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Formulation And Evaluation Of Polyherbal Toothpaste

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Abstract – The herbal wordings are further taken because they affirm that they're more trustable than synthetic. This examination paper aims to provide a safe and effective natural polyherbal toothpaste that has the fewest to no side effects from the natural origin of sodium isethionate from coconut fruits. These formulations contain various herbs such as clove, neem, and acacia derived from natural sources that have multiple medicinal benefits like reducing dental plaque, gingivitis, tooth decay, cavities, gum diseases, and mouth ulcers. The good foaming ability of this toothpaste gives it optimum cleaning efficiency. The surfactant is derived from the *cocos nucifera* well-known as coconut. The preventive agent present in this formulation has a beneficial impact on maintaining oral hygiene. The laboratory toothpaste was evaluated for its organoleptic, stability-based, and quality standards to formulate a good quality product such as PH, and spreadability, homogeneity, stability, foaming ability. Extrutabilitty. Moisture content, inertness. In vitro, studies are carried out to check the antimicrobial or antibacterial potential against both gram-positive and gram-negative bacterial cultures. Upon formulation brownish aromatic toothpaste was obtained with have wise zone of inhibitions against both gram-positive and gram-negative bacteria. The sodium isethionate was successfully added to the toothpaste formulation to enhance clinging efficiency and reduce dental disease with minimum to no side effects.

Keywords: - Polyherbal, Toothpaste, Organoleptic, sodium isethionate, antimicrobial

Introduction-

From ancient civilizations to our modern-day formulations, toothpaste has been a constant companion in our pursuit of oral hygiene. The toothpastes are used to maintain oral hygiene by reducing dental disease with the aid of a toothbrush. The history of the toothpaste evaluation is followed as the quest for a clean mouth dates back at least 5,000 years. In ancient Egypt around 3,000 BC, a dental paste made of oxen hooves, myrrh, eggshells, pumice, and water was developed. In the late 1800s, the British Dental Association (BDA) approved the first tube of commercial toothpaste. In the 1850s, American dentist John Harris discovered the benefits of fluoride in toothpaste. In the late nineteenth century, Dr. Washington Sheffield, an English dental surgeon, developed a toothpaste containing soap and salt. Our modern oral hygiene practices with toothpaste, toothbrush, and floss began in the 1950s. Toothpaste is an integral part of our daily oral hygiene routine. (1)

After 1950, several formulation advancements of different detergents had begun, and sodium lauryl sulfate had been used as a foaming/emulsifying agent until now. The practice of keeping one's oral cavity clean and free of diseases such as *cavities*, *dental caries*, aphthous ulcers (Canker sores), tooth decay, Oral thrush (candidiasis), Oral herpes, and gum diseases, including gingivitis and periodontitis is oral hygiene. Several

infections can affect the mouth. These may be caused by bacteria, viruses, or fungi. An estimated 1 in 4 people experience dry mouth, a condition characterized by an underproduction of saliva.4 While not usually a life-threatening condition, it can indicate a deeper issue or feel uncomfortable. Dental plaque is a sticky, non-mineralized mass of bacteria that forms on a tooth's surface. It accumulates when substances containing refined carbohydrates (starches and sugars) are routinely left on the teeth. Plaque builds up when you don't practice good oral hygiene and visit your dentist for routine cleanings. It can erode your enamel and cause tooth decay. Once plaque hardens, it turns into tartar (calculus). Tartar can cause periodontal disease and can only be removed during a professional dental cleaning.

Canker sores, also called *aphthous ulcers*, are small, shallow lesions that develop on the soft tissues in your mouth or at the base of your gums. Unlike cold sores, canker sores don't occur on the surface of your lips and they aren't contagious. They can be painful, however, and can make eating and talking difficult. Most canker sores are round or oval with a white or yellow center and a red border. They form inside your mouth on or under your tongue, inside your cheeks or lips, at the base of your gums, or on your soft palate. You might notice a tingling or burning sensation a day or two before the sores appear. These types are sores appear due to the side effects of currently marketed formulations containing chemicals like sodium lauryl sulphate or triclosan. These chemical constituents have various side effects such as irritation, sensitivity, redness or dryness in the mouth, itchiness, peeling, and scaling. The formulation currently developed counters all these diseases and does not harm the patient. (2)

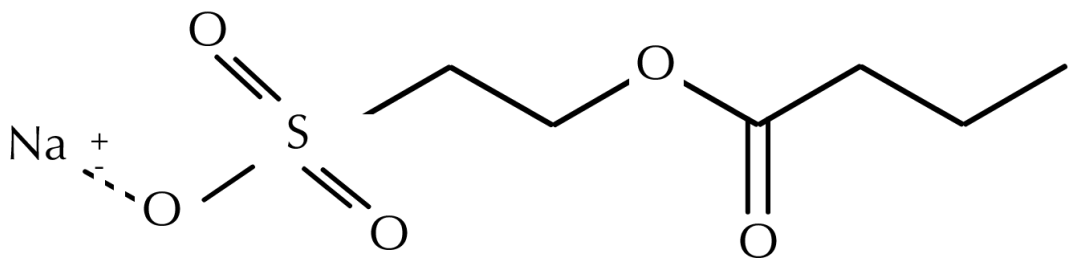
Materials and method-

1) Preparation of plant Extract:

Sodium Cocoyl Isethionate -

Sodium Cocoyl Isethionate is a naturally derived ingredient that comes from the fatty acids that are present in *isethionic acid* and coconut oil. It is prepared by a process called esterification. During this process, the fatty acids in the coconut oil are reacted with *isethionic acid* to produce the final product. The result is a white powder or flakes that have excellent cleansing properties and create a luxurious lather when mixed with water. *Sodium cocoyl isethionate* not only effectively removes dirt and impurities but also helps moisturize and soothe the skin due to its mild nature. *Sodium Cocoyl Isethionate* appears as a fine white powder. It is a cleansing ingredient used in skincare and haircare formulations. *Sodium cocoyl isethionate* is derived from coconut milk separated by centrifugation and separated coconut oil. To that oil add coconut oil acid, sodium isethionate, choline chloride, and a eutectic mixture of *fluorine-containing ethansulphuric acid* and heat the mixture until it melts completely. Let them react for some time and cool it at room temperature. The colorless crystal mixture was obtained and that is sodium cocyl isethionate. (3)

It is primarily used in soaps, cleansers, shampoos, and cleansing products due to its surfactant abilities. Surfactants help to lift oil and dirt from the skin and allow it to be washed away. This is why *sodium cocoyl isethionate* can be found in products that help to cleanse the skin and hair. *Sodium cocoyl isethionate* is used as a fine white powder that has a mild scent. It is usually used in concentrations that range between 10-25%. There are considered to be no issues with irritation, sensitivity, or toxicity at these concentrations. It is enlisted in the list of safer drugs by the United States Environmental Protection Agency.



Img.1. Structure of sodium cocoyl isethionate

It is Surfactants, and Surfactants work by reducing the surface tension between two phases, between a liquid and a solid or a liquid and liquid. Disruption of the surface tension allows for dirt and oils to be lifted from the teeth where they can be easily washed away from the skin.

The safety of sodium cocoyl isethionate has been evaluated by the Cosmetic Ingredient Review Expert Panel, a group responsible for reviewing the safety of skincare and cosmetic ingredients. The Expert Panel has reviewed the available data on sodium cocoyl isethionate and found the ingredient to be safe in its current uses and concentrations. Sodium cocoyl isethionate is considered safe in concentrations up to 50% in rinse-off products and 17% for leave-on products. The research conducted on sodium cocoyl isethionate by the Cosmetic Ingredient Review Expert Panel determined that it was not found to be sensitizing to the skin or produce phototoxic effects. It has a good Foaming ability that creates a thick and luxurious lather, its Mildness is Gentle on the skin without causing irritation with Cleansing Power which effectively removes dirt, oils, and impurities.

The extract was prepared by simple maceration method, Firstly we took buds of clove or bark of neem around 1 mg then they were dried pulverized in air, and then soaked with 100ml of suitable solvent which is methanol for 24 hours, The total extract was combined and filter and evaporate it on heating mantle, and the obtained end product was dried and stored in a desiccator for further use.

2. Formulation of Toothpaste:

All herbal ingredients were dried and ground using a mortar and pestle, then the required quantity of powdered ingredients was weighed as per the given formula and taken in the mortar (Calcium carbonate, Sodium isethionate, methyl-paraben, titanium dioxide, Sodium saccharine) was triturated in the mortar. After that Acacia, Hydroxypropyl methylcellulose (HPMC), and Glycerin were mixed into the above mixture. This solution was added dropwise into a mortar containing herbal ingredients and triturate well until the paste consistency was formed. At semi-solid consistency add clove and neem extract to the above preparation until the paste-like consistency occurs and at the end add the menthol extract to it. (4)

Materials-

Sr.no	Common Name	Botanical Name	Parts used	Category
1	Clove	***Syzygium aromaticum***	Bud	Antibacterial
2	Neem	***Azadirachta indica***	Bark	Antibacterial
3	Honey	***Apies melifera***	-	Sweetening Agent
4	Acacia	-	Powder	
5	Calcium Carbonate	-	Powder	Abrasive
6	Glycerine	-	Drops	Humectant
7	HPMC	-	Powder	Stabilizer
8	Sodium Saccharin	-	Crystals	Sweetening agent
9	Sodium Isethionate	-	Powder	Detergent/ Foaming agent
10	Methyl Paraben	-	Powder	Preservative
11	Titanium dioxide	-	Powder	Whitening agent
12	Menthol	***Mentha Piperita***	Crystals	Cooling agent
13	Purified Water	-	-	Vehicle

Equipment's-

Sr.No	**Equipment**	**Model No**
1	Hot air oven	AI- 7981
2	Digital PH meter	LT – 11
3	Analytical balance	HR – 250A
4	Spreadability meter	-
5	Crimping machine	HX 050

The procedure of preparation of herbal toothpaste -
All the herbal ingredients such as Clove (anti, Honey, acacia, honey, and Neem are extracted and placed in separate containers. The sodium isethionate is synthesized with the help of a chemical reaction by the addition of eutectic solvents. (5)

Method of preparation – There are two types of methods for the preparations

1) Dry gum Method
2) Wet gum Method

Dry gum Method –

1. All the solid ingredients such as calcium carbonate, sodium isethionate, methyl paraben, sodium saccharine were weighed accurately as per given in the formula and sieved with sieve no.80 to maintain the particle size of all the ingredients.

2. Further, these chemicals were subjected to mixing in mortar and pestle and triturated with accurately weighed sorbitol until semisolid mass formed. Addition of herbal ingredients-

3. Accurately weighed herbal extract in form of powders were sieved and added to the base along with clove oil.

4. Menthol oil was added as a flavoring at the end. (6)(17)

Evaluation –

1. Physical Examination

Colour, odour, taste, smoothness, and relative density all these parameters are evaluated to check the compatibility of the formulation. Colour was tested by the visual observation and odour is determined based upon its smell sensation, the taste was determined by practically tasting the formulation, The density of the substances varies with pressure and temperature so it is necessary to specify the pressure and the temperatures at which the densities and the masses are to be determined.(7)(18)

2. Inertness of tube: the inertness is observed to check whether any sign of deterioration or chemical reactions occurred in the container due to material of the tubes container or ant external atmospheric factor. The container used for herbal toothpaste was not produce any corrosion or deterioration in normal storage conditions such as room temperature ranges around 45 0C for few days. Inertness of tube was checked by cutting the internal surface of toothpaste container and observing whether any sign of chemical reactions such as phot-oxidation, deterioration or other occurred in the container or not upon stable atmospheric conditions. (8)(19)

3. pH: the aqueous suspension toothpaste was prepared by taking about 10 gm of toothpaste from the container in a 50 mL beaker and add 20 mL of distill water and Stir well and determine the PH of the solution using digital PH meter.

4. Foaming capacity-

The foam production plays an important role in the cleaning efficacy and its distribution. The optimized foaming behavior leads to a good cleansing effect. The initial volume was noted by taking 2g of formulation with 5ml water in a measuring cylinder and the volume of the liquid was adjusted with the water up to 10 ml the solution was shaken 10 times to produce a foam and the measuring cylinder was covered with a watch glass and allows

to stand for 15 minutes and height of the foam produced was measured. The final volume of foam was noted. (9) The foaming ability of herbal toothpaste was determined. Foaming power is calculated by using the following formula

Foaming power = V1 – V2

Where, V1 - Volume in ml of foam with water

V2 - Volume in ml of water only

5. Storage stability -

The stability study was carried out for the prepared toothpaste at a temperature of 37 °C for 2 months. The toothpaste was filled in a toothpaste tube for storage and stored for 45 days at room temperature and 45oC. Then the toothpaste tube was cut and whether the liquid component was separated from the toothpaste tube or not. The amount of liquid components separated gives the storage stability evaluation efficacy. (10)(15).

6. Moisture content -

10 g of toothpaste was weighed and taken in a Porcelain dish and dried in the hot air oven at 105 °C then it was cooled in a desiccator to achieve constant weight. The loss of weight will be recorded as a percentage of moisture content and calculated by the given formula. (11)

The formula for calculating moisture content is:

% Moisture = Original sample weight – dry sample weight/ Original sample weight

Moisture Content (%) = Initial Weight−Dry Weight×100

Where:

Initial Weight is the weight of the toothpaste sample before drying.

Dry Weight is the weight of the toothpaste sample after drying.

7. Net content:

Formula to calculate net content;

Net content = weight of filled tube – the weight of empty tube.

Antimicrobial activity -

The common pathogenic microorganisms were used in the study as test microorganisms, such as gram-positive bacteria like *Staphylococcus aureus* and gram-negative bacteria like *Escherichia coli and Pseudomonas aeruginosa*. (12)

Disc diffusion method -

The disc diffusion method was used to evaluate the antimicrobial activity of the toothpaste. A teste microorganism suspension was prepared. Autoclaved agar media was poured into each Petri plate, then the swabbing of the bacterial colonies from the inoculums of the test microorganisms on prepared media plates with the help of sterile cotton swabs, which was then incubated for 15 min at 37 °C to allow proper adsorption and active growth of the pathogen. (13) Different concentrations of formulated toothpaste are taken such as 100,

250, and 500 mg/ml, and poured into the inoculated agar plates and incubated for 37 ºC for 48 hours. Then the diameter of the zone of inhibition was measured against the tested organisms. The plates were placed on a black surface, upon a non-reflecting background, and illuminated with reflected light to observe the zone of inhibition. (14)(16).

RESULTS AND DISCUSSION –

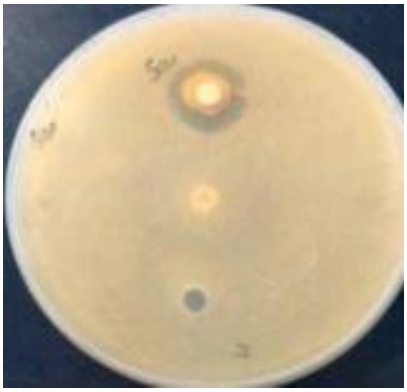
Table - Organoleptic evaluation of formulated polyherbal toothpaste

Organoleptic evaluation Result –

Sr.no	**Parameters**	**Result**
1	Colour	Cremish Brown
2	Odour	Pleasant (clove)
3	Taste	Sweet
4	PH	7.6
5	Texture	Course
6	Moisture content	15.46
7	Storage stability	Stable (separation of a liquid component is observed slightly after two months)
8	Foaming character	10 7.6 ± 0.115 (ml)
9	Viscosity	Slightly viscous
10	Homogeneity	Homogenous
11	Spreadability	Spreadable 6.2 ± 0.115 (cm)
12	Tube Extrudibility	62.67 ± 1.45 (%)

The formulated toothpaste was tested for antibacterial activity against Staphylococcus aureus, Escherichia coli, and Pseudomonas aeruginosa with different concentrations of toothpaste. The potency was qualitatively and quantitatively assessed by the presence or absence of a zone of inhibition and zone diameter values. Different concentrations show different readings in terms of the zone of inhibition. The formulated toothpaste exhibited a highly significant effect on all the tested bacteria, whereas the negative control did not produce an observable inhibitory effect for any of the tested bacteria.

Staphylococcus aureus



Pseudomonas aeruginosa

E-Coli

Among all the tested bacteria used Staphylococcus aureus was found to be most sensitive to the formulated toothpaste as seen by a zone of inhibition (10-15 mm) followed by Escherichia coli (9- 12 mm) and Pseudomonas aeruginosa (9-11 mm).

Table: Antimicrobial activity of the formulated polyherbal toothpaste

Sr.no	Medium	Zone of inhibition in mm
1	Staphylococcus aureus (gram + positive)	13
2	Escherichia coli (Gram-negative)	9
3	Pseudomonas aeruginosa (Gram-negative)	10

Upon observation, the sodium isethionate has a potential impact on the inhibition of both gram-positive and gram-negative bacteria. The antibacterial activity of the formulated polyherbal toothpaste also showed significant antibacterial activity against all the tested microorganisms. This observation indicates that the activity is due to the presence of large varieties of phytoconstituents present in the extract. Hence, the observed antibacterial activity of the toothpaste was due to the presence of active constituents of the extract. This was a good sign to do further studies on that to make it one of the commercial herbal toothpastes for the treatment of oral bacterial infections.

Conclusion and recommendation -

The formulated polyherbal toothpaste was successfully evaluated using different standard parameters including antimicrobial properties. The sodium isethionate compound showed promising antimicrobial effects against both gram-positive and gram-negative organisms. The formulated toothpaste may be safer compared to fully synthetic toothpaste. Further studies are warranted to prove the in-vivo activity for safety studies and anticancer activity of the formulation to market the formulation for use.

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