

DEVELOPMENT AND EVALUATION OF CHAMELI LOZENGES AS A TREATMENT FOR MOUTH ULCERS.

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ABSTRACT:

The present study focuses on the formulation and evaluation of herbal lozenges using *Psidium guajava* (Guava) and *Jasminum grandiflorum* (Chameli) leaves for the treatment of mouth ulcers. These medicinal plants, long utilized in traditional Ayurvedic practices, are known for their rich phytochemical profiles and therapeutic properties such as anti-inflammatory, antimicrobial, and wound healing effects. Lozenges were formulated with varying concentrations of plant powders, along with other natural ingredients like tulsi, mentha, clove oil, honey, sugar, and jaggery. Phytochemical screening confirmed the presence of alkaloids, phenolics, tannins, saponins, glycosides, and amino acids. The lozenges underwent comprehensive evaluation for physical parameters including hardness, friability, disintegration time, moisture content, PH, and weight variation. Among the three formulations tested, F1 and F3 showed promising results in terms of desirable physicochemical properties and stability. This study suggests that herbal lozenges incorporating guava and chameli leaves may serve as an effective and natural therapeutic approach for managing mouth ulcers.

KEYWORDS:

Mouth ulcers; Herbal lozenges; *Psidium guajava*; *Jasminum grandiflorum*; Phytochemical screening; Anti-ulcer activity; Ayurvedic formulation; Natural remedies; Lozenges evaluation; Medicinal plants.

INTRODUCTION:

The necessity of substituting some medications because of their negative side effects is a prime example of the widespread use of plants to treat illness and preserve health. Since ancient times, people have used medicinal plants to heal a variety of illnesses; this method is known as phototherapy¹. Plants' seeds, bark, roots, leaves, and fruits are the best sources of active metabolites. As a result, these phytochemicals have been used by many plants as a defensive mechanism against infections².

Ulcers:

An ulceration is a crater-shaped lesion or wound that can develop on the stomach, colon, or oral mucosa. When an ulcer develops, the area may bleed or release disagreeable substances, resulting in a painful sore that is prone to infection. Defects in the underlying connective tissue, the epithelium, or both can be indicative of ulceration. Because each organ has a variety of possible origins and presenting characteristics, diagnosing ulcerative lesions can be challenging³.

The potential of *Jasminum grandiflorum* (chameli) and *Psidium guajava* (guava) leaves to heal mouth ulcers is investigated in this study. These plants, which have been utilized traditionally in Ayurveda, contain a variety of bioactive chemicals that may have therapeutic uses. The tropical fruit guava is indigenous to South America, Bangladesh, Indonesia, and India⁴. Extracts from its leaves have been used in traditional medicine for a long time because of their anticancer, antimalarial, anti-diabetic, antioxidant, anti-diarrheal, and antibacterial qualities⁵. Guava leaves are also thought to support liver and heart health, blood sugar regulation, high cholesterol, and vision issues⁶.

Jasminum grandiflorum, generally known as Chameli, is prized for its beautiful, ambrosial flowers. In Ayurveda, Chameli leaves are used clinically for crack mending⁷. They've been traditionally employed to treat a wide range of affections, including body pangs, stomach pangs, toothaches, boils, ulcers, nausea, constipation, detoxification, etc⁸. Chameli leaves are also masticated for oral hygiene, as they're allowed to strengthen teeth and epoxies and palliate stomatitis (inflammation of the mouth filling). Fresh splint juice is used as a topical remedy for sludge, and the leaves themselves are masticated for mouth ulcers⁹. Both Guava and Chameli leaves are rich in phytochemicals, naturally being composites with implicit health benefits. The presence of these phytochemicals is linked to the anti-ulcer exertion of these shops.

Mouth Ulcer:

An ulcer that develops on the oral depression's mucous membrane is referred to as a mouth ulcer. Although mouth ulcers are extremely prevalent and can be caused by a wide range of factors and diseases, there is typically no significant underlying cause. A breach in the skin or mucous membrane that results in the loss of a face towel as well as the breakdown and necrosis of an epithelial towel is called an ulcer. In contrast to a corrosion or commination, an ulcer damages both the epithelium and the lamella propria. A superficial fracture of the epithelium with minimal harm to the underlying lamella propria is called a corrosion. A transgression of the epithelium that is shallower than an ulcer but deeper than a corrosion is sometimes referred to as commination¹⁰.



Fig No. 1: Mouth Ulcers

TYPES OF MOUTH ULCER:

Mouth ulcers can be categorized as minor, major, or herpetiform based on their size and number.

The primary varieties of oral ulcers are:

Minor ulcers:

These often go away in ten days to two weeks and measure between two and eight millimeters around the periphery.

Major ulcers:

Are larger, deeper, and often have an uneven or elevated border. A mouth scar may result from these ulcers, which might take weeks to cure.

Herpetiform ulcer:

This kind of ulcer consists of dozens of pinhead-sized blisters on the lower side¹¹.

Lozenges:

Tablets are solid phrasings containing specifics in a sweet and seasoned base. They're designed to dissolve sluggishly in the mouth, analogous to treated delicacies, furnishing relief to bothered throat apkins. tablets are extensively used due to several advantages, including dragging the drug's presence in the mouth, enhancing immersion, reducing stomach vexation, and bypassing original liver metabolism¹².



Fig No. 2: Lozenges

TYPES OF LOZENGES:**Medicated Lozenges:**

Contain active pharmaceutical ingredients intended for therapeutic use.

Non-Medicated Lozenges:

Do not contain active pharmaceutical ingredients and are used for soothing or refreshing purposes.

CLASSIFICATION OF LOZENGES:

- According to the site of action:

Local Effect:

Example: Decongestants and antiseptics.

Systemic Effect:

Example: Nicotine and vitamins.

- Based on composition and texture:

Chewable lozenges:

These chewable tablets include herbal ingredients and provide a convenient method of administering medication mixtures to the afflicted oral tissues.

Example: Vitamins

Hard lozenges:

They are thick and disintegrate slowly, releasing herbal extracts that may help oral apkins heal, soothe, and reduce inflammation.

Example: lollipops

Soft Lozenges:

Designed to slowly dissolve or disintegrate, releasing herbal extracts with healing packages to relieve and treat discomfort related to ailments such as oral ulcers.

Example: Bentasil

Compressed Lozenges:

Made with a contraction mechanism similar to compressed tablets, these lozenges provide a delayed dissolution profile and are non-disintegrating for heat-sensitive ingredients.

Example: Troches¹³.

PLANT PROFILE:**Chameli leaves (Jasmine)****Fig No. 3: Chameli**

- **Synonym:** Jasminum sambac, Arabian jasmine
- **Biological Name:** Jasminum sambac
- **Family:** Oleaceae (Olive family)
- **Chemical Consituent:** Volatile oil- benzyl acetate, flavonoids, saponins, tannins.
- **Uses:**
 - Aromatic and fragrant properties.
 - Used in traditional medicine for its anti-inflammatory and antiseptic properties.
 - Used in skincare products for its antioxidant and moisturizing properties.

Guava leaves**Fig No. 4: Guava leaves**

- **Synonym:** Psidium guajava, Apple guava
- **Biological Name:** Psidium guajava
- **Family:** Myrtaceae (Myrtle family)
- **Chemical Consituent:** Volatile oil, flavonoids, phenolic acids, glycosides
- **Uses:**
 - Rich in vitamins A and C, potassium, and fiber.
 - Antioxidant and anti-inflammatory properties.
 - Used in traditional medicine for its antimicrobial and antidiarrheal properties.

MATERIALS AND METHODS

Formulation of lozenges:

Formulation	F1	F2	F3
Chameli Powder	2g	1.5g	1.0g
Guava Powder	1g	1g	0.5g
Tulsi Powder	0.5g	0.5g	0.2g
Mentha Juice	3ml	3ml	3ml
Clove oil	2-3 drops	2-3 drops	2-3 drops
Honey	5ml	5ml	5ml
Sugar	20g	-	15 g
Jaggery	-	10 g	-

Table No. 1: Formulation of lozenges

Collection of Plant Material:

The Chameli leaves and Guava Leaves Was collected from farm. The plant material was identified by **Dr. V. N. Chavhan (Botanist)** Arts, Commerce and science college, Maregaon.

Method of Preparation of Lozenges:

Hard candy lozenges were prepared using molten sugar as base.

- All powdered materials (Chameli leaves (jasmine), guava leaves, Tulsi leaves powder) were weighed and mixed homogenously.
- Weighed quantity of sugar was melt on water bath. By maintaining temperature between 110 to 130°C.
- Powder mixture was added to molten mass while it was hot.
- After the mixture was well distributed, Mentha juice, honey and clove oil were added while being constantly stirred. After being poured into silicone molds, the mixture was left to cool at room temperature¹⁴.

Phytochemical Evaluation:

Alkaloids:

Wagner's Reagent:

Wagner's reagent was applied in little drops down the test tube's sides to 1 milliliter of the sample solution. When alkaloids are present, a reddish-brown precipitate will form.

Phenolic compounds and tannins:**Quinones:**

a small amount of strong hydrochloric acid was added to 1 milliliter of powder. precipitate's yellow appearance.

Saponins:

A small amount of distilled water was added to 1 milliliter of extract, and the mixture was shaken quickly. The presence of saponins is indicated by the development of foam.

Ferric Chloride:

Test involved adding a few drops of neutral 5% ferric chloride to one milliliter of extract. a dark green color's look.

Glycosides:**Kellar-Killiani test**

Concentrated sulfuric acid, a few drops of ferric chloride, and one milliliter of glacial acetic acid were added to one milliliter of sample solution. Glycosides are present when a reddish-brown ring forms at the liquid-liquid interface.

Amino Acid:

Ninhydrin test: Two drops of the ninhydrin reagent were applied to one milliliter of the sample solution. The presence of amino acids is shown by the purple color formation.

EVALUATION PARAMETERS:**Microscopical Evaluation:**

Evaluate clarity, texture, and consistency of the medicated lozenges. Assess texture for stickiness visually¹⁵.

Weight Variation Test:

Using an analytical balance, weigh six lozenges (Height: 1 cm, Width: 1.5 cm) from each batch separately to determine the average weight and standard deviations¹⁶.

Diameter and Thickness:

Measure diameter and thickness using a vernier scale, crucial for tablet uniformity and patient acceptance (measured in mm)¹⁷.

Hardness Test:

Use a Monsanto hardness tester to determine the hardness of the prepared lozenges¹⁷.

PH Calculation:

A digital pH meter was used to determine the lozenges' pH.

Friability:

A Roche friabilator was used to measure friability. The friability of lozenges is assessed using a friabilator. For four minutes, the apparatus rotates at 25 rpm. After the lozenges' initial weights are determined, they are put in the friabilator. The lozenges were de-dusted and weighed once more following the revolution. The value that was observed was not greater than 1%¹⁸.

Disintegration Time:

Using disintegration test equipment, the disintegration time of six lozenges was determined. Each lozenge was placed within the basket rack assembly's tube of the disc-free disintegration equipment. The assembly was placed in the disintegration media-filled beaker, which was kept at $37 \pm 2^\circ\text{C}$. The amount of time needed for the assembly to completely disintegrate was noted as the disintegration time¹⁸.

Moisture Content:

Weigh a 1-gram sample that has been in a desiccator for 24 hours to determine the moisture content gravimetrically¹⁹.

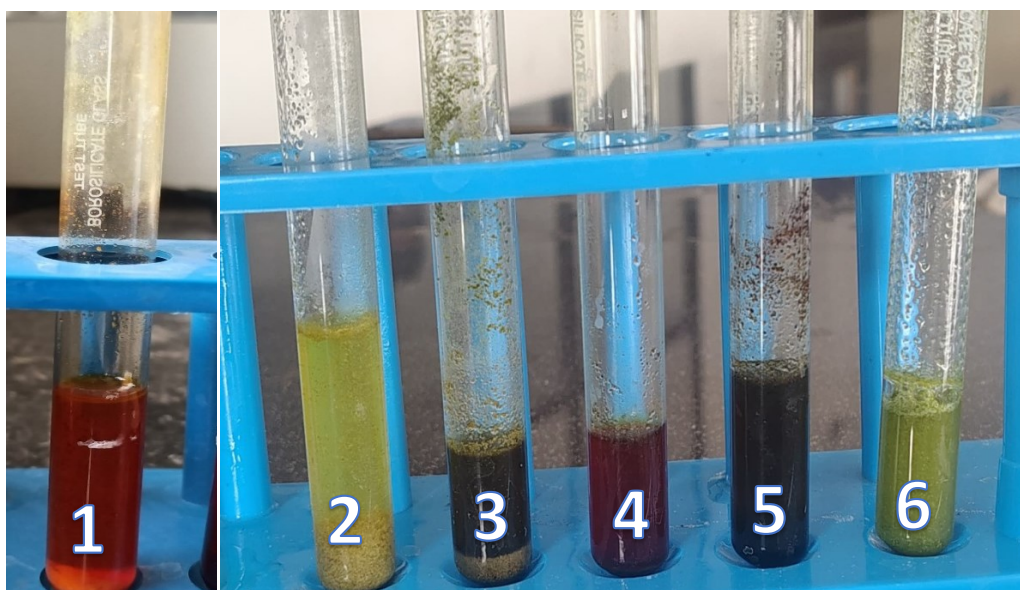


Fig No. 5: Lozenges- Final product

RESULT AND DISCUSSION:**Phytochemical Evaluation**

SR NO	CHEMICAL TEST	OBSERVATION	INFERENCE
1.	Alkaloids Wagner's	Appearance reddish brown precipitate	Present
2.	Phenolic Compound and Tannin: Quinones	Appearance Of Yellow Precipitate.	Present
3.	Phenolic Compound and Tannin: Ferric chloride test	The appearance of dark green colour	Present
4.	Glycosides: Keller-Kiliani Test	Appearance of Reddish-brown Ring at junction of Liquid	Present
5.	Amino Acids: Ninhydrin Test	The Appearance of Purple. Colour	Present
6.	Saponin:	The Appearance Of fo am.	Present

Table No. 2: Phytochemical Evaluation

Observation:**Fig No. 6: Phytochemical Evaluation****EVALUATION TEST:****Macroscopical Evaluation:**

Formulation	Colour	Odour	Taste	Texture	Shape
F1	Brown	Aromatic	Sweet	Soft	Hexagon
F2	Dark Brown	Pungent	Bitter	Smooth	Improper
F3*	Light Brown	Aromatic	Sweet And Spicy	Smooth	Hexagon

Table No. 3: Macroscopical evaluation**Weight variation:**

Formulation	Weight Variation ($\pm 5\%$ Range)
F1	3.06g to 3.35g
F2	-
F3*	2.31g to 2.56g

Table No. 4: Weight Variation

Diameter and Thickness:

Formulation	Diameter	Thickness
F1	2.1 cm	0.5 cm
F2	-	-
F3*	2.1 cm	0.3 cm

Table No. 5: Diameter and Thickness**Hardness:**

Formulation	Hardness
F1	5kg/cm
F2	-
F3*	10kg/cm

Table No. 6: Hardness**Moisture Content:**

Formulation	Moisture Content
F1	0.05%
F2	-
F3*	0.01%

Table No. 7: Moisture Content**pH Determination:**

Formulation	Ph
F1	5.65
F2	6.01
F3*	6.8

Table No. 8: PH Determination**Friability:**

Formulation	Result
F1	1.21% >1.0 %
F2	-
F3*	0.82% <1.0 %

Table No. 9: Friability

Disintegration Time:

Formulation	Disintegration Time
F1	4.00 min
F2	-
F3*	4.5 min

Table No. 10: Disintegration Time**CONCLUSION:**

The present study successfully formulated and evaluated polyherbal lozenges using Chameli (*Jasminum grandiflorum*), Guava (*Psidium guajava*), Tulsi (*Ocimum sanctum*), Mentha (Peppermint), and Clove oil for the treatment of mouth ulcers. These ingredients were selected for their known anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties. Three formulations (F1, F2, F3) were prepared using the melting and molding technique and tested for various physical and chemical parameters. Phytochemical screening confirmed the presence of beneficial compounds like flavonoids, alkaloids, tannins, and saponins. Among the formulations, F3 performed the best, exhibiting optimal hardness, low friability, fast disintegration, ideal pH, and minimal moisture content. F1 was acceptable but had higher friability, while F2 failed due to molding issues. The study concludes that F3 is the most effective and stable formulation, offering a natural, safe, and efficient alternative to synthetic drugs for managing mouth ulcers, with strong potential for further development and commercial use.

F3 is the most effective and stable formulation overall.

F1 is acceptable but needs friability improvement.

F2 was not successful due to manufacturing issues (non-demolding).

Thus, polyherbal lozenges emerge as an effective, safe, and natural therapeutic modality for the management of mouth ulcers, addressing both symptomatic relief and healing, while promoting holistic oral health.

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