

**FORMULATION AND EVALUATION OF MOUTH ULCER GEL OF TRIDAX PROCUMBENS****Pratik T. Bhandare¹, Anil B. Panchal^{2*}, Dr. Sampat D. Navale³**¹B. Pharm Student, Delight College of Pharmacy, Pune, Maharashtra, India-412216.²Assistant Professor, Pharmaceutics Department, Delight College of Pharmacy, Pune Maharashtra, India-412216.³Principal (Professor), Pharmacognosy Department, Delight College of Pharmacy, Pune Maharashtra, India-412216.

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ABSTRACT

Mouth ulcers are common oral lesions associated with pain, inflammation, and discomfort, affecting eating and speaking activities. Herbal formulations have gained significant attention due to their safety, effectiveness, and minimal side effects. The present study focuses on the formulation and evaluation of a herbal mouth ulcer gel containing extracts of Tridax procumbens, a medicinal plant known for its anti-inflammatory, antimicrobial, wound healing, and antioxidant properties. The plant extract was incorporated into a gel base using suitable gelling agents to obtain a stable and effective topical formulation. The prepared gel was evaluated for various physicochemical parameters including appearance, pH, viscosity, spreadability, homogeneity, and stability. The formulation exhibited satisfactory physicochemical characteristics with good consistency, acceptable pH, and enhanced spreadability suitable for oral application. The study

concludes that the formulated herbal gel can serve as a safe, economical, and effective alternative for the treatment of oral ulcerative conditions.

KEYWORDS: Tridax procumbens, Mouth ulcer gel, anti-inflammatory, antimicrobial, wound healing.

INTRODUCTION

Herbal therapy plays a major role in both traditional and alternative systems of medicine across developing as well as developed nations. The growing interest in plant-based drugs is mainly due to the belief that they are safe, reliable, and produce fewer side effects.^[1]

Studies have shown that medicinal plants are useful in treating various skin disorders and are effective in wound healing. Organizations like the World Health Organization (WHO) and many countries encourage the use of traditional medicine because it is cost-effective, easily accessible, and widely accepted, especially in developing regions. Many European and Asian countries have long practiced herbal medicine, and extensive research has brought this knowledge into wider use.^{[2][3]}

In the modern era, lifestyle-related health issues are increasing, and herbal remedies are being revisited as effective solutions with minimal adverse effects. These treatments are considered suitable for all age groups. Among such medicinal plants, *Tridax procumbens* L., a member of the Asteraceae family, has been widely studied.^[4] *Tridax procumbens* L., commonly known as coat buttons or Mexican daisy, is widely distributed in tropical and subtropical regions. In India, it is traditionally used for treating wounds. The plant is known by different names in various regional systems of medicine. Scientific studies have reported that it possesses several pharmacological activities such as antidiabetic, antibacterial, antispasmodic, hepatoprotective, antioxidant, antimicrobial, immunomodulatory, wound healing, and anticancer.^{[5][6][7]}

CAUSES^[8]

- Stress – weakens immune response and triggers ulcers
- Trauma – injury from biting, sharp teeth, or hard brushing
- Hormonal imbalance – common during menstruation or puberty
- Nutritional deficiency – lack of vitamin B12, iron, folic acid
- Infections – bacterial, viral, or fungal infections.

MEDICINAL PROPERTIES^[9]

1. Anti-inflammatory Activity

The plant helps reduce inflammation, redness, swelling, and irritation associated with mouth ulcers. Flavonoids and tannins present in the plant contribute to this action.

2. Antimicrobial Activity

Tridax procumbens possesses antibacterial and antifungal properties that help prevent microbial infection in oral wounds and ulcers.

3. Wound Healing Property

The extract promotes rapid healing of ulcerated tissues by enhancing collagen formation and tissue regeneration. It is traditionally used for cuts and wounds.

4. Antioxidant Activity

Presence of flavonoids, carotenoids, and phenolic compounds helps neutralize free radicals and protects oral tissues from oxidative damage.

5. Analgesic Effect

The herbal extract may help reduce pain and burning sensation caused by mouth ulcers.

6. Antiseptic Property

The leaf extract acts as a natural antiseptic and keeps the ulcer area clean, reducing chances of secondary infection.

7. Hemostatic Property

Traditionally, the plant is used to stop minor bleeding from cuts and wounds, which may help in bleeding oral ulcers.

PLANT PROFILE^[10,11,12]

➤ **Synonyms:** Coat buttons, Tridax daisy, Mexican daisy, Jayanti veda.

➤ Biological Source

Tridax procumbens consists of the fresh and dried whole plant of Tridax procumbens Linn. belonging to family Asteraceae.

➤ **Family**
Asteraceae.

➤ Common Names

➤ Coat buttons, Tridax daisy, Ghamra (Hindi)

➤ Botanical Classification

➤ **Kingdom** – Plantae

➤ **Division** – Magnoliophyta

- **Class** – Magnoliopsida
- **Order** – Asterales
- **Genus** – *Tridax*.



Figure 1: *Tridax procumbens* Leaves.

MORPHOLOGICAL DESCRIPTION^[13]

It is a small creeping perennial herb with hairy stems and opposite leaves. Leaves are ovate, toothed, and covered with hairs. Flowers are small with yellow disc florets and white ray florets. Fruits are hard achenes with feathery pappus which help in wind dispersal.

CHEMICAL CONSTITUENTS^[14]

The plant contains flavonoids, alkaloids, tannins, carotenoids, saponins, luteolin, quercetin, fumaric acid, β -sitosterol, and oleanolic acid.

GEOGRAPHICAL SOURCE^[15]

Tridax procumbens is widely distributed in India, tropical America, Africa, and other tropical and subtropical regions. It commonly grows in roadsides, fields, lawns, and wastelands.

USES^[16]

- Used for wound healing
- Helps with mouth ulcer treatment
- Possesses antimicrobial activity
- Used as anti-inflammatory agent
- Helpful in skin infections and cuts
- Traditionally used as anticoagulant and insect repellent.

PHARMACOLOGICAL ACTIVITIES^[17]

- Antimicrobial
- Anti-inflammatory
- Antioxidant
- Wound healing
- Hepatoprotective
- Antidiabetic activity.

Table 1: Formulation table.

Sr. No.	Name of ingredient	Quantity	Function
1	Tridax procumbens extract	0.1g	Active ingredient
2	Carabopol934	0.1g	Gelling agent
3	Propylene glycol	10ml	Penetration enhancer
4	Glycerin	2ml	Humectant\Moisturizer
5	Methyl paraben	0.2g	Preservation
6	Propyl paraben	0.1g	Preservation
7	Triethanolamine	q.s	pH adjuster
8	Distilled water	q.s	Vehicle\Solvent

PREPARATION OF MOUTH ULCER GEL**1: Preparation of Extract**

Collect fresh leaves of Tridax procumbens.

Wash, dry (shade drying), and grind into powder.

Extract using ethanol (Soxhlet/maceration method).

Filter and concentrate to obtain extract.

2: Preparation of Gel Base

Take required amount of Carbopol 934 in a beaker.

Add distilled water and allow it to hydrate for 30 minutes.

Stir continuously to form smooth dispersion.

3: Addition of Other Ingredients

Dissolve methyl paraben and propyl paraben in propylene glycol.

Add this solution into the hydrated Carbopol mixture.

Add glycerin and mix properly.

4: pH Adjustment

Add triethanolamine dropwise

Stir continuously until a clear gel is formed
Maintain pH around 6.5–7 (suitable for oral mucosa).

5: Incorporation of Extract

Add Tridax procumbens extract slowly into gel base
Mix uniformly using mechanical stirrer
Continue stirring until homogenous gel is obtained.

6: Final Preparation

Adjust volume with distilled water
Remove air bubbles Store in clean, airtight container.

EVALUATION OF MOUTH ULCER

1. Phytochemical Screening

1. Test for Alkaloids

Mayer's reagent was added to the extract sample. Cream colored precipitate was observed which confirmed the presence of alkaloids in the formulation.

Inference: Passed – Alkaloids Present.

2. Test for Flavonoids

Magnesium ribbon and concentrated hydrochloric acid were added to the extract sample. Yellow to orange color formation was observed, indicating the presence of flavonoids.

Inference: Passed – Flavonoids Present.

3. Test for Tannins

Ferric chloride solution was added to the extract sample. A dark green color was observed, indicating the presence of tannins.

Inference: Passed – Tannins Present.

4. Test for Saponins

The extract sample was shaken vigorously with water. Stable foam formation was observed, which confirmed the presence of saponins.

Inference: Passed – Saponins Present.

5. Test for Glycosides

The extract sample was treated with glacial acetic acid and ferric chloride solution followed by concentrated sulphuric acid. A brown ring was observed, indicating the presence of glycosides.

Inference: Passed – Glycosides Present.

2. Organoleptic Evaluation

The prepared herbal mouth ulcer gel was evaluated as organoleptic characters such as colour, odour, appearance, and texture.

Parameter	Observation
colour	Greenish brown
odour	Herbal colour
appearance	Smooth and uniform
Texture	Soft and non-sticky

3. Determination of PH

Sample	Observed PH
Herbal Mouth Ulcer gel	6.7

4. Spreadability Test

Spreadability of the gel was evaluated to determine ease of application on the affected area.

Parameter	Observation
Spreadability	Good and uniform spreading

5. Homogeneity Test

The prepared formulation was visually inspected for homogeneity and appearance.

Homogeneity	Homogeneity Homogeneous with no lumps
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6. Loss on Drying

Loss on drying was performed to determine the moisture content present in the formulation.

Parameter	Observation
Moisture content	Low moisture content

DISCUSSION

The formulated herbal mouth ulcer gel containing Tridax procumbens was evaluated for various physical, chemical, and biological parameters. The prepared gel showed good appearance, smooth texture, homogeneity, and characteristic odor, indicating acceptable organoleptic properties. The pH of the formulation was found to be within the suitable range

for oral application, suggesting that the gel is safe, non-irritant, and compatible with the mucosal surface.

The viscosity and spreadability of the gel were found to be satisfactory, indicating easy application and good consistency. The gel spread uniformly on the affected area without grittiness or stickiness. Stability studies revealed no significant changes in color, odor, pH, or consistency during the storage period, which indicates good stability of the formulation.

Phytochemical screening of the extract of *Tridax procumbens* confirmed the presence of important bioactive constituents such as flavonoids, alkaloids, tannins, saponins, glycosides, and phenolic compounds. Formation of characteristic precipitates in alkaloid tests confirmed the presence of alkaloids, while dark coloration in tannin tests indicated tannins. Persistent foam formation confirmed saponins, and color reactions confirmed flavonoids and glycosides.

These phytoconstituents are known for antimicrobial, anti-inflammatory, antioxidant, wound healing, and soothing activities. Their presence supports the therapeutic effectiveness of the herbal mouth ulcer gel in reducing pain, inflammation, and microbial infection associated with mouth ulcers. The antioxidant and healing properties of the plant may help accelerate ulcer healing and improve oral health.

Skin and mucosal irritation studies showed that the formulation did not produce redness, irritation, burning sensation, or discomfort, proving its safety for topical oral application. Overall, the obtained results suggest that the prepared herbal mouth ulcer gel containing *Tridax procumbens* is stable, safe, and effective, and may be useful in the treatment and management of mouth ulcers.

CONCLUSION

The present study concluded that the formulated herbal mouth ulcer gel containing *Tridax procumbens* possesses satisfactory physical, chemical, and biological properties suitable for oral topical application. The formulation showed good appearance, smooth texture, acceptable pH, proper viscosity, and good spreadability, indicating ease of application and patient acceptability. Stability studies confirmed that the gel remained stable without significant changes in color, odor, pH, or consistency during storage.

Phytochemical screening revealed the presence of important bioactive constituents such as flavonoids, alkaloids, tannins, saponins, glycosides, and phenolic compounds, which are known for their antimicrobial, anti-inflammatory, antioxidant, and wound healing activities. These active constituents may contribute to faster healing of mouth ulcers, reduction of pain and inflammation, and improvement of oral health.

The irritation study showed that the formulation is safe and non-irritant for topical oral use. Overall, the results suggest that the prepared herbal mouth ulcer gel containing *Tridax procumbens* is safe, stable, and effective, and can be considered a promising herbal formulation for the treatment and management of mouth ulcers.

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