

Formulation And Evaluation Of A Herbal Oral Gel Containing Guava Leaf (*Psidium Guajava* L.) And Jamun (*Syzygium Cumini* L.) For The Management Of Oral Ulcers

Sneha Rushikesh Palimkar^{1*}, Snehal Santosh Pendbhaje²

Wani College Of Pharmacy, Ganegaon, Maharashtra (Affiliated to Dr Babasaheb Aambedkar Technological University, Lonere, Raigad)

ABSTRACT

Oral ulcers are common lesions of the oral mucosa that may cause pain, burning, difficulty in eating and discomfort during speaking. They may develop because of local trauma, infection, nutritional deficiency, immune changes and several other factors. Treatment is mainly aimed at reducing pain and inflammation and helping the ulcer heal. Herbal medicines are being studied as supportive options because many medicinal plants contain phenolic compounds, flavonoids and tannins with antioxidant, antimicrobial and anti-inflammatory properties. Guava leaf (*Psidium guajava* L.) is traditionally used in oral care and has been investigated for antimicrobial and antioxidant activity. Jamun (*Syzygium cumini* L.) also contains several polyphenolic compounds and has shown antioxidant, antimicrobial and anti-inflammatory potential. The present review discusses the possible use of guava leaf and jamun extracts in a herbal oral gel for oral-ulcer management. It covers the causes and features of oral ulcers, phytochemical profile and biological activities of both plants, formulation considerations, suitable evaluation tests, possible mechanism, research gap and future scope. A mucoadhesive gel may provide better contact with the affected mucosa and may help retain the herbal constituents at the site of application. However, the combined guava-jamun formulation requires proper laboratory evaluation, stability studies and clinical investigation before its therapeutic effectiveness can be confirmed.

Keywords: Oral ulcer, recurrent aphthous stomatitis, *Psidium guajava*, *Syzygium cumini*, guava leaf, jamun, herbal gel, mucoadhesive gel, oral mucosa, wound healing.

INTRODUCTION

Oral ulcers are among the common problems affecting the oral mucosa. They may occur as single or multiple painful lesions and can make eating, drinking, speaking and maintaining oral hygiene difficult. Recurrent aphthous stomatitis is one of the commonly reported forms of oral ulceration. Its exact cause is not fully understood and several local and systemic factors may be involved.⁽¹⁾

The management of oral ulcers depends on the cause and severity of the lesion. Topical preparations are commonly preferred because they can act directly at the affected area. Corticosteroids, analgesics, antiseptics and other agents may be used according to clinical requirements. However, conventional oral preparations can be removed quickly by saliva, which may reduce the time of contact with the ulcer.⁽²⁾

Medicinal plants are receiving attention because they contain several naturally occurring compounds with biological activity. Guava leaves contain flavonoids, tannins and phenolic compounds and have been investigated for oral antimicrobial and antioxidant activity. Jamun leaves are also rich in polyphenolic compounds and have reported antioxidant and antimicrobial properties. A combination of the two plants in a suitable oral gel may therefore provide a useful research approach for local application to oral ulcers.⁽³⁾

Oral health is an important component of general health and quality of life. The oral cavity is continuously exposed to mechanical irritation, microorganisms, food components, changes in temperature, and various chemical substances. Because of these factors, different types of oral mucosal disorders may develop. Among them, oral

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ulcers are one of the most frequently encountered conditions and may affect individuals of different age groups. Oral ulcers are characterized by localized loss or disruption of the oral mucosal epithelium and are commonly associated with pain, inflammation, burning sensation, difficulty in eating, swallowing, and speaking.⁽⁴⁾

Recurrent oral ulcers, particularly recurrent aphthous ulcers, are common inflammatory lesions of the oral mucosa. They generally appear as well-defined, painful ulcers surrounded by an erythematous margin. Although many uncomplicated ulcers heal spontaneously within a limited period, the associated pain and inflammation can significantly interfere with normal oral activities. Repeated episodes may also affect nutritional intake, oral hygiene, work performance, and overall quality of life. The exact cause of oral ulceration may vary among individuals and can involve local trauma, microbial infection, nutritional deficiencies, stress, immune alterations, hormonal changes, and systemic conditions.⁽⁵⁾

The management of oral ulcers mainly aims to reduce pain and inflammation, control microbial contamination, protect the ulcerated area, and promote healing of the damaged mucosa. Conventional treatment may involve topical analgesics, antiseptic agents, anti-inflammatory drugs, corticosteroids, antimicrobial agents, and protective preparations. Although these approaches can provide symptomatic relief, prolonged or inappropriate use of some conventional agents may be associated with adverse effects, unpleasant taste, irritation, poor patient acceptability, or recurrence after discontinuation. These limitations have encouraged researchers to investigate safer and more acceptable alternatives for the local management of oral ulcers.⁽⁶⁾

Medicinal plants have received considerable attention as potential sources of biologically active compounds for oral healthcare. Plant-derived materials contain several classes of phytoconstituents, including flavonoids, phenolic compounds, tannins, terpenoids, alkaloids, glycosides, and other secondary metabolites. Many of these constituents have been reported to possess antioxidant, antimicrobial, anti-inflammatory, astringent, and tissue-protective properties. Such properties may be useful in

managing the local factors associated with oral ulceration and supporting the natural healing process. However, the biological activity of a plant extract depends on several factors, including plant species, geographical origin, extraction method, solvent, concentration, and standardization of the extract.⁽⁷⁾

Among medicinal plants, guava (*Psidium guajava* L.) has attracted interest because its leaves are rich in biologically active phytoconstituents. Guava leaves contain flavonoids, phenolic compounds, tannins, triterpenoids, and other secondary metabolites. Compounds such as quercetin and related polyphenolic constituents have been investigated for antioxidant and antimicrobial activities. The presence of tannins may also contribute to an astringent effect, which can be relevant to topical oral preparations. These characteristics provide a scientific basis for investigating guava leaf extract in herbal preparations intended for oral mucosal applications.⁽⁸⁾

Jamun (*Syzygium cumini* L.), commonly known as Indian blackberry or Java plum, is another medicinal plant traditionally used in different systems of medicine. Its leaves contain various phytoconstituents, including phenolic compounds, flavonoids, tannins, and other secondary metabolites. Extracts of different parts of the plant have been investigated for antioxidant, antimicrobial, anti-inflammatory, and other pharmacological activities. The phytochemical profile of jamun therefore provides a rationale for exploring its potential contribution to a herbal formulation intended for oral care.⁽⁹⁾

The combination of guava leaf and jamun may provide a broader phytochemical profile than the use of either plant alone. Guava may contribute flavonoids, tannins, and phenolic constituents, whereas jamun can provide additional polyphenolic and tannin-rich components. A combination approach may therefore be investigated for antioxidant, antimicrobial, and inflammation-related activities relevant to oral ulcer management. However, the presence of two plant extracts should not automatically be considered synergistic; any combined effect needs to be established experimentally through appropriate formulation and biological evaluation.⁽¹⁰⁾

The selection of a suitable dosage form is equally important for the effective application of herbal extracts. An oral gel can provide several advantages for localized treatment because it can be applied directly to the affected mucosal area. Compared with liquid preparations, a gel may provide better residence at the application site and can facilitate prolonged contact between the active constituents and the ulcerated mucosa. The incorporation of a suitable gelling and mucoadhesive system may further improve retention and ease of application. Carbopol and other pharmaceutically acceptable polymers are commonly investigated for gel preparation because they can provide desirable viscosity, spreadability, and mucoadhesive characteristics.⁽¹¹⁾

A properly developed herbal oral gel should possess suitable physical and pharmaceutical characteristics in addition to biological activity. Parameters such as appearance, homogeneity, pH, viscosity, spreadability, extrudability, mucoadhesive strength, extract or marker content, antioxidant activity, antimicrobial activity, in-vitro release, and stability can be considered during formulation development. Evaluation of these parameters is necessary to identify an acceptable formulation and to establish its consistency and quality.⁽¹²⁾

Despite the increasing interest in herbal preparations for oral healthcare, formulation-specific studies combining guava leaf and jamun in an oral gel for oral ulcer management remain limited. Therefore, development of a standardized herbal oral gel containing *Psidium guajava* leaf and *Syzygium cumini* leaf extracts may provide a useful research approach for investigating a locally applied plant-based formulation. The present work is focused on formulation development, optimization, and pharmaceutical evaluation of the herbal oral gel, along with assessment of selected phytochemical and biological properties relevant to oral ulcer management.⁽¹³⁾

Oral Ulcers

- ❖ **Definition :** An oral ulcer is a localized break in the continuity of the oral mucosal epithelium. The lesion is usually associated with pain, redness and tenderness. The appearance and duration of an ulcer depend on its cause and the condition of the patient.⁽¹⁴⁾

❖ Common Causes

- Local trauma or accidental injury
- Stress and other triggering factors
- Nutritional deficiencies
- Infections
- Immune-related conditions
- Systemic diseases
- Certain medicines
- Recurrent aphthous stomatitis

- ❖ **Recurrent Aphthous Stomatitis :** Recurrent aphthous stomatitis is characterized by repeated episodes of painful oral ulcers. The lesions are commonly found on non-keratinized oral mucosa. They may be classified as minor, major or herpetiform according to clinical presentation. Treatment generally aims to control pain and inflammation and to shorten the duration of the lesion.⁽¹⁵⁾

- ❖ **Need for Herbal Oral Gel :** An oral gel can be applied directly over the affected area and may provide better local contact than a liquid preparation. A mucoadhesive gel can remain on the mucosal surface for a longer period and may reduce rapid removal by saliva. Herbal extracts may provide several biological activities in the same formulation. Therefore, a guava-jamun gel is a suitable concept for investigation, provided that its safety, quality and effectiveness are properly established.⁽¹⁶⁾

Plant profile

1. Guava Leaf (*Psidium guajava* L.)



Fig no 1 : Guava Leaf

❖ Botanical Information

- Biological name: *Psidium guajava* L.
- Family: Myrtaceae
- Common name: Guava
- Proposed plant part: Leaves.⁽¹⁾

❖ Phytochemical Constituents

Flavonoids

Tannins

Phenolic compounds

Quercetin

Guajjaverin

Catechin

Epicatechin

Rutin

Kaempferol

Triterpenoid compounds

❖ Pharmacological Importance

Guava leaf extracts have been reported to possess antimicrobial and antioxidant properties. Studies related to oral health have investigated their activity against oral microorganisms. Phenolic and flavonoid compounds may contribute to free-radical scavenging and modulation of inflammatory processes. Traditional use of guava leaves in mouth-related conditions also provides a basis for further investigation.⁽²⁾

❖ Relevance to Oral Ulcers

The possible value of guava leaf in oral-ulcer management is related to its antimicrobial, antioxidant and anti-inflammatory properties. These activities may help create a favorable local environment for healing. Recent clinical research has also examined a guava-based herbal gel in recurrent aphthous stomatitis, supporting the need for further formulation studies.⁽²⁾

2. Jamun (*Syzygium cumini* L.)



Fig no 2 : Jamun

❖ Botanical Information

- Biological name: *Syzygium cumini* (L.)
- Family: Myrtaceae
- Common names: Jamun, Indian blackberry and Java plum
- Proposed plant part: Leaves.

❖ Phytochemical Constituents

Tannins

Flavonoids

Phenolic compounds

Gallic acid

Ellagic acid

Malic acid

Essential-oil constituents

Other polyphenolic compounds

❖ Pharmacological Importance

Jamun leaves have shown antioxidant and antimicrobial activity in experimental studies. The polyphenolic content may contribute to these effects. Anti-inflammatory activity has also been reported in studies of different parts or extracts of the plant.⁽⁵⁾

❖ Relevance to Oral Ulcers

The antioxidant and antimicrobial properties of jamun provide a reasonable basis for studying its use in an oral formulation. However, direct clinical evidence for jamun leaf specifically in oral-ulcer treatment is still limited. This makes systematic formulation and biological evaluation important.⁽²⁾

❖ Rationale for Combining Guava Leaf and Jamun

Both plants contain flavonoids, tannins and other phenolic compounds. Their reported biological properties suggest that they may complement each other in a topical oral formulation. The proposed combination is expected to be studied for antimicrobial, antioxidant and anti-inflammatory potential while the gel base may improve local retention. Any synergistic effect between the two extracts should be confirmed experimentally and should not be assumed only from their individual activities

Herbal Oral Gel as a Drug Delivery System

A gel is a semisolid preparation in which a liquid phase is held within a polymeric network. For oral application, the formulation should spread easily, remain at the site for a suitable period, have an acceptable pH and be non-irritant. Mucoadhesive polymers can increase contact time with the mucosal surface and may improve local delivery.⁽⁶⁾

MATERIALS & METHODOLOGY**1. Material**

❖ Herbal Materials

- **Guava leaves (*Psidium guajava* L.)** – selected as the primary herbal material because of its reported antimicrobial, antioxidant and anti-inflammatory properties.
- **Jamun leaves (*Syzygium cumini* L.)** – selected as the second herbal material because of its reported antioxidant, antimicrobial and polyphenolic constituents.

❖ Excipients

Material	Category/Role
Carbopol 934	Gelling and mucoadhesive agent
Glycerin	Humectant
Propylene glycol	Co-solvent/humectant
Triethanolamine	Neutralizing and pH-adjusting agent
Sodium benzoate	Preservative, if required
Suitable sweetening agent	Taste masking
Suitable flavour	Improvement of palatability
Purified water	Vehicle

2. EXTRACTION OF GUAVA LEAVES

Collection → Authentication → Washing → Shade drying → Powdering → Extraction → Filtration → Concentration → Drying → Storage

Procedure

1. Fresh and healthy guava leaves are collected.
2. The leaves are washed carefully with purified water to remove dust and foreign matter.
3. The cleaned leaves are dried in shade at room temperature.
4. Completely dried leaves are powdered using a suitable grinder.
5. The powdered material is passed through a suitable sieve.
6. A measured quantity of powder is subjected to extraction using a suitable solvent such as **ethanol or hydroalcoholic solvent**.
7. The extraction may be carried out by maceration or Soxhlet extraction depending on the experimental design.

8. The extract is filtered through suitable filter paper.
9. The filtrate is concentrated under reduced pressure or at controlled temperature.
10. The concentrated extract is dried and stored in an airtight container until further use.^(1,5,16)

Percentage Yield

$$\text{Percentage Yield} = \frac{\text{Weight of dried extract}}{\text{Weight of powdered drug}} \times 100$$

3. EXTRACTION OF JAMUN LEAVES

Process :

Collection → Authentication → Cleaning → Shade drying → Powdering → Extraction → Filtration → Concentration → Drying → Storage

The dried jamun leaf powder is extracted using the selected solvent. After extraction, the filtrate is concentrated under controlled conditions and stored in a well-closed container.

The percentage yield is calculated using^(2,7)

$$\text{Percentage Yield} = \frac{\text{Weight of dried jamun extract}}{\text{Weight of powdered jamun leaves}} \times 100$$

4. PRELIMINARY PHYTOCHEMICAL SCREENING

Phytoconstituent	Suggested test
Alkaloids	Mayer's/Dragendorff's test
Flavonoids	Shinoda test
Tannins	Ferric chloride test
Phenolic compounds	Ferric chloride test
Saponins	Foam test
Glycosides	Suitable chemical test
Terpenoids	Salkowski test
Steroids	Liebermann–Burchard test

FORMULATION OF HERBAL ORAL GEL

Process

1. Accurately weigh the required quantity of Carbopol 934.
2. Slowly sprinkle the polymer into purified water with continuous stirring.
3. Allow the polymer to hydrate completely.
4. Prepare a separate solution/dispersion of guava and jamun extracts.
5. Add glycerin or propylene glycol to the extract mixture where required.
6. Incorporate the herbal extract mixture slowly into the hydrated Carbopol dispersion.
7. Stir continuously to obtain uniform distribution.
8. Add the required preservative and taste-masking agents.
9. Adjust the pH gradually using a suitable neutralizing agent such as triethanolamine.
10. Continue stirring until a smooth and homogeneous gel is obtained.
11. Remove entrapped air by keeping the formulation undisturbed or using an appropriate de-aeration method.
12. Transfer the gel into suitable well-closed containers.^(2,3)

EVALUATION PARAMETERS

1. Physical Appearance

Purpose : To determine the physical characteristics and uniformity of the prepared gel.

Process : A small quantity of gel is placed in a clean glass container and examined visually under suitable lighting.⁽⁵⁾

Observe:

- Colour
- Odour

- Appearance
- Texture
- Clarity/opacity
- Presence of lumps
- Presence of foreign particles
- Phase separation

Process

1. Take a sufficient quantity of gel in the sample container.
2. Allow the sample to equilibrate at room temperature.
3. Use a suitable Brookfield viscometer.
4. Select an appropriate spindle and rotational speed.
5. Record the viscosity in **cP or mPa·s**.
6. Perform measurements in triplicate.

2. Homogeneity

Process : A small amount of gel is pressed between two clean glass slides or spread over a clean surface.⁽⁶⁾

The formulation is examined for:

- Uniform colour
- Uniform texture
- Absence of lumps
- Absence of coarse particles
- Absence of phase separation

3. pH

Purpose : The pH of an oral gel should be suitable for the oral mucosa and should minimize irritation.⁽⁷⁾

Process

1. Accurately weigh approximately **1 g of gel**.
2. Disperse it in a suitable quantity of distilled/purified water.
3. Allow the dispersion to equilibrate.
4. Calibrate the digital pH meter using standard buffer solutions.
5. Immerse the electrode into the sample.
6. Record the pH.

4. Viscosity

Purpose : Viscosity determines the flow characteristics, ease of application and residence behavior of the gel.⁽⁸⁾

5. Spreadability

Purpose : To determine how easily the gel spreads over the affected mucosal area.⁽¹⁾

Method

1. Place a known quantity of gel between two glass slides.
2. Apply a known load for a fixed period.
3. Measure the spreading distance or determine the time required for a specified movement.

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

Where:

S = Spreadability

M = Weight applied

L = Length moved by the slide

T = Time taken

6. Extrudability

Purpose : To determine the ease with which the gel can be removed from its container/tube.⁽²⁾

Process

1. Fill the gel into a collapsible tube.
2. Close the tube properly.
3. Apply controlled pressure.
4. Observe the amount of gel extruded.
5. Compare different formulations.

7. Mucoadhesive Strength

Purpose : To determine the ability of the gel to adhere to mucosal tissue.⁽³⁾

Process

1. Suitable biological mucosal tissue or a validated mucin-based model is prepared according to the laboratory protocol.
2. A known quantity of gel is placed between the mucosal surfaces.
3. The surfaces are brought into contact under controlled conditions.
4. A force is gradually applied until the gel separates.
5. The detachment force is recorded.

8. Stability Study

Purpose : To determine whether the optimized formulation remains acceptable during storage.⁽⁴⁾

Parameters

- Appearance
- Colour
- Odour
- pH
- Viscosity
- Spreadability
- Mucoadhesive strength
- Marker/phenolic content

- Microbial quality

Process

The optimized formulation is stored under selected stability conditions according to the applicable stability protocol. Samples are withdrawn at predefined intervals and compared with initial values.⁽⁵⁾

CONCLUSION

The combination of *Psidium guajava* (guava) and *Syzygium cumini* (jamun) leaves offers a promising herbal approach for the management of oral ulcers due to their reported antioxidant, antimicrobial and anti-inflammatory properties. Formulating these extracts as an oral gel may provide direct application, better mucosal contact and improved patient acceptability. Evaluation of physicochemical, phytochemical and biological parameters can help establish the quality and potential effectiveness of the formulation. Further optimization, stability and clinical studies are required to confirm its safety and therapeutic potential.

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