

# Formulation and Evaluation of Herbal Lozenges for Sore Throat Treatment

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**Abstract:** Mouth ulcers are another issue that significantly impacts oral health and patient comfort. These lesions are breaks or ruptures in the mucous membrane lining the interior of the mouth, and they can appear anywhere within the oral cavity. The ulcer's appearance is typically yellow or white, with a depressed center that may cause significant discomfort.

This study focused on developing and testing fast-dissolving oral films comprising extracts of *Glycyrrhiza glabra* and *Moringa oleifera* for the treatment of mouth ulcers. The extracts were mixed into films made using the solvent casting method with a polymer using HPMC, Glycerine served as a plasticiser and sweetener. The films were tested for thickness, colour variation, weight variation, folding endurance, surface pH, % moisture uptake, percentage moisture loss, disintegration time, in vitro drug release, and stability.

The dry powder of *Glycyrrhiza glabra* and *Moringa oleifera* were used in this research. The film focused on the treatment of oral ulcer with improved bioavailability and patient compliance. The developed formulation can be the modern dosage form for the improvement of the drug release.

**Keywords:** *Glycyrrhiza glabra*, *Moringa oleifera* Mouth ulcer, Oral film, Solvent casting method, Improved bioavailability

## I. INTRODUCTION

### NEED OF INVESTIGATION:-

#### 1. Prevalence and Impact of Mouth Ulcers

Mouth ulcers, or aphthous stomatitis, are common lesions that cause significant discomfort, affecting eating, speaking, and overall quality of life. While they often resolve spontaneously, recurrent cases necessitate effective treatment options.

#### 2. Limitations of Conventional Treatments

Traditional treatments, including corticosteroids and antiseptics, may offer symptomatic relief but can be associated with side effects such as mucosal irritation or systemic absorption issues. Moreover, these treatments may not be suitable for all patient populations.

#### 3. Advantages of Herbal Therapies

Herbal remedies have been traditionally used for their anti-inflammatory, antimicrobial, and wound-healing properties. For instance, extracts from plants like *Moringa olifera* (Drumstick) and *Glycyrrhiza glabra* (Licorice) have demonstrated efficacy in promoting oral health and healing ulcers.

#### 4. Clinical Trials:

Large-scale, randomized controlled trials are necessary to establish the efficacy and safety profiles of herbal oral films compared to standard treatments

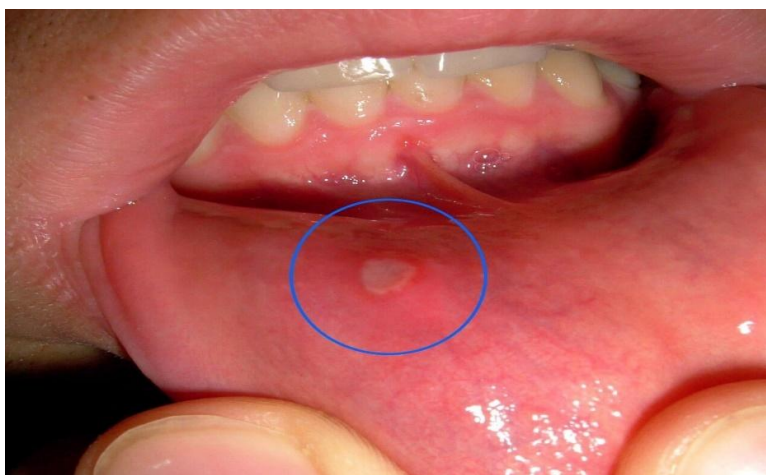
### Objective:-

- Targeted Drug Delivery: To deliver medication directly to the site of the ulcer for faster and more effective treatment.
- Pain Relief: To provide immediate or sustained relief from the pain associated with mouth ulcers.



- **Improved Patient Compliance:** To offer a convenient, easy-to-apply dosage form that doesn't require water or swallowing, especially beneficial for children and elderly patients.
- **Mucoadhesion:** To adhere to the mucosal surface, ensuring prolonged contact time at the site of the ulcer for better therapeutic effect.
- **Controlled Drug Release:** To allow for sustained or controlled release of the active pharmaceutical ingredient (API), reducing the frequency of application.
- **Protection of Ulcer Site:** To form a protective barrier over the ulcer, shielding it from irritation caused by food, saliva, or mechanical abrasion.
- **Minimized Systemic Side Effects:** To reduce the likelihood of side effects by localizing the drug action and minimizing systemic absorption.
- **Rapid Onset of Action:** To ensure that the therapeutic effect begins quickly after application.
- **Enhanced Stability:** To provide a stable formulation that extends the shelf-life of the active ingredients.

A mouth ulcer (aphtha), or sometimes called a canker sore or salt blister, is an ulcer that occurs on the mucous membrane of the oral cavity.[1] Mouth ulcers are very common, occurring in association with many diseases and by many different mechanisms, but usually there is no serious underlying cause. Rarely, a mouth ulcer that does not heal may be a sign of oral cancer. These ulcers may form individually or multiple ulcers may appear at once (i.e., a "crop" of ulcers). Once formed, an ulcer may be maintained by inflammation and/or secondary infection.



**Fig no.1 mouth ulcer**

Based on the duration ulcers can be broadly classified into acute (short term) or chronic (long term). Acute ulcers persist no more than three weeks and regress spontaneously such as traumatic ulcers, aphthous ulcers, herpetic ulcers and chancres. Chronic ulcers persist for weeks and months such as major aphthous ulcers, ulcers from odontogenic infection, malignant ulcers, gummas, ulcers secondary to debilitating systemic disease and some traumatic ulcers (with a persistent traumatic element)

### **Types of Mouth Ulcers:-**

#### **1. Minor ulcers (most common):**

- Small (less than 1 cm), oval, with a red edge
- Heal on their own in 7–10 days without scarring

#### **2. Major ulcers:**

- Larger and deeper
- May last several weeks
- Can leave scars after healing



### 3. Herpetiform ulcers:

- Tiny ulcers that appear in clusters (not caused by herpes virus)
- May merge into larger ulcers
- Painful and may recur frequently

Overview of the oral cavity:-

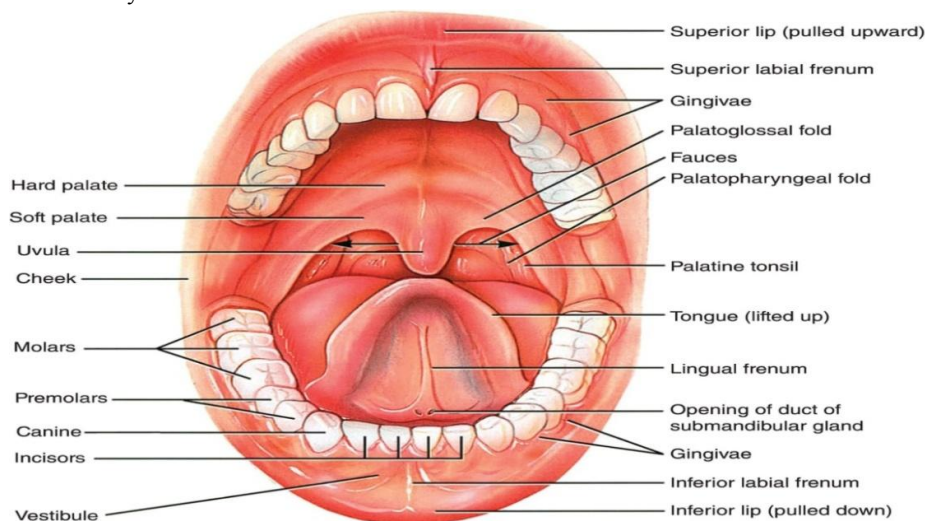


Fig no.2 Anatomy of oral mucosa

The basement membrane, lamina propria, submucosa, and stratified squamous epithelium are some of the layers that make up the oral mucosa. The oral mucosa is in between the intestine and epidermis in terms of permeability. Interestingly, the permeability of the buccal mucosa is 4–4000 times higher than that of the skin. Furthermore, because the oral mucosa varies in structure and function, different areas of the oral cavity have different amounts of permeability.

**Sublingual gland:-** Located under the tongue, the sublingual glands play a crucial role in saliva production, facilitating food lubrication, bolus formation, and swallowing. Additionally, these glands enable direct drug absorption into the systemic circulation due to their thinness, high permeability, and rich blood supply. The sublingual glands produce mucin, which contributes to saliva production, making them a vital component of the oral cavity. The oral cavity is lined with a mucous membrane composed of squamous cells and mucous glands, which facilitate saliva production through salivary glands, including the parotid, submandibular, and submaxillary glands. Saliva mixes with food, enabling easy chewing and swallowing. The absorption of drugs into systemic circulation is inversely proportional to the thickness of the absorption layer. The sublingual route offers the fastest absorption, followed by buccal, gingival, and palatal routes. Due to its high permeability and rich blood supply, the sublingual route enables rapid onset of action, making it suitable for drugs with short delivery periods and frequent dosing regimens.

### Mechanism of Absorption:-

Upon sublingual administration, drugs are rapidly absorbed into the bloodstream through the reticulated vein beneath the oral mucosa, bypassing the gastrointestinal tract. The absorbed drugs are then transported through the facial, internal jugular, and brachiocephalic veins, eventually draining into systemic circulation. This direct access to the bloodstream enables rapid absorption, with the sublingual route exhibiting 3-10 times greater absorption than the oral route, surpassed only by intravenous injection. The primary mechanism of drug absorption through the oral mucosa is passive diffusion across the lipoidal membrane.

### WHAT IS MOUTH DISSOLVING FILM ?

\* It is the film that disintegrates and dissolves rapidly in the saliva within a few seconds.



- \* There is no need of drinking water or chewing.
- \* They provide a variety of benefits over conventional dosage form such as tablets and capsules by removing swallowing issues and increases patient compliance.



Fig no.3 mouth dissolving oral film

#### **IDEAL PROPERTIES OF MOUTH DISSOLVING FILM :-**

1. It should easily dissolve and disintegrate
2. Have a pleasing taste
3. It should have ability to permeate through oral mucosal layer
4. It should be stable in water and saliva
5. Be less sensitive to environmental conditions like temperature and humidity
6. It should not require water and other liquid to swallow

#### **Ideal Characteristics of oral films :-**

- A thin, attractive film.
- It comes in a variety of sizes and forms
- It is unobtrusive.
- It has excellent mucoadhesion,
- It dissolves and releases quickly.

#### **Classification of oral films:-**

There are three different subtypes of oral films:

- Flash release wafers
- Mucoadhesive melt away wafers
- Mucoadhesive sustained release wafer .



Fig.no 4 Oral film

#### **Advantages of Mouth dissolving film: -**

1. No need of water to take oral film
2. Best for pediatric and geriatric
3. Convenient to administer during travelling without need of water
4. Quick onset of action and enhance efficacy
5. Excellent mouth feel property produced by use of flavors and sweeteners





6. Available in various sizes and shapes
7. Fast disintegration and dissolution
8. Taste masking
9. Enhanced stability
10. Small size for improved patient compliance
11. To avoid first pass metabolism

#### DRUG PROFILE:-



The plant materials of *Glycyrrhiza glabra*, *Moringa olifera* were collected from home premise. The collected roots of *Glycyrrhiza glabra*, leaves of *Moringa olifera* and dried under shade. honey used as sweetener. HPMC (Hydroxypropyl Methylcellulose) are used as polymer.it derived from cellulose. And quantity sufficient using water. After proper drying, all materials were grinded using mixer and the powders were passed through sieve no.120 to get a fine powder. This study was performed to expedite a new formulation and evaluation of formulated herbal oral film to know their effectiveness against the minor mouth ulcer problem.

*Glycyrrhiza glabra*:(Licorice root)



*Glycyrrhiza glabra*

1. Synonyms  
Common Names:-Licorice, Liquorice  
Other Names:-Sweetwood, Mulethi (Hindi), Gan Cao (Chinese)
2. Botanical Name :-*Glycyrrhiza glabra*
3. Family:- Fabaceae(Leguminosae)



**4. Description:-**

- Licorice is a perennial herb native to parts of Europe and Asia.
- It grows up to 1 meter tall with pinnate leaves having 9–17 leaflets.
- The flowers are purple to pale whitish-blue, and the fruit is a small pod containing several seeds.
- The root is the medicinal part, sweet in taste and brownish-yellow in color.

**5. Chemical Constituents:-**

- Glycyrrhizin(major active compound; sweet saponin glycoside)
- Glabridin(an isoflavone)
- Liquiritin and isoliquiritin(flavonoids)
- Glycyrrhetic acid
- Polysaccharides
- Coumarins(e.g., umbelliferone)
- Essential oils

**6. Medicinal Uses:-**

- Anti-inflammatory: Used in conditions like arthritis and eczema.
- Expectorant & demulcent: Helps in cough, sore throat, and bronchitis.
- Gastroprotective: Useful in treating ulcers and gastritis.
- Antiviral & antimicrobial: Effective against certain viruses and bacteria.
- Hepatoprotective: Supports liver function.
- Adaptogenic: Reduces stress and boosts adrenal function.

**2. DRUMSTICK TREE:-(*Moringa oleifera*)**



*Moringa oleifera*

**1. Synonyms:-**

Common Names:-Drumstick tree, Horseradish tree, Ben oil tree

Other Names:- Sahjan (Hindi), Munaga (Telugu), Murungai (Tamil), Malunggay (Filipino)

**2. Botanical Name:-**Moringa oleifera

**3. Family:-**Moringaceae

**4. Biological source:** Leaves, seeds, pods, bark, and roots of the plant Moringa oleifera

**5. Description:-**

- Moringa oleifera is a fast-growing, drought-resistant tree native to the Indian subcontinent.
- It can grow up to 10–12 meters tall.



- Leaves are feathery, tripinnate, and rich in nutrients.
- Flowers are fragrant, white, and borne in clusters.
- The fruits are long, slender pods known as drumsticks, commonly consumed as a vegetable.
- Almost every part of the plant is edible or used in traditional medicine.

**5. Chemical Constituents:-**

- Vitamins: A, B-complex, C, E
- Minerals: Calcium, Iron, Potassium, Magnesium, Zinc
- Amino acids: All essential amino acids
- Flavonoids: Quercetin, Kaempferol
- Phenolic compounds
- Glucosinolates and isothiocyanates
- Alkaloids
- Saponins and Tannins

**6. Medicinal Uses:-**

- Nutritional supplement: High in vitamins, minerals, and protein; used to combat malnutrition.
- Anti-inflammatory: Used in arthritis and inflammatory diseases.
- Antioxidant: Helps protect cells from oxidative stress.
- Antidiabetic: Supports blood sugar regulation.
- Antimicrobial: Effective against various bacteria and fungi.
- Cardioprotective: Helps manage cholesterol and blood pressure.
- Liver-protective: Aids in detoxification and liver health.
- Lactation aid: Used to increase milk production in nursing mothers.

**HONEY :-(MADHU)**



*HONEY*

Synonyms of Honey: Madhu (Sanskrit)

Biological Source:

Honey is a natural substance produced by honey bees (*Apis mellifera* and other *Apis* species) from the nectar of flowers or secretions of living parts of plants, which the bees collect, transform, and store in honeycombs

Family : Apidae

Medicinal Uses of Honey:

- Honey has been used in traditional and modern medicine for centuries due to its various therapeutic properties:
- Antibacterial and antiseptic: Due to hydrogen peroxide and low pH
- Wound healing: Promotes tissue regeneration and reduces infection (e.g., Manuka honey)
- Soothing cough and sore throat: Especially in children and during infections
- Antioxidant: Protects cells from oxidative stress
- Digestive aid: Mild laxative effect and prebiotic properties (supports gut flora)
- Energy source: Instant energy due to simple sugars



**Plan of work :**

- Literature survey
- Selection of herbal drugs
- Determine Active Constituent of Herbal Drug
- Selection of Excipients
- Selection of material and equipment
- Preparation of Formulation

**LITERATURE SURVEY**

1. Tranay Verma et.al (2024) : "Formulation of herbal oral film" This study focused on developing and testing fast-dissolving oral films comprising extracts of Licorice root and Moringa oleifera for the treatment of mouth ulcers. The extracts were mixed into films made using the solvent casting method with a polymers using HPMC . Glycerine served as a plasticiser and sweetener. (Tranay Verma et.al 2024)

2. Lamdade Shubhangi et.al (2024): "Formulation And Evaluation Of Mouth Dissolving Film Of Ocimum Tenuiflorum Linn. And Glycyrrhiza Glabra Linn. By Solvent Casting Method" from journal "International journal of creative research thoughts" These films are prepared by solvent casting method. These films have several advantages over normal conventional dosage forms. They deliver the drug at target site so dose frequency is reduced, it avoids the hepatic first pass metabolism and due to this the bioavailability is enhanced. (Lamdade Shubhangi et.al 2024)

3. Raghvendr Kumar Yadav et.al (2021): "A Review on Mouth Ulcer and Its Various Treatment" An oral ulcer is a sore that develops on the oral cavity's membrane. "A breach within the mucosal surface of the buccal cavity," according to the definition. Ulcers are uncovered sores of the surface or mucous membrane in which inflammatory dead tissue is removed. Despite their significant incidence, the etiopathogenesis of many diseases is unknown. It's frequently painful, and it's accompanied by redness, swelling, and bleeding in the affected area. The mouth ulcer commonly causes pain and discomfort, and it might affect a person's eating preferences as it heals. According to how they present and progress, they might be classed as acute or chronic. (Raghvendr Kumar Yadav et.al.,2021)

4. Pratiksha Vadde et.al (2023): "Preparation and evaluation of herbal mouth ulcer gel: A Research" from the journal of International Journal of Research in Pharmacy and Pharmaceutical Sciences In comparison to conventional medications, an Indian medicinal plant has a greater variety of pharmacological activity, is safer for the body, and is easier to obtain. Several types of herbs, including guava, betel, amla, neem, tulsi, mentha, curcumin, honey, etc., are utilised in gel formulations to treat mouth ulcers. They exhibit a range of qualities, including those that are antiseptic, antibacterial, anaesthetic, antioxidant, anti-inflammatory, relaxing, and ulcer healing. The condensed mass and liquid that are interpenetrated by the solid or semisolid system that makes up the pharmaceutical gel preparation are at least two different components. The herbal remedy is superior to the synthetic remedy in terms of effectiveness. (Pratiksha vadde et.al.,2023)

5. Anowaar Z. Abo-shady et.al (2020): "Formulation and clinical evaluation of mucoadhesive buccal films containing hyaluronic acid for treatment of aphthous ulcer" from journal of "drug delivery science and technology" The prepared HA films were evaluated for their physicochemical properties including folding endurance, surface pH, thickness, mucoadhesion properties, tensile strength and in vitro drug release. (Anowaar Z.Abo-shady et.al.,2020).

**MATERIALS AND METHODS**

**INGREDIENT AND ROLE:**

Sr.no	INGREDIENT	ROLE
1	Glycyrrhiza glabra extract	antiulcer
2	Moringa oleifera extract	antiulcer
3	Glycerine	plasticizer
4	HPMC E15	Film forming agent
5	Honey	Sweetening agent





6	Water	vehicle
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Table no.1

**FORMULATION TABLE OF HERBAL ORAL FILM :-**

Sr.no	INGRIDIENTS	F1	F2	F3
1	Glycyrrhiza glabra extract(mg)	10mg	10mg	10mg
2	Moringa oleifera extract(mg)	8mg	8mg	8mg
3	Glycerine(ml)	2ml	2ml	2ml
4	HPMC E15(mg)	20mg	18mg	20mg
5	Honey(ml)	2ml	3ml	2ml
6	Water	q.s	q.s	q.s

Table no.2

**EXTRACTION PROCESS:-**

extraction process for Licorice (*Glycyrrhiza glabra*) root powder and Moringa oleifera (Drumsticks) powder  
Water Decoction Extraction (Traditional Method)

**Materials:**

- \* Licorice root powder and Moringa oleifera powder (dried and finely ground)
- \* Distilled water
- \* Heating vessel (stainless steel or glass)
- \* Heating source
- \* Stirring rod
- \* Filter (filter paper)
- \* Storage container

**Procedure:**

1. Weigh the Licorice Powder: 50 grams of licorice root powder and Moringa oleifera powder
2. Add Water: Add 10 times the volume of water ( 500 mL of distilled water).
3. Boiling: Boil gently for 30–60 minute with occasional stirring.  
Avoid vigorous boiling to preserve sensitive compounds.
4. Cooling: Let it cool naturally to room temperature.
5. Filtration: Filter the decoction to remove residues.
7. Storage: Store in airtight containers, preferably amber bottles.  
Refrigerate if no preservatives are added; use within 3–5 days.





Moringa powder extraction



Licorice root powder extraction

Solvent casting method to formed herbal oral film

1. Preparation of the Polymer Solution

- \* Weigh the required amount of film-forming polymer(HPMC E15)
- \* Dissolve the polymer(HPMC E15) in the solvent (e.g., distilled water or ethanol-water mixture).
- \* Stir the solution continuously (using a magnetic stirrer) until a clear, homogeneous solution is obtained.
- \* Let it stand for some time to remove air bubbles.

2. Addition of Plasticizer

- \* Add a suitable plasticizer (like glycerin) to improve film flexibility.
- \* Stir thoroughly to ensure uniform mixing.

3. Incorporation of Herbal Extract

- \* Accurately weigh the required amount of herbal extract.
- \* Dissolve or disperse it in a small quantity of solvent.
- \* Add it slowly to the polymer-plasticizer solution while stirring.

4. Addition of Optional Ingredients

- \* Add sweeteners, flavors as desired.
- \* Mix thoroughly to get a uniform mixture.

5. Casting the Solution

- \* Pour the final solution into a clean, leveled Petri dish or casting plate.
- \* Spread evenly using a glass rod or a doctor blade to achieve uniform thickness.

6. Drying

- \* Dry the cast film in a controlled environment (e.g., 40–45°C in a hot air oven or at room temperature).
- \* Dry until the solvent completely evaporates (typically 24–48 hours).

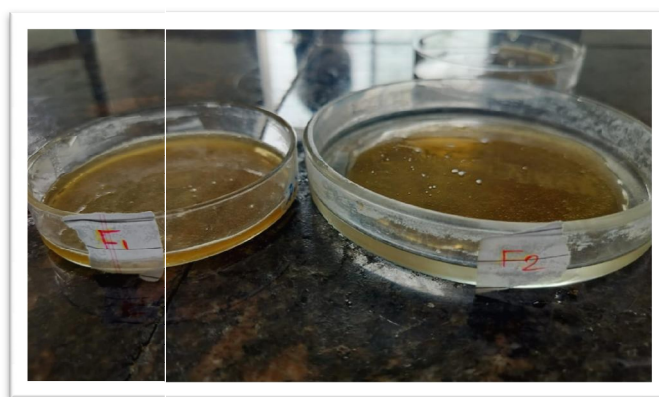
7. Film Cutting and Packaging

- \* Once dried, carefully remove the film from the casting surface.
- \* Cut into desired sizes (usually 2×2 cm or 2×3 cm).
- \* Store in airtight, moisture-proof packaging.





Casting process



Solvent in petri dish



Herbal oral film

#### Evaluation Tests :

##### 1. Morphological properties

Visual observations were made of the morphological characteristics, such as the homogeneous nature of the films, color, transparency, and surface texture. All the formulations were stored at room temperature  $25 \pm 30$  °C in air-tight containers.



## 2. Weight variation

Films can be weighed on an analytical balance to determine the average weight for each film. It is helpful in ensuring that a film includes the appropriate amount of excipients and medication.

## 3. Folding Endurance

The folding endurance of the film was evaluated by folding a tiny strip of film (2x2cm<sup>2</sup>) repeatedly until it broke. The number of times that the film could be folded at the same place without breaking gives the value of folding endurance.

## 4. Surface pH

The film kept in a Petri dish was moistened with 5 ml of distilled water and kept for a few minutes. The pH was noted after bringing the electrode of the pH meter in contact with the surface of the formulation and allowing equilibration for 1 min 19s.

## 5. Disintegration time

In vitro disintegration time was determined visually in a glass beaker. 25 ml distilled water maintained at 37°C is taken in the beaker and the OFDF strip was added. The time taken for the film to disintegrate is noted.

## 6. Stability studies

The accelerated stability was checked by keeping the film at room temperature up to 30 days. Samples were evaluated for assay and drug release.

## RESULT AND DISCUSSION:-

Sr.no	Test	F1	F2	F3
1	Morphological properties			
a	colour	Pleasant	Pleasant	Pleasant
b	odour	Pleasant	Pleasant	Pleasant
c	Surface texture	Smooth	Smooth	Smooth
2	Weight variation	Fail	Pass	Pass
3	Folding endurance	4	3	5
4	Surface pH	8	7.5	7.1
5	Disintegration time	0.43	0.5	0.37
6	Stability studies	Stable	Stable	Stable

## II. CONCLUSION

The primary objective of the present study was the formulation and evaluation of a mouth-dissolving film containing *Moringa oleifera* and *Glycyrrhiza glabra* for the treatment of mouth ulcers. The plant extracts were obtained using the maceration method and were found to contain beneficial phytoconstituents such as fixed oils, saponins, tannins, and flavonoids. Multiple film formulations were prepared using various polymers, including HPMC E15, along with suitable plasticizers.

The resulting films exhibited good appearance and a smooth texture. Among the different batches, the F3 batch demonstrated optimal thickness and stability. Based on the results of this study, it can be concluded that *Moringa oleifera* and *Glycyrrhiza glabra* can be effectively formulated into mouth-dissolving films for potential therapeutic use in treating mouth ulcers.

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