

Preparation and evaluation of herbal mouth ulcer gel: A Research

Pratiksha Vadde^{1*}, Mayuri Jagtap¹, Komal Sul²

¹ B Pharmacy, Delonix society's Baramati College of Pharmacy, Barhanpur Tal-Baramati. Dr. Babasaheb Ambedkar Technological University, Maharashtra, India

² Professor, Department of Pharmacology, Delonix society's Baramati College of Pharmacy, Barhanpur Tal-Baramati. Dr. Babasaheb Ambedkar Technological University, Maharashtra, India

Abstract

One of the most widespread diseases is oral 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 formulations on the market. Topical gel is designed to be applied to specific mucosal surfaces or skin surfaces for local action and percutaneous absorption of dose forms.

In comparison to conventional medications, an Indian medicinal plant has a greater variety of pharmacological activity, is safer for the body, and is easier to obtain. Several types of herbs, including guava, betel, amla, neem, tulsi, mentha, curcumin, honey, etc., are utilised in gel formulations to treat mouth ulcers. They exhibit a range of qualities, including those that are antiseptic, antibacterial, anaesthetic, antioxidant, anti-inflammatory, relaxing, and ulcer healing. The condensed mass and liquid that are interpenetrated by the solid or semisolid system that makes up the pharmaceutical gel preparation are at least two different components. The herbal remedy is superior to the synthetic remedy in terms of effectiveness.

Keywords: mouth ulcer, herbs, mouth ulcer gel

Introduction

Oral ulcer

Oral/mouth ulcers are painful lesions that are open sores or canker sores. Gum, lip, inner cheek, and palate ulcers can develop in the mouth. A mouth ulcer is the loss or erosion of the mucosal membrane, the fragile tissue that lines the mouth. Keep in mind that mouth sores are distinct from cold sores, which are brought on by a virus that manifests itself in the lips. Canker sores, cold sores, leukoplakia (a thick white or grey area), and candidiasis or thrush (a fungal infection) are the most prevalent types of mouth sores. The erosion or loss of some of the fragile tissue lining inside of the mouth in mouth ulcers.



Fig 1: Mouth ulcer

Causes of mouth ulcer

1. Microbial disease

Herpetic stomatitis, Chickenpox, Herpes zoster, Hand, foot and mouth disease, Herpangina, Infectious mononucleosis,

HIV infection, Acute necrotizing gingivitis, Tuberculosis, Syphilis, Fungal infection.

2. Cutaneous disease

Lichen planus, Erythema multiforme, Dermatitis herpetiformis, Linear IgA disease, Chronic ulcerative stomatitis.

3. Malignant neoplasms

4. Blood disorder

Anaemia, Leukemia, Neutropenia, Other white cell dyscrasias.

5. Rheumatoid disease

Lupus erythematosus, Behcets syndrome, Sweets syndrome.

6. Gastrointestinal disorder

Cocliac disease, Crohns disease, Ulcerative colitis.

7. Drugs

Cytotoxic agents, Nicorandil, Other.

8. Radiotherapy

9. Other causes of mouth ulcers include –

- Accidental cheek biting, toothbrush injuries, constant rubbing against braces or dentures.
- Burns from eating hot food.
- Irritation from potent antiseptics like mouthwash. Reactions to certain medications.
- Autoimmune diseases, underlying vitamin or iron deficiency.
- Stress.
- Illness or extreme fatigue.

Types of oral ulcer

Based on the lesions' size

1. Minor ulcers- These are 2 to 8 mm wide and often go away in 10 to 2 weeks. The discomfort from this ulcer is not severe.
2. Major ulcers- These are broad, deep, and may have an uneven or elevated border.^[1]

Based on their number and appearance in the mouth they are divided as

1. Minor: This type is the most prevalent, with numbers of roughly 4-6.
2. Major- more serious and big ulcers that typically appear all at once
3. Herpetiform- 100 or more ulcers

Material

Herbal plant used in formulation

Table 1

Common name	Scientific name	Family	Chemical constituent	properties
Guava leaves	<i>Psidium guajava</i>	Myrtaceae	Quercetin, avicularin, gallic acid, catechin, chlorogenic acid, caffeic acid, apigenin.	Anti-inflammatory, antibacterial
Betel leaves	Piper betle	piperaceae	caryophyllene, cadinene, Y-lactone, allyl catechol, p-cymene, eugenol	Antibacterial, antiseptic
Amla leaves	<i>phyllanthus emblica</i>	phyllantaceae	vitamin C (ascorbic acid), polyphenols, (ellagic acid, chebulinic acid, gallic acid, chebulagic acid, apeigenin, quercetin, leutolin)	Anti-inflammatory
Neem leaves	<i>Azadirachta indica</i>	Meliaceae.	Phytoconstituents (nimbin, nimbidin, nimbolide, limonoids, quercetin and sitosterols.	Antibacterial, antifungal and anti-inflammatory
Tulsi leaves	<i>Ocinum tenuiflorum</i>	Lamiaceae	Phytoconstituent (eugenol, methyl eugenol, carvacrol, sesquiterpine, apigenin, luteolin, ursolic acid.	Antibacterial, anti-oxidant, anti-inflammatory, analgesic, antipyretic.
Mentha leaves	<i>Mentha spicata</i>	Lamiaceae	Vitamin A, Vitamin C, Iron, Calcium, Magnesium,	Anti-bacterial, antimicrobial activity
Turmeric powder	<i>Curcumin longa</i>	zingiberaceae	analgesic, antioxidant, antiseptic, antibac-terial, anti-inflammatory and immunomodulatory.	Antiseptic, antimicrobial and anti-inflammatory.
Honey	<i>Apis mellifera (Bees)</i>	Apidae	Carbohydrate, Protein, Vitamin, Amino acid, Minerals, Oraganic salt, Flavonoids, Polyphenols, Glycosides.	Antibacterial and anti-inflammatory
clove	<i>Syzygium aromaticum</i>	Myrtaceae	Flavonoids (quercetin, kaempferol) and phenolic acids like ferulic, caffeic, ellagic, and salicylic acids.	Anti-microbial, anti-inflammatory

Collection of materials

From the medicinal garden are harvested, including all herbs. With rinsed water, clean the herbs. Then let the herbs dry in the sun for 5 to 6 days. These herbs are transformed into fine powder after drying. followed by usage in formulation.

Formulation of gel

The gelling ingredient carbopol 934 is utilised in the formulation of gels. is used as a gelling agent in the

treatment of mouth ulcers. After being adequately soaked in distilled water for the night, Carbopol 934 was combined with distilled water while being constantly stirred with a mechanical stirrer. With constant stirring, all plant extract was combined with the necessary amount of methyl paraben and propyl paraben. The fluid also included propylene glycol. created with water for up to 20 ml, and the pH was then adjusted by adding triethanolamine to get the desired consistency of gel. The herbal gel formulations were created.



Fig 3: Herbal Mouth Ulcer Gel

Method of preparation of simple herbal gel

Combined demineralized water and carbopol 934



Add 5 ml of distilled water with the propyl paraben and methyl paraben



Warming in a water bath



When it has cooled, add propylene glycol. Then mix in various extracts or powdered herbs in varying concentrations.



All chemicals were combined with carbopol 934. Triethanolamine should be added gradually while stirring to get the required pH. (6.5- 7) ^[1]

Formulation Table

Table 2

Sr.no.	Name of ingredient	Quantity	Use (Activity)
1	Carbopol 934	2.5gm	Gelling agent
2	Propylene glycol	2ml	Co- solvent
3	Methyl paraben	0.015gm	Preservative
4	Propyl paraben	0.01 gm	Preservative
5	Triethanolamine	Q.S.	Adjust pH
6	Guava leaves powder	1.5gm	Antioxidant, anti-inflammatory
7	Amla leaves powder	1gm	Anti-inflammatory
8	Betal leaves powder	0.5gm	Antibacterial, antiseptic
9	Neem leaves powder	1gm	Antibacterial, antifungal, anti – inflammatory
10	Tulsi leaves powder	0.5 gm	Antioxidant, antiinflammatory, antipyretic, immunomodulator, antimicrobial
11	Mentha leaves powder / mint oil	0.6gm	Antimicrobial, anti-bacterial, cooling agent
12	Clove powder (clove oil)	0.4gm	Anti-inflammatory, pain reducing activity.
13	Turmeric powder	0.5gm	Antiseptic, antioxidant, antibacterial, anti- inflammatory.
14	Honey	2ml	Antibacterial, anti – inflammatory.
15	Distilled water	Q.S.	Makeup volume

Evaluation Of Herbal Mouth Ulcer Gel

1. Visual appearance- (clarity)

Colour, clarity, texture, transparency, and the presence of any grit were all checked in the created gels. This entire parameter displays the formulation's look.

2. Physical evaluation

Visual checks were made for physical characteristics such colour, smell, and consistency.

Colour

A visual inspection was done to determine the formulation's colour.

Consistency- By applying the product to skin, consistency was evaluated.

Odour

By combining the gel with water and sniffing the mixture, the formulation's odour was assessed. ^[3]

Table 3

Formulation	Physical appearance	ph	Homogeneity	Spread ability (gm.cm/sec)
mouth ulcer gel	greenish	6.8-7	good	5.70-0.1

3. Homogeneity

Tests for homogeneity were conducted on all created gel compositions. After the gels have been placed in the container, visually. They underwent testing to determine whether or not any aggregates were present.

4. Stability study

Studies using open and closed containers were conducted. Here, the product was left at room temperature for a month. Next, examine the stability. ^[4]

Table 4

Open container	Closed container
unstable	stable

5. Measurement of pH

A digital pH metre was used to determine the pH of herbal gel compositions. 1 gm of gel was used and distributed. For two hours, set aside 10 ml of distilled water in the mixture.

The formulation's pH was measured three times, and the average values are presented. Stability study: pH of gel formulation was reported.

6. Spreadability

Is measured in seconds as a measure of time. Under the influence of a specific load, taken by two slides to slide off of gel that is positioned in between the slides. Better if less time is required to separate two slides. Spreading capacity. Spreadability is determined using the following formula:

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

L = the length of the glass slides, M = the weight fastened to the upper slide.

T is the duration it took to divide the slides.^[3]

$$S = 31.90 \text{ (gm. Cm/sec)}$$

7. Anti-fungal activity

Antifungal activity of blank formulation and optimized formulation were carried out by using the Cup-plate method, the effectiveness of all the samples and the control samples were assessed in comparison to commercially available samples. *Candida albicans* was used to carry out the test. Nutrient that had been prepared was brought, placed into sterile petri dishes, and set away for cooling and drying. Indicates that a micron wire loop was used to disseminate the *Candida albicans* culture. Drilling holes 4 mm deep required a sterile cork borer with a 6 mm diameter. Then place 0.5 gm of gel from each formulation into holes. After that, plates were incubated for 48 hours at 27°C. The zone of inhibition (diameter in mm) was determined.

Table 6

Formulation	Zone of Inhibition (mm)
Standard drug	27
F (mixed)	25
Blank	14

8. Viscosity

All of the developed formulations' viscosities were examined. Using spindle number 96 at 10 rpm and the Brookfields viscometer LVDVE with helipath.

Conclusion

Due to their cost effectiveness and lack of side effects, herbal formulations are currently in high demand on the market. From the aforementioned information, it is evident that gel formulations containing herbal ingredients like guava, neem, tulsi, amla, honey, clove, mentha, and shami have good viscosity and antibacterial activity, both of which are essential for managing oral ulcers.^[2] In order to manage oral ulcers, a durable and effective gel incorporating herbal ingredients can be created. The results indicated that new herbal formulations with strong antifungal and anti-inflammatory activities had been generated as a result of combination dosage forms. As a result, it is good, reliable, and less expensive for treating mouth ulcers. According to an ancient study, acid secretion is the primary cause of mouth ulcers, and reducing it is the major goal of treatment.

Objective

- Easy to use, agreeable, and convenient.
- Avoid using first-pass metabolism.
- The capacity to distribute drugs more accurately to a particular place.
- Permitting the use of drugs with a brief biological half-life.
- Enhancing the pharmacological and physiological effects of the medication.

- Improve patient compliance.
- It is applicable for self-medication.
- Avoid intravenous therapy's risks and downsides as well as the various absorption circumstances, like the presence of enzymes and PH changes.
- The drugs can be stopped quickly if necessary.

Result

From the result it is clearly shown that all the prepared gel formulations having good homogeneity and gelling properties. The pH of all gel formulations was in the range of compatible with normal pH range of the skin. The rheological behavior also indicates that the gels were neither too thick nor too thin. 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 containing gel was not stable and close container gel was stable. Formulated gel containing open container when expose to ambient room temperature then syneresis was observed it means liquid exudates separating. Syneresis occurs when the interaction between particles of the dispersed phase becomes so great that on standing. In that dispersing medium is squeezed out in droplets forms and the gel shrinks. Syneresis it means the form of instability in aqueous gels. Formulation showed antifungal activity against *Aspergillus aureus* and *Candida Albicans* this are main microorganism responsible for mouth ulcer and formulation it can also use to treat mouth ulcer infection. When particles interact, it's called syneresis. the dispersed phase becomes so great that on standing. In that dispersing medium is squeezed out in droplets forms and the gel shrinks. Syneresis it means the form of instability in aqueous gels. Formulation showed antifungal activity against *Aspergillus aureus* and *Candida Albicans* this are main microorganism responsible for mouth ulcer and formulation it can also use to treat mouth ulcer infection.

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