

# A Review on Formulation and Evaluation of Herbal Mouth Ulcer Gel Using Ocimum Sanctum

Nikita Shelke<sup>1\*</sup>, Rudresh R. Ratnaparkhe<sup>1</sup>, Sanny Shah<sup>2</sup>, Disha Kandalkar<sup>2</sup>, Sayli Kote<sup>2</sup>

Department of Pharmaceutics<sup>1</sup>

Rashtrasant Janardhan Swami College of Pharmacy, Kokamthan, Ahilyanagar, Maharashtra, India.

Corresponding Author: Nikita Shelke

E-mail: balpanderenuka3@gmail.com

**Abstract:** Mouth ulcers are among the most common painful lesions affecting the oral cavity and are associated with inflammation, infection, nutritional deficiencies, stress, and impaired immunity. Conventional therapies provide symptomatic relief but are often associated with adverse effects and recurrence. Herbal medicines have gained considerable attention because of their safety, affordability, and therapeutic efficacy. Among medicinal plants, *Ocimum sanctum* Linn. (Tulsi), commonly known as Holy Basil, occupies an important position in traditional medicine due to its antimicrobial, anti-inflammatory, antioxidant, and wound-healing properties.

Tulsi contains several biologically active constituents including eugenol, ursolic acid, rosmarinic acid, flavonoids, tannins, and phenolic compounds which contribute to its medicinal activities. Incorporation of Tulsi extract into a gel formulation provides prolonged contact with the ulcer surface and enhances therapeutic effectiveness. Herbal mouth ulcer gels prepared with natural ingredients such as honey, glycerin, coconut oil, guar gum, and peppermint oil provide soothing action, reduce inflammation, inhibit microbial growth, and accelerate tissue regeneration.

The present review highlights the causes and pathophysiology of mouth ulcers, phytochemistry of *Ocimum sanctum*, pharmacological activities, formulation approaches, evaluation parameters, recent research studies, advantages, limitations, and future perspectives of Tulsi-based herbal mouth ulcer gel. The review emphasizes the potential of herbal formulations as a safe and effective alternative to synthetic preparations for the management of oral ulcers.

**Keywords:** *Ocimum sanctum*, Tulsi, Mouth Ulcer, Herbal Gel, Oral Drug Delivery, Antimicrobial Activity, Wound Healing, Phytoconstituents

## I. INTRODUCTION

Herbal medicine has gained significant importance in recent years owing to its therapeutic efficacy and comparatively fewer adverse effects. Medicinal plants are rich sources of bioactive constituents that possess antimicrobial, anti-inflammatory, antioxidant, and wound-healing properties, making them useful for the management of various oral disorders.

Mouth ulcers, commonly known as aphthous ulcers, are small painful lesions that occur on the mucosal surfaces of the oral cavity such as the tongue, cheeks, lips, and gums. These ulcers are associated with discomfort, burning sensation, and difficulty in eating and speaking. Several factors including nutritional deficiencies, emotional stress, hormonal changes, trauma, microbial infections, and systemic conditions are considered responsible for the occurrence of oral ulcers.

Although conventional medications such as corticosteroids, analgesics, antiseptics, and antibiotics are commonly employed for the treatment of mouth ulcers, prolonged use of these agents may lead to undesirable side effects. Consequently, the use of herbal remedies has increased due to their safety profile, cost-effectiveness, and improved patient acceptability.



Ocimum sanctum is one of the most widely used medicinal plants in traditional systems of medicine. It possesses diverse pharmacological activities including antimicrobial, anti-inflammatory, antioxidant, and wound-healing effects. These therapeutic properties are mainly attributed to the presence of various phytoconstituents such as flavonoids, tannins, phenolic compounds, alkaloids, and essential oils.

Formulation of Tulsi extract into a gel dosage form provides advantages such as easy application, enhanced contact time with the affected area, improved therapeutic efficacy, and targeted local action. Therefore, Tulsi-based herbal mouth ulcer gel may serve as a promising and safer approach for the effective management of oral ulcers.



Fig. 1 Mouth ulcer

#### **Causes of Mouth Ulcers**

- Nutritional deficiencies
- Stress and anxiety
- Hormonal changes
- Mechanical trauma and injuries
- Viral, bacterial, and fungal infections
- Autoimmune disorders
- Genetic predisposition
- Poor oral hygiene
- Tobacco and alcohol consumption

#### **Symptoms of Mouth Ulcers**

- Pain
- Burning sensation
- Difficulty in swallowing
- Inflammation
- Redness and irritation

#### **Classification of Mouth Ulcers**

- Minor aphthous ulcer
- Major aphthous ulcer
- Herpetiform ulcer



### **Classification of Gels**

#### **1. Based on Nature of Dispersed Phase**

- Single phase gels
- Two phase gels

#### **2. Based on Route of Administration**

- Topical gels
- Oral gels
- Ophthalmic gels
- Nasal gels
- Vaginal gels
- Rectal gels

#### **3. Based on nature of solvent**

- Hydrogels
- Organogels
- Xerogels

#### **4. Based on Source of Gelling Agent**

- Natural polymers
- Semi-synthetic polymers
- Synthetic polymers

#### **5. Based on Drug Release**

- Immediate release gels
- Sustained release gels

### **Advantages**

- Quick pain relief.
- Reduces inflammation & swelling.
- Speeds up ulcer healing
- Kills bacteria & prevents infection
- Soothes burning & irritation
- Natural and safe ingredients
- Keeps ulcer moist
- Easy to apply and spreads well

### **Taxonomical Classification**

**Kingdom:** Plantae

**Division:** Magnoliophyta

**Class:** Magnoliopsida

**Order:** Lamiales

**Family:** Lamiaceae

**Genus:** Ocimum

**Species:** Ocimum sanctum

### **Vernacular Names**

- English
- Hindi
- Marathi
- Sanskrit
- Kannada



- Siddha



#### **Phytochemicals constituents**

1. **Alkaloids:** Alkaloids are important bioactive compounds present in *Ocimum sanctum*. They contribute to the medicinal properties of the plant and are generally identified by Dragendorff's and Mayer's tests.
2. **Flavonoids:** Flavonoids are natural antioxidants present in Tulsi that help protect cells from oxidative stress. These compounds are commonly detected by the Shinoda test.
3. **Tannins:** Tannins possess astringent and antimicrobial properties and play an important role in wound healing. Their presence is confirmed by the ferric chloride test.
4. **Saponins:** Saponins exhibit antimicrobial and anti-inflammatory activities. They are usually identified by the foam test.
5. **Glycosides:** Glycosides are biologically active compounds that contribute to the therapeutic effects of Tulsi. They are detected by Keller-Killiani test.
6. **Phenolic Compounds:** Phenolic compounds are known for their antioxidant activity and help in reducing inflammation. These compounds are identified by ferric chloride test.
7. **Steroids:** Steroidal compounds present in Tulsi exhibit anti-inflammatory activity and are detected by Liebermann-Burchard test.
8. **Carbohydrates and Proteins:** Carbohydrates provide energy, whereas proteins are essential for tissue repair and healing. They are identified by Molisch's test and Biuret test, respectively.

#### **Mechanism of Mouth Ulcer Formation**

Pathophysiology of Mouth Ulcer

Tissue injury or stress initiates inflammation.

Release of inflammatory mediators such as prostaglandins and cytokines.

Infiltration of neutrophils and lymphocytes.

Breakdown of epithelial layer.



Formation of painful ulcer with erythematous border.

Secondary microbial infection may delay healing.

### **Mechanism of Action of Tulsi Mouth Ulcer Gel**

#### **1.Antimicrobial Mechanism**

Eugenol damages bacterial cell membrane.

Inhibits microbial growth and colonization.

#### **2.Anti-inflammatory Mechanism**

Reduces prostaglandin synthesis.

Suppresses inflammatory mediators.

#### **3.Antioxidant Mechanism**

Neutralizes free radicals.

Prevents oxidative damage.

#### **4.Wound Healing Mechanism**

Stimulates collagen synthesis.

Promotes epithelial regeneration.

Accelerated tissue repair .

**Table 1**

| Sr.no | Ingredients      | Use                                 |
|-------|------------------|-------------------------------------|
| 1     | Tulsi extract    | Antimicrobial and anti-inflammatory |
| 2     | Corn starch      | Stabilizer                          |
| 3     | Gaur gum         | Gelling agent                       |
| 4     | Glycerine        | Humectant                           |
| 5     | Peppermint oil   | Analgesic and cooling effect        |
| 6     | Rose water       | Flavouring agent                    |
| 7     | Honey            | Preservatives                       |
| 8     | Coconut oil      | Moisturing and soothing effect      |
| 9     | Beetroot extract | Colouring agent                     |
| 10    | Distilled water  | Vehicle                             |

### **Evaluation Parameters**

#### **1.Physical Appearance**

The colour , consistency, and smell of the herbal gel were assessed. They have an opaque, light pink appearance, no grittiness, and a uniformly distributed

#### **2.pH Determination**

For pH determination a standard digital pH meter was used. 1.0g gels was weighed and dissolved in 100ml of distilled water and it was stored for 2 hrs. The pH of each gel formulation was noted 14.

#### **3.Homogeneity**

A small quantity of the formulation was taken on a clean glass slide and spread evenly. The sample was first observed visually for colour, uniformity, smoothness, and absence of lumps. Then the slide was examined under a microscope to check for fine particles or any grittiness. The formulation was checked for uniform distribution of all ingredients without separation.

#### **4.Spreadability**

The spreadability of gel formulations was determined by measuring the spreading diameter of 1g of gel between Two horizontal slides. Spreadability was calculated by following formula

Formula:

$$S = M \times L / T$$

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Where,

S = Spreadability

M = Weight tied to upper slide

L = Length of glass slide

T = Time required to separate slides

#### **5. Viscosity**

Viscosity of the gel was determined using a Brookfield viscometer at room temperature, and the readings were recorded in centipoise (cP).

#### **6. Extrudability**

Extrudability of the gel was evaluated by measuring the ease with which the formulation was extruded from the tube under applied pressure.

#### **7. Washability Test**

Apply a small amount of gel on the skin, Wash gently with plain water, Observe whether the gel is easily washable or leaves residue.

#### **8. Irritancy Test**

Apply the gel on the inner forearm .Observe for 15-20 minutes. Check for redness, itching, burning, or swelling. No reaction = Non-irritant.

#### **9. Stability Studies**

Store the gel at room temperature and refrigerator conditions for 3 days. Check daily for color, odor, pH, phase separation, and consistency. No change Stable formulation.

#### **10. Phase Separation**

Prepared cream was kept in a closed container at a temperature of 25-100 °C away from light. Then phase separation was checked for 24 h for 30 d. Any change in the phase separation was observed/checked..

#### **11. Greasiness**

Here the cream was applied on the skin surface in the form of smear and checked if the smear was oily or grease-like.

#### **12. Antimicrobial Activity**

Antimicrobial activity of the gel was evaluated against selected microorganisms using the agar diffusion method by measuring the zone of inhibition

#### **13. Accelerated Stability Studies**

Accelerated stability studies were performed by storing the gel under specified temperature and humidity conditions, and evaluating its physical and chemical stability over time.

#### **Future Perspectives**

Mucoadhesive herbal gels.

Nano-herbal formulations.

Controlled release gels.

Combination herbal therapy.

Clinical trials for safety and efficacy.

## **II. CONCLUSION**

Herbal formulations have gained considerable attention due to their safety, efficacy, and minimal side effects. Ocimum sanctum (Tulsi) possesses significant antimicrobial, anti-inflammatory, antioxidant, and wound-healing properties, making it a promising medicinal plant for the management of mouth ulcers. Incorporation of Tulsi extract into a gel formulation provides prolonged contact with the affected area and enhances therapeutic effectiveness. This review highlights the causes of mouth ulcers, phytochemical constituents and pharmacological activities of Tulsi, formulation aspects, and evaluation parameters of herbal mouth ulcer gel. Overall, Tulsi-based mouth ulcer gel represents a safe,



economical, and effective alternative to conventional therapies. However, further standardization and clinical studies are necessary to establish its therapeutic potential and ensure its wider application in oral healthcare.

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#### **Conflict of Interest**

The authors declare that there is no conflict of interest regarding the publication of this review article.

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