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Formulation and Evaluation of Herbal Tooth Paste

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ABSTRACT

The present work deals with development and evaluation of herbal toothpaste containing tulsi leaves, bay leaves, mango leaves, guava leaves as herbal ingredients. The aim of the study was to collect data by conducting laboratory experiments or from various journals and textbooks and recording the observation. To formulate and evaluate an herbal toothpaste so as to minimize the side effects of the synthetic toothpaste. The objective of the study is to extract the herbal specimen using different extraction methods, to optimize the formulations for the preparation of toothpaste, to evaluate the formulation with respect to various physicochemical parameters and to identify the optimized formula. Different types of formulations will be formulated using calcium carbonate as abrasive and sorbitol solution as humectant in varied concentrations based on factorial design. All the formulations will be evaluated for various parameters like dryness, color, appearance, consistency, wash ability and foaming power. In optimized formulation, the powdered extract of Tulsi (powder of leaves of *Ocinum tenuiflorum*), bay leaf (powder of leaves of *Laurus nobilis*), mango leaves (powder of leaves of *Mangifera indica*), Guava leaves (powder of leaves of *Psidium guajava*) are loaded and herbal toothpaste is prepared. This formulation shows good color, appearance, consistency, wash ability, pH, spread ability and foaming capacity.

INTRODUCTION

Oral hygiene or oral care is practice of keeping the mouth clean and is means of prevention from dental caries, gingivitis, periodontal diseases, bad breath and other dental disorders. It consists of both professional and personal care. Regular cleanings, usually done by the dentistsand dental hygienists, are recommended to remove tarter that may develop even with careful brushing and flossing. Professional cleaning includes scaling, various instruments or devices to loosen and remove deposits from the teeth. Regular brushing is recommended by healthcare professionals twice a day in order to prevent formation of plaque and tarter[1]. A toothbrush can remove plaque on most surfaces of teeth except for areas between teeth. As a result, flossing is also considered a necessity to maintain oral hygiene. Dental flocks remove plaques from areas which could otherwise develop caries.The purpose of cleaning teeth is to remove plaque which consists mostly of bacteria.

Teeth are attached to underlying bones of jaw via periodontal ligament. The white part of tooth is enamel 1-3mum below enamel is slightly softer, yellow tissue called dentin. It is supported by pulp which lies in center of tooth.

Enamel: Enamel is hardest and most highly mineralized substance of body and with dentin, cementum and dental pulp is one of four major tissues which make up the tooth. It is normallyvisible dental tissue of tooth. Ninety-six percent of enamel consists of mineral, with water and organic material. The color of enamel varies from light yellow to greyish white. Enamel's primary mineral in hydroxyapatite, which in a crystalline calcium phosphate. It has two unique classes of proteinscalled amelogenins and enamellings.

Dentin: Dentin is a mineralized connective tissue with an organic matrix of collagenous proteins. Dentin is substance between enamel and pulp chamber. It is secreted by odontoblasts of dentalpulp. The formation dentin known as dentinogens, which is a porous yellow-hued material made up of 70% inorganic materials, 20% organic materials and 10% water. Dentin as Microscopic Channel called Dentinal Tubules. These canals have different configuration in different species and the diameter ranges between 0.8-2.2µm.

Cementum: It is specialized bony substance covering the root of a tooth. It is 45% inorganic material, 33%organic material and 22% water. Cementum is excreted cementoblasts within the root of the tooth and is thickest at Toot apex. The principle role of cementum is to serve as a medium by which periodontal ligaments can attach to the tooth for stability.

Humans are diphyodont, as they develop two sets of teeth throughout life. The first set normallystarts to appear at about six months of age, although some babies are born with one deciduoustooth evenly distributed cross tie mouth's quadrant. Each quadrant of five teeth has a Central incisor, lateral incisor, cuspid, first molar, second molar as shown in figure 1. The second permanent set of teeth consists of 32 teeth, twenty-eight of them appear between the ages of about 6 und 12 year. Secondary teeth do not push deciduous teeth out of their sockets; a group of cells forms in front of tip of second tooth and dissolves the base of first tooth. Finally, the first tooth is held by tissues of gums[2,3].

Figure 1: Anatomy of teeth

Deciduous molars are replaced by premolars. The third molars are final teeth to erupt usually around age 20. It is possible for a person to have four molars and have been present in dentition. Permanent teeth are evenly distributed across mouths quadrants. Each quadrant of eight teeth has entral incisor, lateral incisor, first premolar, second premolar, first molar, second molar and third molar as shown in figure 2.

Abnormalities of the dentition

- Abnormalities with size of teeth.
- Amelogenesis imperfecta- a condition in which tooth’s primary surface, the enamel does not form properly or at all.
- Anodontia -total lack of tooth development.
- Dental fluorosis- white spotted yellow, brown, black and sometimes pitted teeth from over ingesting fluoride.
- Dentinogenetic imperfect- affects the underlaying layer of tooth.

- Hyper calcification- excess of calcium.
- Hyperdontia- presence of higher-than-normal number of teeth.
- Hypocalcification- reduction of calcium.
- Hypodontia- missing teeth[4,5].

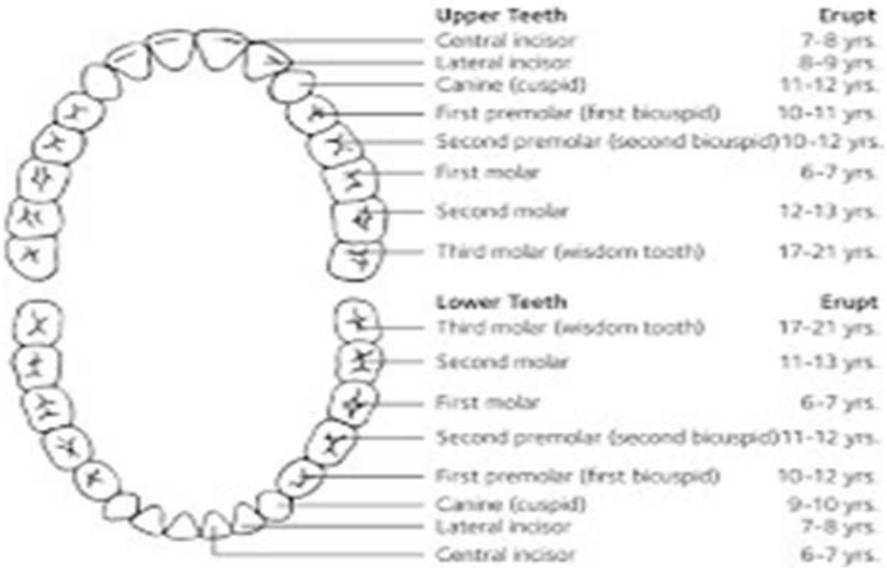

Figure 2: Dentition in human teeth

Teeth are attached to underlying bones of jaw via periodontal ligament. The white part of tooth is enamel 1-3mum below enamel is slightly softer, yellow tissue called dentin. It is supported by pulp which lies in center of tooth. Enamel is hardest and most highly mineralized substance of body and with dentin, cementum and dental pulp is one of four major tissues which make up the tooth.

Dental Preparations

Dentifrices are preparations intended for use with toothbrush for the purpose of cleaning the accessible surface of teeth. These have been prepared in paste, powder and to a lesser extent in liquid and block forms. Brushing with dentifrices reduce the incidence of tooth decay, helps maintain healthy gingiva. Good dental health increases the good general health, a leading secondary result of cleaning teeth. To develop dentifrices capable of effecting greater reduction in incidence of tooth decay or gingival disorders than possible a tooth-cleaning dentifrice so, these tooth-cleaning agents have incorporated in them, some drug or chemical by virtue of its bactericidal, bacteriostatic enzyme inhibiting or acid neutralizing

qualities reduce of dental caries or aid in the control of periodontal diseases. To take of various dental problems and maintain dental health and oral cavity variouspreparations are classified as follows as dental care preparations such as toothpastes, tooth powders, solid and liquid dental preparations and mouthwashes[6].

Tooth Paste

Toothpaste is a paste or gel to be used with toothbrush to maintain and improve oral health andanesthetics. Since their introduction, several thousand years ago toothpaste formulations have evolved considerably from suspensions of crushed egg cells or ashes to complex formulationswith often more than 20 ingredients. Among these can be compounds to combat dental caries, gum disease, malodor, calculus, erosion and dentin hypersensitivity. Furthermore, breathe freshening and dyes for better visual appeal. Effective toothpastes are those that are formulated for maximum bioavailability of their activities. This however, can be challenging are compromises will have to be made when several different activities are formulated in one phase[7].

Herbal Tooth Pastes

Herbal toothpastes are made of numerous herbs which have ability to remove the bad odor, freshen and prevent various gum diseases. Herbal dentifrices appear to have become an attractive alternative for some consumers and its use gains appreciable acceptance. This could be partly due to the perception that herbal toothpaste like other herbal products are natural, devoid of chemicals and therefore superior to regular toothpastes. Aggressive advertisement of the products such as glossitis and intolerance to spicy food seen in patients attending the oral digestion clinic are usually associated with anemia and nutritional deficiency states. The disturbing trends of an increasing number of patients presenting with such oral mucosa symptoms associated with the use of herbal dentifrices promoted this study[8].

Advantages of herbal toothpaste:

1. Herbal toothpastes are to fight against them bacteria that cause problems regardingteeth like gums, dental, dental cavity and gingivitis.

2. The herbal dentifrices have been used for ages and are, therefore, trusted amongst some communities for oral hygiene.

3. Herbal dentifrices are not as expensive as the chemical counterparts.

4. Herbal toothpastes have great advantage of having low chemical composition. Chemicals used in the manufacture of drugs have side effects.

5. Herbal toothpastes do not have artificial colors, flavors or fluoride that that many ofthe artificial products contain[9,10].

MATERIALS AND METHODS

Herbal extracts used for preparation of herbal paste are TULSI, BAY, LEAF (Bay Laurel), GUAVA LEAF and MANGO LEAF as shown in figure 3. The other ingredients are common for tooth powders and tooth pastes such as **abrasives and polishing material** (calcium carbonate, tricalcium phosphate, dicalcium phosphate, aluminum sulphate and magnesium triplicate), **detergents and foaming materials** (Sodium lauryl sulphate, sodium lauryl sarcosinate, diethyl sodium lauryl sulphosuccinate), **humectants** (glycerin, sorbitol and propylene glycol), **binding agents** (starch of gum, gum arabic, tragacanth gum, chondrus or irish moss, carboxymethyl cellulose, sodium aldinate, carbopol, bentonite, veegum), **sweetening materials** (sodium saccharine, sodium cyclamate), **flavors** (peppermint oil, spearmint oil, clove oil, cinnamon oil, cassia oil and menthol), **preservatives** (methyl para hydroxy benzoate, propyl Para hydroxy benzoate, sodium benzoate and formalin), **colors (**Pink, Red, Green), **bleaches (**sodium perforate, stabilized hydrogen peroxide and magnesium peroxide) and **lubricants (**liquidparaffin)[11,12,13].

Figure 3. Different leaves and powder forms of various herbal plants

Extraction techniques of medicinal plants

Extraction as a term is used pharmaceutically, involves the separation of medicinally active portions of plant or animal tissues from the inactive or inert procedures. The products so obtained from plants are relatively impure liquids, semisolids or powders intended only for

oral or external use. These include classes of preparations known as decoctions, infusions, maceration, circulatory extraction, digestion, percolation, hot continuous extraction (Soxhlet) and extraction under reflux and steam distillation, aqueous alcoholic extraction by fermentation, counter-current extraction, ultrasound extraction (sonication) and supercritical fluid extraction as shown in figure 4. Such preparationspopularly have been called purpose of standardized extraction procedures for crude drugs are to attain the therapeutically desired portion and to eliminate the inert material by treatment with selective solvent known as menstruum[14].

The extract thus obtained may be ready for the use as a medicinal agent in the form of tinctures and fluid extracts, pilular (semisolid) and powdered extracts as it may be further processed to be incorporated in any dosage form such as tablets or capsules, or it may be fractionized to isolate individual chemical entities such as ajmalicine, hyoscine and vincristine, which are modern drugs. Thus, standardization of extraction procedures contributes significantly to the final quality of herbal drug.

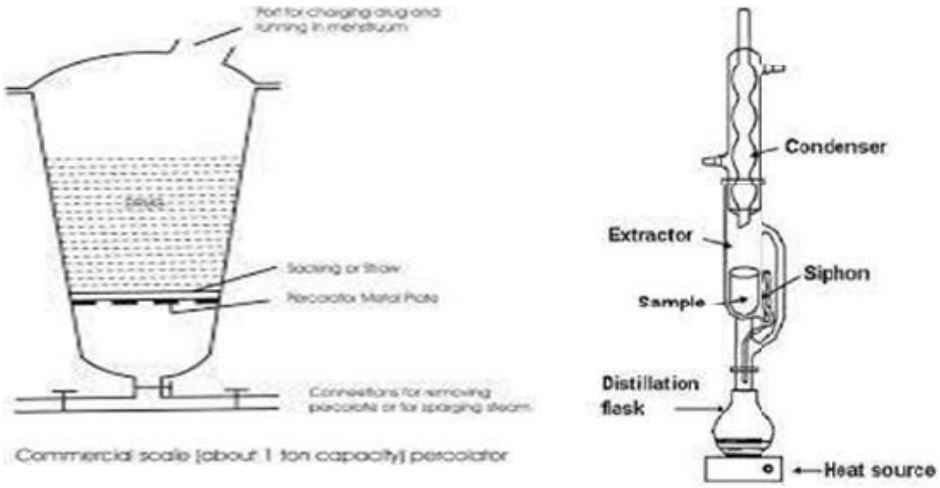

Figure 4: Percolation and hot continuous extraction (Soxhlet apparatus)

Equipment

Toothpastes or dental creams are not so simply compounded as dental powders. Until and unless the manufacturing operations are carefully carried out, defects may appear later in the finished product during shelf-life. Care should be taken to select the right kind of mixers, mills and filling equipment's for a kind of product as different pastes/gels may vary in their consistencies. Even after desirable mixing it is desirable to pass the product through an ointment mill to break the lumps, if any. It will also enable to mix the undistributed

materials and produce a more homogenous and smoother product[15].

The equipment's generally required are a jacketed or tin-lined stainless-steel kettle which is meant to prepare mucilage's and solutions of gelling agents, tanks to half flavors, a properly designed mixer and an ointment mill. All these equipment's should be made from materials that will not affect the color or taste, for example, tin lined copper, or glass lined metal or stainless steel. It helps in preventing discoloration of the product and avoidance of interference of metallic ions of copper and iron with the taste of the product. The ease with which the mixer and other equipment can be cleaned should alsoplay an important place in its selection. Successful toothpaste preparation requires a means of excluding or removing entrapped air. This is best accomplished by conducting the entire manufacturing operation under vacuum. Commercial equipment's such a Day-Nauta vacuum mixer, which is a large conical mixing vessel with a swing arm and helical screw mixer, supplemented by high-speed grinding mills inserted at the base in employed. The other equipment, Abbe mill uses a paddle mixer plus high-speed milling capacity. Both units operate under a vacuum of 28 inches mercury or even greater. Wherever vacuum equipment is unavailable or if additional equipment is desired, equipment called versator may be employed. This consists of a rapidly spinning disk enclosed in a vacuum chamber. The paste is drawn into the chamber under vacuum and dispersed as a thin layer on the rapidly revolving disk. It becomes instantly de-aerated during its passage. Laboratory equipment may simply be a small stainless-steel tank fitted with an air-tight cover and connected to a laboratory vacuum pump. In addition to this, an appropriate tube filling and sealing equipment is required to pack the finished product.

Preparation techniques: Toothpastes are prepared either by the dry gum technique or wet gum technique. In the first technique all the solid components, including the binding agent (excluding the surfactants) is first dry mixed and then humectants and water is gradually added. While in the second technique, the binding agent is first mixed in the liquid phase, a mucilage prepared and then the rest of the solid ingredients are added (excepting surfactants) and mixed well to produce a homogenous paste mass. The homogenous paste obtained from either process must then be mixed with both the surfactant and flavor under vacuum. Based on these techniques, several acceptable procedures are in use.

Cold process: The paste is prepared as follows, the humectant such as glycerin or sorbitol is added to the bowl of the mixer. The hinder is sprinkled in under agitation, so that the particles are dispersed in the absence of water, preventing swelling at this point. A separate

liquid phase is prepared, which includes the available water, sweetener, preservatives and any therapeutic additives. This solution is then added to the humectant's binder mixture. The mixture is placed under vacuum for about 5mins to de-aerate the thick gelatinous liquid phase. The vacuum is opened, and the abrasives are added with mixing until they are thoroughly wet down. Vacuum is reapplied and the paste is mixed for at least 30mins under more of vacuum. In the meantime, the surface-active agents and flavors are dispersed in about 5% of the available humectant. At the conclusion of the 30 min time, the vacuum is again opened, and the flavor mixture is added. Five minutes of additional mixing under vacuum, it will usually produce a smooth air free paste.

Hot liquid-phase process: In this method the abrasive, binder and the preservatives are premixed as dry powders in the mixer. A hot solution of the humectant, water and sweetener is then slowly added with mixing to the dry powders. The resulting mass is mixed under vacuum for 30 minutes after which the solution of the flavor and surfactant is addedfor final 5 minutes of vacuum mixing.

Multiple liquid-phase process: This method is particularly adaptable to formulations using magnesium aluminum silicate-carboxyl methyl cellulose (CMC binder system). Magnesium aluminum silicate is added to hot water in the mixing vessel followed by the sweetener. A separate phaseis prepared consisting of the bulk of the humectant, the binder, the flavor and the preservatives. This solution is added to the mixer, followed by the balance of the humectant. Five minutes of vacuum mixing should be performed to de-aerate the liquid mixture. Abrasives are added and again mixed for 30 minutes under the vacuum. After this step, the surfactant is added in dry form, followed by another 5minutes of vacuum mixing. Similar methods are used to prepare clear-gel dentifrices. In this case the cold-vacuum procedure is found to be most effective. However, when the abrasive system consists of both an abrasive silica and a thickening silica, the abrasive silica should be first, followed by the increment addition of the thickening silica.

Industrial manufacturing: The formulator who has an experience of various manufacturing techniques can adjust and the fine-tune his formulations for the most efficient commercial production as well as assist in solving production problems. Bulk toothpaste, manufactured in vacuum mixing kettles, as previously described, is pumped to storage or holding tanks, till they are filed. Pumps, piping, storage tanks and all surfaces that meet product must be constructed of non-reactive material such as stainless steel. Pumps must be

capable of moving high viscosity-high density pasteswithout aeration. Paste is pumped to the hoppers of tube filling machines[16].

PROCEDURE FOR PREAPARTION OF HERBAL TOOTHPASTE

Tulsi leaves, bay leaves, guava leaves, mango leaves were taken and washed inorder to take out the impurities from them. They were shade dried for about 4 days, after proper drying, they were grounded to fine powder which was passed through sieve no-6. The powder was packed in Soxhlet apparatus and continuouslyextraction process was done for about 6 hours at 50°C with ethanol. After extraction process, the product was collected, and shade dried for 10 days and the extract was powdered. The standard toothpaste base was formulated. Extracts of the leaves wereincorporate in the base in various concentrations. All the formulation was filled inregular metal tubes used in toothpastes as shown in table 1. The storage in tubes was done to correctthe problems of crusting and drying to extruded toothpastes during evaluation andstability tests[17].

Table 1: Formulation of herbal tooth paste

S No	Ingredients	Quantity	Category
1.	**Tulsi leaf powder**	1 gm	Anti-inflammatory
2.	**Bay leaf powder**	0.5 gm	Whitening
3.	**Mango leaf powder.**	1 gm	Anti-bacterial
4.	**Guava leaf powder**	1 gm	Anti-bacterial
5.	**Calcium carbonate**	46.5 gm	Abrasive
6.	**Sodium saccharin**	0.05	Sweetener
7.	**Methyl paraben**	0.15	Preservative
8.	**Sodium lauryl sulphate**	1.3 gm	Foaming agent
9.	**Sorbitol**	30 gm	Humectant
10.	**Peppermint oil**	1 ml	Binding agent
11.	**Tulsi leaf powder**	1 gm	Anti-inflammatory
12.	**Water**	Q.S.	Solvent

Filling and packing of toothpastes

Toothpaste are filled and packaged in collapsible tubes. The tube is a perfect package for viscous products such as dentifrices. The first tubes manufactured back in the mid 1800's were for artist colors. Shortly, thereafter, a dentist saw the convenience his patients could enjoy if the tube could contain dental creams, replacing powders and the use of a rather

unsanitary commonjar. Hence, the toothpaste tube with all its benefits became an acceptable container for filling and Packing of toothpastes and enjoys the same status till date. The original tubes were produced from soft metals, mostly lead or an alloy of these. Thealuminum tube was introduced in the mid 1800's and has been consistently improved in the years that followed.

Today, the metal tabs are predominantly aluminum, madeup of highest grade of Aluminum Alloy-1170. This 99.7% pure in virtually free of trace substances and extrudes a seamless package. New, high barrier internal liners and specially sealed necks made the aluminum tube the package of choice for products. In the 1950, metal tubes were joined by the plastic tube as shown in figure 5. The first practical plastic tube patent was issued in 1954. The patent covered the process of making a thin plastic sleeve by extrusion method and then injection molding a head on one end to produce a tube. Many plastics can be used to make the tabs, but LDPE (Low Density Polyethylene) is the primary material used today. It has high moisture burrier properties, low cost and good appearance A.92 g/cm3 density resin with a melt index of 1.0 in the primary LPDE resin used by tube manufactures.

Figure 5: Tube filling machine

It has good process ability, excellent stress crack resistance to product attack and an extremely low gel content, which reduces surface irregularities that would affect printing quality. Its lack of oxygen and flavor barrier has been improved with barrier coatings. Later, barrier coatings were developed and the plastic tubes became a practical container for the general packaging COEX tubes, co-extrusion of EVOH (Ethylene-Vinyl Alcohol) and

polyethylene, has been demonstrated to have excellent barrier properties enabling manufacturers of products that are adversely affected by air or moisture transmission, the option of using the plastic tube. It was quickly adopted by toothpaste manufacturers where flavor loss in conventional plastic tubes was unacceptable[18].

Plastic tubes are produced by two principal methods commercially, that in either Strahm method or by Down's method. Both processes make excellent tubes. In the early 1970s, laminate tubes were introduced. The barrier properties of laminate coupled inclusion of an aluminum foil layer, gave laminate greater product appeal for products such as toothpaste. The laminated materials consisted of 7 layers with paper, plastic and fail acting as the barrier. The foil was far superior to the plastic tubes then available and minimized flavor loss to acceptable levels. The laminate replaced the lead tube then being used by Procter and Gamble for Crest Co-extrusion methods are now available for producing laminates.

FILLING OF DENTRIFICES IN TUBES

Industrial production of Toothpaste tubes comprises of two major processes.

1. Manufacture of an empty tube (metallic, plastic or laminate).

2. The working process of a tube filling/closing machine can be divided into fourstages.

a) Handling of tubes

b) Tube preparation

c) Filling of tubes

d) Tubes closing and sealing

Handling of tubes: For lower speed, tubes are fed manually by in feed conveyors or chutes into the machine, medium-speed machines are typically fed by cassettes or magazines and high speed machines are normally equipped with their own tube loader that picks up tubes, row by row, from the case and feeds them, on the conveyors to the first work station. The tube is put into the vertical position and pushes into the tube holder. An orientation mark on the tube is read by an electronic eye to position thelabel panels. For sale separation, method is tipping of the nab by suction blocks into the tube holders and vacuum cups for tube discharge.

Tube preparation: Checking for presence of cap and cap-tightening by means of seniors and adjustable clutches or torque-controlled motors. Checking for damage to the open end of the tube by mechanical or photoelectricsensors. Cleaning of the tube by clean-air blast and vacuum, also purging of the tube with inert gas to reduce the amount of residual event in the filled tube (it may be re-collected that oxygen present in the tube may oxidize certain components in the formulation an destabilize the product). Printing registration and code verification by means of photo eyes and scanners. Tubes are rotated and adjusted by means of clutch brakes or servomotors. Inkjetcoding of the tube can be done while the tube is rotating.

Filling of tubes: The tubes are filled by a filling nozzle that dives into the rules before the filling process. As the material is discharged from the nozzle, the nozzle is retracted out of the tube, keeping a constant, distance between the nozzle outlet and the rising level. This relative movement between the tube and the filling system ensured continuousfilling without air entrapment. After the predetermined amount of filling material is cut-off (using different nozzle systems in different products). Most tubes are filledwith a single product. But there are more and more applications, mostly in the toothpaste industry, where two or three components, arranged in stripes over the whole tube length have to be filled. This so called deep-filling system is becomingpopular in dentifrices.

Filling nozzle systems depend mostly on the nature of the product to be filled, specially its rheological properties. A basic and common design is used for the design system which comprises of a volumetric pump dosing system (consisting ofa cylinder and piston with two valves) or a three-way rotary valve. One of the mostcritical parts of this system is the seal between the piston and the cylinder. For abrasive products such as toothpaste, the necessary sealing materials must be carefully selected. Various components and parts of the filling assembly which comes contact with the filling material in tube fillers should be of such material and design such that they can be easily dismantled, cleanest and sanitized.

Tube closing and sealing: Different materials require different types of closure. Normally, most tube fillers areequipped for one type of tube closure, for example.

Metal tubes: They are closed by folding that is, the tube end is flattened and folded over. Various types of fold are possible, double fold, four-fold and saddle fold. The actual folding process is carried out by two folding jaws and a hinged folding tool. For the required precision and speed, the system is cam driven. In many cases, a latex or heated-sealable

lacquer is applied inside the fold area for a hermetic seal.

Plastic tubes: Today, the most common tube material is plastic. Originally, Polyethylene was used in a single layer and the tubes were sealed between heated jaws. The system applied heat on the outside of the tube to heat the inside for sealing. This is less efficient than high frequency sealing, where the heat is generated directly at the inside layer to be sealed. Consequently, the hot jaw system requires a longer heating time and therefore a reduced cycling speed. This is the reason why thissystem is hardly used today in new machines.

Foil laminate tubes: The safest method of sealing plastic tubes with a thin aluminum foil layer is high-frequency sealing. High frequency generates an eddy current in the aluminum layer, which heats up the aluminum and the neighboring plastic layers. The preferred method of sealing laminated, and plastic tubes today is hot air sealing. This system heats the seal area inside the tube by hot air. In a subsequent station, the tube is then pressed and chilled. The system is suitable for speeds well in excess of 100 min. The pressing station for the hot air system is also necessary for the other types of tube closure. It provides a tight seal and improves the asthetics of the tubes and it is also easy to apply a code (that is batch number or expiration date). Filled and sealed tubes pass on a conveyor belt to an automatic cartoner. The cartoner is fed with folded individual cartons, which are opened, the tube is inserted, and cartons are closed. Cartoned tubes are either cellophane-bundled or packed into shipping cartons[19].

QUALITY CONTROL AND EVALUATION OF FINISHED PRODUCTS

Various official and other tests need to be performed to assure the quality of dentifrices. Chemists, physicists and dentists have all contributed to the vastly increased knowledge of the performance of oral products. Indian Standard IS: 5383-1978, comprise of specification for the tooth powder. This standard prescribes the requirements and the methods of sampling and the test for toothpowders. As per this standard, toothpowder shall be smooth, uniform, free flowing fine powder, free from foreign matter. It shall be from hard abrasive materials. The other requirements as per this standard are determination of fineness, moisture and volatile matter, pH of 10% aqueous suspension, foaming power, presence of lead arsenic and hand sharp edged abrasive particles. The standard also gives directions for the labelling and packing requirements of toothpowders.

The Indian standard for toothpaste in described in IS: 6356-1993 (refer latest amendments).

This standard prescribes the requirements and methods of sampling and test procedures for toothpastes. According to this document which is published by the Bureau of Indian Standards (BIS), New Delhi, and revised from time to time, Toothpastes shall of two types, namely Non-fluorinated or Type l and Fluoridated or Type 2. This standard prescribes requirements for the composition, Homogeneity, stability, Tube inertness, Shelf-life, Labeling Packing and Marketing. Annexure B of this standard describes tests for determination of hard and sharp edged abrasive particles, determination of spread ability, determination of heavy metals, determination of Arsenic, determination of Foaming power, determination of fluoride ion and determination of microbial purity. The products may be tested for certain features as prescribed in this standard and if it complies with the requirements of the standard under a well-defined system of inspection, testing and quality control, then the manufacturer is permitted to mark his containers with the standard mark of Bureau of Indian Standards. If the container is displaying the standard mark, then it should display a list of ingredients in decreasing order of quantity present. The product is also required to be free of any carcinogenic material. Apart from complying with the ISI standards and provisions of the Drug and Cosmetics Act 1940 and Rules 1945, the manufacturer is also required to submit to the Bureau of Indian Standards, clearance from state pollution control board, regarding water and air pollution control measure. The product is also expected to be dermatologically safe and made up of packaging materials which are environment friendly.

Other studies that can be conducted for the performance of dentifrices are done chiefly for their abrasive action. Some of the reported techniques for the measurement of the abrasive quality of dentifrices are the interference microscopy, replication techniques, shadowgraph method, surface profile method, radiotracer method, etc. Additional test like determination of lusture and sheen have also been tried. Rheological studies and organoleptic evaluation using survey methods can also be carried out.

EVALUATION OF FORMULATION

I) Preliminary Test

a) Drying tendency: General evaluation of toothpaste was done on basis of drying tendency of the preparation at room temperature for a week and selected batches were evaluated for further evaluation parameters.

b) Organoleptic characters: Selected batches were characterized based on organoleptic characters likeappearance, color, odor, texture, after taste and extrudability.

II) Physicochemical Properties

1) Determination of grittiness: The paste was extruded about 15 to 20mm length from the collapsible tube of each sample on a butter paper. Then all the samples were tested by pressing it along its entire length by finger for the presence of hard- and sharp-edged abrasive particles.

2) Determination of pH: The net quantity of 5gm of sample was accurately weighed and placed in a 150mlbeaker. To this 45ml of freshly boiled and cooled water was added at 27°C. It was stirred well to make a thorough suspension. The pH was determined within 5 min by using pH meter (sartorius CP124S, Swisser instrument, India.

3) Determination of Foaming power: About 5gn of sample was accurately weighed and placed in a 10ml glass beaker. To this 10ml of water was added and the beaker was covered with a watch glassand allowed to stand for 30min. This operation was carried out to disperse the toothpaste in water. The contents of beaker were stirred with a glass rod and theslurry was transferred to a 250ml graduated measuring cylinder, during this transfer ensured that no foam was produced, and no lump paste went into that measuring cylinder. The content of cylinder is adjusted to 50ml by adding enough water and content must be maintained at 30°C. Stir the contents of cylinder with 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 5min and the volume of foam with water(V_1) and only water(V_2) was noted as samples[20].

Determination of foaming power

$$\textit{Foaming power} = V_1 - V_2$$

V_1 = volume in ml of foam with water

V_2 = volume in ml of water only

RESULTS AND DISCUSSION

The optimization of the toothpaste bases was done on the basis of dry tendency. Evaluation of selected formulation was done on the bases of grittiness, pH and foamingpower parameters

such as range and results were as shown in table 2. The formulation having highest foaming capacity among batches was prepared. Herbal extracts of active ingredients were evaluated for different parameters**.**

Table 2: Evaluation parameter of herbal tooth paste

S no	Evaluation parameter	Range	Result
1.	Foaming power	10-40cm	20 cm
2.	Color	Green	Olive green
3.	Appearance	Paste	Paste
4.	Taste	Sweet	Slightly sweet
5.	Abrasiveness	Good	Good
6.	Homogeneity	Good	Good
7.	Moisture content	15-50	35.2
8.	pH	7-9	8

CONCLUSION

Herbal formulations have growing demand in the global market. Natural remedies are more acceptable in the belief that they are safer with fewer side effects then the synthetic ones. It is very good attempt to establish the herbal toothpaste containing alcoholic extracts of Tulsi leaves (*Ocimum sanctum Linn.)* bay leaves (*Cinnamomum tamala*), guava leaves (*Psidium guajava)* and mango leaves (*Magnifera indica)* as herbal ingredients. The evaluation of formulation reveals that it has good abrasive nature and foaming ability.

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