

FORMULATION AND EVALUATION OF GEL CONTAINING *MANGIFERA INDICA* LEAVES EXTRACT FOR THE TREATMENT OF MOUTH ULCERS

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Article Received on 25/05/2025

Article Revised on 14/06/2025

Article Accepted on 03/07/2025

ABSTRACT

The present study focuses on the formulation and evaluation of a topical gel incorporating *Mangifera indica* (mango) leaves extract for the treatment of mouth ulcers. *Mangifera indica* leaves are known for their anti-inflammatory, antimicrobial, and antioxidant properties, making them a promising natural remedy for oral lesions. Mouth ulcers are a common oral condition characterized by painful lesions that can significantly impact daily activities such as eating and speaking. In recent years, there has been growing interest in herbal remedies due to their safety, efficacy, and biocompatibility. *Mangifera indica* (mango) leaves are rich in bioactive compounds such as flavonoids, tannins, and phenolic acids, which exhibit anti-inflammatory, antimicrobial, and antioxidant properties-making them a promising candidate for oral ulcer therapy. This review aims to provide a comprehensive overview of the formulation and evaluation parameters for gels incorporating *Mangifera indica* leaf extract, with a focus on their therapeutic potential in treating mouth ulcers. The gel contains the main ingredients mango Leaves extract, & Carbopol 934 as a gelling agent and Propylene glycol as a co-solvent. Another ingredient Glycerin as a humectant, Propylene glycol as a solvent & stabilizer, Methyl paraben as a preservative, Sodium saccharin as a Sweetener, Sodium bicarbonate as pH adjuster & mint oil as cooling agent. The formulated gel was tested for different parameters such as physicochemical parameters (pH, viscosity, distribution ability, etc.) The gel is homogeneous mixture that shows the pH 6.8. This gel was stable at room temperature protected from any germs and thus safe for use on mouth sores. The gel was prepared using a carbopol-based formulation, and its physicochemical properties, including pH, viscosity, spreadability, and homogeneity, were systematically evaluated. Results demonstrated that the formulated gel exhibited desirable physicochemical characteristics and enhanced ulcer healing. These findings suggest that *Mangifera indica* leaves extract gel may serve as an effective and natural therapeutic option for the management of mouth ulcers.

KEYWORDS: *Mangifera indica*, mouth ulcer, herbal gel, anti-inflammatory, antimicrobial, oral care.

INTRODUCTION

Ulcer: An ulcer is a sore or open wound that develops on the skin or mucous membranes, often due to damage caused by stomach acid or infection.

▪ Types of Ulcers

1. Peptic Ulcers (most common)
2. Mouth Ulcers
3. Skin Ulcers

Mouth Ulcers

Mouth ulcers are painful sores that appear inside the mouth. This leaflet talks about the most common type, called aphthous mouth ulcers. About 1 in 5 people will get these at some point in their lives, and women are more likely to have them than men. An oral ulcer (also known as a mouth ulcer) is a sore that forms on the soft

tissue inside the mouth. These round or oval sores usually appear on the inner cheeks or lips and can be very painful. Eating, drinking, or brushing your teeth can make them hurt more. Common causes include a lack of nutrients, especially iron and vitamins like B12 and C. Mouth ulcers can be caused by poor hygiene, certain diseases, depression, indigestion, physical injury, food intolerance, hormonal imbalances, skin conditions, and more. A mouth ulcer is a break or sore in the mucous membrane inside the mouth.



Fig no. 1: Mouth ulcer.

▪ **Types of Mouth ulcer:** On basis of size and number of ulcers.

1. Minor Aphthous Ulcers (Mikulicz ulcers)

Size: Small (less than 10 mm in diameter) & Number: Usually 1-5 at a time.

Features: Shallow, round or oval with a red border and a yellowish or greyish center.

Healing Time: 7-14 days without scarring.

2. Major Aphthous Ulcers (Sutton disease or periadenitis mucosa necrotica recurrens)

Size: Large (greater than 10 mm) & Number: Usually 1-2, but can be more

Features: Deeper and more painful than minor ulcers

Healing Time: Several weeks (up to 6 weeks) and may leave scarring.

GEL

According to the I.P. (2013) definition of Gel is given by Singh Vijay Kumar et al., gels are homogeneous, semisolid preparations typically composed of solutions or dispersions of one or more drugs in suitable hydrophilic or hydrophobic bases. The inorganic particles form a three-dimensional, "house of cards"-like structure.



Fig no. 2: Gel.

The stiffness or thickness of a gel comes from a network formed by the gelling agent. The structure of this network, and the physical properties of the gel, depend on the type of force that holds the particles together and the kind of particles involved.

▪ **CLASSIFICATION OF GELS**

Gels can be categorized according to various criteria such as colloidal phases, the type of solvent used, their

physical state, and their flow properties (rheology), etc. (Gaire Arjun et al., 2021).

1) Based on colloidal phases

They are divided into.

a) **Inorganic gels** - These consist of a two-phase system.

b) **Organic gels** - These consist of a single-phase system.

2) Based on the nature of solvent used

They are divided into:

a) **Hydrogels** (water based)

b) **Organic gels** (non-aqueous solvent)

c) **Xerogels**

3) Based on rheological properties

They are divided into:

a) **Plastic gel**

b) **Pseudo plastic gel**

c) **Thixotropic gel**

4) Based on physical nature

They are divided into:

a) **Elastic gels**

b) **Rigid gels**

5) Based on gel forming polymers

They are divided into

a) **Natural polymer**

b) **Semi-synthetic polymer**

c) **Synthetic polymer**

▪ **Uses of Gels**

- ✓ As drug delivery systems for oral medications.
- ✓ For topical application of drugs directly to the skin, mucous membranes, or eyes.
- ✓ As long-acting drug forms, administered through intramuscular injection or implanted into the body.
- ✓ As binders in tablet formulation, protective agents in suspensions, thickeners in oral liquids, and bases for suppositories.

▪ **Mangifera indica Linn**

Mangifera indica (MI), commonly known as mango or "aam," has been an important herb in Ayurvedic and traditional medicine systems for over 4,000 years. Mangoes belong to the genus Mangifera, which includes around 30 species of tropical fruit-bearing trees in the flowering plant family Anacardiaceae. According to Ayurveda, various parts of the mango tree are attributed with diverse medicinal properties. Mango is one of the most popular tropical fruits. Mangiferin, a polyphenolic antioxidant and a glucosyl xanthone, exhibits strong antioxidant, anti-lipid peroxidation, immunomodulatory, cardioprotective, hypotensive, wound-healing, neuroprotective, and antidiabetic and antiulcer properties. Different parts of the plant are used traditionally as dentifrice, antiseptic, astringent, diaphoretic, stomachic, vermifuge, tonic, laxative, and diuretic.

They are also used to treat conditions such as diarrhea, dysentery, anemia, asthma, bronchitis, cough, hypertension, insomnia, rheumatism, toothache, leucorrhea, hemorrhage, and piles.

Phytochemicals: *Mangifera indica* linn extract has saponins, tanins, flavanoids, alkaloids, The qualitative phytochemical analysis of the aqueous mango leaves extract revealed the presence of phenols, flavonoids, saponins, tannins, terpenoid, glycosides, carbohydrate & sugars, fixed oils and fats and alkaloids.



Fig no.3: mango leaves.

Pharmacological Activities

- Anticancer activity
- Anti-diabetic
- Antioxidant activity
- Anti-microbial activity
- Antiulcer activity
- Gastrointestinal benefits
- Liver protection
- Cardio-protection

ANTI ULCER ACTIVITY

Mangifera indica, commonly known as mango, has been traditionally used for its medicinal properties. Research suggests that mango extracts may possess anti-ulcer activity, including mouth ulcers.

ANTI MICROBIAL ACTIVITY

The antimicrobial activities of methanolic extracts of MI have been investigated. The results show that MI extracts exhibited antimicrobial activities at a concentration of 20 mg/ml. Overall, MI extract show more antimicrobial activity tested on organisms.

MATERIALS AND METHODS

▪ Ideal properties of Ingredient

1. **Mango leaves extract:** - The mango (*Mangifera indica* L.) leaves extracts present in gel used to kill or inhibit common secondary oral pathogens of mouth ulcer. It shows antimicrobial activity, anti-inflammatory activity, anti-oxidant activity, ect.
2. **Carbopol- 934:** - Carbopol is polymer which is most essential ingredient in our gel. This is because it contains natural gelling agent & helps to provides excellent viscosity even at low concentration. It

forms a smooth & clear gel which adheres well and stays localized.

3. **Glycerin:** - It attracts & moisture at the site of the ulcer, preventing dryness & promoting a moist wound environment which aids healing. It also provides a cooling, soothing sensation, which helps to relieve pain & discomfort related with mouth ulcer. It used as Humectant agent in gel.
4. **Propylene glycol:** - it helps to retain moisture in gel. safe for sensitive oral tissues with no allergic reactions. It keeps the ulcer area moist & hydrated, unpleasant taste.
5. **Methyl paraben:** - methyl paraben used as preservative in our herbal gel formulation. It inhibits the growth of bacteria. Extend shelf life, it works well at low concentration and maintaining efficacy of product.
6. **Sodium saccharin:** - sodium saccharin serves primarily as a sweetening agent in our gel formulation for mouth ulcer. Unlike sugar, it does not promote tooth decay, making it a safer sweetener for oral products. Chemically stable.
7. **Sodium bicarbonate:** - sodium bicarbonate helps to maintain an optimal pH in our gel formulation, because mango leaves extract can be acidic. It can also help to neutralize excess oral acidity which is often related with ulcer discomfort. Enhance the absorption.
8. **Mint oil:** - also known as Mentha oil or peppermint oil, it contains menthol which provides a cooling sensation & temporary pain relief, soothing the ulcerated area. It also has mild anti-inflammatory properties, reducing swelling and redness around the ulcer. Improves the taste & freshness.
9. **Purified water:** - In our formulation water used as vehicle. It is used to extract bioactive compounds due to its polarity & safety for oral use. Helps in moisturizing and soothing the ulcerated area which is crucial in oral ulcer treatment.

▪ Qualitative phytochemical analysis of aqueous extract of mango leaves

1. **Phenolic compounds (Ferric chloride test):** 1-2 ml of aqueous extract was taken in test tube then add few drops of 5.0% neutral ferric chloride solution into test tube and the develop dark green colour which indicated the presence of phenolic compounds.
2. **Tannin test:** 1-2 ml of extract was taken into test tube & add few drops of 1% ferric chloride solution in test tube. It develops greenish black color which indicated the presence of tannins in the extract.
3. **Alkaloids test:** pour about 2-3 ml of extract in test tube then add 1-2 drops of Wagner's reagent in test tube. It develops reddish brown color which indicated the presence of tannins in the extract.

Formulation

Table no. 1: Formulation batches (for 50 gm gel formulation).

Sr. No	Ingredient	Quantity			
		F1	F2	F3	F4
1	Mango leaves extract	5 ml	4 ml	6 ml	5 ml
2	Carbopol-934	0.5 gm	1 gm	0.8 gm	1 gm
3	Glycerin	5 ml	4 ml	5 ml	5 ml
4	Propylene glycol	5 ml	5 ml	5 ml	5 ml
5	Methyl paraben	0.05 gm	0.04 gm	0.05 gm	0.05 gm
6	Sodium saccharin	0.1 gm	0.1 gm	0.1 gm	0.1 gm
7	Sodium bicarbonate	Q. s	Q. s	Q. s	Q. s
8	Mint oil	Q.s (1-2 drops)	Q.s (1-2 drops)	Q.s (1-2 drops)	Q.s (1-2 drops)
9	Purified water	Up to 50 ml	Up to 50 ml	Up to 50 ml	Up to 50 ml

Method of preparation

1) Extraction preparation

- Collection & identification of plant material then wash & dry mango leaves
- Grind the powder of dried mango leaves & Weigh known quantity of powder.
- Add weighed mango leaves material into beaker & add purified water as extraction solvent.
- Then place beaker in water bath & set the temperature to 60-80 °c.
- Allow the extraction to proceed for 30 minutes to 1 hours & stirred occasionally.
- After extraction, cool mixture at room temp. & filter the extraction. Store filtrate in clean container



Fig no 4: preparation of mango leaves extract.



2) Gel Base Formulation

- Take Carbopol -934 in beaker & dispersed into purified water & heated on water bath.
- After cooling, add Glycerin & propylene glycol in mixture with occasionally stirred.
- Then add methyl paraben while stirring & Incorporation of active extract: slowly mix mango leaves extract into gel base.
- After that adjust the pH to 5.0- 6.2 using sodium bicarbonate with stirring.
- Add sodium saccharin & 1-2 drops mint oil with mixing until homogenous.
- At last, store in sterile container, labelled the container & packed it.



Fig no: 5 Gel base.



Fig no. 6: Final gel formulation.

▪ Evaluation Parameters

- 1. Organoleptic properties:** The formulation was studied for physical appearance, colour and odour were checked.
- 2. Measurement of pH:** The pH measurement was done using pH meter. pH of mouth was near to neutral.
- 3. Skin Irritation test:** It is carried out by applying herbal gel on the skin for 10 min.
- 4. Test of Spread ability:** The test of Spread ability consisted of applying the product repeatedly onto a glass slide.
- 5. Skin Sensitivity:** It was carried out by applying the product in the form of a patch on the skin for 30 min and observe the reaction.
- 6. Clarity of gel:** The clarity of gel was Determine by visual inspection.
- 7. Homogeneity:** Gel formulations were tested for homogeneity by visual inspection after the gels have been set in to the container.
- 8. Viscosity:** Viscosity was determined by using Brookfield viscometer. Formulated gels were tested at 25°C. The measurement was made over range of speed from 20rpm with 30seconds between 2 successive speeds & record.

▪ RESULT AND DISCUSSION

▪ Phytochemical investigation of extracts

Table no. 2: Phytochemical investigation of extracts.

Sr.no	Phytochemical constituent	Mango leaves aq. extract	Observation
1	Phenolic compound(mangiferin)	+	Dark green color
2	Tannin	+	Green- black color
3	Alkaloids	+	Reddish- brown color

▪ Organoleptic evaluation

Table no. 3: Organoleptic evaluation.

Sr.no	Formulations	Colour	Odour	Texture	Homogeneity	Clarity
1	F1	Drak yellow	Characteristics	Thick	Not good	Not clear
2	F2	Light yellow	Characteristics	Semi-solid	Mild good	Less Clear
3	F3	Slightly yellow	Characteristics	Less soft	Good	Clear
4	F4	yellow	Characteristics	Smooth	Very Good	Clear

▪ Skin Sensitivity

It was carried out by applying the product in the form of a patch on the skin for 30 min and No signs of irritation, dryness observed.

▪ Evaluation parameters of prepared gel formulation

Table 4: evaluation parameters of prepared gel formulation.

Sr.no	Formulation	pH	Viscosity (CPs)	Skin irritation
1	F1	5.6	1384	Mild irritation
2	F2	5.8	1831	Slight irritation
3	F3	6.1	2048	No irritation
4	F4	6.2	2258	No irritation

▪ Spread ability test



Fig no. 6: spreadability.

Table 5: spreadability.

Sr. No	Spread ability observation
1	good spread ability
2	Less spread ability
3	Slightly spread ability
4	Excellent spread ability

CONCLUSION

- A topical gel was successfully formulated using *Mangifera indica* (mango) leaf extract.
- Designed for oral ulcer treatment forms a protective layer, reducing pain and promoting healing.
- Mango leaf extract exhibits antimicrobial, anti-inflammatory, antioxidant, and antibacterial properties.
- The formulation was tested for antimicrobial activity, effectively inhibiting ulcer-causing pathogens.
- Final batch (F4) results:
 - ✓ Contains phenolic compounds, tannins, and alkaloids
 - ✓ Smooth texture, yellow color, clear appearance
 - ✓ pH: 6.2, Viscosity: 2258 cP, No skin irritation
 - ✓ Excellent Spread ability and homogeneity

Future Scope

1. Therapeutic Advancements: -Alternative to Synthetic Drugs & Dual Action (Healing + Antimicrobial)
2. Analysis of anti- microbial activity & stability study

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