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Design, Development and Characterization of Herbal Gargle Against Throat Infection

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Abstract: *Herbal gargles have gained significant attention as potential alternatives to conventional oral care products due to their perceived natural composition and reported therapeutic benefits. This review aims to provide a comprehensive overview of the efficacy of herbal gargles in promoting oral health and preventing various oral ailments. Our oral cavity is a sweet able place to grow different types of bacterial species either harmless or harmful for human. From ancient age medicinal plants are considered as a store room of different types of biological activity in Ayurveda, Unani and Siddha, and have important role to cleanse tooth and prevent different human pathogens are responsible for unpleasant odour, inflammation of teeth root, dental plaque. The study evaluates a wide range of herbal ingredients commonly found in mouth gargles, including essential oils, plant extracts, and traditional herbal remedies. It explores their antimicrobial properties, antioxidant activity, and potential for reducing plaque formation, gingivitis, and bad breath. In this research work herbal gargle was evaluated depends on various parameter like color, pH, Phase separation, Homogeneity and antibacterial properties. Herbal gargles show potential as adjuncts to conventional oral car, Herbal gargle is suitable for any age group due to less side effect.*

Keywords: Gargle, *Syzygiumcumini* Linn, Excipient profile, Formulation, Extraction , Evaluation

I. INTRODUCTION

The first known references to mouth rinsing are described in Ayurveda and Chinese medicine in2700 BC. Mouth gargle is a chemotherapeutic agent used as effective home care system by the patient. [1]In the Greek and Roman periods, mouth rinsing became common among the Hippocrate.They recommended a mixture of salt, alum and vinegar.[1]

Gargles are aqueous solutions used to treat the problem related to pharynx and nasopharynx by pushing air from the lungs through the gargle while it is held in the throat. Often, gargles need to be diluted with water before use. Gargles are used to get the medication onto the mucosal surface of the throat.[2,3] The preparations need to have acceptable organoleptic qualities and be quick-acting.

Natural: Natural gargles which are also known as herbal gargles. eg: liquorice, clove, ginger, salt water.

Chemical: Gargles, made from chemical compound. eg,: Methyl salicylate, Saccharine sodium.

Such a variety of health advantages come from gargling and rinsing with salt water. It promotes good oral hygiene and dental health with gargling and it supports the postoperative care process. It aids in the recovery of canker sores. Sometimes pregnancy difficulties may be avoided with its aid.

Gargle can be dangerous for children when used orally they didn't even know how to gargling. Due to oral cavity sometimes, gargle might produce sensation and itching in mouth. [4]

Syzygiumcumini Linn (family Myrtaceae), commonly known as " Jamun " has promising therapeutic value with various phytoconstituents such as tannins, alkaloids, steroids, flavonoids, terpenoids, fatty acids, and vitamins.[5] The ripe *S. cumini* fruit has many therapeutic properties such as liver stimulation, digestive, carminative, coolant and hypoglycemic effects. Its leaves contain essential oils with a pleasant odour. The oil contains terpenes, dipentenes, sesquiterpenes, ellagic acid, isoquercitin, quercetin, kaempferol and myricetin in different concentrations . The barks, leaves and seeds extracts of *S. cumini* have been reported to possess anti-inflammatory , and antidiarraheal effects . The leaves have been extensively used to treat diabetes and constipation , fever, gastropathy, strangury and dermopathy[5]

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Fig No.2: Jamunleaves[6]

Fig No.2: Jamun leaf powder[7]

ADVANTAGES OF Gargles:

Easy to use for the treatment of infection of pharynx just by gargling the solution using air from the lungs.
Relieve Soreness In Mild Throat Infection.
Supplied in conc. For so reduce container size.
Suitable for variety of drugs like antibiotic, antiseptic.

Difference between mouthwash and gargle:

Mouthwash	Gargles
1. Mouthwashes are aqueous solution with pleasant taste and smell for refreshing effect.	1. Gargles are aqueous solution used to prevent or treat throat infections.
2.used to make clean and deodorise the buccal cavity.	2.these are gargled to bring in intimate contact with mucus membrane of throat.
3.more used for cosmetic purpose.	3.used for medicated purpose.
4.ex. compound sodium,chloridemouthwash	4.ex. potassium chlorate gargle

Excipient profile :

Excipient is a substance formulated alongside the active ingredient of a medication. Excipients serve various purposes, including long-term stabilization, bulking up solid formulations containing potent active ingredients in small amounts (often referred to as "bulking agents", "fillers", or "diluents"), or enhancing the therapeutic properties of the active ingredient in the final dosage form. They can facilitate drug absorption, reduce viscosity, or enhance solubility.[11,12] Excipients can also aid in the manufacturing process by improving the handling of active substances, facilitating powder flowability, or preventing denaturation and aggregation during the expected shelf life. The selection of excipients depends on factors such as the route of administration, dosage form, and active ingredient.

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Saccharin: Saccharin is a synthetic, white, crystalline powder, that contains the -$CONHSO_2$– (*N*-sulfonyl amide) structural unit, common to several compounds with a sweet taste. In its pure state, saccharin is 550 times sweeter than sugar.

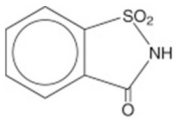

Fig no.3: Chemical Structure of Saccharin

Chemical Name	1,2 Benzisothiazol -3(2H) – one 1,1 dioxide
Molecular weight	183.18
Physical form	Solid, powder
Density (bulk)	0.7 – 1.0 g/cm3
Melting point Oc	228 – 230 oC (Decomposes)
Density (tapped)	0.9 – 1.2g/cm3
Solubility	1 in 25 (water); 1 in 50 (glycerin). Slightly soluble in ethanol, acetone and DMF. Soluble in dilute alkali hydroxide solutions

Applications in Pharmaceutical Formulation:
Saccharin is a sweetening agent. It is used as an intense sweetening agent in beverages, food products, table – top sweeteners and oral hygiene products such as toothpastes and mouthwashes.
In oral pharmaceutical formulations, it is used at a concentration of 0.02 – 0.5% w/w. it has been used in chewable tablet formulation as a sweetening agent. Saccharin has been used to form various pharmaceutical co-crystals.
Stability and Storage Conditions:
Saccharin is stable under the normal range of conditions employed in formulations. In the bulk form it shows no detectable decomposition and only when it is exposed to a high temperature (125 at a low (pH 2) for over 1 hour does significant decomposition occur. The decomposition product formed is (ammonium–o–sulfo) benzoic acid, which is not sweet. The aqueous stability should be stored in a well closed container in a dry place.[17].

Sorbitol :
Sorbitol, a polyol also known as glucitol, plays a significant role in the pharmaceutical industry as a versatile excipient and active pharmaceutical ingredient (API). This sugar alcohol is widely utilized for its unique properties, serving various functions in drug formulation and manufacturing processes.

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Manufacturing of Sorbitol:

Sorbitol occurs naturally in certain fruits like apples, pears, and peaches, but its commercial production for pharmaceutical purposes involves more controlled processes. The majority of pharmaceutical-grade sorbitol is derived from glucose through catalytic hydrogenation. This process yields a sugar alcohol with a sweet taste, making it suitable for pharmaceutical applications.

Function of Sorbitol as Excipients:

- **Sweetening Agent:** Sorbitol is used as a sweetening agent in pharmaceutical formulations, providing a sweet taste without contributing to dental caries. It is particularly useful in pediatric and diabetic formulations where sugar content needs to be controlled.
- **Humectant:** As a humectant, sorbitol helps retain moisture in pharmaceutical formulations, preventing products like tablets and lozenges from drying out and maintaining their physical integrity.
- **Stabilizer:** Sorbitol acts as a stabilizer, enhancing the stability of certain pharmaceutical formulations. It helps maintain the physical and chemical properties of a product, contributing to its overall shelf life.
- **Vehicle for Drug Delivery:** Sorbitol is utilized as a vehicle in chewable tablets, oral liquids, and other drug delivery systems. Its pleasant taste and solubility in water make it an effective medium for drug administration, particularly for pediatric and geriatric populations.
- **Osmotic Agent:** The osmotic properties of sorbitol are harnessed in certain pharmaceutical formulations, influencing drug release and absorption. It is used in controlled-release and sustained-release formulations to achieve specific therapeutic profiles.
- **Bulking Agent:** In oral dosage forms like tablets and capsules, sorbitol can act as a bulking agent, contributing to the mass and volume of the formulation. This is especially important in formulations where precise dosing is required.
- **Flavoring Agent:** Sorbitol's sweet taste can serve as a flavoring agent, improving the palatability of oral pharmaceutical formulations. It is often used to mask the bitter taste of certain drugs.
- **Diluent in Liquid Formulations:** Sorbitol is commonly used as a diluent in liquid oral formulations, providing volume and improving the pourability of the solution. It ensures uniform distribution of the active ingredients.
- **Compatibility Enhancer:** Sorbitol enhances the compatibility of different ingredients in a formulation, contributing to the overall stability of the product. It helps prevent phase separation and maintain a homogeneous mixture.[18]

Sodium lauryl sulfate:

Sodium Lauryl Sulfate also referred to as Sodium laurilsulfate or Sodium dodecyl sulfate is a synthetic organic compound widely used in personal care products as an anionic surfactant. It is similarly used in pharmaceutical products taking advantage of its surfactancy properties.

In the pharmacopoeia, Sodium lauryl sulfate is described as a mixture of sodium alkyl sulfates, consisting chiefly of sodium lauryl sulfate [CH3(CH2)10CH2OSO3Na]. The Ph.Eur and B.P specified the assay content of Sodium lauryl sulfate which should be not less than 85% of sodium alkyl sulfates calculated as C12H25NaO4S.

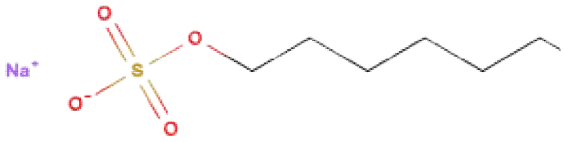

Fig no.4: chemical structure of SLs

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Chemical name	Sulfuric acid monododecyl ester sodium salt
Empirical Formula	C12H25NaO4S
Molecular Weight	288.38 g/mol
Physical form	Solid, powder
Appearance	White or cream to pale yellow coloured crystals, flakes, or powder
Melting point	204-207 oC
Solubility	Freely soluble in water

Chemical structure:

Applications in Pharmaceutical Formulations:

Sodium lauryl sulfate is widely used as an anionic surfactant, detergent, emulsifying agent, skin penetrant, tablet and capsule lubricant and wetting agent. It is used in solid dosage forms and topical products largely due to its surface-active properties. It may also be used to aid the dissolution rate of poorly soluble active substances during dissolution test measurements.

Stability and Storage Conditions:

Sodium lauryl sulfate is a fairly stable excipient under standard storage conditions. The shelf-life is reported as 24-36 months. In solution, Sodium lauryl sulfate may undergo hydrolysis to lauryl alcohol and sodium bisulfate when pH falls significantly (e.g< pH 2). Therefore, solutions should be used soon after preparation and/or not be exposed to extreme conditions.[19]

Ethanol :

Ethanol is a primary alcohol that is ethane in which one of the hydrogens is substituted by a hydroxy group. It has a role as an antiseptic drug, a polar solvent, a neurotoxin, a central nervous system depressant, a teratogenic agent, a NMDA receptor antagonist, a protein kinase C agonist, a disinfectant, a human metabolite, a Saccharomyces cerevisiae metabolite, an Escherichia coli metabolite and a mouse metabolite. It is a primary alcohol, an alkyl alcohol, a volatile organic compound and a member of ethanols. It is a conjugate acid of an ethoxide.

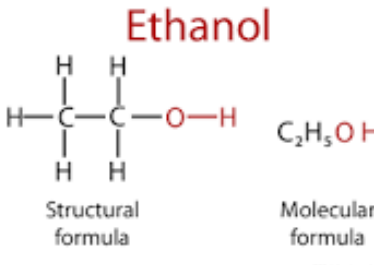

Fig no.5: chemical structure of ethanol

Molecular Formula: C_2H_6O, CH_3CH_2OH

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Synonyms: ethanol
ethyl alcohol
Molecular Weight: 46.07 g/mol
Color: Clear, colorless, very mobile liquid
Boiling Point: 173.3 °F
Melting Point: -173.4 °F
Uses: Clear, colorless liquid rapidly absorbed from the gastrointestinal tract and distributed throughout the body. It has bactericidal activity and is used often as a topical disinfectant. It is widely used as a solvent and preservative in pharmaceutical preparations as well as serving as the primary ingredient in ALCOHOLIC BEVERAGES.
Safety and Hazards: Inhalation or contact with material may irritate or burn skin and eyes. Fire may produce irritating, corrosive and/or toxic gases. Vapors may cause dizziness or asphyxiation. Runoff from fire control or dilution water may cause environmental contamination(HIGHLY FLAMMABLE).[20]

Formulation Table:

Table no.1: Formulation of gargle

Ingredients		Batches		Role of Ingredient
		B1	B2	
Jamun leaf powder		1 mg	1 mg	Antibacterial
Cinnamon		0.6 mg	0.7 mg	Flavoring agent and antibacterial activity
Clove oil		0.6 ml	1 ml	Analgesic and anti-inflammatory
Saccharin		3 gm	2 gm	Sweetener
Sorbitol		0.5 gm	1 gm	Emollient

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Sodium lauryl sulfate		**0.5 gm**	**0.5 gm**	**Co-surfactant**
Ethanol		**5 ml**	**10 ml**	**Vehicle**
Distilled water		**Adjust upto 50ml**	**Adjust upto 50 ml**	**Solvent**

III. EXTRACTION OF PLANT EXTRACT

Extraction is the first step to separate the desired natural products from the raw materials. Extraction methods include solvent extraction, distillation method, pressing and sublimation according to the extraction principle. Solvent extraction is the most widely used method. The extraction of natural products progresses through the following stages:

(1) the solvent penetrates into the solid matrix

(2) the solute dissolves in the solvents

(3) the solute is diffused out of the solid matrix

(4) the extracted solutes are collected.

Any factor enhancing the diffusivity and solubility in the above steps will facilitate the extraction. The properties of the extraction solvent, the particle size of the raw materials, the solvent-to-solid ration, the extraction temperature and the extraction duration will affect the extraction efficiency [8,9,10].

Fig no.5: Extraction process

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Chemical tests:

Test	Procedure	Observation	Result
Test for alkoloids	Mayer's test :3ml filtrate was taken in test tube and add few drops of mayer's reagent.	cream precipitate was observed,indicates presence of alkoloids.	
Test for tannins	To the extract, a few drops of dilute solution of ferric chloride was added.	Color of the solution changed to the dark blue shows the presence of tannins.	
Test for flavonoids	Ferric chloride test: to the small quantity of alcoholic solution of extract, few drops of neutral ferric chloride was added.	Color changed to blakish red colur indicates the presence of flavonoids.	
Test for carbohydrates	Fehling;stes: small portion of the extract was treated with fehling's solution and then heated on water bath.	brick red color precipited was not found and blue colur is obtained indicating absence of carbohydrate.	
Test for Terpenoids.	Salkowski test: extract was mixed with chloroform and concentrated sulphuric acid was carefully added to form a layer.	Reddish brown coloration indicates the presence of terpenoids.	

Method of preparation:

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Weighted quantity of each ingredient will be taken.

↓

Extract were taken mixed thoroughly in mortar and pestle properly with small quantity of water. All other remaining ingredient will be gradually added with good mixing.

↓

Drop by drop clove oil will be added and mixed properly taking care to avoid lump formation.

↓

Sorbitol and SLS will then be added and mixed well.

↓

Finally, water added to make volume and preservative will be added and the product will be packed in an attractive, well closed container.

Evaluation Parameters:

1) Colour- Dark Brownish

2) Odour- Characteristics

3) pH- pH of prepared herbal gargle was measured by using Digital pH meter. The pH meter was previously calibrated using standard buffer solution. Collect about 1 ml of gargle and dissolved in 50 ml of distilled water and it's pH was found 5.84 at room temperature.

4) Weight per ml:

Table no.2:Weight per ml test

Sample quantity	Weight of empty volumetric flask	Weight of empty volumetric flask	Result (wt/ml)
25ml	42.21 gm	67.53 gm	1.01gm/ml

6) Stability studies:

Stability test aims to ensure that the gargle formulations are usable and can maintain the same characteristics in the long term basis.

The formulation and preparation of a pharmaceutical product is incomplete without proper stability studies of the prepared product.

This is done in order to determine the physical and chemical stability of the prepared product.

Table no.3: Stability Studies Of Formulated Herbal Gargle

Sl. No.	Parameters	Observations			
		Initial	10 days	20 days	30 days
1	Colour	Dark brown	Dark brown	Dark brown	Dark brown
2	Odour	Characteristics	Characteristics	Characteristics	Characteristics
3	Consistency	Stable	Stable	Stable	Stable
4	Phase separation	Nil	Nil	Nil	Nil
5	pH	5.83	5.82	5.84	5.85
6	Homogeneity	Good	Good	Good	Good

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Fig no.6:Colour of formulation

IV. RESULT

The look of gargle retained its colour and homogeneity after a one-month examination. The gargle's formulation showed no signs of phase separation. Gargle has maintained its pH and has a mildly acidic character. This mouth-gargle entirely prepared from plants parts and safe for health.

V. CONCLUSION

The present liquid herbal gargle can work in long way to help people to cure the various throat disorder . Present herbal formulation is acceptable for a long period. Furthermore the prepared herbal gargle were standardized by various physicochemical studies like pH, appearance of solution, consistency, phase separation and all test results are in limit. So the prepared herbal formulation is very good and safe for any age group.

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