INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Research Paper

Formulation And Evaluation of An Anti-Inflammatory and Anti-Microbial Gel Using Clitoria Ternatea Linn

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ARTICLE INFO

Published: 27 Aug 2026
Keywords:
Anti-inflammatory activity, Anti-microbial activity, Clitoria ternatea, Oral ulcer, Herbal gel, Topical drug delivery
DOI:
10.5281/zenodo.22129807

ABSTRACT

Oral ulcers are common inflammatory conditions that may be associated with pain, irritation, tissue damage, and microbial infection, highlighting the need for effective, safe, and patient-friendly topical treatments. In recent years, herbal medicines have attracted considerable interest in pharmaceutical research because of their therapeutic potential, natural origin, and relatively fewer adverse effects. Clitoria ternatea Linn. (butterfly pea) is a medicinal plant traditionally recognized for its pharmacological properties and is reported to contain bioactive constituents such as flavonoids, anthocyanins, phenolic compounds, and other phytochemicals with potential anti-inflammatory, antioxidant, antimicrobial, and wound-healing activities. The present study was undertaken to formulate and evaluate a herbal gel containing a hydroalcoholic extract of Clitoria ternatea flowers for its potential application in the management of oral ulcers. The flowers were subjected to hydroalcoholic extraction, and the obtained extract was incorporated into a suitable gel base prepared using Carbopol and Hydroxypropyl Methylcellulose (HPMC) as gelling agents. The formulated gel was evaluated for its physical appearance, colour, odour, homogeneity, pH, spreadability, viscosity, and drug content uniformity to determine its suitability for topical application. In vitro anti-inflammatory activity was investigated using the protein denaturation method, while antimicrobial activity was assessed against selected bacterial strains associated with microbial infections. The developed formulation demonstrated satisfactory physicochemical characteristics, including acceptable appearance, suitable pH, good spreadability, smooth and homogeneous consistency, and uniform drug content, indicating good formulation quality and suitability for topical administration. The formulation also exhibited appreciable anti-inflammatory activity, with the activity

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

increasing with increasing concentration of the extract. Furthermore, the gel demonstrated antimicrobial activity against the selected microorganisms, supporting the potential of Clitoria ternatea as a multifunctional herbal therapeutic agent. Overall, the findings indicate that the developed Clitoria ternatea herbal gel possesses promising anti-inflammatory and antimicrobial properties and may provide a safe, stable, and effective topical approach for the management of oral ulcers and associated inflammatory conditions. Further in vivo studies and clinical investigations are recommended to establish its therapeutic efficacy and safety.

INTRODUCTION

Oral ulcers are common lesions characterized by the loss of the epithelial lining of the oral mucosa, leading to exposure of the underlying connective tissue. These lesions are often associated with pain, inflammation, redness, a burning sensation, and difficulty in eating and speaking, thereby significantly affecting the patient's quality of life. Oral ulcers may arise due to various factors, including trauma, microbial infections, nutritional deficiencies, immune disorders, stress, or the use of certain medications. Conventional treatment approaches primarily involve the use of topical corticosteroids, antiseptics, analgesics, and antimicrobial agents; however, prolonged use of these medications may result in adverse effects such as mucosal irritation, opportunistic infections, and the development of drug resistance.[1 2]

Herbal medicines have gained considerable attention as safer and effective alternatives due to the presence of diverse bioactive phytochemicals possessing anti-inflammatory, antimicrobial, antioxidant, and wound-healing properties. Natural products are widely accepted because of their lower incidence of side effects, improved patient compliance, and significant therapeutic potential in managing oral inflammatory conditions.[3]

Clitoria ternatea Linn. (Family: Fabaceae), commonly known as butterfly pea, is a well-known medicinal plant extensively utilized in traditional Ayurvedic medicine. The flowers are rich in anthocyanins, flavonoids, phenolic compounds, tannins, and other phytoconstituents that exhibit antioxidant, anti-inflammatory, antimicrobial, analgesic, and wound-healing activities. These pharmacological properties make *Clitoria ternatea* a promising candidate for the development of herbal formulations for the treatment of oral ulcers and other inflammatory conditions of the oral cavity.[4–5]

Topical drug delivery systems are preferred for the management of oral ulcers as they enable direct delivery of the therapeutic agent to the affected site, resulting in rapid onset of action, prolonged local drug retention, reduced systemic absorption, and enhanced patient compliance. Among the various topical dosage forms, gels are widely favored due to their excellent spreadability, non-greasy nature, ease of application, bio-adhesive properties, and ability to maintain prolonged contact with the oral mucosa.[6–7]

Therefore, the present study aimed to formulate and evaluate an anti-inflammatory and antimicrobial herbal gel using *Clitoria ternatea* flower extract for the effective management of oral ulcers.

MATERIALS AND METHODS

3.1 Plant Material :

The flowers of *Clitoria ternatea* Linn. (Family: Fabaceae), commonly known as Butterfly Pea or Aparajita, were used in the present study. Fresh, healthy, and mature flowers were collected from the botanical garden of Shivajirao S. Jondhale College of Pharmacy during the flowering season. The plant material was authenticated by Dr. Harshad M. Pandit, Director, Botany Research Laboratory, Azadnagar Road, Andheri (West), Mumbai–400058, Maharashtra, India.[8]

Biological Source

- **Scientific name:** *Clitoria ternatea* Linn.
- **Family:** Fabaceae
- **Common names:** Butterfly Pea, Blue Pea, Aparajita, Gokarna
- **Plant part used:** Dried flowers[8]

Figure 1 *Clitoria ternatea* Linn.

3.2 CHEMICALS AND REAGENT

Carbopol 940 (Loba Chemie Pvt. Ltd., Mumbai, India), Hydroxypropyl Methylcellulose (HPMC K15M) (HiMedia Laboratories Pvt. Ltd., Mumbai, India), Glycerin (Merck Life Science Pvt. Ltd., Mumbai, India), Propylene Glycol (Loba Chemie Pvt. Ltd., Mumbai, India), Triethanolamine (Merck Life Science Pvt. Ltd., Mumbai, India), Potassium Sorbate (Loba Chemie Pvt. Ltd., Mumbai, India), Citric Acid (SD Fine-Chem Ltd., Mumbai, India), Methanol (Analytical grade, Merck Life Science Pvt. Ltd., Mumbai, India), and Distilled Water were used throughout the study. All chemicals and reagents used were of analytical reagent (AR) grade.[9]

3.3Preparation of Plant Material

The collected flowers were washed thoroughly with distilled water to remove dust and other impurities and shade-dried under well-ventilated conditions at room temperature. After complete drying, the flowers were coarsely powdered and stored in an airtight container until further use.[8,10]

3.4 Extraction of Plant Material

The powdered flowers of *Clitoria ternatea* Linn. were extracted by the maceration method using a hydroalcoholic solvent system. The powdered plant material was soaked in the solvent for an appropriate period with intermittent stirring to facilitate the extraction of phytoconstituents. The extract was filtered using Whatman No. 1 filter paper and concentrated under reduced temperature. The concentrated extract was stored in an airtight container at 4 °C until further use for phytochemical screening and gel formulation.[10,11]

3.5 Preliminary Phytochemical Testing

The hydroalcoholic extract of *Clitoria ternatea* Linn. flowers were subjected to preliminary phytochemical screening using standard qualitative methods to detect the presence of major phytoconstituents. The screening was performed to identify bioactive compounds that may contribute to the anti-inflammatory and antimicrobial activities of the formulated herbal gel.[8,9]

The extract was qualitatively evaluated for the presence of anthocyanins, flavonoids, phenolic compounds, tannins, alkaloids, glycosides, saponins, and steroids using established pharmacognostic procedures. [8,9,11]. Anthocyanins were identified by the pH differential method in acidic and alkaline media, while flavonoids were confirmed by the Shinoda test and lead acetate test.[11]. Additional tests, including the ammonia test, sodium bisulfite test, ferric chloride test, and alkaline reagent test, were performed to detect the respective phytochemical constituents.[8911]. The results were interpreted based on characteristic colour changes or precipitate formation and recorded accordingly. [8]

3.6. Procedure

The herbal gel containing the hydroalcoholic extract of *Clitoria ternatea* Linn. was prepared using Carbopol 940 and Hydroxypropyl Methylcellulose (HPMC) as gelling agents. Initially, the required quantity of purified water was taken in a beaker, and the gelling agent was gradually dispersed with continuous stirring to prevent lump formation. The dispersion was allowed to hydrate for 30–60 minutes to obtain a uniform gel base.[67]

The hydroalcoholic extract of *Clitoria ternatea* was mixed separately with glycerin and propylene glycol under continuous stirring until a homogeneous solution was obtained. The prepared extract phase was then added slowly to the hydrated gel base while stirring continuously at 500–800 rpm to ensure uniform distribution of the extract throughout the formulation.[67]

Triethanolamine was added dropwise to neutralize the Carbopol dispersion and develop the desired gel consistency. Potassium sorbate was incorporated as a preservative, and the pH of the formulation was adjusted to 5.5–6.5 using citric acid or a suitable buffer solution. Finally, the volume was adjusted with purified water wherever required, and the gel was stirred for an additional 20–25 minutes to achieve complete homogenization. The prepared formulation was transferred into clean, sterile containers and stored in a cool, dry place until further evaluation.[67]

3.7 Evaluation of Formulated Gel:

3.7.1. Organoleptic Evaluation: The formulated herbal gel was evaluated for its organoleptic characteristics, including colour, odour, appearance, consistency, and homogeneity. The evaluation was carried out by visual inspection to assess the physical appearance and overall acceptability of the formulation. The observations were recorded for each formulation batch. [7]

3.7.2. pH Determination: The pH of the formulated herbal gel was determined using pH paper to evaluate its suitability for topical application. The pH was measured at room temperature, and values within the range of 5.0–6.5 were considered acceptable for application to the oral mucosa. [6]

3.7.3. In Vitro Anti-microbial Activity *(Escherichia Coli no-8739 Staphylococcus aureus ATCC no-6538*[56-58]: The antimicrobial activity of the test formulation was evaluated by determining its ability to inhibit the growth of selected microorganisms, which serves as an *in-vitro* marker for antimicrobial potential. The study was carried out against *Escherichia coli* (ATCC no8739) and *Staphylococcus aureus* (ATCC no-6538) using the agar well diffusion method. The formulation was tested at different concentrations (5 mg/mL and 10 mg/mL), and the activity was assessed by measuring the zone of inhibition. The results indicated a concentration-dependent increase in antimicrobial activity, confirming the formulation possesses mild antibacterial potential.[12-14]

The test microorganisms used for the anti-microbial activity are shown in Figure 2

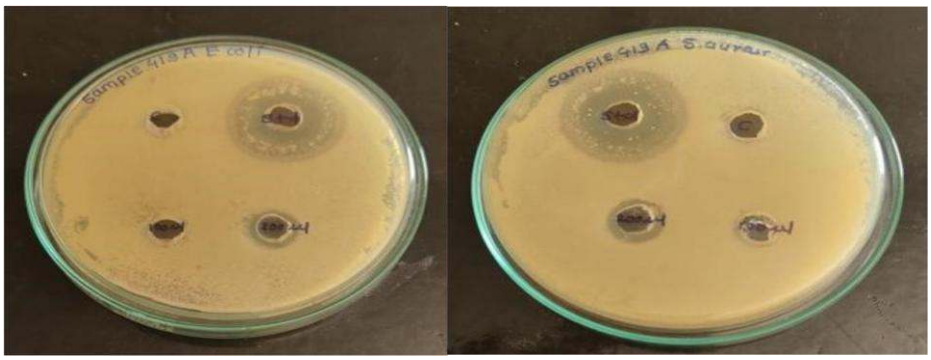

Figure 2 a) ***Escherichia Coli ATCC no-8739*** **b)** ***Staphylococcus aureus ATCC no-6538***

5. In vitro Anti-inflammatory activity by Protein Denaturation Method The in vitro anti-inflammatory activity of the formulated herbal gel was evaluated using the protein denaturation method. Diclofenac sodium was used as the standard drug. The absorbance of the reaction mixtures was measured using a UV–Visible spectrophotometer, and the percentage inhibition of protein denaturation was calculated to determine the anti-inflammatory potential of the formulation. [15-16]

The control, standard diclofenac sodium, and the sample formulation used in the protein denaturation assay are shown in figure 3.

Figure 3 (a)Control, (b) Std Diclofenac sodium, (c) Sample Anti-inflammatory activity

4.Result:

4.1. Preliminary studies:

The preliminary phytochemical screening of the hydroalcoholic extract of *Clitoria ternatea* flowers revealed the presence of anthocyanins and flavonoid, as summarized in Table 1

Table 1 Preliminary studies

Sr no		Test	Result
1	Anthocyannins	pH differential test in acidic medium	Positive
2		pH differential test in alkaline medium	Positive
3		Ammonia test	Positive
4		Sodium Bisulfite	Positive

5	Flavonoids	Shinoda test	Positive
6		Lead acetate test	Positive
7		Alkaline reagent test	Positive

A) Oragnoleptic properties of flower:

B) Physicochemical Studies

4.2 Evaluation of Poly-herbal gel:

A) Organoleptic properties:

The organoleptic characteristics of the formulated herbal gel are presented in Table 2.

Table 2 Organoleptic properties:

Sr no	parameter	observation
1	Colour	Faint purple
2	Odour	Pleasant
3	Taste	No taste

Table 3 Organoleptic properties observation

Parameter	Batch 1	Batch 2	Batch 3	Inference
Colour	Faint purple	Violet	Violet	Colour enhanced with increase in extract concentration.
Odour	No smell	No smell	No smell	Mild characteristic odour due to theherbal extract
Appearance	Glossy	Glossy	Lustrous	Proper formulation and good physical stability
Consistency	Runny	Smooth	Smooth	Good consistency with a smooth texture and slight gloss
Homogeneity	Lump present	Homogenous	Homogenous	Homogeneous with no visible lumps, phase separation

b) pH determination:

The pH values obtained for the different formulation batches are presented in Table 4.

Table 4 pH determination

Parameter	Batch 1	Batch 2	Batch 3	Interference
pH	6.2	6.5	6.0	Range (5-6.5) Thus Optimal Batch 2 acceptable

c) In-vitro anti-microbial activity(Escherichia Coli ATCC no8739 Staphylococcus aureus ATCC no-6538)

The *in vitro* antimicrobial activity of the herbal gel formulated using *Clitoria ternatea* was evaluated by the agar diffusion method and compared with the standard drug Streptomycin, a widely used antibiotic. The standard drug exhibited significant antimicrobial activity in a concentration-dependent manner, showing a progressive increase in the zone of inhibition with increasing concentration. The herbal gel also demonstrated noticeable antimicrobial activity, indicating the presence of bioactive phytoconstituents responsible for its antimicrobial effect. The results confirmed the effectiveness of the formulation and the validity of the experimental model.

Result: The gel shows mild antibacterial activity, which increases with concentration but remains significantly lower than the standard antibiotic

1.The gel exhibited very low activity at 5 mg/mL with inhibition zones of 1 mm for both organisms.
2.At a higher concentration of 10 mg/mL, the activity improved to 4 mm against *E. coli* and 6 mm against *S. aureus*, indicating slightly better effectiveness against Gram-positive bacteria.

d) In vitro Anti-inflammatory activity by Protein Denaturation Method

The percentage inhibition of protein denaturation observed for the standard diclofenac sodium and the sample formulation at different concentrations is presented in Table 5.

Table 5 In vitro Anti-inflammatory activity by Protein Denaturation Method

Sr. No.	Sample	Conc. µg/ml	O. D			Mean	Percent Inhibition
1.	Control		0.82	0.89	0.87	0.860	
2.	Std Diclofenac sodium	200	0.25	0.24	0.21	0.233	72.87
		400	0.19	0.18	0.19	0.187	78.29
		600	0.15	0.17	0.16	0.160	81.40
		800	0.13	0.14	0.12	0.130	84.88
		1000	0.11	0.18	0.09	0.127	85.27
3.	**Sample formulation**	200	0.69	0.67	0.68	0.680	2.093
		400	0.52	0.53	0.55	0.533	37.98
		600	0.54	0.57	0.52	0.543	36.82
		800	0.49	0.47	0.43	0.463	46.12
		1000	0.45	0.46	0.47	0.460	**46.51**

The *in vitro* anti-inflammatory activity of the herbal gel formulated using *Clitoria ternatea* was evaluated by the protein denaturation method and compared with the standard drug Diclofenac sodium, a widely used non-steroidal antiinflammatory drug (NSAID).The standard drug showed strong inhibition of protein

denaturation in concentration dependant manner, with inhibition increasing from
72.87% at 200 ug/ml to 85.27% at 1000 ug/ml, confirming the validity and sensitivity of experimental model.

Result: The present study indicates that sample (polyherbal anti-inflammatory gel) exhibits moderate in vitro anti-inflammatory activity as evidenced by its ability to inhibit protein denaturation.

- At 200 µg/mL, the herbal gel exhibited **20.93% inhibition**, indicating low initial antiinflammatory activity.
- The activity increased with increasing concentration, reaching **46.51% inhibition at 1000 µg/mL**, demonstrating moderate anti-inflammatory potential.
- A general decrease in absorbance values with increasing concentration further supports the ability of the formulation to stabilize proteins and inhibit denaturation.

DISCUSSION

The present study was undertaken to formulate and evaluate an herbal gel containing hydroalcoholic extract of Clitoria ternatea flowers for its potential anti-inflammatory and antimicrobial activity. Preliminary phytochemical screening of the hydroalcoholic extract indicated the presence of anthocyanins and flavonoids. The presence of these phytoconstituents may contribute to the biological activities observed in the present study. The formulated herbal gel showed acceptable organoleptic characteristics, including faint purple to violet colour, pleasant or mild characteristic odour, smooth consistency, glossy appearance, and satisfactory homogeneity. The variation in colour among the formulation batches was associated with the concentration of the herbal extract. The formulations were generally smooth and homogeneous, indicating satisfactory physical characteristics.

The pH of the formulation batches ranged from 6.0 to 6.5. These values were considered suitable according to the evaluation criteria used in the present study. Batch 2 showed a pH of 6.5 and was considered acceptable based on the specified range.

The in vitro antimicrobial study demonstrated that the herbal gel exhibited antibacterial activity against Escherichia coli and Staphylococcus aureus. At 5 mg/mL, the formulation showed an inhibition zone of 1 mm against both microorganisms, while at 10 mg/mL, the inhibition zones increased to 4 mm against E. coli and 6 mm against S. aureus. These findings indicate an increase in antimicrobial activity with increasing concentration. However, the activity remained lower than that observed with the standard antibiotic.

The anti-inflammatory activity of the formulation was evaluated using the protein denaturation method, with diclofenac sodium used as the standard drug. The standard showed strong inhibition of protein denaturation, increasing from 72.87% at 200 µg/mL to 85.27% at 1000 µg/mL. The sample formulation also demonstrated inhibition of protein denaturation, with the percentage inhibition reaching 46.51% at 1000 µg/mL. Thus, the formulation demonstrated measurable in vitro anti-inflammatory activity, although it was lower than that of the standard drug.Overall, the results indicate that the Clitoria ternatea herbal gel possessed acceptable physical characteristics and demonstrated both antimicrobial and in vitro anti-inflammatory activity. The findings support the potential of Clitoria ternatea flower extract for further investigation in herbal topical gel development. However, additional studies are required to establish the safety, stability, and therapeutic effectiveness of the formulation.

CONCLUSION

The present study successfully formulated and evaluated an herbal gel containing hydroalcoholic extract of Clitoria ternatea flowers. The formulated gel exhibited acceptable organoleptic properties, suitable pH, satisfactory consistency, and good homogeneity. The formulation demonstrated mild antibacterial activity against Escherichia coli and Staphylococcus aureus, with increased activity observed at the higher tested concentration. The formulation also showed in vitro anti-inflammatory activity in the protein denaturation assay, although the activity was lower than that of the standard diclofenac sodium. Among the evaluated formulation batches, F3 demonstrated comparatively better physical characteristics and was selected as the optimized formulation based on the evaluation parameters used in the present study. Overall, the findings indicate the potential of Clitoria ternatea flower extract as an herbal ingredient for topical gel development. Further studies involving detailed stability evaluation, safety assessment, and additional biological investigations are required to establish the suitability of the formulation for oral ulcer management.

REFERENCES

1. Kumar V, Abbas AK, Aster JC. *Robbins and Cotran Pathologic Basis of Disease*. 10th ed. Philadelphia: Elsevier; 2020.
2. Rang HP, Dale MM, Ritter JM, Flower RJ, Henderson G. *Rang and Dale's Pharmacology*. 9th ed. London: Elsevier; 2019.
3. Kokate CK. *Pharmacognosy*. 55th ed. Pune: Nirali Prakashan; 2017.
4. Kirtikar KR, Basu BD. *Indian Medicinal Plants*. 2nd ed. Dehradun: International Book Distributors; 2006.
5. Mukherjee PK. *Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals*. New Delhi: Business Horizons; 2019.
6. Aulton ME, Taylor K. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*. 5th ed. Edinburgh: Elsevier; 2018.
7. Ansel HC, Allen LV, Popovich NG. *Pharmaceutical Dosage Forms and Drug Delivery Systems*. 10th ed. Philadelphia: Lippincott Williams & Wilkins; 2014.
8. Kokate CK, Purohit AP, Gokhale SB. *Pharmacognosy*. 57th ed. Pune: Nirali Prakashan; 2023.
9. Indian Pharmacopoeia Commission. *Indian Pharmacopoeia*. Ghaziabad: Indian Pharmacopoeia Commission; latest edition.
10. Khandelwal KR. *Practical Pharmacognosy: Techniques and Experiments*. 30th ed. Pune: Nirali Prakashan; 2021.
11. Harborne JB. *Phytochemical Methods: A Guide to Modern Techniques of Plant Analysis*. 3rd ed. London: Chapman & Hall; 1998.
12. Gaikwad, A., Harshad, R., & Patil, S. B. (2024). Formulation, Evaluation, and Antioxidant Properties of Herbal Soap for Anti-Acne Treatment. International Journal of Novel Research and Development, 9(8), August 2024. ISSN: 2456-4184. Retrieved from www.ijnrd.org.
13. Hufford CD, Funderburk JM, Morgan JM, Robertson LW (1975).Two antimicrobial alkaloids from heartwood of Liriodendron tulipifera. I.J.pharm. Sci., 64:789-792.
14. Umadevi S, Mohanta G P, Chelladurai V, Manna PK, Manavalan R(2003).Antibacterial and antifungal activity of Andrographis echiodes.J. Nat. Remedies., 3:185-188.

15. Mizushima Y, Kobayashi M. Interaction of anti-inflammatory drugs with serum proteins, J. Pharm. Pharmacol., 1968; 20: 169–173. 2
16. Sakat SS et al., In vitro anti-inflammatory activity of some medicinal plants, Int J Pharm Pharm Sci, 2010; 2(4): 146–155

HOW TO CITE: Swati Wakchoure, Pritee Gole, Bhakti Indulkar, Rishabh Jain, Chaitali Jaware, Priyanshu Kalwar, Formulation And Evaluation of An Anti-Inflammatory and Anti-Microbial Gel Using Clitoria Ternatea Linn, Int. J. of Pharm. Sci., 2026, Vol 4, Issue 8, 4094-40, https://doi.org/10.5281/zenodo.22129807