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## Research Article

# Formulation and Evaluation of Herbal Lozenges for the Treatment of Mouth Ulcer

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## ABSTRACT

Mouth ulcers, clinically known as ulcers or “Recurrent Aphthous stomatitis” rank among the most prevalent oral mucosal conditions affecting approximately 10–20% of the global population. Defined by superficial sores, on non-keratinized oral tissue RAS significantly disrupts chewing, swallowing and overall quality of life. Present therapeutic choices, topical corticosteroids, anesthetics, antiseptics and systemic immunomodulators provide symptom relief; however their effectiveness is often limited by undesirable systemic side effects or inadequate local retention at the targeted area. Consequently there is increasing focus on creating safe, natural and “patient acceptable dosage forms”, like herbal lozenges. This research concentrates on the development, analysis and assessment of an Herbal lozenge created to deliver anti-inflammatory, Antimicrobial and mucosal-calming phytochemicals directly to the target area. Cinnamon (*Cinnamomum verum*) was chosen as the active compound due, to its rich concentration of cinnamaldehyde, known for its strong Antimicrobial, antioxidant and tissue-repairing effects (Ranasinghe et al., 2013). Extra botanical components, such as honey, Turmeric, Tulsi, ginger extract and menthol were incorporated to boost combined effects, in alleviating pain controlling microbes and promoting epithelial healing.

## INTRODUCTION

Mouth ulcers, medically termed Aphthous ulcers or canker sores, are small, painful Lesions that develop on the mucous membranes inside the mouth. These ulcers can make eating, Drinking, and even speaking uncomfortable, impacting daily

life significantly. While various Factors can contribute to their development, including stress, injury, or underlying health Conditions, finding effective treatments is crucial for managing symptoms and promoting healing [1]. The word “Aphthous” originated from the Greek word “aphtha”, the meaning of which is ulcer.

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Aphthous stomatitis is one of most common ulcerative disease associated mainly with the oral mucosa characterized by the extremely painful, recurring solitary, multiple ulcers in the upper throat and oral cavity. These types of ulcers are usually small, multiple, ovoid or round with circumscribed margins .which are having gray or yellow floors and are encompassed by erythematous halo [2, 3]. It was delineated in 400 B.C by Hippocrates; the disease is known by lay public and professionals by several other names such as cold sores, canker sores, “Recurrent Aphthous stomatitis “(RAS), and recurrent Aphthous ulcers (RAU). His is the most prevailing oral ulcerative disorder affecting up to 10-20% of our inhabitants and recurrence rate of 3 months in 50% of population [4]. These are quite painful that leads to difficulty in eating, speaking and swallowing that’s why it negatively affects the patient’s quality of life [5]. Aphthous stomatitis is divided into three varieties: minor aphthae, major aphthae and herpetiform. Minor aphthae also called as Miculiz’s aphthae, is one of the most common variant that constitute 75-85% of all RAS cases. These types of ulcers have size usually less than 1 cm (10 mm) and heal without leaving scarring within 10 to 14 days. His type is commonly found in the non-keratinized mucosal surfaces like buccal mucosa, labial mucosa, and mouth floor. Major Aphthae also called as Sutton’s disease; usually exceeds 1 cm (10 mm) cause deeper ulceration thus leave scar. It constitutes only 10-15% of RAS cases. These ulcers may remain about 10-20 days and may take months also. He usual sites are throat, lips and soft palate. He Herpetiform is least common variant of RAS that constitutes only 07-10% of RAS cases. Ulcer size is very small measuring 2-3 mm in diameter; numerous in numbers (around 100 ulcers at once) can fuse together producing large irregular lesions that last for 7-10 days without leaving scars [6-7].

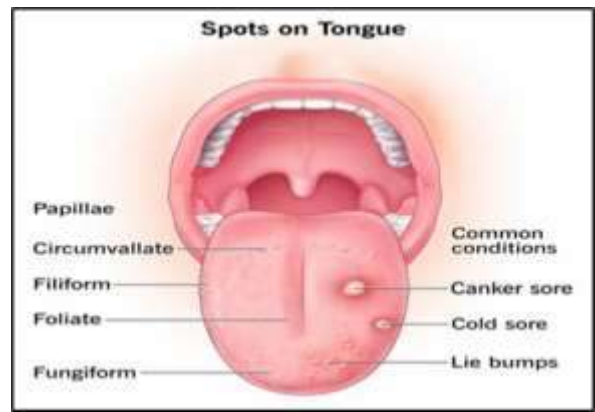


Figure 1: Mouth Ulcer

## ANATOMY OF THE ORAL MUCOSA [8-12]

The oral cavity is lined by a mucous membrane (mucosa) that varies in thickness and keratinization depending on the location and function.

1. **Keratinized Epithelium:** Found in areas subject to friction like the gums, hard palate, and the top (dorsal) surface of the tongue. It has a tougher, protective layer of keratin.
2. **Non-Keratinized Epithelium:** Lines the softer, more flexible areas such as the inner cheeks (buccal mucosa), lips, floor of the mouth, and the underside (ventral) of the tongue. This area is more permeable and where most common ulcers (Aphthous ulcers) form.

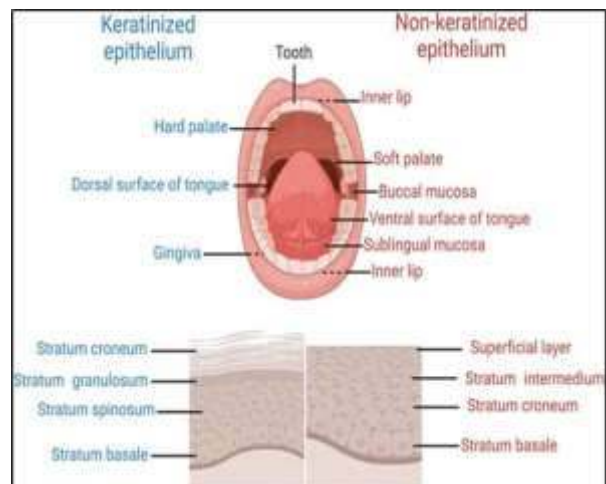


Figure 2: Anatomy of oral mucosa

## PHYSIOLOGY

The process of ulcer formation and healing is broadly similar to skin wounds but with key differences, particularly less inflammation and the absence of scarring in most cases.

### Pathophysiology of Oral Aphthae Ulcer

The pathogenesis of recurrent aphthous stomatitis (RAS) remains not completely understood. It likely involves a predominantly cell-mediated inflammation involving T-cells and TNF- $\alpha$  (tumor necrosis factor-alpha) production. Light and electron-microscope examination of oral Aphthae ulcers showed a penetrating, early, lympho-monocyte infiltration of the epithelium. According to a study by Lehner [13], under light microscopy, oral ulcer epithelium showed considerable intercellular edema and degenerative changes. There was epithelial hyperplasia and only the basement membrane adjacent to the ulcer was affected, the rest of the basement membrane appeared intact. Mononuclear cells normally infiltrate the basal-cell and prickle-cell layers of the epidermis and they are most commonly lymphocytes and monocytes, but superficial to and immediately adjacent to the ulcer neutrophil polymorphs were also found. According to Lehner [13], the Intra-nuclear inclusion bodies were found in 3 out of the 25 biopsies examined by electron microscopy. The affected nuclei were slightly larger and the nucleoli were uneven in shape. Inclusion bodies were not seen in the cytoplasm. Herpetiform ulcers differ from recurrent Aphthae ulcers in that they showed epithelial vesicles and intra-nuclear inclusion bodies, suggesting a virus etiology. The immunofluorescent studies showed predominantly IgG and IgM binding only in autologous tissues from patients with Aphthae ulcers [14]. This reaction could indicate blood group antigens, trapped globulins due to the inflammatory reaction, non-

immunological Physicochemical binding of the fluorescent conjugate, or normal immunoglobulin transport through the oral mucosa. An immunofluorescent examination couldn't detect specific globulin binding to salivary gland tissue in the oral Aphthae lesion. Major Aphthae ulcers do not differ much from minor Aphthae ulcers, but they have an increase in the degree of severity of the pathological changes. There were no vascular abnormalities and fibrinous necrosis noticed in recurrent oral ulcers. A three-fold rise in mast cells was found in recurrent oral Aphthae, in contrast to a decreased count in non-specific ulcers. Mast cell count was present in all three groups of oral ulcers when it was compared with that in other oral lesions and normal tissue. Leukocytes have a normal chemotactic function in oral aphthosis but in Behcet's disease, they showed hyperactive function [13]. There's a chance that a few immunologically arbitrated mechanisms are playing an important role in the pathogenesis of oral aphthosis. It may be due to an unopposed or excessive production of IL (interleukin)-1 or IL-6, which is essential for its development, a concept that may explain why ulceration worsens after local injury, or cessation of smoking, or both [15].

### Pathophysiological Mechanisms [8-12]

The exact cause of the most common type, "Recurrent Aphthae stomatitis "(RAS), is often unknown but is considered multifactorial, involving a T-cell-mediated immune response.

- **Immune Dysregulation:** An abnormal immune response, potentially triggered by certain bacteria or systemic factors, is the primary pathogenic mechanism. The inflammatory response involves immune cells (neutrophils and macrophages) releasing cytokines like TNF- $\alpha$ .



- **Tissue Injury:** Trauma (e.g., accidental biting, sharp food, ill-fitting dentures) can cause direct damage, leading to an inflammatory reaction and ulcer formation.
- **Systemic Factors:** Deficiencies in iron, folate, or vitamin B12 can be contributing factors. Other associations include stress, hormonal changes, certain medications, and underlying systemic diseases like Crohn's disease or Behçet's disease.
- **Malignancy:** A persistent, non-healing ulcer (lasting more than 3 weeks) can rarely be a sign of oral cancer, which involves disorganized tissue growth and infiltration.

#### TYPES OF MOUTH ULCER:

- **Minor Aphthous Ulcers:** Small, typically less than 1 cm in diameter. Round or oval-shaped. Typically Heal within 1 to 2 weeks without scarring.
- **Major Aphthous Ulcers:** Larger than minor Ulcers, often exceeding 1 cm in diameter. – Can have an irregular shape. – May take longer to heal, and scarring is possible.
- **Herpetiform Ulcers:** Individual ulcers are usually 1 To 3 millimeters in diameter. – Small, round or oval Shaped. – Usually heal on their own within 1 to 2 Weeks [17].

#### ETIOLOGY

##### CAUSE OF MOUTH ULCER:

- **Mechanical Trauma:** Accidental biting of the Cheek, tongue, or lip. Dental appliances, braces, or Rough or sharp edges of teeth that cause irritation. Stress and Anxiety: Emotional stress and anxiety can weaken the

immune system, making Individuals more susceptible to developing mouth Ulcers.

- **Nutritional Deficiencies:** Insufficient intake of Essential nutrients, such as vitamin B12, iron, folic Acid, and zinc, can contribute to the formation of Mouth ulcers.
- **Food Sensitivities:** Certain foods, especially acidic or spicy ones, may trigger the development of Mouth ulcers in sensitive individuals.
- **Certain Medications:** Side effects of medications like nonsteroidal anti-inflammatory drugs (NSAIDs), beta-blockers, and certain antibiotics can include mouth ulcers.
- **Smoking and Tobacco Use:** Smoking or using other tobacco products can irritate the oral tissues and contribute to the development of mouth ulcers.

#### SYMPTOMS OF MOUTH ULCER:

- **Pain:** Mouth ulcers are often associated with pain or discomfort, particularly when eating, drinking, or brushing teeth.
- **Difficulty Eating or Drinking:** Due to the pain and sensitivity associated with mouth ulcers, Individuals may find it uncomfortable or painful to Eat or drink, especially when consuming acidic or Spicy foods.
- **Irritation or Burning Sensation:** Some people May experience a burning or tingling sensation in the area surrounding the ulcer.
- **Swelling:** The tissues around the ulcer may appear slightly swollen or inflamed.



- Red or White Lesion: The ulcer itself may be red or White, with a defined border.[18]

## 1. DRUG CLASSIFICATION

### 1) First line therapy

Topical antiseptic	Chlorhexidine Gluconate, Triclosan
Topical/ Systemic Anti-inflammatory/ Analgesic	Benzydamine Hydrochloride, Diclofenac
Topical Anesthetic	Lidocaine, Benzocaine
Topical antibiotic	Chlortetracycline, Doxycycline
Topical corticosteroids	Hydrocortisone hemisuccinate, Triamcinolone acetonide, Betamethasone valerate, Beclometasone dipropionate, Budesonide, Clobetasol

### 2) Second Line Therapy

Systemic Immunomodulator	Levamisole, Colchicine, Hydrocortisone and Triamcinolone, Thalidomide, Dapsone, Pentoxphylline, 5-Amino salicylic acid, Azathioprine, Prostaglandin E2
Systemic Antibiotic	Penicillin G Potassium
Systemic Corticosteroids	Prednisone

## 2. HERBAL TREATMENT FOR MOUTH ULCER

### CINNAMON BARK

**Synonyms:-**[21,22]

Dalchini, Ceylon Cinnamon, Cinnamon bark

#### Biological Source

Cinnamon is the dried inner bark of the coppiced shoots of *Cinnamomum zeylanicum* Nees., belonging to family Lauraceae.

### Botanical Classification

- **Kingdom** – Plantae
- **Sub kingdom** – Tracheophytes
- **Super division** – Angiosperms
- **Division** – Magnoliids
- **Class** – Magnoliopsida

### Morphological characteristic

- **Colour:** Externally dull yellowish brown, internally dark yellowish brown
- **Odour:** Aromatic
- **Taste:** Warm and very refined (Sweetish and aromatic)
- **Size:** Length is about 1 meter, diameter is nearly 1 cm and thickness is approx
- **Shape:** Compound

### Chemical Constituent:

Volatile oil, tannins mucilage, calcium oxalate, starch, mannitol, Cinnamon oil

**Geographical source:** Sri lanka, Malabar Coast of India, Jamaica and Brazil



Fig 3.Cinnamon bark

### Uses of cinnamon bark

Bark is used as-

- Carminative
- Stomachic
- Flavouring Agent
- Stimulant
- Antiseptic
- Weight Loss

**Commercially used as:**

In preparation of candy dentrifices and perfumes.

## HONEY

### Synonyms

Madhu, Madh, Mel, Purified Honey.

### Biological Source

Honey is a viscid and sweet secretion stored in the honey comb by various species of bees, such as *Apis mellifera*, *Apis dorsata*, *Apis florea*, *Apis indica* and other species of *Apis*, belonging to family Apidae (Order: Hymenoptera).

### Morphology of Honey

- **Colour** -Pale yellow to reddish brown viscous fluid
- **Odour**-Pleasant and characteristic
- **Taste**-Sweet, slightly acrid
- **Extra Features**- Taste and odour depend entirely on the nectar of surrounding flowers. On prolonged storage, honey can turn opaque and granular due to the crystallization of dextrose, known as 'Granulated honey'.

### Chemical Constituents

- Dextrose 23–36%
- Levulose (Fructose) 30–47%
- Sucrose 0.4–6%
- Dextrin
- Gums 0–7%
- Ash 0.1–0.8%

### Geographical Source

Africa, India, Jamaica, Australia, California, Chili, Great Britain and New Zealand.



**Fig 4.Honey**

### Uses

- Burns
- Cough
- Foot sores in people with diabetes.
- Dry eye
- Sores and ulcers of the mouth and gums caused by herpes virus

### HALDI (HINDI); CURCUMA;

### Biological Source

Turmeric is the dried rhizome of *Curcuma longa* Linn. (syn. *C.domestica* Valetton), belonging to family Zingiberaceae.

### Chemical Constituents

- Turmeric contains yellow colouring matter called curcuminoids (5%)
- essential oil (6%)
- curcumin I (60%) in addition with small quantities of curcumin III, curcumin II and dihydrocurcumin.
- mono- and sesquiterpenes like zingiberene (25%)
- $\alpha$ -phellandrene
- sabinene

### Geographical Source

The plant is a native to southern Asia and is cultivated extensively in temperate regions. It is grown on a larger scale in India, China, East Indies, Pakistan, and Malaya.



Fig 5. Turmeric

### Uses

1. Anti-inflammatory & Antioxidant: Curcumin, the active compound, is known for reducing inflammation and fighting oxidative damage

2. Digestive Aid: Used to reduce bloating, gas, and aid digestion

### TULSI

#### Synonyms

Sacred basil, Holy basil.

#### Biological Source

Tulsi consists of fresh and dried leaves of *Ocimum sanctum* Linn. belonging to family Labiatae.



Fig 6. Tulsi

### Chemical Constituents

- Eugenol
- Vitamin C
- Maleic, citric acid
- Tartaric acid.

### Geographical source

- India

### Uses

- antibacterial
- stimulant
- aromatic
- spasmolytic

## GINGER

### Synonyms

Rhizoma zingiberis, Zingibere.

### Biological Source

Ginger consists of the dried rhizomes of the *Zingiber officinale* Roscoe, belonging to family Zingiberaceae.

### Chemical constituents

- Gingerol
- Gingerberine
- volatile oil

### Geographical Source

It is mainly cultivated in West Indies, Nigeria, Jamaica, India, Japan, and Africa.

### Uses

Antiemetic, positive inotropic, spasmolytic, aromatic stimulant, carminative, condiment, and flavouring agent.



Fig 7. Ginger

### 3. LOZENGES/ CANDY: [23]

Lozenges are solid formulations that include medications in a sweet and flavored base. They are

meant to dissolve slowly in the mouth, like medicated candies.

Providing relief to the irritated tissues in the throat. Lozenges are a commonly used type of medicine. The advantages of medicated lozenges include prolonging the time. The medicine stays in the mouth, improving its absorption, reducing stomach irritation, and avoiding the initial metabolism in the liver.

### TYPES OF LOZENGES:

- Medicated lozenges.
- Non-medicated 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 [24].

### Organization of Lozenges:

#### Rendering near Position of Act:

- 1 **Home-grown Result:** Examples include disinfectants then, Decongestants.
- 2 **Systemic Effect:** Instances comprise vitamins and nicotine

#### Giving to touch then arrangement:

1. **Chewable Lozenges:** Combine herbal ingredients with a chewable texture, providing a convenient way to deliver medicinal compounds. To affected oral tissues. Example: Vitamins

2. **Hard Lozenges:** Have a firm consistency and dissolve slowly, releasing Herbal extracts that may soothe, reduce inflammation, and Promote healing in oral tissues. Example: Lollipops [25].
3. **Soft Lozenges:** Designed to dissolve or disintegrate slowly, releasing herbal extracts with therapeutic properties to soothe and heal Discomfort associated with conditions like mouth ulcers. Example: Bentasil.
4. **Compressed Lozenges:** Formulated for heat-sensitive ingredients using a Compression method similar to compressed tablets, offering a non-disintegrating and slower dissolution profile. Example: Troches [26].

#### **Advantages and disadvantages of Lozenges [27, 28]**

1. Lozenges offer many advantages to easily administer to geriatric and pediatric population It extends the time of drug in the oral cavity to elicit a specific effect, Easy to prepare, with minimum amount of equipment and time, it can be useful for those patient who have difficult to swallowing.
2. Medicated lozenges also have drawbacks like non-ubiquitous distribution of drug within saliva for local therapy and possible draining of drug from oral cavity to stomach along with saliva.

#### **4. LITERATURE REVIEW**

##### **Rina G Maskare et al., 2022[1]**

Mouth ulcers, or Aphthae ulcers, are common oral lesions that cause significant discomfort and can interfere with daily activities such as eating and speaking. This research focuses on the development and evaluation of herbal lozenges

incorporating Neem (*Azadirachta indica*) and Tulsi (*Ocimum sanctum*) as primary active ingredients for the treatment of mouth ulcers. Neem is renowned for its potent anti-inflammatory, Antimicrobial, and wound-healing properties, while Tulsi is valued for its analgesic and anti-inflammatory effects. The lozenges were formulated to dissolve slowly in the oral cavity, ensuring prolonged contact with ulcerated tissues, thereby maximizing therapeutic efficacy. Comprehensive evaluation included assessments of Physicochemical properties, taste, texture, and stability, alongside in vitro studies to determine Antimicrobial and healing potential. Results demonstrated that the synergistic combination of Neem and Tulsi in lozenge form provided effective pain relief, reduced inflammation, and promoted faster healing of mouth ulcers. The formulation was well-tolerated and exhibited favorable organoleptic properties. These findings suggest that herbal lozenges represent a promising, natural, and patient-friendly approach for the management of mouth ulcers, warranting further clinical investigation for widespread therapeutic use.

##### **Pooja Yadav et al., 2018[29]**

Lozenges are one of the widely used solid dosage forms. They contain medicament and are meant to be in mouth or pharynx. Lozenges have been in use since 20 th century and are still in commercial production. Lozenges provide a palatable means of dosage form administration and possess excellent advantages; though they suffer certain disadvantages too. Lozenges are adopted for both local and systemic administrations and a wide range of active ingredients can be incorporated in them. Lozenges currently available in market are: Caramel based soft lozenges, hard candy lozenges and compressed tablet lozenges. This present review covers researches performed till date,

formulation and evaluation parameters, packaging and applications of lozenges.

**Surbhi chaurasaya et al., 2018[30]**

Lozenges are one of the very popular and better innovative dosage form and oral confectionary products. Lozenges have been in use since 20th century and are still in commercial production. Lozenges have bright future as a novel method of delivering drugs for local action and systemic effect in the oral cavity. The “lozenges are solid medicated, flavored and sweetened base dosage forms intended to be sucked and hold in the mouth/pharynx”. The benefits of the medicated lozenges is they increase the retention time of the dosage form in oral cavity which increases bioavailability, reduces gastric irritation and bypasses first pass metabolism. The acceptance for lozenges as a dosage form is high by adults and also more by children. Different types of lozenges available in market are compressed lozenges, hard lozenges & soft lozenges and their methods of preparation along with ingredients used in their preparation are discussed. The present review covers more or less all aspects associated with lozenges and also throws light on the applications of lozenges. It includes various researches performed till date, formulation and evaluation parameters, packaging and applications of lozenges.

**5. AIM AND OBJECTIVE**

**Aim:**

To formulate and evaluate herbal lozenges for effective treatment of mouth ulcers.

**Objectives:**

- To prepare herbal lozenges using natural herbal ingredients.
- To study the physicochemical properties of prepared lozenges.
- To evaluate hardness, friability, weight variation, thickness, and dissolution time.
- To assess Antimicrobial and anti-ulcer activity.
- To improve patient compliance using herbal therapy.

**Need of the Study:**

- Increasing prevalence of mouth ulcers.
- Demand for herbal and safer formulations.
- Need for prolonged local action in the oral cavity.
- Reduction of side effects associated with synthetic drugs

**6. MATERIAL AND METHODS**

**Ingredient Category Role**

Ingredient	Category	Role	Quantity
Jaggery (Base)	Sweetener/ Vehicle	Provides the bulk and structure	60 g
Honey	Demulcent/ Sweetener	Soothes the throat.	15 ml
Turmeric & Ginger	Active Ingredients	Anti-inflammatory and Antimicrobial Properties.	10 g
Tulsi Extract	Active Ingredient	Immune support and respiratory relief.	5 g
Menthol & Cinnamon oil	Flavouring/ Cooling	Improves palatability and provides a cooling Sensation.	2 ml
Citric acid	Preservatives	Prevents microbial and fungal growth.	1 g
water	solvent	vehicle	q.s

## PROCEDURE

### • Step-by-Step Manufacturing Procedure

- We will use the Heating and Congealing (Molding) Method:
- **Syrup Preparation:** Melt the jaggery with a very small amount of water in a Stainless steel vessel.



- **Concentration:** Add the Liquid Glucose and Honey. Heat the mixture. You need to reach the “hard crack stage,” which is exactly the 145°C – 155°C range you noted. This ensures the lozenge hardens properly upon cooling.



- **Incorporation of Actives:** Once the temperature starts to drop slightly (around 90°C), stir in your Turmeric powder, Ginger juice/extract, and Tulsi extract. Mix thoroughly to ensure uniform distribution.
- **Final Additions:** Add the preservatives (dissolved in a tiny amount of warm water or glycerin) and the Citric acid. Flavoring: Add

Menthol and Cinnamon oil at the very end (just before pouring) to minimize the loss of volatile oils due to heat.

- **Molding:** Pour the hot, viscous mass into pre-lubricated molds.

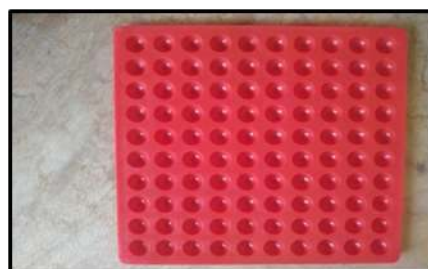


Fig. Mold

- **De-molding & Packaging:** Allow them to cool at room temperature. Once set, wrap them individually in foil or moisture-proof cellophane to prevent them from becoming sticky (as jaggery is very hygroscopic).



Fig. Packaging

## 7. RESULT

**1. Physical Observation:** The colour, odour, texture and taste of the lozenges were evaluated by direct observation.

### • Physical Evaluation

Sr.No.	Observation	Batch 1	Batch 2
1	Colour	Brown	Brown
2	Odour	Slightly sweet	Sweet
3	Texture	Hard	Hard
4	Taste	Sweet	Sweet

- Weight Variation:** Weight variation test is performed to calculate individual weight deviation from average weight calculated. Average weight = 2.500 g  
**Weight variation**

Weight Variation= Average weight-Individual weight/Average weight\*100

Sr. No.	Weight of Individual Lozenges(gm)		Percent Weight Variation (%)	
	Batch 1	Batch 2	Batch 1	Batch 2
1	1.525	2.510	88	99
2	1.498	2.485	87	99
3	1.520	2.530	88	98
4	1.525	2.470	88	98
5	1.553	2.505	87	99
6	1.623	2.490	87	99
7	1.543	2.520	87	99
8	1.525	2.447	88	99
9	1.546	2.515	87	99
10				

- Weight Variation**

Sr.No.	Observation	Batch 1	Batch 2	Inference
1	Average weight	13.650gm	2.500 gm	Acceptable weight variation limit lies between 85%-115%
2	Average weight variation	84%	90 %	

- Friability:** The friability of lozenges is used to evaluate shock absorption during transportation and is determined by using roche friability tester  
 Final weight= 24.890  
 $\% \text{ Friability} = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} * 100$

Initial weight= 25.010 for 10 g

**Friability test**

Sr. No.	Observation	Batch 1	Batch 2	Inference
1	Friability	1.2	0.48	Limit of friability upto 1%

- Hardness:** Hardness of the lozenges is determined by Monsanto hardness tester. **Hardness testing**

Sr. No.	Observation	Batch 1	Batch 2	Inference
1	Hardness	4.8 kg/cm <sup>2</sup>	5.9 kg/cm <sup>2</sup>	It should range from 4.4- 7.5 ± 0.5 kg/cm <sup>2</sup>

Sr. No.	Observation	Batch 1	Batch 2	Inference
1	Thickness	0.7 cm	0.8 cm	It should lie between 0.5-1cm
2	Diameter	1.7	1.8cm	It should lie between 1-1.5cm



- **Moisture Content:** Moisture content of lozenges is determined to check its stability on exposure to moisture by using moisture balance apparatus

Weight of empty dish+ sample after drying (W2)  
=65.18 gm

Weight of sample= 1.690 gm

Weight of empty dish+ sample before drying (W1)  
= 65.21gm

**%Moisture content**=  $W1 - W2 / W * 100$

Sr. No.	Content	Batch 1	Batch 2	Interference
1	Moisture content	1.9 %	1.3%	Moisture content should not be more than 1.5%

## 8. FUTURE SCOPE

- Clinical studies on patients.
- Development of sugar-free lozenges.
- Commercial scale-up of formulation.
- Advanced herbal combinations for faster healing

## 9. CONCLUSION

Herbal lozenges containing cinnamon, tulsi, ginger, turmeric, showed promising therapeutic potential in the treatment of mouth ulcers due to there antimicrobial, anti-inflammatory, and analgesic properties. which can reduce pain, prevent secondary infections, and promote healing by remaining in the mouth for extended contact. The formulation provided prolonged contact time in the oral activity; which may help in reducing pain and promoting ulcer healing.

## REFERENCES

1. Rina G. Maskare, Ayush P. Agrawal, Mayuri S. Pal, Jidnyasa R. Yerne, Megham Chaudhri, Anup R. Bawankar, Gaytri B. Sonkusre. A Review on New Herbal Remedies for treatment of Mouth Ulcer. Asian Journal of Pharmaceutical Research. 2022;
2. Preeti L, Magesh K, Rajkumar K, Karthik R (2011) Recurrent Aphthous stomatitis. J Oral Maxillofac Pathol 15: 252-256.
3. Pongissawaranun W, Laohapand PP (1991) Epidemiologic study on "Recurrent Aphthous stomatitis "in a thai dental patient population. Community Dent Oral Epidemiol 19: 52-53.
4. Shashy RG, Ridley MB (2000) Aphthous Ulcers: A difficult clinical entity. Amer J Otolaryngol 21: 389-393.
5. Wadhawan R, Sharma S, Solanki G, Vaishnav R (2014) Alternative medicine for Aphthous stomatitis: A Review. Int J Adv Case Rep 1: 5-10.
6. Munoz-Corcuera M, Esparza-Gomez G, Gonzalez-Moles MA, Bascones-Martinez A (2009) Oral ulcers: clinical aspects. A tool for dermatologists, Part I, Acute ulcers. Clin Exp Dermatol 34: 289-294.
7. Tarakji B, Gazal G, Al-Maweri SA, Azzeghaiby SN, Alaizari N (2015) Guideline for the diagnosis and treatment of "Recurrent Aphthous stomatitis "for dental practitioners. J Int Oral Health 7: 74-78.
8. InformedHealth.org - Overview: Canker sores (mouth ulcers), National Institutes of Health (NIH).
9. Revisited and innovative perspectives of oral ulcer - Frontiers.
10. Mouth ulcer - Wikipedia.



11. Mouth ulcers - Better Health Channel.
12. Oral Aphthae: Pathophysiology, Clinical Aspects and Medical... - PMC, National Institutes of Health (NIH).
13. Brozović S, Vučićević-Boras V, Buković D. Serum IgA, IgG, IgM and salivary IgA in recurrent Aphthae ulceration. *Coll Antropol.* 2001; 25(2):633–7.
14. Scully C, Porter S. Oral mucosal disease: recurrent Aphthae stomatitis. *Br J Oral Maxillofac Surg.* 2008; 46(3):198–206. Doi: 10.1016/j.bjoms.2007.07.201.
15. Brozović S, Vučićević-Boras V, Buković D. Serum IgA, IgG, IgM and salivary IgA in recurrent Aphthae ulceration. *Coll Antropol.* 2001; 25(2):633–7. [PubMed]
16. Scully C, Porter S. Oral mucosal disease: recurrent Aphthae stomatitis. *Br J Oral Maxillofac Surg.* 2008; 46(3):198–206. Doi: 10.1016/j.bjoms.2007.07.201.
17. Rina G. Maskare, Shital D. Thakre, Om D. Patle, Shirali S. Vishwakarma, Dhyanesh N. Dahake, Rima J. Jagnit, Rohit S. Rahangdale. Novel Formulation for Treatment of Mouth Ulcer. *Asian Journal Of Pharmacy and Technology*
18. Mahesh Babasaheb Kolap, Pratiksha Kisan Omase, Abhijeet Vijay Dashwant, Rutuja Shrikant Namde. Review on Lozenges. *Research Journal of Pharmacology and Pharmacodynamics*
19. Jurge S, Kuffer R, Scully C, Porter SR. Number VI Recurrent Aphthae stomatitis. *Oral Dis.* 2006; 12(1):1–21. Doi: 10.1111/j.1601-0825.2005.01143.x
20. Cui RZ, Bruce AJ, Rogers RS. Recurrent Aphthae stomatitis. *Clin Dermatol.* 2016; 34(4):475–481. Doi: 10.1016/j.clindermatol.2016.02.020
21. 16 Edition of Trease and Evans Pharmacognosy Text Book (Pg. No. :-283 )
22. <https://www.sciencedirect.com/science/article/pii/S2225411014000200>
23. Mahesh Babasaheb Kolap, Pratiksha Kisan Omase, Abhijeet Vijay Dashwant, Rutuja Shrikant Namde. Review on Lozenges. *Research Journal of Pharmacology and Pharmacodynamics*
24. Vikash Sharma, Vaquil. A review on medicinal Properties of neem (*Azadirachta indica*). *The Pharma Innovation Journal* 2018; 7(4): 648-650.
25. Jose Francisco Islas, Ezeiza Acosta, Zuca G-Buentello, Juan Luis Delgado-Gallegos, María Guadalupe Moreno-Treviño, Bruno Escalante, et al. An overview Of Neem (*Azadirachta indica*) and its potential impact On health, *Journal of Functional Foods*.<https://www.sciencedirect.com/science/article/pii/S1756464620303959>
26. Suchitra Pundir, Abhay Murari Lal Verma. Review on Lozenges. *Journal der PharmazieForschung*,2014.[https://www.researchgate.net/publication/63474102\\_Review\\_on\\_Lozenge19](https://www.researchgate.net/publication/63474102_Review_on_Lozenge19).
27. Deepak R, Sanjay S. Formulation and evaluation of antianthelmintic Chewable tablet. *Int Pharma Scientia.* 2012; 2(1): 13-26.
28. Allen LV. Troches and lozenges, *SecundumArtem.* Current and Practical Compounding Information for the Pharmacist. 2001; 4(2): 23-25.
29. *Research Journal of Pharmacy and Technology* 11 (4), 1307-1312, 2018
30. *Journal of Drug Delivery & Therapeutic* 8, 2018

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