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(RESEARCH ARTICLE)

Formulation and evaluation of a mouth ulcer gel using *Clitoria ternatea* flower extract

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Abstract

Mouth ulcers, also known as aphthous stomatitis, are common, painful lesions that affect the mucosal surfaces of the oral cavity. Their pathophysiology is complex, involving genetic, immunological, and environmental factors. Although the exact cause remains unclear, dysregulation of the immune system plays a central role. Inflammatory responses are triggered by the activation of T lymphocytes, which lead to the release of cytokines, resulting in epithelial cell damage and ulcer formation. Genetic predisposition, stress, trauma, nutritional deficiencies (especially of B vitamins, folic acid, and iron), and microbial factors have all been implicated as contributing factors. The local tissue response is characterized by an imbalance between pro-inflammatory and anti-inflammatory mediators, with cytokines including interleukin-1 (IL-1), interferon-gamma (IFN-γ), and tumor necrosis factor-alpha (TNF-α) being upregulated. This leads to neutrophil infiltration, edema, and increased vascular permeability, all of which worsen the lesion. While current research attempts to clarify the exact molecular pathways involved in order to generate more focused medicines, treatment tactics frequently concentrate on symptomatic alleviation. Understanding the pathophysiology of mouth ulcers is critical for improving treatment outcomes and minimizing recurrence. Treatment options include over-the-counter pain relievers, topical medications, and avoiding irritants. In most cases, mouth ulcers will heal on their own within a week or two. However, if they persist or are accompanied by other symptoms, it is important to seek medical attention. Because of the clinician's limited experience to the illnesses that may cause the lesions and their comparable looks, diagnosing and treating oral lesions can be difficult. By removing irrelevant variables, this study attempts to provide a methodical approach to the diagnosis of oral ulcers based on their clinical and histological characteristics. Recurrent and painful ulcerations on the moveable or nonkeratinized oral mucosae are a hallmark of recurrent aphthous stomatitis (RAS), one of the most prevalent oral mucosal disorders. Three forms of RAS may be distinguished clinically: minor, major, and herpetiform varieties. The tongue, buccal mucosa, and labial mucosa are more frequently affected by RAS. RAS is a multifactorial immune-dysregulated illness caused by T cells, according to earlier research.

Keywords: *Clitoria ternatea*; Mouth ulcer; Herbal gel; Formulation; Antimicrobial activity; Carbopol 934; Natural remedy; Oral lesions

1. Introduction

Mouth ulcers are tiny, painful lesions that develop on the mucosal surfaces inside the oral cavity. They are often referred to as aphthous ulcers or canker sores. They can be quite uncomfortable when speaking, eating, or swallowing and are a frequent clinical issue. Large or recurring ulcers can impair quality of life and interfere with everyday activities, even though they usually go away on their own. Mouth ulcers are known to occur as a result of a number of circumstances, including as stress, trauma (such as unintentional bites), hormonal shifts, nutritional deficiencies (particularly in iron,

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folic acid, and vitamin B12), and microbial infections. Traditionally, mouth ulcers are treated with topical corticosteroids, analgesics, antiseptics, and

antibiotics. While these therapies can be effective, they often come with side effects such as mucosal irritation, altered taste sensation, and potential systemic absorption with long-term use. Therefore, there is growing interest in the use of herbal and natural remedies that offer a safer and more biocompatible alternative for oral care.

Butterfly pea, or *Clitoria ternatea*, is a traditional medicinal plant that is a member of the Fabaceae family. Because of its many pharmacological qualities, including as antibacterial, antioxidant, anti-inflammatory, and wound-healing activities, it is frequently employed in Ayurvedic and folk medicine. Bioactive substances including flavonoids, anthocyanins, tannins, and phenolic acids are abundant in *Clitoria ternatea* flowers. These components have been demonstrated to prevent microbial development, lessen oxidative stress, and encourage tissue regeneration, which makes the plant a desirable option for the treatment of oral mucosal disorders including ulcers.

Topical gels are among the most preferred dosage forms for treating mouth ulcers due to their ability to adhere to the mucosal surface, provide localized action, and offer a soothing effect. Gels can be formulated using biocompatible polymers such as Carbopol 934, which provides desirable viscosity and mucoadhesive properties. Incorporating plant extracts into a gel base allows for sustained release of the active constituents and enhances the therapeutic effect at the site of application.

Figure 1 *Clitoria ternatea*

Objective of the Study

This study's main goal is to create a herbal gel that is both stable and efficient for treating mouth ulcers by utilizing floral extract from *Clitoria ternatea*. To ascertain the manufactured gel's eligibility and efficacy as a natural therapy for oral ulcers, its physical properties, pH, spreadability, viscosity, medication content, and antibacterial activity are assessed.

2. Materials

Plant Material: Fresh *Clitoria ternatea* flowers were collected and authenticated by a botanist.

Chemicals and Reagents:

- Solvent for extraction: Ethanol (or Methanol) – AR grade
- Gelling agent: Carbopol 934
- Humectant: Glycerin
- Preservative: Methylparaben
- pH adjuster: Triethanolamine
- Distilled water
- Every chemical utilized was of analytical quality and came from reputable vendors.

2.1. Extraction of *Clitoria ternatea* Extract

- After removing dust and debris with distilled water, the harvested flowers were shade-dried for seven to ten days.
- The dried flowers were ground into a powder and then sieved through a 60 mesh screen.

- Ethanol was used as a solvent for 6–8 hours while 50 grams of powder underwent Soxhlet extraction.
- After being concentrated using a rotary evaporator, the extract was kept at 4°C in an airtight container until it was needed again.

Figure 2 *Clitoria ternatea* Extraction Process

2.2. Formulation of the Herbal Gel

The gel was prepared using Carbopol 934 as the base. The following steps were followed:

- Preparation of the gel base: Carbopol 934 (1–2% w/w) was dispersed in a small amount of distilled water and allowed to swell overnight.
- Glycerin (5–10% w/w) was added to the dispersion as a humectant.
- Incorporation of extract: The prepared *Clitoria ternatea* extract (concentration as per trial, e.g., 2–5% w/w) was added to the gel base with continuous stirring.
- Preservative addition: A little amount of water was used to dissolve methylparaben (0.2% w/w) before adding it to the mixture.
- pH adjustment: Triethanolamine was slowly added dropwise to adjust the pH of the gel between 6.5 and 7.0 (suitable for oral mucosa).
- Final mixing and storage: The gel was stirred continuously to ensure homogeneity and transferred into airtight containers for evaluation.

Table 1 Formulation Composition of *Clitoria ternatea* Mouth Ulcer Gel (Batch F1, F2, F3)

Ingredients	F1 (% w/w)	F2 (% w/w)	F3 (% w/w)
Clitoria ternatea Extract	2.0	3.0	4.0
Carbopol 934	1.0	1.0	1.0
Glycerin	5.0	5.0	5.0
Methylparaben	0.2	0.2	0.2
Triethanolamine (q.s.)	To adjust pH	To adjust pH	To adjust pH
Distilled Water	q.s. to 100 g	q.s. to 100 g	q.s. to 100 g

Figure 3 Formulation of *Clitoria ternatea* Mouth Ulcer Gel

3. Evaluation Parameters

To ensure the formulated gel is effective, stable, and suitable for oral use, several physicochemical and biological evaluations were conducted. The following parameters were assessed:

3.1. Physical Appearance

- Purpose: To visually inspect the gel for color, homogeneity, and consistency.
- Observation Criteria:
- Colour: Should reflect the natural pigment of *Clitoria ternatea* (bluish-purple).
- Texture: Smooth and uniform, without any grittiness.
- Phase Separation: No separation of liquid or oil phase from the gel.

3.2. pH Measurement

Purpose: To ensure compatibility with oral mucosa (ideal pH ~6.5–7.0).

Method:

1 g of gel was dispersed in 10 mL of distilled water.

pH measured using a calibrated digital pH meter.

Figure 4 pH Measurement Test

3.3. Viscosity

- Purpose: To assess the gel's thickness and flow behavior, which influences retention time in the oral cavity.
- Method: Measured using a Brookfield Viscometer at a specified spindle speed and temperature (typically 25°C).

Figure 5 Viscosity test

3.4. Spreadability

Paraphrased: Purpose: To measure how easily the gel spreads, which affects ease of application and coverage over the ulcer area.

3.4.1. Paraphrased: Method

- Paraphrased: A known weight (usually 1 g) of gel is placed between two glass slides.
- Paraphrased: A fixed weight (e.g., 500 g) is placed on top for a specific time, and the diameter of the spread is measured.

3.5. Formula

$$\text{Spreadability (g\cdotpcm/s)} = M \times L / T$$

Where:

- M = weight applied
- L = length moved by the slide
- T = time taken

Figure 6 Spreadability test

3.6. Drug Content (Extract Content Uniformity)

- Purpose: To determine whether the extract is evenly distributed in the gel and present in the correct amount.
- Method:1 g of gel is dissolved in ethanol, filtered, and analyzed spectrophotometrically (typically using a UV-Vis spectrophotometer at the extract's λmax).

3.7. Antimicrobial Activity

- Purpose: To evaluate the gel's effectiveness against common oral pathogens responsible for secondary infection of ulcers.

3.7.1. Method:

Mueller-Hinton agar or Sabouraud dextrose agar (for fungi) are used in the agar well diffusion method.

Candida albicans, Staphylococcus aureus, and *Streptococcus mutans* were the microorganisms that were evaluated. Zone of inhibition (in mm) is measured around the well containing the gel.

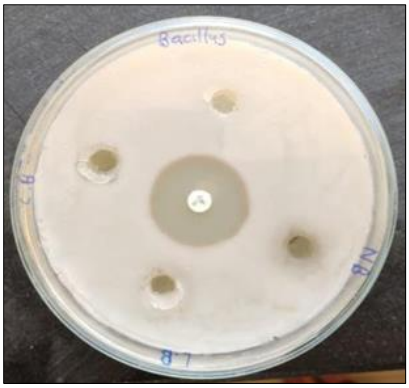

Figure 7 Antimicrobial Activity

3.8. Stability Studies

- Purpose: To evaluate the physical and chemical stability of the gel over time under different storage conditions.
- Method: Gels stored at 4°C, room temperature (~25°C), and 40°C for 30 days.

Observations include:

- Change in pH
- Change in color or odor
- Phase separation
- Microbial contamination

4. Results

The formulated herbal gel was evaluated through various physicochemical and biological tests to assess its suitability for the treatment of mouth ulcers.

4.1. Physical Appearance

All three batches (F1, F2, and F3) were bluish-purple in color due to the anthocyanin content of *Clitoria ternatea*, and exhibited smooth, homogenous texture without phase separation. The appearance was aesthetically pleasing and acceptable for oral application.

4.2. pH

The formulations' pH values fell between 6.6 and 6.9, which is within the typical range for oral mucosa. This guarantees that applying the gel won't result in any irritation or pain.

4.3. Viscosity

The viscosity was found to be in the desirable range for topical oral gels (e.g., 8,000–10,000 cP), ensuring adequate mucoadhesion and retention in the oral cavity without being too stiff.

4.4. Spreadability

Spreadability values ranged between 18–22 g·cm/s, indicating good spreadability, which is essential for easy application and coverage of the ulcer area.

4.5. Drug Content

The drug content across batches was consistent and ranged from 95% to 98% of the expected value, indicating uniform distribution of the *Clitoria ternatea* extract throughout the gel matrix.

4.6. Antimicrobial Activity

The gel exhibited significant antimicrobial activity against tested oral pathogens.

- Streptococcus mutans: Zone of inhibition ranged from 16 mm (F1) to 22 mm (F3)
- *Candida albicans*: 14 mm (F1) to 20 mm (F3)
- *Staphylococcus aureus*: 15 mm (F1) to 21 mm (F3)

Batch F3, containing the highest concentration of extract (4%), showed the most potent antimicrobial effect.

4.7. Stability Study

After 30 days of storage at various conditions, no significant changes in physical appearance, pH, or microbial contamination were observed. This indicates that the formulation is physically and chemically stable.

5. Discussion

The results confirm that *Clitoria ternatea* extract is effective when incorporated into a gel base. The formulation exhibits suitable physical characteristics, retains its consistency, and demonstrates antimicrobial potential. The increasing concentration of the extract improved antimicrobial activity, making Batch F3 the most effective.

6. Conclusion

The study successfully formulated a stable and effective herbal mouth ulcer gel using *Clitoria ternatea* extract. The gel demonstrated desirable physicochemical properties such as appropriate pH, spreadability, viscosity, and uniform drug content. It also exhibited strong antimicrobial activity against common oral pathogens, particularly at higher concentrations of the extract. The formulation was stable over the study period and well-suited for oral application. These findings suggest that *Clitoria ternatea* gel can serve as a natural, safe, and effective alternative for the treatment of mouth ulcers. Further clinical studies are recommended to evaluate its therapeutic efficacy in human subjects

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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