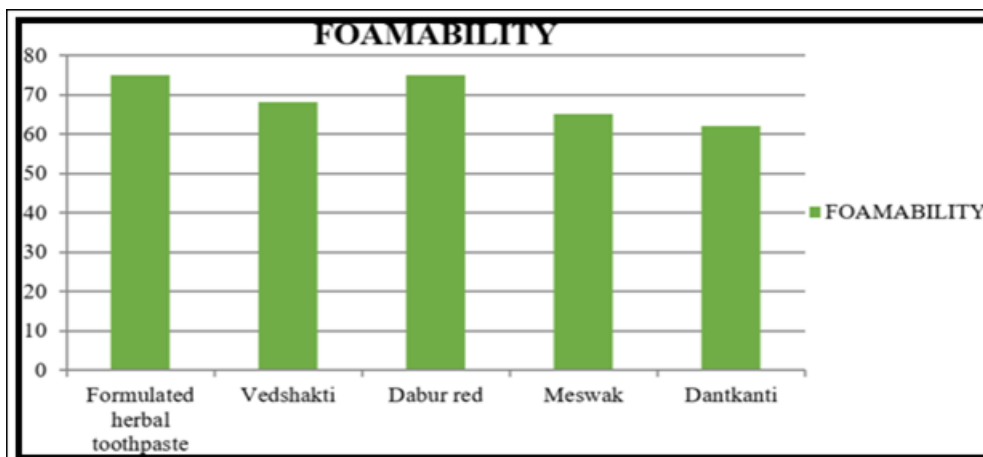
Formulated herbal toothpaste evaluation tests were carried out to compare different properties of formulated herbal and marketed toothpastes. All the results of evaluating parameters were given in tables. In the present study, comparatively equal and rarely better result have been observe with the formulated herbal toothpaste than the marketed herbal toothpastes.

Visual inspection

Sr. No	Particular	Examination
1.	Color	Greenish brown
2.	Odor	Characteristic
3.	Smoothness	Smooth
4.	Taste	Characteristic

Relative density -10.21

Sr. No.	Parameters	Observations
1	pH	8.2
2	Homogeneity	Good
3	Abrasiveness	Good abrasive
4	Moisture content	15.6%
5	Spreadability	3.5cm/sec (Good)
6	Stability	Stable



The foamability of formulated herbal toothpaste is more than commercial formulation. Loss on drying of formulated herbal toothpaste was found to be minimum than other marketed herbal formulation. While zone of inhibition of formulated herbal toothpaste was found to be 10mm the activity increases in terms of abrasiveness and spread ability. Comparison of abrasiveness of marketed pastes with formulated herbal toothpaste suggests that formulated herbal toothpaste has more abrasiveness than the marketed pastes.

The Smoothness was tested by rubbing the paste formulation between the fingers. The pH of formulated herbal toothpaste was compared to other herbal marketed formulations and it was found to be 9.10.

We found that all the toothpastes were having good consistency and smooth texture and also shown no symptoms for deterioration such as phase separation, gassing, fermentation when all samples were place at temperature of 34 +/-30C for period of 30 days. It confirmed that the toothpaste is stable.

Stability:

At 34 ± 3°C, 60% ± 5% RH (3rd month)

Sr.No.	Colour	Appearance	Sparedability	pH
1	Greenish brown	Homogeneous	3.5	8.2

Antimicrobial activities of formulated herbal toothpaste were compared with marketed herbal toothpaste. It was observed that, formulated herbal toothpaste has good antimicrobial activity and same efficacious with that of marketed one.

Antimicrobial activity of herbal tooth paste against selected microbes

Sr.No.	Name of microbes	Zone of inhibition		
		Herbal tooth paste		
		25mg/ml	50 mg/ml	100mg/ml
1.	<i>Staphylococcus aureus</i>	19±0.471	20±0.942	24±0.816
2.	<i>Streptococcus mutans</i>	13±0	15±1.88	15±1.88

Evaluation of Tooth paste on different parameter like fragrance and shape retention test.

S. no.	Evaluation parameter	Grades on the basis of evaluation criteria			Reference Grade
		F1	F2	F3	
1.	Fragrance	A	A	A	A
2.	Threading property	A	A	B	A
3.	Shape retention	A	A	A	A

CONCLUSION

Herbal toothpastes have an emphasized role in maintaining the oral hygienic nature as well as preventing dental caries. The formulated polyherbal toothpaste was successfully evaluated using different standard parameters including antimicrobial properties. The extract showed promising antimicrobial effects against both organisms. The formulated toothpaste may

be safer compared to fully synthetic toothpaste. Further studies are warranted to prove safety and efficacy of the formulated toothpaste. Herbal toothpaste was equally efficacious as marketed popular toothpastes in terms of all evaluation properties of toothpaste. The formulated herbal toothpaste has good scope in the future by increasing natural ingredients for manufacturing more and safer natural remedies, in the research and health of

dental care of public, society and nation. It is concluded that formulated Herbal toothpaste was found to be of good quality.

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