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# FORMULATION AND EVALUATION OF POLYHERBAL TOOTHPASTE AND COMPARATIVE STUDY WITH MARKETED FORMULATIONS

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***Abstract:*** Toothpaste is a gel or paste formulation product and is use to clean and maintain oral hygiene with the aid of toothbrush. The majority of the cleaning is performed by the mechanical utilization of the toothbrush with the help of excipients used in toothpaste. The aim of this investigation is to evaluate herbal toothpaste formulations. Several chemicals, preventive agents have beneficial effects in the control of plaque and to reduce or prevent oral disease. But some of these substances show undesirable side effects such as tooth staining and altered taste. The objective of the present research work to formulate herbal toothpaste containing natural ingredients like clove fruit, Neem leaves, Honey and Acacia powder etc. which were traditionally used for tooth cleaning. The formulated toothpaste was evaluated for its organoleptic and physical properties as per standards specified by Bureau of Indian Standards and compare with marketed toothpaste formulations. Lab made herbal toothpaste was formulated by suitable ingredients to get formulation more stable. Evaluation and comparison of results with commercial Herbal toothpaste are demonstrated that Lab made toothpaste is having Equal patronizing and engrossing passion over the marketed formulations (Dantkranti, Himalaya, Babool and Colgate). This preliminary in vitro study demonstrated that Labmade Herbal toothpaste was equally efficacious as three commercially popular toothpastes in terms of all evaluation properties of toothpaste. Hence, by the evidence of in vitro studies, it is concluded that Lab made Herbal toothpaste formulated in a laboratory was found to be of good quality.

**Keywords :-** Polyherbal, Toothpaste, Organoleptic, Spreadability.

## I. INTRODUCTION

Toothpastes have been used since the ancient past and are one of main irreplaceable components of oral health care. The design of toothpaste formulations began in China and India, as 300-500 BC. During that period, squashed bone, pulverized egg and clam shells were utilized as abrasives as a part of tooth cleaning. Modern toothpaste formulations were developed in the 19th century. Later on, chalk and soap were incorporated to those formulations. After 1945, several formulation advancements of different detergents had begun, sodium lauryl sulfate had been used as foaming/emulsifying agent. In recent years, the focus has shifted towards the release of active ingredients during formulation developments to prevent and /or treat oral illness.[1]Toothpaste is a gel or paste formulation product and is use to clean and maintain oral hygiene with the aid of toothbrush.[8]Oral hygiene is the practice of keeping the mouth and teeth clean to prevent dental issues, most commonly, dental cavities, gingivitis, periodontal, (gum) diseases and bad breath. The oral infection are cause by plaque forming bacteria and yeast which reside in the oral cavity such as *actinomyces*, *actinobacillus*, *streptococcus* and *candida* species.[9]The majority of the cleaning is performed by the mechanical utilization of the toothbrush with the help of excipients used in toothpaste. The main aim of this investigation is to evaluate the Herbal toothpaste formulations.[1] Toothpaste is a paste or gel dentifrice used, with a toothbrush, to clean and maintain the aesthetics and health of teeth. Toothpaste serves as an harsh that aids in detaching the dental plaque and food from the teeth, assist in defeating halitosis, and fulfil active ingredients such as fluoride or xylitol to prevent tooth and gum disease.[2]Dental plaque deposit on teeth is a concern because of its cosmetic and pathogenic nature. Presence of plaque may be the culprit deposit for dental caries, gingivitis, periodontal problem, and halitosis. Numerous supports used worldwide to detach or control plaque, including toothbrushes, dental floss, and mouth rinses, and denti- Plaque frices (Barnes VM, Ritcher R, De Vizio W, 2010).

Mechanical plaque removal is one of the most accepted methods of controlling plaque and gingivitis. Mechanical plaque control is time consuming and some individuals may lack motivation for these procedures (Mullaly BH et al, 1995).[3]Several chemicals, preventive agents have beneficial effects in the control of plaque and to reduce or prevent oral disease. Hence, various chemical formulations were tried in dentifrices (George J et al, 2009). There has been a search for years for chemical agents that could supplant patient- dependent me-losan and chlorhexidine have been added in mouth rinses and dentifrices to prevent plaque and gingivitis. But some substances show undesirable side effects such as tooth staining and altered taste (Barnes VM, Ritch- er R, De Vizio W, 2010 and De Oliveira SM et al, 2008). This led to paying increased attentiveness on using natural ingredients in herbal dentifrices. Herbal ingredients have several benefits, commonly used herbal ingredients are Aka Clove (*Eugenia caryophllata ),* Neem (azadirachtaindica), Honey (*Floral nectar.* Neem have antibacterial (Nayak A et al, 2011) and anti-inflammatory properties. Neem also have anti-caries properties (Prashant GM et al, 2007 and PackiaLekshmi NCJ et al, 2012).

The antimicrobial effects of neem have been appeared against S.mutans and S.faecalis (Siswomihardjo W, 2007 and Almas K, 1999). Dried chewing twig of neem shows maximum antibacterial activity against S.mutans(Chava VR et al, 2012 ). There are limited studies available regarding the efficacy of herbal dentifrices hence the present study was undertaken to assess their effect on oral hygiene and gingival bleeding.[3]Natural products have been used for several years in folk medicine (Omar, 2013). Medicinal plants have been used as traditional treatments for numerous human diseases for thousands of years and in many parts of the world (Chitme, 2003). Over the last decade herbal medications in both prophylaxis and treatment of various diseases turned to be a favoured form of therapy throughout the world. Many side effects associated with traditional medicines have been averted by using herbal medicines and thus they are safer to use. These alternative products can be either dental products with natural ingredients or herbal products.[4] Previous studies have revealed that dental plaque can be controlled by physical removal and use of various pharmaceutical formulations like antimicrobial toothpastes and mouthwashes. Mechanical plaque control methods include tooth brushing and interdental cleansing using oral hygiene aids and professional prophylaxis. Chemical plaque control has been used only as adjunct to mechanical means and not a substitute even though various chemicals are widely used nowadays. Toothpaste is by far the most widespread form of fluoride usage and the decline in the prevalence of dental caries in developed countries is mainly attributed to its increased use. Fluoride therapy has been the cornerstone of caries preventive strategies since the introduction of water fluoridation schemes over five decades ago. Since the 1980s nearly all commercially available toothpaste formulations contain fluoride. The intensive promotion of fluoridated toothpastes by the oral health care industry is a major factor in their increased use (Ramji et al., 2005).[4]There has been a search for years for chemical agents that could displace patient- dependent mechanical plaque control and thus reduce or prevent oral disease. Several chemical preventive agents have beneficial effects in the control plaque and reduce or prevent oral disease. Hence, various chemical formulations were tried in dentifrices.[5] Chemicals, mainly triclosan and chlorhexidine have been added in mouth rinses and dentifrices to prevent plaque and gingivitis. But some of these substances show undersirable side effects such as tooth staining and altered taste[6]. This increased attention on using natural ingredients in herbal dentifrices. Herbal ingredients have several benefits. The objective of this research work to formulate herbal toothpaste containing natural ingredients like clove fruit, Neem leaves, Honey and Acacia powder etc. which were traditionally used for tooth cleaning. In this work formulated herbal toothpaste was evaluated for there organoleptic and physical properties as per specified standards by Bureau of Indian Standards and compare with commercially marketed toothpaste formulations.

## MATERIALS AND EQUIPMENTS

### Material

**Table no-1**

| No | Common name | Botanical name | Parts used | Category |
|---|---|---|---|---|
| **1** | Clove | *Eugenia caryophllata* | Flower | *Antibacterial* |
| **2** | Neem | *Azadracitaindica(Meliaceae)* | Leaves&bark | *Antibacterial* |
| **3** | Honey | *Apis melifera(Apidae)* | | Sweetening agent |
| **4** | Acacia | - | Powder | Prevention and treat. of gingivitis |
| **5** | Calcium carbonate | - | | Abrasive |
| **6** | Glycerine | - | | Humectant |
| **7** | HPMC | - | | Stabilizer |
| **8** | Sod.sachharin | - | | Sweeteners |
| **9** | Sodium lauryl sulfate | - | | Detergent/Foaming agent |
| **10** | Methyl paraben | - | | Preservative |
| **11** | Propyl paraben | - | | Preservative |
| **12** | Titanium dioxide | - | | Whitener |
| **13** | Menthol | - | | Cooling agent |
| **14** | Purified water | - | | |

**EQUIPMEMTS**

| Sr No. | Equipments | Model No. |
|---|---|---|
| 1 | Hot air oven | MVTEX |
| 2 | Digital pH meter | - |
| 3 | Analytical balance | AUW0D |
| 4 | Spreadability meter | - |

## EXPERIMENTAL DEVELOPEMENT

### Procedure of preparation of herbal toothpaste

Herbal toothpaste was prepared using Clove, Neem, Honey, acacia, honey, calcium carbonate, sodium lauryl sulphate. Clove flower posses anti-bacterial activity. Neem leaves shows an positive activity in case of mouth ulcer. Honey is added to show an anti-fungal activity and as sweetner agent. Sodium lauryl sulphate used giving foaming. Methyl & Propyl paraben is preserve the product. Acacia to prevent gingivitis and also act as gelling agent : water as a vehicle.

All the herbal ingredients were sun dried and beach using domestic mixer. The required quantity of ingredients were weighed and taken in mortar. Calcium carbonate, sodium lauryl sulphate, HPMC, honey and glycerine were mixed in water. Acacia were added into the above mixture. This solution was added drop wise into mortar containing herbal ingredients and other remaining ingredients triturated well untill a paste consistency is formed.[3]

### Final batch formula

**Table no-2**

| Ingredients | Quantity (gm) |
|---|---|
| **Clove** | 03.00 |
| **Neem Leaves** | 03.00 |
| **Honey** | 02.00 |
| **Acacia** | 03.00 |
| **Calcium carbonate** | 35.00 |
| **Glycerine** | 25.00 |
| **HPMC** | 01.00 |
| **Sod. sachharin** | 00.30 |
| **Sodium Lauryl Sulphate** | 01.50 |
| **Methyl paraben** | 00.10 |
| **Propyl paraben** | 00.02 |
| **Titanium dioxide** | 00.50 |
| **Menthol** | 01.50 |
| **Purified water** | q.s |

### Evaluation of herbal toothpaste :-

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

### Composition :-

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

### 1) Homogenecity:

Container by applying of normal force at 27±20C. As well, bulk of contents shall be extrude from the groove of container and then cruise it gradually.

### 2) 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 2-3 collapsible tubes. Press with the contents of the entire length with finger tip for the presence of sharp and hard edged abrasive partical.

### 3) Spreadability:

In this method spreadability was measured on the basis of slip and drag characteristics of gels. An overabundance of gel(about 2 g) under study was deposite on the ground slide. The gel was then interject

between this slide and another glass slide having the dimension of fixed ground slide and provided with a hook. 1 kg weight was deposite at the top of the two slides for 5 minutes to ban air and to provide a uniform film of the gel between the slides. Excess of the gel was throw away from the edges. The top plate was then subjected to pull of 80 g with the help of string link to the hook and the time (in seconds) required by the top slide to cover a distance Spreadability was calculated using the following formula:

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

Where,
S = Spreadability
M = Weight of the pan (tied to the upper slide)
L = Length moved by the glass slide
T = Time (in sec.) taken to discrete the upper slide from the ground slide.

**4) Determination of fineness :**

Weigh exactly 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 scatter. Transfer the solution to 150 micron IS sieve and wipe with a slow stream of tap water. Allow running tap water drained on sieve and dry (at 105±20C) the sieve by place it in an oven. Transfer residue particle present on the sieve to a watch glass and weigh it.

Calculation: i. Material on the sieve % by (Retained mass / Material taken) x 100 icles. Toothpaste shall not contains such particles.

**5) Determination of foaming power:**

About 5 gm of each sample was weighed and put down in a 100ml glass beaker. To this10ml ofwater was append and the beaker was covered with a watch glass and allowed to stand for 30minutes, this operation was carried out to distribute the toothpaste in water. The contents ofthe beaker were agitate with a glass rod and the slurry was shifted to a 250ml graduatedmeasuring cylinder, during this shifting ensure that no foam was produced and no lump pastewent into the measuring cylinder. The residue left in the beaker was transferred with furtherportion of 5-6 ml of water to the cylinder.

The content of cylinder was adjusted to 50ml by adding sufficient water and the content has to bemaintained at 30°C. Stir the contents of the cylinder with a glass rod to ensure a uniform suspension. As soon as the temperature of the content reached 30°C, the cylinder was stoppered and 12 complete shakes were given to it. The cylinder was allowed to stand for 5 minutes and the volume of foam with water and water only was noted for all samples.

**Determination of foaming power :-**

Foaming power = V1 – V2
V1 - Volume in ml of foam in water
V2 - Volume in ml of water only

**6) pH determination :-**

Weigh 10 g of toothpaste put 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.

**7) Determination of moisture :-**

Weigh 5 g of sample put down in a porcelain dish containing 6-8 cm in diameter and 2- 4 cm depth in it. Dry the sample in an oven at $105^0$C.

**Calculation**

% by mass =100 M1/M
M1 - loss of mass (in grams) on drying M - Mass (in grams) of the material taken for the test.[1]

**8) Determination of Heavy Metals:**

Accurately weigh 2 g of the sample in a kjeldahl flask. An acid mixture of HNO3:HClO4 (4:1) was added in the flask and heated constantly till the solution becomes colorless. The sample was then lift to a 25 ml volumetric flask and volume was made up with distilled water. The standard of Lead (Pb) was prepared as per the protocol in the manual and then the sample was visually analyzed and compared with the standard solution of lead.

**9) Stability**

The toothpaste shall be steady, but not to be deteriorating, ferment and isolate 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 babbling can be observed. Also exposed to cool conditions such as 50C for 1 hour, no obstruction of extrudable form from the container is observed.

## RESULTS AND DISCUSSION

Herbal toothpaste formulation was prepared from Clove, Neem leaves, natural ingredient and small amount synthetic ingredient. At the time of formulation development three batches (F1, F2 and F3)were prepared among them two batches (F1and F2) were discarded due to the problem viz, homogeneity, spreadability& foamability. Rest of the batch (F3 ) was selected for further study. The developed herbal dental gel was showed different Colour range from light green to dark greenish brown with good smoothness (Table no.-3) and showed good homogenecity with absence of lumps. The values of spreadability designate that the gel is easily transmissible by small amount of shear .Spreadability of formulated toothpaste (F2 ) was 3.5:10 g cm/sec and spreadability of marketed formulation was 3,4,3gm/sec respectively. (fig no.-3) Hence spreadability of Lab made formulation was good as compared to marketed formulation. Their extrudability of the herbal toothpaste formulation was good at the time of preparation (initial days) (Table no.-5 ).

**Physical evaluation (color, appearance, transparency, smoothness, moisture content viscosity, pH etc.) of herbal dental gel formulation:**

The results of the evaluating parameters shows the encouraging results as compare to marketed formulations. Hence, the labmade herbal toothpaste was found to be of good quality.

**Table 1:-**

**1) Organoleptic properties:**

| Parameter | Result | | |
|---|---|---|---|
| 1)Oraganoleptic properties | f1 | f2 | f3 |
| a)Appearance | Semisolid | Semisolid | Semisolid |
| b)Colour | Brownish | Brownish | Brownish |
| c)Odour | Characteristics | Characteristics | Characteristics |
| d)Taste | Bitter | Sweet | Sweet |
| e)Texture | Smooth | Smooth | Smooth |

**Table 2:**

**2)Homogenicity and Hard and Sharp edged abrasive particles :-**

| Name of formulation | Homogenicity | Hard and Sharp edged abrasive particles |
|---|---|---|
| Dantkranti | Excellent | Present |
| Himalaya | Excellent | Absent |
| Babool | Very Good | Absent |
| Colgate | Good | Absent |
| Lab made | Very Good | Absent |

**3) Spreadability of lab made and marketed toothpaste :**

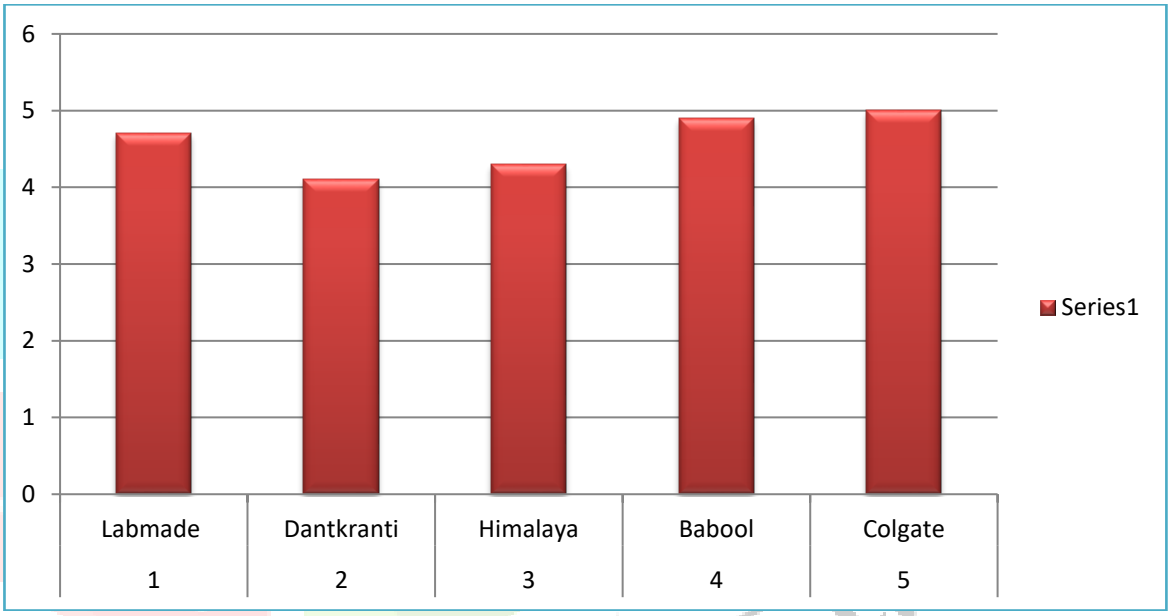


**Fig no.1 Spreadability**

**Fineness of labmade and marketed formulation**

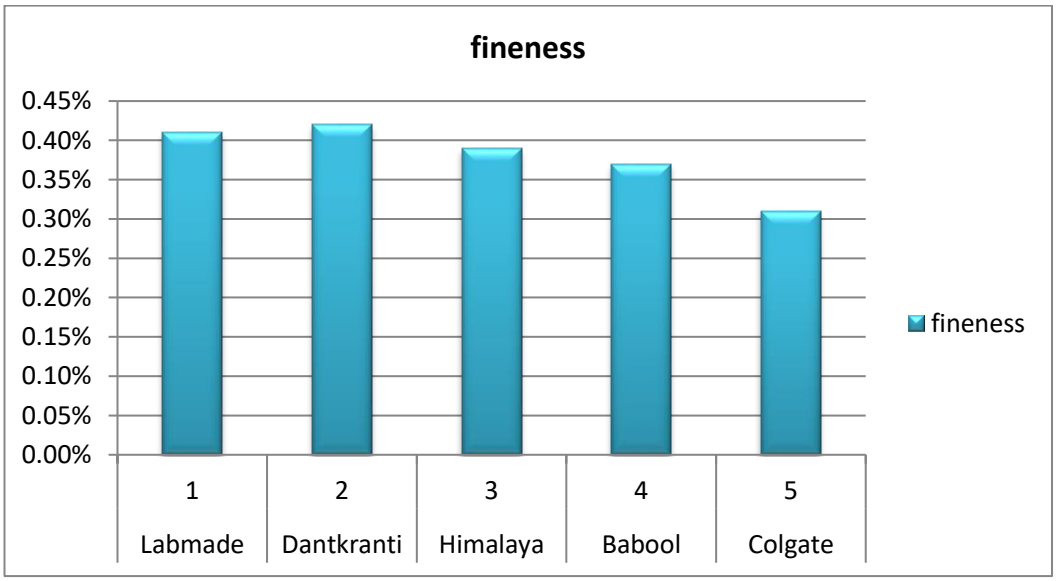


**Fig-5-Fineness**

**5)Foaming ability of lab made and marketed formulation**

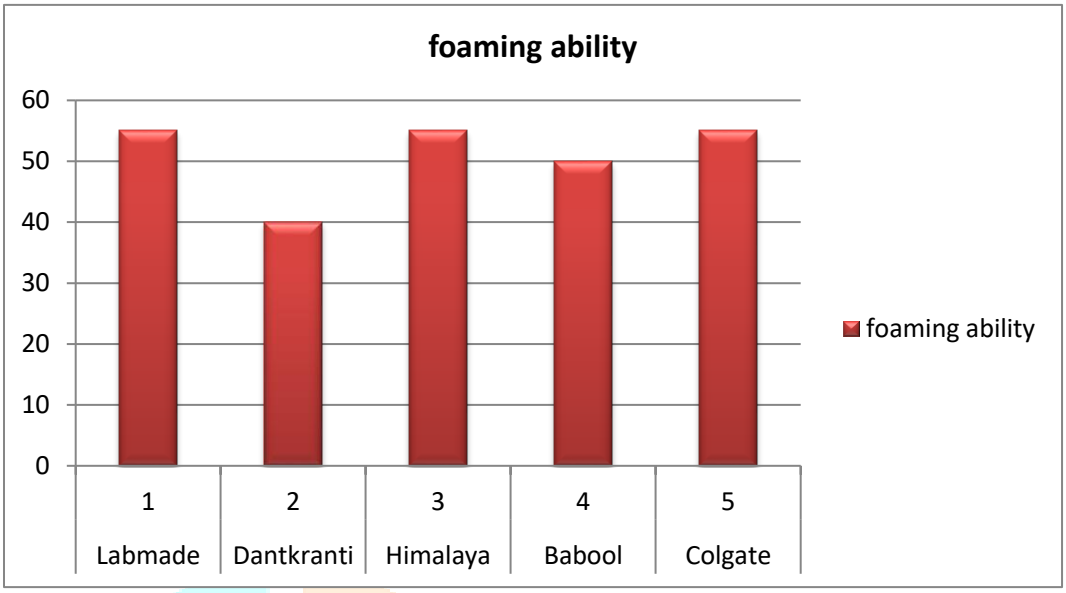


**Fig.4 :- Foaming ability**

**pH of lab made and marketed formulation**

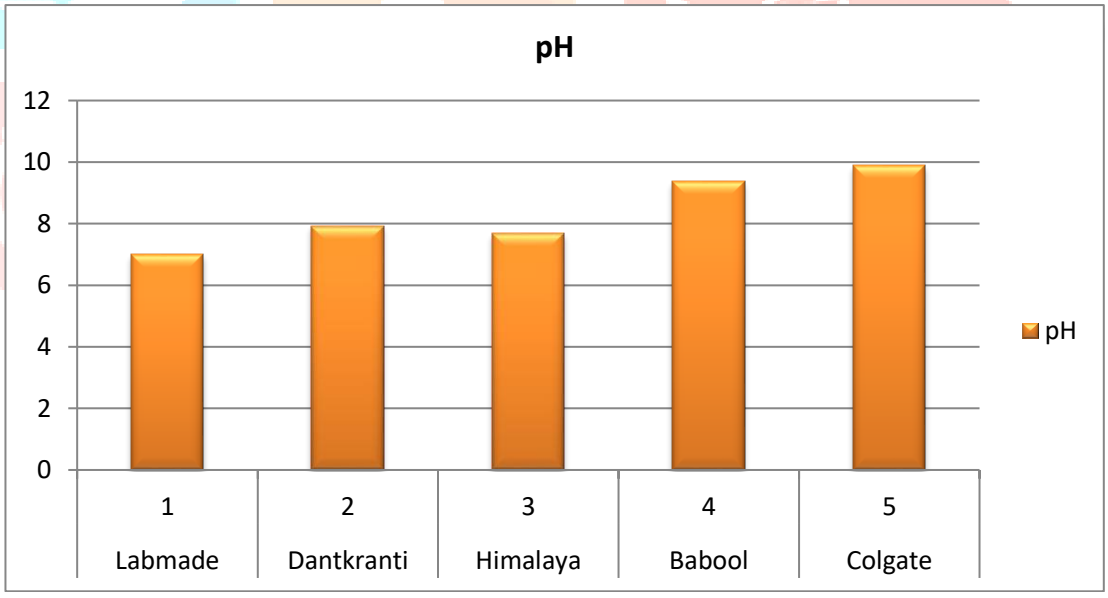


**Fig-2-pH**

**7)Moisture content of labmade and marketed formulation**

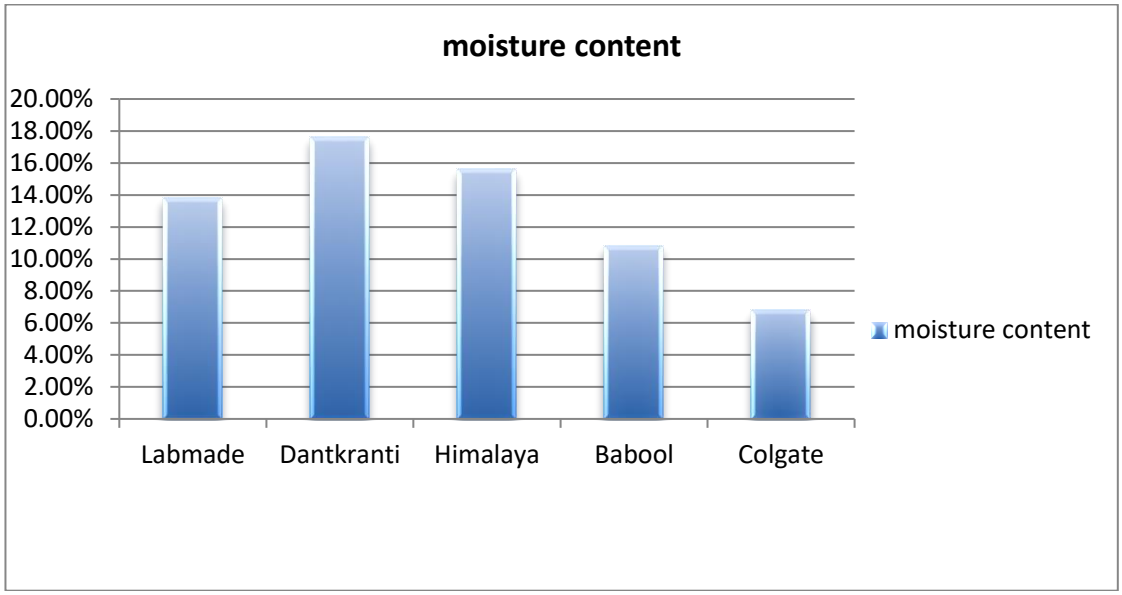


**Fig no. 3Moisture content**

**Table no.3**

**8)Test for lead**

| Formulations | Lead |
|---|---|
| Labmade | Absent |
| Dantkranti | Absent |
| Himalaya | Absent |
| Babool | Absent |
| Colgate | Absent |

**Table no.4**

**9)Test for stability :-**

| Formulations | Stability |
|---|---|
| **Labmade** | Good |
| **Dantkanti** | Good |
| **Himalaya** | Good |
| **Babool** | Good |
| **Colgate** | Good |

**CONCLUSION :-**

Usually Herbal toothpastes having an highlight role in the maintaining the oral hygienic nature as well as preventing dental caries. Based on this design, Lab made Herbal toothpaste was formulated by pick up suitable ingredients to get the formulation more stable. Evaluation and comparison of results with commercial Herbal toothpaste are demonstrated that Lab made toothpaste is having Equal patronizing and engrossing passion over the marketed formulations (Dantkranti, Himalaya, Babool and Colgate). All marketed Herbal tooth pastes and Lab made Herbal toothpaste which has been evaluated, compared with standard and specified by Bureau of Indian standards. This preliminary in vitro study demonstrated that Labmade Herbal toothpaste was equally efficacious as three commercially popular toothpastes in terms of all evaluation properties of toothpaste. Hence, by the evidence of in vitro studies, it is concluded that Lab made Herbal toothpaste formulated in a laboratory was found to be of good quality.

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