

Formulation And Evaluation of Herbal Gel for Mouth Ulcer

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Abstract— One the most widespread diseases are oral mouth ulcer. Oral ulcers, commonly referred to as tiny sores, are painful lesions that appear at the gum line inside the mouth. There are numerous formulations used to treat mouth ulcers. There are numerous synthetic and natural formulation on the market. India has used its knowledge of traditional or herbal medicine to prevent and cure diseases. As the mouth ulcer is healing, it frequently causes pain and discomfort and may change the person's eating preferences. A gel is a soft, solid or solid-like material which consists of at least two components, one of them being a liquid, present in substantial quantity. There are number of synthetic gels in the market as compared to herbal or natural gel, but synthetic gels have some harmful effects on skin like irritation and dryness of skin. The herbal oral gel of *Ocimum sanctum*, *Aloe Vera*, *Psidium guajava* Linn leaves, and *Curcuma longa* Linn rhizomes to treat mouth ulcer. The traditional medical study is an integral part of the culture and the interpretation of health by indigenous population in almost world. This review explores the potential of a using. Tulsi for mouth ulcer recovery. The plants have been used in traditional medicines for their anti-inflammatory, antimicrobial, and wound-healing properties. Guava leaves have been usually used to govern several diseases such as rheumatism, diarrhea, diabetes mellitus, wound sore throat, cough and it also gives good antimicrobial, antifungal, anticancer activity.

Index Terms— Herbal gel: mouth ulcer, *Psidium guajava* linn, *Curcumin longa*, *Ocimum sanctum* and *Aloe Vera*.

I. INTRODUCTION

A large number of Indian herbal medicinal plant are attributed with medicament preparation. Over three fourths of world population depend mainly on the plants and plants derived from herbal medicines. These countries contribute two third of the plant used in modern system of medicine and the indigenous system of medicine provides health care system rural

population.[1] The word “gel” is derived from “gelatin” and both “gel” and “jelly” can be drawn back to the Latin *gelu* for “frost” and *gel* are, meaning “freeze” or “congeal” [2]. Gel is mainly semi-solid formulation having a liquid phase that has been thickened with some other components. Topical gel preparation is used for the skin application or percutaneous penetration of medicament or local action to certain mucosal surfaces [3]. Mouth ulcers are also known as canker sore -painful lesions that develop in mouth at base of your gum. A mouth ulcer is the loss or erosion of the mucosal membrane the fragile tissue that lines the mouth Nutritional deficiencies, such as iron deficiency, vitamin deficiencies, particularly B12 and C, poor dental hygiene, infection, stress, indigestion, mechanical damage, food allergies, hormonal imbalance, skin conditions, etc. [4].



Fig. no.1 Mouth Ulcer

Synthetic and semi-synthetic medicaments are suggested to treat mouth ulcers like antibiotics and antiseptics, local anesthetics, local analgesics, steroidal and non-steroidal anti-inflammatory drugs [5]. The treatment of mouth ulcers are topical gels, mouth washes, oral liquids, cream, ointments, patches, lozenges and tablets. The leaves of this plant have

therapeutic application in ayurveda for managing wounds. This plant is well known for aromatic flowers [6]. *Ocimum Tenuiflorum* also known as Tulsi is a medicinal plant with numerous health benefits belonging to family Lamiaceae. [7] *Psidium guajava* known as Guava, is a medicinal plant belonging to the family Myrtaceae. *Psidium Guajava* is a well-known traditional medicinal plant used in various indigenous system of medicine.

II. PATHOPHYSIOLOGY

The underlying source of the ailment determines how it develops specially. Xerostomia, or dry mouth brought on by a reduction in saliva production, is one of the simple mechanisms that raises the risk of oral trauma and ulcers. The mouth lining may become more vulnerable to damage if saliva production is reduced because it typically lubricates the mucous membrane and aids in bacterial control. Ulceration frequently coexists with stomatitis, a condition that refers to inflammation in mouth. They are common conditions that affects most people at some point in their lives. The anatomical characteristics make the mouth cavity susceptibility to many conditions that impact the gastrointestinal system and skin. Some conditions can only manifest in the mouth, even though they often impact entire digestive system. [8] The clinical picture is further complicated by the increased risk of secondary infections in these ulcers due to the high bacterial presence in the mouth.

III. MECHANISM OF ACTION

The mechanism of action a mouth ulcer is primarily the disruption of the oral mucosa's protective lining, which is a complex process triggered by various factors including trauma, infection, and systemic conditions. Trauma from physical injury or irritants is a direct cause, while infections can trigger ulcer formation through microbial interactions. Additionally, conditions like stress, vitamin deficiencies, autoimmune disorders, and hormonal changes can weaken the mouth's defenses, leading to ulcer development.

Trauma: Mechanical, thermal, or chemical irritant breach the protective epithelial barrier, Examples including; biting the inside of the cheek, sharp or ill-fitting dental work, Irritating foods

Infection: Viral infection, like herpes simplex virus (HSV), can lead to the formation of painful ulcers after a vesicle breaks down. A disruption in the balance of oral microbes (dysbiosis) can lead to opportunistic infection that may cause ulceration.

Weakened mucosal defenses: Dry mouth (xerostomia): Saliva normally lubricates the mouth and controls bacteria. Without it, the lining becomes more fragile and susceptible to injury. **Epithelial atrophy:** A thinning of the mouth's lining, which can occur after radiotherapy, makes it more vulnerable.

IV. TYPE OF MOUTH ULCERS

1. Minor Ulcers
2. Major Ulcers
3. Herpetiform Ulcers

Minor Ulcers:

- **Size:** These are typically 2-8mm in diameter and heal in 10 days to 2 weeks.
- **Characteristics:** These are shallow lesions with a well-defined border, often with a yellowish or white center and a red halo around the edges.
- **Healing Time:** Minor ulcers usually heal within 10 days to 2 weeks without scarring.
- **Prevalence:** The most common type of mouth ulcer usually associated with minor trauma or stress.

Major Ulcers:

- **Size:** These are larger than minor ulcers, with diameters ranging from 1cm to 3cm.
- **Characteristic:** Major ulcers are deeper and often present with a raised, irregular border. They can cause significant pain and discomfort.
- **Healing Time:** They can take several weeks to heal (sometimes up to 6 weeks or more) and often leave a scar after healing.
- **Complication:** These ulcers may result in functional difficulties.

Herpetiform Ulcers:

- **Size:** These ulcers are characterized by numerous small, pinhead size lesions (about 1-2mm in diameter) that group together.
- **Characteristics:** Herpetiform ulcers form a cluster and are often very painful. Despite their small

size, they can form irregular patterns and coalesce into larger areas.

- **Healing Time:** These types of ulcers may take 1-2 weeks to heal, but recurrence is common.
- **Prevalence:** Herpetiform ulcers are less common than minor or major ulcers but are associated with conditions such as immunosuppression or stress.[9]

V. CAUSES OF MOUTH ULCERS

1. Nutritional Deficiencies
2. Poor Oral Hygiene
3. Stress
4. Food allergies
5. Hormonal Imbalance
6. Skin diseases
7. Mouth injuries

Symptoms

1. Painful sores
2. Redness and Inflammation
3. Difficulty eating
4. Early Sensation

Factor affecting of mouth ulcers

1. Mechanical Trauma
2. Genetics
3. Infection agent
4. Allergies and sensitivity
5. Viral infection

Limitation

1. Delivery challenges
2. Variability in response
3. Side effects
4. Diagnosis challenges
5. Poor drug retention

Future Prospects

1. Advanced drug delivery systems
2. Biomaterials and regenerative medicine
3. Targeted therapies
4. Natural and herbal alternatives

Various Dosage form used for the Treatment of Mouth Ulcers

- Pastes

- Mouthwashes
- Buccal tablet
- Buccal patch
- Medicated chewing gum
- Herbal Gel

VI. HERBAL GEL

Herbal gels for mouth ulcers use plant extracts with anti-inflammatory, anti-microbial, and wound healing properties to relieve pain, inflammation and promote healing. The natural ingredients like Guava leaves, Tulsi leaves, Betel leaves, Neem leaves, Turmeric. These combined with gelling agents like Carbopol.

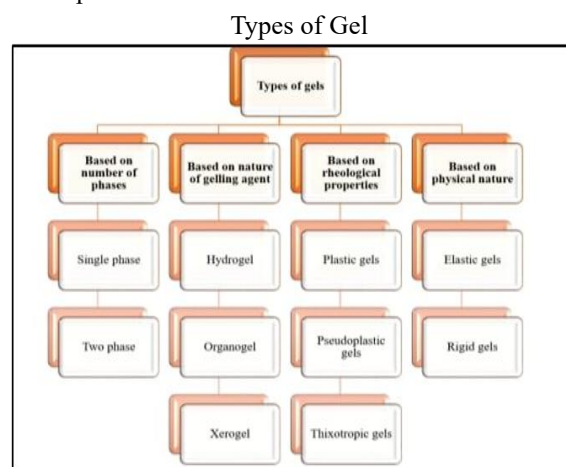


Fig. no: 3 (Types of gels)

Properties of Gels

- It should have appropriate anti-microbial agent.
- The topical gel must not be sticky.
- The ophthalmic gel must be sterilized.
- They exhibit the mechanical characteristics of the solid state.
- Each component is continuous throughout the system.

Characteristics of Gels

- 1) Swelling
- 2) Syneresis
- 3) Ageing
- 4) Rheology

1) Swelling:

This can be observed on as the initial phase of dissolution. Solvent penetrates the gel matrix so that

gel-gel relations are replaced by gel-solvent interactions. [10]

2) Syneresis:

This process stated to as syneresis, is not limited to organic hydrogels, but has been seen in organogels and inorganic hydrogels as well. As these stresses are relieved, the interstitial space existing for solvent is reduced, forcing the expression of fluid. [11]

3) Ageing:

The nature of the particles and the kind of force that is responsible for the linkages determine the structure of the network and the properties of the gel. [12]

4) Rheology.

Solution of the gelling agents and dispersion of flocculated solid are pseudo plastic i, e., showing non-Newtonian flow performance, characterized by a reduction in viscosity with an increase in shear rate. [13]

Uses of Gel

1. As delivery system of orally administered drugs.
2. Lubricant for patch testing.
3. NaCl gel for electrocardiography.
4. Sodium fluoride and Phosphoric acid gel for dental care prophylactic.

Advantages of Gel

- They are non-invasive.
- They have good patient compliance.
- They are applied over skin for slow and prolonged absorption.
- They can localize effect with minimum side effects.

Drug Profile

1. Guava Leaves: (Psidium guajava)



Fig. no.4 Guava Leaves

Psidium guajava Linn. Commonly called guava belongs to the family Myrtaceae and genus *Psidium*, Guava is often hailed as the “Queen of fruits” due to its rich nutrient profile [14]

Mechanism of action

In controlling infection diarrhoea and compare it with quercetin, one of the most reported active.

Table No.1 Taxonomy classification

Synonym:	<i>Psidium guajava</i>
Kingdom:	Plantae
Family:	Myrtaceae
Origin:	India
Genus:	<i>Psidium</i>
Divisions:	Spermophyte
Class:	Dicotyledons
Sub-divisions:	Angiosperm

Biological source: The biological source of guava leaves is the plant species consist of fresh and dried leaves *Psidium guajava* Linn. A member of the Family Myrtaceae (myrtle) [15]

Geographical Distribution: India, Brazil, Colombia, Peru, Ecuador, South Africa, United States of America, Venezuela, Costa Rica.

Morphology characteristics: Roots, stem, tree size, leaves, flowers, and fruits. Guava leaves exhibit an oblong to oval shape, measuring and average of 7-15 cm in length and 3-5 cm in width. The [16]

Chemical Constituents: Guava leaves are rich in bioactive compound including phenolic compounds like gallic acid and glycoside other flavonoids like such as quercetin, guaijaverin, kaempferol. They also contain tannins, terpenoids, triterpenes like oleanolic acid and ursolic acid, saponins, alkaloids, vitamins, carotenoids, glycoside and essential oils caryophyllene oxide. Total Lipids of Proteins, The Dietary fiber moisture essential polysaccharides, minerals.[17]

Properties of Guava leaves

- Antimicrobial
- Anti-inflammation
- Wound healing
- Anti-cancer
- Antioxidant Properties
- Antidiabetic Properties

Uses

- The also used the immunity booster.
- Guava leaves are used in the treatment of aphthous ulcers. Specifically, it reduces the pain of ulcer and effectively decreases the size of ulcer
- That also used to lower risk of cancer.
- It also used to the antimalarial, antiulcer, anthelmintic, analgesic, antispasmodic.
- There are the used to treats constipation.

2 Tulsi (Ocimum sanctum)



Fig. no. 6 Tulsi

Tulsi is the most well-known family plant in India and it is hallowed in Hindu custom. In the India Materia Medicate Tulsi plant are widely brought to use for relieving different illnesses, for example, the basic cold, irritation, intestinal sickness, coronary illness, migraines, stomach issue, kidney stones, heart issue, and some more. [18]

Mechanism of action

The primary mechanism of action for tulsi (holy basil, *Ocimum sanctum*) on mouth ulcers involves its powerful anti-inflammatory, antibacterial, antioxidant, and cytoprotective properties. The anti-inflammatory action of tulsi directly targets the pain and swelling associated with mouth ulcers

Table No.2 Taxonomical classification

Synonyms:	<i>Ocimum sanctum</i>
Kingdom:	Plante
Family:	Lamiales
Origin:	India
Genus:	<i>Ocimum</i>
Class:	Magnoliopsida
Division:	Magnoliophyta
Order:	Lamiales

Biological Source: The biological source of tulsi is the fresh or dried leaves of the plant *Ocimum sanctum* linn, also known as holy basil.

Geographical Source: It is an annual herbaceous plant with several branches that may be found all throughout India and is revered by Hindus. For volatile oil, Tulsi is now commercially grown. [19]

Morphology characteristics: The appearance of a plant, including its roots, stems, leaves, branches, flowers, fruit, and seeds, is studied in morphology. The petiole is slender, 1.5-3cm long and hairy, with an aromatic perfume and peculiar flavour. [20]

Chemical constituents: eugenol, carvacrol, isothymusin, Ursolic acid, circimaritin, cirsilineol, apigenin, and rosameric acid.

Properties Tulsi Leaves

- Antioxidant
- Antimicrobial
- Anti-inflammatory
- Radioprotective activity
- Antiulcer activity:[21]

Uses

- Tulsi helps in healing the sores of ulcers. Anti-ulcer effect of Tulsi is due to cytoprotective effects.
- Tulsi is used in the treatment of different types of ulcers, Tulsi can be promising herb in the treatment of various oral disorders.
- Its analgesic aka pain-relieving properties. Chewing Tulsi leaves or using tulsi extract can improve oral health and treat bad breath and mouth ulcer.

2. Turmeric (Curcuma longa)



Fig .no: 8 Turmeric

Mechanism of action

The mechanism of turmeric's action for mouth ulcers is primarily driven by its active compound, curcumin, which provides antioxidant, anti-inflammatory, and antimicrobial effects.

Table No.3 Taxonomical classification

Synonyms:	Curcuma longa
Kingdom:	Plantae
Divisions:	Angiosperm
Class:	Magnoliopsida
Family:	Zingiberaceae
Origin:	India
Genus:	Curcuma
Order:	Zingiberales

Biological source: The biological source of turmeric of the consist rhizomes of curcuma longa which belongs to family: Zingiberoside.

Morphology characteristics: Size & Shape: Cylindrical, branched slightly curved, Dour: aromatic odour Colour: Yellowish-brown to brown, Taste: slightly bitter, Leaves: large, oblong- ancelate

Geographical source: Telangana, Maharashtra, Karnataka, and Tamil Nadu, with Telangana and Maharashtra being leading producers.

Chemical constituents curcuminoids, curcumin, desmethoxycurcumin, bisdemethoxycurcumin. Some essential oils are present in turmeric, among which turmerone, germacrene, atlantone, and zingiberene are major constituents.[22]

Properties of Turmeric

- Anti-inflammatory
- Anticancer Agent

Uses

- It used antiulcer, anti-arthritis, antioxidant, anti-inflammatory.
- Turmeric is used in the treatment of RAS.
- Turmeric helps in reducing the pain of the ulcer.

3. Aloe vera (Aloe barbadensis)

Fig.no.10 Aloe Vera

Mechanism of action: Aloe vera promotes the healing of mouth ulcers through a multi-mechanism approach that includes anti-inflammatory, immunomodulatory, antimicrobial, antibacterial, antifungal, antiviral, and wound-healing effects.

Table No.4 Taxonomical Classification

Synonyms:	Aloe barbadensis
Kingdom:	Plantae
Division:	Magnoliophyta
Class:	Liliopsida
Family:	Aloaceae
Genus:	Aloe L
Order:	Liliales
Origin:	India

Biological source: The biological source of Aloe Vera is Aloe barbadensis. Aloe is dried latex of leaves of aloe vera. It belonging to the family Xanthorrhoeaceae.

Morphology characteristics: Aloe Vera is a stem less or very short stemmed plant growing to 60-100cm (24-39) tall, spreading by offsets. The leaves are thick and fleshy, green to grey-green, with some varieties showing white flecks on their upper and lower stem surfaces.

Chemical constituents: anthraquinones, saccharides, prostaglandins, fatty acids. Others enzymes, amino acids, vitamins, minerals. Other compound Cholesterol, triglycerides, steroids, uric acid, lignins, beta sitosterol, gibberellin, emodin, aleosin, aloin, salicylic acid.[23]

Properties of Aloe Vera

- Anti-inflammatory:
- Anti-bacterial
- Anti-viral:
- Soothing & cooling
- Safe & well-tolerated

Uses

- It is used analgesic, antibacterial, antiviral, antifungal, antioxidant immune modulating, antiseptics, and anti-inflammatory.
- It helps reduce inflammation and fights bacteria, which contributes to healing.

VII. MATERIALS AND METHODS

Plants Materials

Sr. No	Plant Material	Collection site
1)	Gauava leaves	Collected form the botanical garden of rashtriya college of pharmacy, authenticated by Rashtriya college of pharmacy, Hatnoor.
2)	Tulsi	Collected form a fresh leaf
3)	Turmeric	Collected form agriculture farm of curcumin
4)	Alove	Collected form the botanical garden of rashtriya college of pharmacy, authenticated by rashtriya college of pharmacy, Hatnoor

Chemical and Reagents:

Sr. No	Chemical Names	Reagents
1)	Carbopol 934	Gelling agent
2)	Glycerin	Moisturizer
3)	Sodium benzoate	Preservative
4)	Triethanolamine	pH adjuster
5)	Purified water	Vehicle

VIII. EXPERIMENTAL WORK

Preparation of Plant Extracts:

- 1) Prepare guava leaves & tulsi extract:
 - Take the fresh guava leaves & Tulsi leaves
 - Wash the properly
 - Grind separately with small quantity of purified water
 - The filter the cloth
 - That also collect the 3ml guava extract & 3ml tulsi extract



- 2) Prepare the turmeric extract:
 - Take the 0.3g turmeric powder
 - Add the 3ml of purified water
 - There is warm gently for 3-5min
 - That also cool the mixture
 - The filter the through filter
 - That also collect the clear yellow liquid
- 3) Prepare the alovera gel:
 - It washes the fresh aloe vera leaf with clean water
 - Cut the both sides edges leaf
 - Remove the outer green peel carefully
 - That also transparent inner gel using the spoon
 - The grind to stir the gel gently to make smooth liquid gel
 - That also filter through the filter paper

Formulation of Herbal Mouth Ulcer Gel

Ingredient	Quantity	Function
Guava leaves extract	3ml	Anti-bacterial, wound healing
Tulsi leaves extract	3ml	Anti-inflammatory, antimicrobial
Aloe vera gel	8ml	Soothing agent, healing
Turmeric powder	0.3g	Anti-septic, anti-inflammatory
Honey	4ml	Healing & moisturizing agent
Carbopol 934	0.4g	Gelling agent
Glycerin	2ml	Humectant
Sodium benzoate	0.06g	Preservative
Triethanolamine	q.s	pH adjuster
Purified water	30ml	Vehicle

Apparatus:

Beakers, Measuring cylinder, Stirrer, Test tube, Water bath, Mortal-pestle, fennel,

Base Formulation:

1. Soak Carbopol 934 in purified water and allow it to hydrate for 1-2 hours.
2. Add glycerin slowly with continuous stirring.
3. Mix guava leaf extract, tulsi leaf extract, aloe vera gel, turmeric extract, and honey separately.
4. Add the herbal mixture into the Carbopol base slowly with stirring.
5. Dissolve sodium benzoate in a small quantity of water and add to the gel.

6. Add Triethanolamine dropwise until a clear gel consistency is obtained.
7. Make up the final volume to 30g with purified water.
8. Mix thoroughly and store in a clean airtight container.



Prepare Herbal Gel

Evaluation of Herbal Gel

Visual Appearance

The prepared gels were tested for colour, clarity, texture, transparency, and presence of any gritty particles.

Measurement of pH

The pH of herbal gel formulation was determined by using digital pH meter. 1gm of gel was taken and dispersed in 10 ml of distilled water and kept aside for two hours. The measurement of pH of formulation was carried out in three times and the average values are reported. pH of gel formulation was reported.

Homogeneity

All developed gel formulation 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.

Spread ability

Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel that is placed in between the slides under the direction of certain load. If the time taken for separation of two slides is less then better the spreadability. Spreadability is calculated by using the formula.

$$S = M \times L / T$$

Where M = weight tied to upper slide

L = length of glass slides

T = time taken to separate the slides

Spread ability of gel formulation were reported.

Viscosity

The viscosity of all the prepared formulation was analyzed by the Brookfields viscometer with helipath, using spindle number 96 at 10 rpm.

IX. RESULTS AND DISCUSSION

From the results it is clearly shown that all the prepared gel formulation having good homogeneity and gelling properties. The pH of all gel formulation was in the range of compatible with normal pH range of the skin. The spreadability shows that with increasing viscosity of formulation, spreadability decreases and vice versa. The gelling and bioadhesive strength of all the batches was found in the suitable range. One month stability study was done with open and close container and it's showed that open container gel was stable. The observation reveals that the gels within the range.

X. CONCLUSION

The main aim is to formulated herbal oral mouth ulcer gel that will cure mouth ulcer and reduce pain and irritation and side effects also. Due to their cost effectiveness and lack of side effects, herbal formulation is currently in high demand on the market. The gel formulation of containing herbal ingredients like guava leaf, tulsi leaf, aloe vera, turmeric, honey have the good viscosity and antimicrobial activity, both the essential for managing oral ulcers. In order to manage oral ulcer, a durable and effective gel incorporating herbal ingredients can be created. The result indicated that new herbal formulation with strong antifungal and anti-inflammatory activities had been generated as a result of combination dosage forms. As a results, it is good, reliable, and less expensive for treating mouth ulcers.

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