

TO FORMULATE AND EVALUATE HERBAL GEL AT DIFFERENT CONCENTRATIONS FOR THE MANAGEMENT OF MOUTH ULCERS

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ABSTRACT

Mouth ulcers, also known as recurrent aphthous stomatitis, are common painful lesions of the oral mucosa that significantly affect daily activities such as eating and speaking. These lesions may occur due to factors such as stress, trauma, nutritional deficiencies, or microbial infections. Conventional treatments provide temporary relief but are often associated with side effects like irritation and hypersensitivity. The present study aims to formulate and evaluate a herbal gel for the management of mouth ulcers using natural therapeutic agents. The formulation includes *Psidiumguajava* (guava), *Glycyrrhizaglabra* (liquorice), and *Aloe vera*, which are known for their antimicrobial, anti-inflammatory, and wound healing properties.^[1,2,4] The gel was prepared using Carbopol 934 as a gelling agent to achieve suitable consistency and stability for oral application. The formulated gel was evaluated for various physicochemical parameters such as appearance, pH, homogeneity, viscosity, and spreadability. Additionally, antimicrobial activity was assessed against common oral pathogens. The results indicated that the gel exhibited good stability, appropriate pH for oral use, and satisfactory spreadability. It also demonstrated significant antimicrobial activity and enhanced healing potential. In conclusion, the developed herbal gel is safe, stable, and effective for the management of mouth ulcers and can serve as a promising alternative to conventional treatments with minimal side effects and improved patient compliance.^[6,8]

KEYWORDS: Herbal gel, Mouth ulcers, Aloe vera, Wound healing.

INTRODUCTION

Mouth ulcers, commonly referred to as recurrent aphthous stomatitis, are among the most prevalent inflammatory conditions affecting the oral mucosa. These lesions typically appear as small, round or oval ulcers with a white or yellow necrotic center surrounded by an erythematous halo. They are often associated with pain, burning sensation, and discomfort, which can interfere with essential daily activities such as eating, speaking, and swallowing. The etiology of

mouth ulcers is multifactorial and may include local trauma, stress, hormonal imbalance, nutritional deficiencies (such as vitamin B12, iron, and folic acid), microbial infections, and immune system disturbances.

Conventional treatment approaches for mouth ulcers primarily focus on symptomatic relief and include the use of topical anesthetics, anti-inflammatory agents, corticosteroids, and antimicrobial drugs. Although these therapies are effective to some extent, their prolonged use is often associated with adverse effects such as mucosal irritation, hypersensitivity reactions, and the risk of recurrence. Additionally, the increasing preference for safer and more natural treatment options has led to a growing interest in herbal formulations.

Herbal medicines have been widely used in traditional systems of medicine due to their therapeutic efficacy, biocompatibility, and minimal side effects. Natural plant-based ingredients are known to possess a wide range of pharmacological activities, including antimicrobial, anti-inflammatory, antioxidant, and wound healing properties, which are essential for the effective management of oral ulcers. Furthermore, herbal formulations often provide a synergistic effect, enhancing the overall therapeutic outcome.

In the present study, a herbal gel formulation was developed using *Psidiumguajava* (guava), *Glycyrrhizaglabra* (liquorice), and *Aloe vera*. Guava leaves are rich in flavonoids and tannins, which exhibit strong antimicrobial and antioxidant activities. Liquorice is well known for its anti-inflammatory and demulcent properties, primarily due to the presence of glycyrrhizin. Aloe vera plays a crucial role in promoting wound healing and tissue regeneration, along with providing a soothing effect on the affected mucosa.

Topical drug delivery systems, such as gels, are particularly suitable for the treatment of mouth ulcers due to their ease of application, prolonged contact time, and ability to provide localized therapeutic action. Gels offer advantages such as better spreadability, patient compliance, and controlled release of active constituents at the site of action.

Therefore, the present study aims to formulate and evaluate a herbal gel for the effective management of mouth ulcers by utilizing the therapeutic potential of selected herbal ingredients. The formulation is expected to provide a safe, effective, and economical alternative to conventional treatments.

Types of Mouth Ulcers

Mouth ulcers, also known as recurrent aphthous stomatitis, can be classified into different types based on their size, number, severity, and healing time. The major types are as follows:

1. Minor Aphthous Ulcers

Minor aphthous ulcers are the most common type, accounting for approximately 70–80% of all cases. These ulcers are small in size (usually less than 1 cm in diameter), round or oval in shape, and have a white or yellow center surrounded by a red halo. They typically occur on non-keratinized mucosal surfaces such as the inner lips, cheeks, and floor of the mouth.

These ulcers are usually not very severe and heal spontaneously within 7–10 days without leaving any scar. However, they may cause mild discomfort and irritation during eating and speaking.

2. Major Aphthous Ulcers

Major aphthous ulcers are less common but more severe than minor ulcers. They are larger in size (greater than 1 cm in diameter), deeper, and more painful. These ulcers can occur on any part of the oral mucosa, including the lips, soft palate, and throat.

Major ulcers take a longer time to heal, usually ranging from 2 to 6 weeks, and may heal with scarring. Due to their severity, they can significantly interfere with normal oral functions and may require medical treatment.

3. Herpetiform Ulcers

Herpetiform ulcers are the least common type but are characterized by the presence of multiple small ulcers occurring in clusters. Each ulcer is very small (1–2 mm in diameter), but they may merge to form larger irregular lesions.

Despite their name, these ulcers are not caused by the herpes virus. They are highly painful and may affect any part of the oral mucosa. Healing usually occurs within 7–14 days without scarring, but the recurrence rate is relatively high.

Summary

The classification of mouth ulcers into minor, major, and herpetiform types helps in understanding their severity, duration, and appropriate treatment approach. Among these, minor ulcers are the most common, while major and herpetiform ulcers require more attention due to their severity and recurrence. Understanding these types is essential for selecting suitable therapeutic strategies, including herbal formulations for effective management.

LITERATURE REVIEW

Mouth ulcers, also known as recurrent aphthous stomatitis, are among the most common oral mucosal disorders, affecting a significant portion of the population worldwide. These lesions are characterized by painful ulcerations that may interfere with normal oral functions such as eating and speaking. Various studies have highlighted the multifactorial etiology of mouth ulcers, including microbial infections, nutritional deficiencies, stress, and immune dysregulation.^[27]

Herbal medicine has gained considerable attention in recent years as a safer and more effective alternative to conventional therapies. Numerous plant-based formulations have been explored for their therapeutic potential in oral healthcare due to their antimicrobial, anti-inflammatory, antioxidant, and wound healing properties.^[5,8] Among these, *Psidiumguajava*, *Glycyrrhizaglabra*, and *Aloe vera* have been extensively studied for their beneficial effects in the management of oral lesions.

Psidiumguajava (guava) leaves are rich in bioactive compounds such as flavonoids, tannins, and saponins, which contribute to their strong antimicrobial and antioxidant activities. Studies have demonstrated that guava leaf extracts exhibit significant inhibitory effects against oral pathogens, thereby reducing the risk of infection in ulcerated tissues (16,20). Additionally, the antioxidant properties of guava help in minimizing oxidative stress, which plays a crucial role in tissue damage and delayed healing.^[19]

Glycyrrhizaglabra (liquorice) is another important medicinal plant widely used for its anti-inflammatory and anti-ulcer properties. The presence of glycyrrhizin and flavonoids contributes to its ability to reduce inflammation and promote mucosal healing. Research studies have reported that liquorice extract effectively suppresses inflammatory mediators

and provides a soothing effect on irritated mucosal surfaces.^[2,13] Its demulcent property further enhances its therapeutic value by forming a protective layer over the ulcerated area.

Aloe vera is well known for its wound healing, antimicrobial, and anti-inflammatory properties. It contains polysaccharides, vitamins, enzymes, and amino acids that contribute to tissue regeneration and repair. Several in vitro and in vivo studies have confirmed the effectiveness of Aloe vera gel in accelerating wound healing and reducing microbial load in oral infections.^[4,7] Its cooling and soothing effect also helps in relieving pain and discomfort associated with mouth ulcers.

The formulation of herbal gels has emerged as an effective approach for the topical delivery of plant-based therapeutics. Gels offer several advantages, including ease of application, prolonged contact time at the site of action, and improved patient compliance. Carbopol-based gels, in particular, are widely used due to their excellent gelling properties, stability, and compatibility with herbal extracts.^[28] Studies on herbal gel formulations have demonstrated improved therapeutic outcomes in the management of oral ulcers compared to conventional dosage forms.^[23,25]

Furthermore, polyherbal or multi-herb formulations have been reported to exhibit synergistic effects, enhancing the overall therapeutic efficacy. The combination of different herbal extracts can target multiple pathways involved in ulcer formation, such as inflammation, microbial infection, and tissue damage.^[8,22] This synergistic approach not only improves healing but also reduces the likelihood of recurrence.

Overall, the available literature strongly supports the use of herbal ingredients such as guava, liquorice, and Aloe vera in the treatment of mouth ulcers. Their combined pharmacological actions make them suitable candidates for the development of an effective and safe topical gel formulation. Therefore, the present study focuses on formulating a herbal gel incorporating these ingredients and evaluating its potential in the management of mouth ulcers.

Plant Profile (Source of Herbal Drugs)

1. Guava

Scientific Name: *Psidium guajava* Family: Myrtaceae

Common Name: Guava Part Used: Leaves



Description

Guava is a tropical medicinal plant widely used in traditional medicine. The leaves are rich in bioactive compounds and are known for their antimicrobial, antioxidant, and anti-inflammatory properties.

Chemical Constituents

- Flavonoids (Quercetin)
- Tannins
- Saponins
- Essential oils

Pharmacological Activities

- Antimicrobial
- Antioxidant
- Anti-inflammatory
- Wound healing

Role in Formulation

Guava leaves help in reducing microbial infection and oxidative stress at the ulcer site, thereby promoting faster healing.

2. Liquorice

Scientific Name: *Glycyrrhiza glabra* Family: Fabaceae

Common Name: Liquorice Part Used: Root

**Description**

Liquorice is a well-known medicinal herb with extensive use in traditional systems due to its soothing and anti-inflammatory properties.

Chemical Constituents

- Glycyrrhizin
- Flavonoids (Glabridin)
- Saponins

Pharmacological Activities

- Anti-inflammatory
- Anti-ulcer
- Demulcent
- Antimicrobial

Role in Formulation

Liquorice provides a soothing effect, reduces inflammation, and forms a protective layer over the ulcer.

3. Aloe Vera

Scientific Name: *Aloe vera* Family: Liliaceae

Common Name: Aloe vera Part Used: Leaf gel

**Description**

Aloe vera is a succulent plant known for its cooling, soothing, and healing properties. It is widely used in topical formulations.

Chemical Constituents

- Polysaccharides
- Vitamins (A, C, E)
- Enzymes
- Amino acids

Pharmacological Activities

- Wound healing
- Anti-inflammatory
- Antimicrobial
- Moisturizing

Role in Formulation

Aloe vera enhances tissue regeneration, provides a soothing effect, and accelerates healing of mouth ulcers.

AIM & OBJECTIVES**AIM**

To formulate and evaluate a herbal gel for the management of mouth ulcers.

OBJECTIVES

- To prepare herbal extracts of guava and liquorice
- To formulate a gel using suitable gelling agent (Carbopol 934)
- To incorporate Aloe vera for enhanced therapeutic effect
- To evaluate physicochemical properties of the gel
- To study antimicrobial activity of the formulation

1. MATERIALS

The following materials were used for the preparation of the herbal gel formulation:

- Guava leaf powder extract
- Liquorice root powder extract
- Aloe vera gel
- Carbopol 934 (Gelling agent)
- Methyl paraben (Preservative)
- Propyl paraben (Preservative)
- Triethanolamine (pH adjusting agent)
- Glycerin (Humectant)
- Distilled water (Vehicle)

2. METHODOLOGY**Preparation of Herbal Extracts****a) Preparation of Guava Extract (Decoction Method)**

Fresh guava leaves were collected and washed thoroughly with distilled water to remove dirt and impurities. The leaves were shade dried and then powdered using a grinder. The powdered material was boiled with distilled water for a specific period (15–30 minutes) to extract the active constituents. The mixture was then cooled and filtered using muslin cloth or filter paper. The filtrate obtained was concentrated to obtain the guava extract.

b) Preparation of Liquorice Extract (Decoction Method)

Liquorice roots were cleaned, dried, and powdered. The powdered drug was boiled with distilled water for 15–30 minutes to extract the active constituents. After boiling, the mixture was cooled and filtered. The filtrate was then concentrated to obtain a semisolid extract.



Preparation of Herbal Gel

Procedure:

1. Carbopol 934 was accurately weighed and dispersed in distilled water with continuous stirring to avoid lump formation and allowed to swell for 30–60 minutes.
2. Glycerin was added to improve the consistency and smoothness of the gel.
3. Methyl paraben and propyl paraben were dissolved in a small quantity of warm water and added as preservatives.
4. The prepared guava extract, liquorice extract, and Aloe vera gel were incorporated into the Carbopol base according to the formulation.
5. The mixture was stirred continuously to obtain a uniform consistency.
6. Triethanolamine was added dropwise to adjust the pH and to neutralize the Carbopol, resulting in gel formation.
7. The final gel was mixed thoroughly to ensure homogeneity and stored in suitable containers.

Preparation of Different Batches

Two formulations were prepared with different concentrations:

- **F1:** Low concentration of herbal extracts
- **F2:** High concentration of herbal extracts

Both formulations contain a combination of guava extract, liquorice extract, and Aloe vera gel, but differ in the concentration of active ingredients.

3. Formulation Table:

Sr.No.	Ingredients	F1	F2	Role
1	Guava extract	1%	2%	Antimicrobial
2	Liquorice extract	1%	2%	Anti-inflammatory
3	Aloevera	3%	5%	Healing agent
4	Carbapol 934	1%	1%	Gelling agent
5	Glycerine	2%	2%	Humectants
6	Methyl paraben	0.1%	0.1%	Preservative
7	Propylparaben	0.05%	0.05%	Preservative
8	Triethanolamine	q.s	q.s	pH-Adjustment
9	Distilled water	q.s	q.s	Vehicle

Evaluation of Herbal Gel

The prepared herbal gel formulations (F1: low concentration and F2: high concentration) were evaluated for various physicochemical and biological parameters to determine their suitability for oral application and therapeutic effectiveness.

1. Physical Appearance

The prepared gels were visually inspected for color, odor, clarity, and texture. A small quantity of gel was observed against a white background to check for uniformity.

Both formulations were found to be smooth, homogeneous, and free from lumps. The gels exhibited acceptable color and odor, indicating proper incorporation of herbal ingredients.

2. pH Determination

The pH of the gel was determined using a digital pH meter. About 1 g of gel was dispersed in 10 ml of distilled water, and the pH was measured.

Maintaining a near-neutral pH is important for oral formulations to avoid irritation and ensure compatibility with oral mucosa.

3. Viscosity

The viscosity of the gel formulations was measured using a Brookfield viscometer at suitable spindle speed.

Viscosity plays a crucial role in determining the consistency and retention time of the gel at the site of application. An ideal gel should have moderate viscosity to ensure easy application and prolonged contact.

4. Spreadability

Spreadability was determined by placing a small amount of gel between two glass slides and applying a known weight. The time required for the slides to separate was recorded.

Formula:

$$S = \frac{M \times L}{T}$$

Where:

- S = Spreadability
- M = Weight applied

- L = Length of slide
- T = Time taken

Good spreadability indicates ease of application on the affected area.

5. Extrudability

Extrudability was evaluated by filling the gel into a collapsible tube and applying pressure to extrude the gel.

This test indicates how easily the gel can be dispensed from the container. Both formulations showed satisfactory extrudability.

6. Homogeneity

The gels were tested for homogeneity by visual inspection and by rubbing between fingers. Both formulations were found to be uniform and free from any coarse particles.

7. Anti-inflammatory Activity (ADD THIS IF NOT ADDED)

The anti-inflammatory activity of the prepared herbal gel formulations was evaluated using the protein denaturation method in an external laboratory. Diclofenac sodium was used as a standard drug. The method is based on the principle that substances which inhibit protein denaturation possess anti-inflammatory activity.

8. Anti-inflammatory Activity

The anti-inflammatory activity of the prepared formulations was evaluated using the protein denaturation method in an external laboratory.

The method is based on the principle that inhibition of protein denaturation indicates anti-inflammatory activity. The formulations were tested at different concentrations and compared with a standard drug (diclofenac sodium).

9. Stability Study

The prepared gel formulations were subjected to short-term stability studies by storing them at room temperature for a specific period.

The formulations were observed for changes in:

- Color
- Odor
- pH
- Consistency

No significant changes were observed, indicating that the formulations were stable.

RESULT AND DISCUSSION

1. Result Evaluation Results

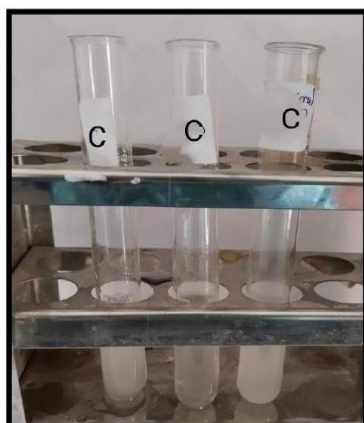
Sr.No.	Parameter	F1	F2
1	Appearance	Smooth	Smooth
2	pH	6.8	7.0
3	Viscosity	Moderate	Slightly High
4	Spreadability	Good	Excellent
5	Homogeneity	Uniform	Uniform
6	Extrudability	Good	Good

Anti- inflammatory activity

The anti-inflammatory activity of the prepared herbal gel formulations (F1 and F2) was evaluated using the protein denaturation method. The results obtained are presented in image.

In vitro anti-inflammatory activity by Protein denaturation method

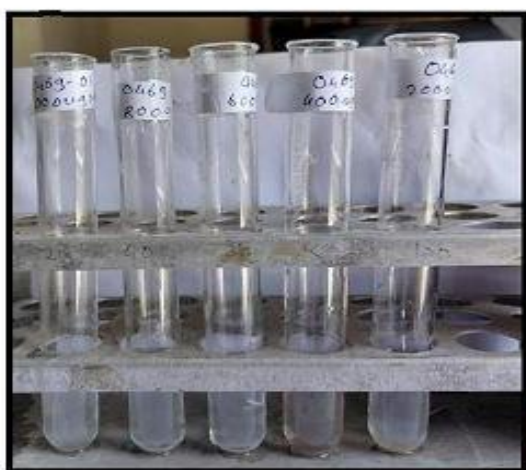
Sr. no.	Sample	Conc. µg/ml	O. D.			Mean	Percent inhibition
1	Control		0.82	0.89	0.87	0.86	
2	Standard Diclofenac sodium	200	0.25	0.24	0.21	0.23	72.87
		400	0.19	0.18	0.19	0.19	78.29
		600	0.15	0.17	0.16	0.16	81.40
		800	0.13	0.14	0.12	0.13	84.88
		1000	0.11	0.18	0.09	0.13	85.27
3	Sample – 01	200	0.48	0.47	0.49	0.48	44.19
		400	0.43	0.41	0.39	0.41	52.33
		600	0.35	0.32	0.29	0.32	62.79
		800	0.29	0.27	0.27	0.28	67.83
		1000	0.24	0.22	0.21	0.22	74.03
4	Sample -02	200	0.38	0.37	0.34	0.36	57.75
		400	0.31	0.29	0.27	0.29	66.28
		600	0.24	0.25	0.24	0.24	71.71
		800	0.21	0.19	0.17	0.19	77.91
		1000	0.15	0.19	0.14	0.16	81.40



Control



Standard Diclofenac sodium



Sample – A



Sample – B

DISCUSSION

The anti-inflammatory activity of the prepared herbal gel formulations was evaluated using the protein denaturation method. This method is based on the principle that inhibition of protein denaturation indicates anti-inflammatory potential.

The control sample showed a high absorbance value, indicating maximum protein denaturation in the absence of any active agent. The standard drug, diclofenac sodium, exhibited strong inhibition of protein denaturation in a concentration-dependent manner, confirming the validity of the experimental method.

Both the prepared formulations (low concentration and high concentration) demonstrated significant anti-inflammatory activity, with inhibition increasing as the concentration increased. This indicates that the herbal constituents present in the formulation possess the ability to stabilize proteins and prevent denaturation.

The high concentration formulation (F2) showed greater percentage inhibition compared to the low concentration formulation (F1) at all tested concentrations. At higher concentrations (1000 $\mu\text{g/ml}$), the activity of the high concentration formulation was found to be comparable to the standard drug, indicating strong anti-inflammatory potential.

The enhanced activity of the high concentration formulation may be attributed to the increased presence of active phytoconstituents from guava and liquorice, which are known for their anti-inflammatory and antioxidant properties. Overall, the results suggest that the formulated herbal gel possesses significant anti-inflammatory activity and can be considered effective for the management of mouth ulcers.

CONCLUSION

The present study successfully formulated and evaluated a herbal gel containing a combination of guava (*Psidium guajava*), liquorice (*Glycyrrhiza glabra*), and Aloe vera for the management of mouth ulcers. Two formulations were prepared with different concentrations of active herbal extracts to assess their effect on physicochemical properties and therapeutic efficacy.

The evaluation studies demonstrated that both formulations possessed acceptable characteristics such as appropriate pH, good viscosity, satisfactory spreadability, homogeneity, and ease of application. These properties indicate that the prepared gels are suitable for oral use and are capable of providing effective local delivery of active constituents.

The in vitro anti-inflammatory activity, assessed by the protein denaturation method, revealed that both formulations exhibited significant inhibition of protein denaturation in a concentration-dependent manner. The high concentration formulation (F2) showed superior activity compared to the low concentration formulation (F1), with results approaching those of the standard drug at higher concentrations.

The enhanced activity of the high concentration formulation may be attributed to the synergistic effect of phytoconstituents present in guava and liquorice, along with the soothing and healing properties of Aloe vera. This indicates that increasing the concentration of herbal extracts improves the therapeutic effectiveness of the formulation.

Overall, the study concludes that the formulated polyherbal gel is safe, stable, and effective for the management of mouth ulcers. The high concentration formulation (F2) was found to be the most promising, showing better anti-inflammatory activity and overall performance.

Thus, the developed herbal gel can be considered a potential alternative to conventional treatments, offering a natural, cost-effective, and patient-friendly approach for oral ulcer therapy.

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