



## Research Article

# Formulation And Evaluation of Herbal Gel for Management of Mouth Ulcer

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### ABSTRACT

This research is about creating and testing a polyherbal gel for the treatment of mouth ulcers, which are a frequent symptom of oral inflammation, pain, and discomfort. Due to exposure to microorganisms, irritants, and mechanical trauma, the oral cavity is particularly vulnerable to inflammation. Typical therapies frequently just provide short-term relief and can have adverse effects when used for a long period of time. An herbal gel was created using extracts from banana flower (*Musa paradisiaca*) and tamarind seed (*Tamarindus indica*), both of which are well known for their anti-inflammatory, antibacterial, and antioxidant effects, in order to address these constraints. Carbopol 940 was used as a gelling agent in the gel's formulation, together with the necessary excipients. The prepared formulations were assessed for physicochemical properties including color, odor, pH, viscosity, spreadability, homogeneity, and washability. The protein denaturation technique was also used to evaluate anti-inflammatory action. With greater concentrations showing improved effects, the findings demonstrated that all formulations had acceptable physical qualities and appreciable anti-inflammatory effects. Between consistency, stability, and therapeutic effectiveness, the optimized formulation performed well across all batches. The created polyherbal gel is a secure, efficient, and affordable option for treating oral ulcers, and the study comes to the conclusion that it may be further developed as a topical herbal therapeutic system.

## INTRODUCTION

The body's normal line of defense against infection is inflammation. When tissues are injured, infected, or irritated, it occurs. Its primary goals are to shield the body, eliminate dangerous substances like bacteria, and aid in the healing process. The oral

cavity (mouth) is made up of the teeth, tongue, lips, gums, cheeks, and palate. The mouth is highly susceptible to inflammation because it is constantly exposed to chemicals, germs, and food. Inflammation in the mouth may result in redness, swelling, discomfort, heat, and occasionally a loss of function. Poor oral hygiene, bacterial infections,

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sharp teeth, dentures, tobacco use, spicy food, stress, and vitamin deficits are all common causes.[4]

Inflammation in the oral cavity can result in redness, edema, pain, heat, and occasionally loss of function. Common causes include stress, vitamin deficiencies, tobacco usage, spicy meals, dentures, sharp teeth, bacterial infections, and poor oral hygiene. [5]

Inflammation is a defensive biological response that aids the body in fending off dangerous stimuli and minimizing tissue damage. It causes a series of physiological events that are coordinated to minimize harm and eliminate the underlying cause of the injury.[6] The arterioles, venules, and capillaries expand during this process, resulting in greater local blood flow. Additionally, plasma proteins and fluid are able to enter damaged tissues due to an increase in vascular permeability. White blood cells then move from the bloodstream to the damaged region to initiate cleanup and protection.

Typically, monocytes and then lymphocytes follow neutrophils as they arrive at the lesion. The main objective is to eliminate and neutralize the harmful agent as soon as feasible. Inflammation acts to limit the damage and prevent it from spreading further if eradication is postponed. It also fosters conditions conducive to tissue healing and functional rehabilitation. Ideally, the healing process shouldn't cause much disturbance to the host's usual physiology. Stress-related biological reactions are also strongly correlated with inflammation. [7]

Pathways like NF-kB can be activated during intense psychosocial stress. This stimulation encourages the release of pro-inflammatory cytokines, frequently via adrenergic signaling.

Therefore, inflammation not only helps to dilute or eliminate harmful substances, but it also starts the healing process. When feasible, repair may happen

by regenerating the original parenchymal cells. Fibroblast-driven scar creation helps fill gaps when regeneration is incomplete.

Tissue defects. A key functional feature throughout this response is efficient leukocyte delivery via increased flow, microvascular changes, and directed accumulation at the injury site.[8, 9] Why the Oral Cavity is Prone to Inflammation.

The oral cavity is one of the most exposed parts of the body. It is constantly in contact with:

- Food and drinks
- Millions of bacteria
- Tobacco, alcohol, and irritant
- Physical injury from teeth, braces, or dentures [1]

### CAUSES OF ORAL INFLAMMATION:

Oral inflammation can be caused by:

1. Poor oral hygiene and plaque accumulation
2. Bacterial, Viral, or Fungal Infection
3. Tooth decay and gum diseases
4. Sharp or broken tooth
5. Ill-fitting dentures or orthodontic appliances
6. Smoking and chewing tobacco
7. Nutritional deficiencies (especially vitamin B complex, iron and vitamin C)
8. Stress and hormonal changes
9. Systemic diseases like diabetes [1]

### TYPES OF INFLAMMATION:

1. Acute inflammation → Duration short few hours to days
2. Chronic inflammation → long term (month weeks or year) [10]
3. Sub-acute inflammation → Intermediate between acute and chronic
4. According to cause → Infectious inflammation, Non-infectious inflammation. [11, 12]



## MECHANISM OF INFLAMMATION:

Chemical irritation, infection, or tissue damage



Cells are harmed



The release of inflammatory mediators ( prostaglandins , leukotrienes , cytokines , PAF , histamine, bradykinin )[13, 14]



Blood vessel dilatation



Increased permeability of blood vessel



Fluid & plasma proteins enter tissues



Redness, warmth , edema, pain



Movement of leukocytes ( WBCs ) to the site of injury [15, 16]



The process of phagocytosis in which pathogens and injured cell are taken up



The arachidonic acid route is activated



Development of prostaglandins & leukotrienes



Increased inflammation



Resolution & healing (or chronic inflammation if uncontrolled) [17, 18, 19]

## TYPICAL INFLAMMATORY DISEASES OF THE MOUTH

### CAVITY:

- gingivitis gum inflammation The gums become red, swollen, and bleed readily. With sufficient oral hygiene, it may be turned around.
- Periodontitis An extreme manifestation of gum inflammation It impacts the bones that support the teeth as well as the deeper tissues. May result in tooth loss if left untreated
- Mouth Ulcers (Apthous ulcers) Stress, injury, or inadequate nutrition can cause painful sores on the lips, tongue, or cheeks [1].

### ORAL INFLAMMATION SYMPTOMS AND SIGNS:

- An oral ache or burning sensation
- Red border surrounding a spherical or oval ulcer with a white or yellow base
- Problems with eating, drinking, or talking
- Increased discomfort when eating hot or spicy foods
- Redness or swelling around the afflicted region
- The dry mouth or excessive salivation
- At times, there may be a slight temperature or general malaise (in extreme cases) [20].

### HERBAL ACTIVE INGREDIENT:

#### Banana flower powder:

**Originating in biology:** The banana flower is produced by the male inflorescence (flower bud) of the banana tree **Musa paradisiaca L.**

**Family:** Musaceae



**Banana flower, banana blossom, banana heart** Anti inflammatory  
are common names.

Anti-microbial

**Properties:** - antioxidant Antidiabetic



**Fig : 1 Banana flower powder**

**Tamarind seed:-**

**Biological source:** Seeds obtained from the mature fruits of *Tamarindus indica* L.

**Family:** Fabaceae (Leguminosae)

**Common name:** Tamarind seed / Imli seed

**Chemical constituent: -**

- Tamarind seed polysaccharide
- Phenolic compound
- Flavonoids and polyphenols
- Fatty Acids
- Proteins and amino acids
- Tannins and saponins [21]



**Fig: 2 Tamarind seed**

### **MOUTH ULCER :**

Antiseptics and corticosteroids can have adverse effects, including irritation. Because of its anti-inflammatory, antibacterial, and wound-healing capabilities, herbal medicine is crucial in oral care. Herbal remedies are safer, have fewer side effects, promote quicker healing, and are ideal for long-term oral care. [20]

### **GEL FORMULATION:**

The stiffness of a gel comes from the network of interacting particles that are created during preparation, and these are often gelling agents. The I.P. describes gels as homogeneous, semi-solid systems made up of solutions or dispersions of one or more medicinal substances in acceptable hydrophilic or hydrophobic bases. The network's structure and the gel's physical characteristics are determined by the makeup of the particles and the kinds of interactions that cause these links. Hydrophilic colloid particles can be made up of small molecules, single macromolecules, or

spherical or isometric aggregates. These particles can exist in a variety of configurations inside a gel matrix. The network in linear polymers is made up of entangled chains, with interaction sites that can be located far apart or form a crystalline structure with several molecules. Conversely, inorganic particles create a three-dimensional "house-of-cards" arrangement. Particle association can be brought about by a variety of forces, from powerful primary valence bonds like those seen in silicic acid gels to weaker hydrogen bonds and Van der Waals forces. The relative weakness of these latter forces is shown by the propensity of gels to liquefy with a small increase in temperature. [23]

### GEL CLASSIFICATION:

Gels can be categorized according to their rheological behavior, physical characteristics, the type of solvent employed, and colloidal phases.

Colloidal stages are the foundation:

1. Organic (single phase system)
2. Inorganic (two phases system) [24]

### METHOD OF EXTRACTION:

#### Preparation of Plant Material (Tamarind Seed):-



Fig: 3 Tamarind seeds extracted form



Fig: 4 After drying powder

#### Sample Preparation (Banana Flower Powder):-

Tamarind seeds were obtained from a local market in India. Because the seeds were extremely hard, they were first dried under sunlight for two days to facilitate grinding. The dried seeds were then powdered using a laboratory grinder. The resulting powder was further refined by passing it through sieve number 25 to obtain a fine powder. The prepared powder was packed in a polythene bag and stored in a refrigerator at 4°C until further use.

### Extraction Procedure:-

For the cold extraction method, 25 g of dried *Tamarindus indica* seed powder was separately extracted with 200 mL of acetone and ethanol using a continuous shaker at 26°C for 48 hours. For hot extraction, the same procedure was followed, but the extraction was performed in a temperature-controlled shaker maintained at 40°C for 48 hours. After completion of extraction, the acetone and ethanol extracts were filtered using a Buchner funnel with filter paper. The filtrates were then dried in a vacuum oven under reduced pressure at a low temperature (40°C). The dried extract of *T. indica* seeds was weighed

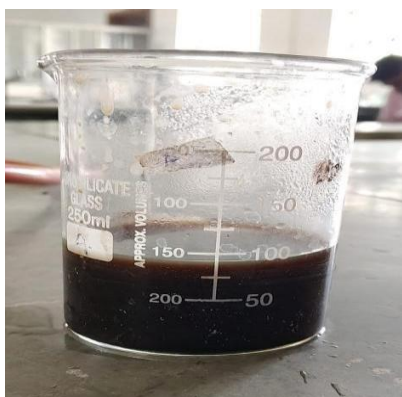
using an electronic balance and stored in airtight vials for further analysis. [25, 30]

Banana blossoms of the *Musa AAA* group and *Musa paradisiaca* were collected about 30 days after the emergence of the inflorescence. To

maintain biological replication, three individual plants from each cultivar were selected separately for sampling. The collected banana blossoms were washed thoroughly and divided into three anatomical parts: bracts, florets, and core. These portions were cut into small pieces (approximately  $0.3\text{--}0.5 \times 2.5\text{--}3.0\text{ cm}^2$ ) and soaked in 1% (w/v) citric acid solution for 15 minutes to reduce enzymatic browning. The samples were then rinsed with distilled water and allowed to drain completely. Afterward, the samples were dried in a tray dryer at  $50\text{ }^\circ\text{C}$  until the moisture content reached  $8 \pm 2\%$ . The dried material was then pulverized using a laboratory grinder and passed through a 60-mesh ( $250\text{ }\mu\text{m}$ ) sieve to obtain a uniform powder. The powdered samples were packed in foil bags and stored at room temperature in a dark environment until further analysis, which was performed within 30 days of collection.

### Sample Extraction:-

Each anatomical part of the banana blossom was extracted using two different solvents: distilled water ( $65 \pm 2\text{ }^\circ\text{C}$ ) and 50% (v/v) ethanol. For extraction, 1 g of powdered sample was mixed with 25 mL of solvent and heated at  $65\text{ }^\circ\text{C}$  for 30 minutes in a digital water bath with intermittent stirring. After extraction, the mixtures were cooled to room temperature ( $25 \pm 2\text{ }^\circ\text{C}$ ) and filtered through Whatman No. 1 filter paper. The filtrates were then freeze-dried following a modified procedure: the samples were first frozen at  $-80\text{ }^\circ\text{C}$  for 24 hours, followed by freeze-drying at  $-40\text{ }^\circ\text{C}$  under 0.1 mbar pressure for 48 hours. The resulting freeze-dried extracts (average yield 11.2%) were stored in airtight containers at  $4\text{ }^\circ\text{C}$  until further analysis. [22]



**Fig: 5 Banana flower powder extracted form**



**Fig: 5 After drying powder**

### PREPARATION OF GEL:

Take approximately 12–15 ml of distilled water in a beaker and disperse the required quantity of Carbopol 940 in it with continuous stirring. The beaker was kept aside to allow the Carbopol to swell for about 30–45 minutes to obtain a uniform dispersion. In another beaker, take a small quantity of distilled water and dissolve the required amount of methyl paraben by heating on a water bath. The

solution was allowed to cool, after which propylene glycol was added and mixed properly. Further, the accurately weighed quantities of tamarind seed extract and banana flower extract were dissolved separately in a small amount of distilled water and then combined to obtain a uniform extract mixture. The above extract solution was added slowly to the Carbopol dispersion with continuous stirring to ensure proper mixing. The preservative solution containing methyl paraben and propylene glycol

was then incorporated into the formulation with gentle stirring. Finally, the volume was made up to 20 ml (or 20 g) by adding the remaining quantity of distilled water and mixed thoroughly to obtain a

uniform, smooth gel-like dispersion. The prepared formulation was transferred into a suitable container. [23]



**Fig:7 Formulated gel**

**Formulation table:**

The method described above was followed for the preparation of the herbal gel and the formulation was tabulated in Table 1. Along with the control

sample, herbal gel was prepared by incorporating the required quantities of tamarind seed extract and banana flower extract into the Carbopol base to obtain a polyherbal gel formulation for topical application.

**Table 1. Composition of various gel formulation**

Ingredients	Q	uantity in gm or ml			
	F1	F2	F3	F4	
Tamarind seed extract	0.4g	0.5g	0.8g	1.2g	
Banana Flower extract	0.4g	0.5g	0.8g	1.2g	
Carbopol 940	0.3g	0.3g	0.3g	0.3g	
Propylene glycol	2ml	2ml	2ml	2ml	
Methyl paraben	0.4g	0.4g	0.4g	0.4g	
Distilled water	Qs to 20g	Qs to 20g	Qs to 20g	Qs to 20g	

**EVALUATION PARAMETER:**

**Physical evaluation:-**

Physical parameters such as color, odour and consistency were checked visually.

**Color:** The color of the formulations was checked by visual inspection.

**Consistency:** The consistency of formulations was checked by applying on skin. **Odour:** The odour of the formulations was checked by mixing the gel in water and observing the smell. Physical evaluations of gel formulations were reported .

**Measurement of PH:-**

The pH of gel formulations were determined by using digital pH meter. Take 1 gm of gel and dissolved in 10 ml of distilled water and keep apart for two hours. Then the measurement of pH of formulations was done by dipping the glass electrode completely into the gel system three times and the average values are reported. The pH of gel formulation was reported. [26]

**Viscosity: -**

Transfer emulgel into Viscometer beaker by using Brookfield Viscometer and by using suitable spindle at specific rpm. Then record viscosity reading in cps .[29]

**Spreadability: -**

Spreadability of the prepared emulgel was determined to evaluate the ease of application on the skin. A known quantity of the formulation was placed between two clean glass slides. A definite weight was placed over the upper slide to form a uniform thin layer. The time required for the upper slide to move a specified distance under the influence of the applied weight was recorded.

**Homogeneity:-**

All prepared gel formulations were tested for homogeneity by visual inspection after the gels have been set in to the container. They were tested for their presence and appearance of any aggregates. Homogeneity of gel formulation was reported.[27]

**Dye test:-**

Take small amount of emulgel on a clean glass slide. Add few drops of suitable dye, Mix gently with a glass rod and Observe under microscope/ eye. [28]

**Washability test: -**

Apply small quantity of emulgel on skin. Allow it to remain for fixed time (5-10 min),

Wash area with tap water. Observe whether formulation remove easily or leaves residue. [28]

**Pharmacological screening: - Anti-Inflammatory test**

All prepared gel formulations were subjected to anti-inflammatory activity by centrifugation method. The reaction mixture containing egg albumin and the prepared gel formulation was taken in a test tube and incubated at suitable temperature. The mixture was then centrifuged and visually observed for the formation of turbidity or precipitate. The formulations were evaluated for their ability to inhibit protein denaturation. The prepared herbal gel showed noticeable inhibition of protein denaturation, indicating good anti-inflammatory activity. [23]

**PHYSICAL EVALUATION: -**

**Table 2. Physical evaluation of gel formulation**

Formulation	Colour	Odour	Consistency
F1	Dark brown	Characteristic herbal odour	Semi-solid
F2	Dark brown	Characteristic herbal odour	Semi -solid



F3	Dark brown	Characteristic herbal odour	Semi -solid
F4	Dark brown	Characteristic herbal odour	Semi -solid

**pH: -**

**Table 3. pH of gel formulation**

Formulation	pH
F1	~5.8 -6.5
F2	~5.2 -5.8
F3	~5.5 -6.0
F4	~4.8 -5.5

**VISCOSITY: -**

**Table 4. Viscosity of gel formulation**

Formulation	Viscosity (cps)
F1	1000
F2	1260
F3	1635
F4	2100

**SPREADABILITY: -**

**Table 4. Viscosity of gel formulation**

Formulation	Spreadability (g'cm/sec)
F1	25
F2	20
F3	16.6
F4	13.6

**HOMOGENEITY:-**

**Table 5. Homogeneity of gel formulation**

Formulation	Homogeneity
F1	Good



F2	Good
F3	Good
F4	Good

**ANTI-INFLAMMATORY:-****Table 6. Anti-inflammatory of gel formulation**

Formulation	% Inhibition
F1	65.8
F2	72.2
F3	80.7
F4	87.1

From the above results, it is observed that all the prepared gel formulations were brownish in colour and showed good homogeneity and acceptable gelling properties. The pH of all formulations was found to be within a range suitable for topical application. The rheological behaviour studied using the Brookfield DV-II+ Pro Viscometer indicated that the viscosity of the gels was appropriate, neither too thick nor too thin for easy application. The spreadability study revealed that spreadability decreased with increase in viscosity of the formulations. The washability and consistency of the gels were found to be satisfactory. Anti-inflammatory activity studies demonstrated that the formulations exhibited significant inhibition of protein denaturation, with higher concentrations showing better activity. Among all batches, F3 showed balanced physicochemical properties along with good anti-inflammatory activity. Thus, it can be concluded that the formulated polyherbal gel possesses suitable characteristics for topical application and can be considered as a promising herbal formulation.

**FUTURE SCOPE :**

The present study demonstrated the successful formulation and evaluation of a polyherbal gel

containing extracts of *Tamarindus indica* and *Musa paradisiaca* with promising physicochemical and anti-inflammatory properties. However, further studies are required to explore the full therapeutic potential of the formulation. Future work may include in vivo studies and clinical evaluation to confirm the safety and efficacy of the gel in human subjects. Advanced studies such as drug release kinetics, permeation studies and stability testing under different environmental conditions can be carried out to improve formulation performance. Additionally, incorporation of other herbal extracts with synergistic activity may enhance the therapeutic effectiveness of the formulation. Development of different dosage forms such as oral gel, spray or mucoadhesive systems can also be explored for better patient compliance. Thus, the formulated herbal gel holds significant potential for further research and development as a safe, effective and economical alternative for topical drug delivery.

**CONCLUSION:**

Natural herbal formulations are gaining increasing acceptance due to their safety, effectiveness and minimal side effects compared to synthetic drugs. In the present study, a polyherbal gel containing extracts of *Tamarindus indica* and *Musa*

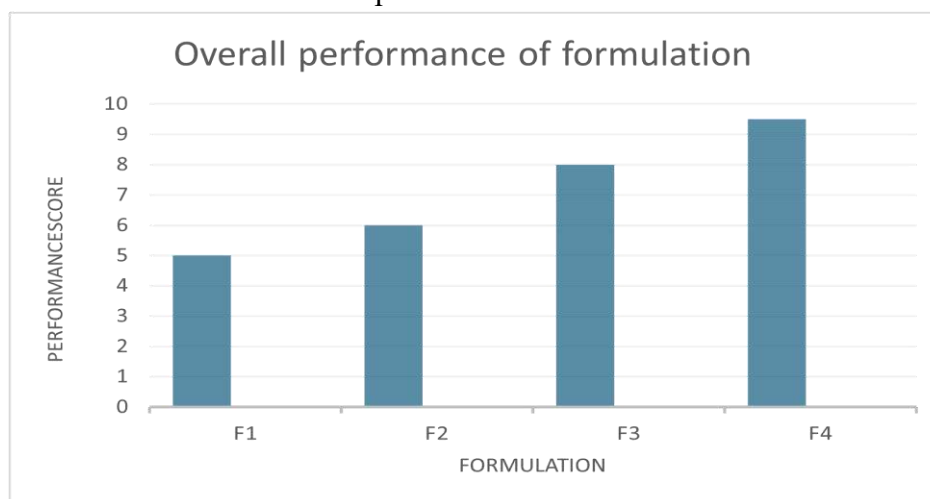


paradisiaca was successfully formulated using a Carbopol-based system. The developed gel exhibited satisfactory physicochemical properties including appropriate pH, viscosity, homogeneity, spreadability and washability, making it suitable for topical application. The antiinflammatory study indicated that the formulation possesses significant activity by inhibiting protein denaturation. Among the different batches, the optimized formulation showed a good balance between consistency and therapeutic performance. The study demonstrates that the prepared herbal gel can serve as a promising, cost-effective and safe alternative for topical drug delivery. Thus, the formulation holds potential for further development and evaluation as an effective herbal therapeutic system.

## RESULT AND DISCUSSION:

A variety of physicochemical characteristics, including color, homogeneity, pH, viscosity, spreadability, washability, and anti-inflammatory activity, were assessed for all the produced gel formulations (F1-F4). All formulas had a brownish hue, a smooth texture, and no obvious lumps, demonstrating that they were well-mixed. The pH of all formulations was determined to be within the safe range for topical application, suggesting that they are compatible with skin. With the help of a

Brookfield viscometer, the viscosity of the preparations was determined, and it was discovered that the viscosity rose along with the concentration of herbal extracts. Higher extract concentration increases internal resistance to flow, as seen by the fact that F4 had the highest viscosity and F1 had the lowest. The spreadability research demonstrated that viscosity and spreadability are inversely related. Because of its lower viscosity, F1 exhibited the greatest spreadability, while F4 showed the least. This suggests that viscosity and spreadability are inversely related. Washability trials revealed that all formulations were easily washable, but that higher concentration batches were a little less washable due to their greater consistency. Protein denaturation was used to assess the anti-inflammatory effects. According to the findings, the percentage inhibition rose with the extract concentration. The greatest suppression was observed with F4, while the least action was seen with F1. With a balance of physicochemical characteristics, F3 demonstrated strong anti-inflammatory effects. Overall, F3 proved to be the best formulation because it struck a balance between spreadability, viscosity, and anti-inflammatory properties.



**Fig: 8 Graphical representations of formulation**

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