

# FORMULATION AND EVALUATION OF HERBAL GEL FOR MOUTH ULCER

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## Abstract

Mouth ulcers are common oral inflammatory conditions that cause pain, discomfort, and difficulty in eating or speaking. Current synthetic formulations provide symptomatic relief but are often associated with side effects or limited patient compliance. Mouth ulcer gels have emerged as a convenient and effective therapeutic option, offering localized action with minimal systemic absorption. The present study aimed to formulate and evaluate a novel herbal gel incorporating *Combretum indicum* extract, a medicinal plant traditionally recognized for its antimicrobial, anti-inflammatory or natural bioactive compounds that help reduce pain, control infection, and promote faster healing of mouth ulcers. Firstly the extract of *Combretum indicum* was infused in agar media to know the antimicrobial activity then, it can be incorporated into a suitable gel base using Carbopol 934 as a gelling agent, glycerin as a humectant, and other excipients to ensure stability and patient acceptability. The prepared formulations were evaluated for parameters such as pH, viscosity, spread ability, extrudability, homogeneity, and in vitro drug release. Antimicrobial and anti-inflammatory activities were also assessed against common oral pathogens and inflammatory markers. The mucoadhesive property of gels ensures prolonged contact with the lesion, thereby enhancing therapeutic efficacy. Results indicated that the optimized formulation exhibited acceptable physicochemical properties, good spread ability, sustained release of active constituents, and significant antimicrobial activity compared to standard marketed formulations. This study highlights the therapeutic potential of *Combretum indicum*-based herbal gel as a safe, effective, and patient-friendly alternative for the management of recurrent mouth ulcers.

## INTRODUCTION

Oral ulcers are frequent lesions of the oral mucosa, defined by open sores with sloughing of necrotic inflammatory tissue. (1). Sloughing of inflammatory dead tissue characterizes mouth ulcers, which are open sores of the skin or mucus membrane lining [2]. One of the most prevalent pathologic disorders involving ulcers in the oral mucosal membrane is Recurrent Aphthous Stomatitis (RAS). Recurrent Aphthous Stomatitis causes a single or multiple chronic ulcers in the oral mucosa, which is painful and has an erythematous halo. Antiseptics, anti-inflammatory, analgesics, lasers, and herbal therapy are all used to treat aphthous stomatitis [3]. Mouth ulcer can occur in any age group or population. Mouth ulcer can also be occurred due to some of the reasons like- diseases, ailments, disorders and conditions that can be serious, sometimes it is life threatening. These include oral cancer and leukoplakia. Mouth ulcers are painful sores on the gums and in the mouth. Canker sores are another name for them. Although most mouth ulcers are harmless, they can be quite uncomfortable for some people, making it difficult to eat, drink, or brush their teeth. The size of a mouth ulcer varies, and the signs of a mouth ulcer vary depending on the type of ulcer.



Aphthous Stomatitis

Fig. No. 01

### Causes of mouth ulcer

- Mouth ulcers are caused by a variety of factors that
- Vary from person to person. Still, there are some common causes:
- Other foods high in acidity or spice, citrus fruits.
- Burns from hot drinks or food.
- Irritation from chemicals that is present in toothpaste or oral rinses.
- Chewing the insides of the cheeks or biting the tongue.
- Braces, poor-fitting dentures, and other instruments that may rub against the mouth and gum.
- Medications including beta-blockers and pain killers.
- Anxiety or stress.
- Some are the genetic factors [4].

### Types of mouth ulcer

Minor, large, and herpetiform canker sores all exist.

#### • Minor

Small round or oval ulcers, known as mild canker sores, heal in one to two weeks without scarring (< 1cm).

• **Major** Canker sores that are big in size (2 to 3 cm). and depth are larger and deeper than those that are small. It can take up to six weeks to repair these uneven edges. Long-term scarring is a risk with major mouth ulcers.

#### • Herpetiform

Herpetiform canker sores are small, cluster in groups of 10 to 100, and most commonly afflict adults. This type of mouth ulcer has irregular edges and will often heal without scarring within one to two weeks [5].

Mouth ulcers are usually generated by a number of causes, such as biting the inner layer of cheek, food allergies, hard teeth brushing, hormonal changes, vitamin deficiencies, bacterial infection and diseases.(6) Treatment of mouth ulcers may include soothing/ antiseptic mouthwashes, such as **chlorhexidine** mouthwash or **povidone iodine** mouthwash or use of antibiotic or anaesthetic gel formulations(7). Semi-solid formulations include gel having liquid phases which are then thickened by other components. Topical gels are intended for the application on skin or to certain mucosal surfaces for local action or percutaneous penetration of medicament preparations (8).

## PATHOPHYSIOLOGY

The cause determines the precise pathophysiology. Simple mechanisms that make the mouth more vulnerable to stress and ulceration include epithelial atrophy (thinning, such as after radiation therapy) and xerostomia (dry mouth), which makes the lining more brittle and readily penetrated because saliva normally lubricates the mucous membrane and regulates bacterial levels. Stomatitis is a broad word for oral inflammation, which is frequently linked to ulceration. Since the mouth serves as a pathological transition between the gastrointestinal tract and the skin, it may be affected by a variety of gastrointestinal and cutaneous disorders. Orofacial granulomatosis and oral Crohn's disease are two examples of illnesses that typically affect the entire gastrointestinal system but only manifest in the mouth [9]. In a similar vein, cutaneous (skin) disorders can sometimes affect the mouth, and occasionally just the mouth, leaving the skin unaffected. Certain cutaneous illnesses that cause distinctive lesions on the skin only cause nonspecific lesions in the mouth due to various environmental factors (saliva, thinner mucosa, trauma from teeth and food). Certain cutaneous problems can result in only nonspecific lesions in the mouth result from unique lesions on the skin. The vesicles and bullae of blistering mucocutaneous illnesses rapidly develop into oral ulcers due to moisture and stress from food and teeth. Ulcers may develop into secondary infections due to the mouth's high bacterial load. Chemotherapy cytotoxic medicines target cancer cells and other cells with high turnover rates. Oral ulceration, or mucositis, is a frequent side effect of chemotherapy due to the high turnover rate of the oral epithelia. Because the underlying lamina propria is visible, erosions that affect the epithelial layer look red. The lesion turns yellow-grey and is covered in fibrinous exudate when the entire thickness of the epithelium is broken through (ulceration). An ulcer appears as a crater in cross section because it is a rupture of the usual lining. There can be a "halo"—a reddening of the surrounding mucosa brought on by inflammation.

Oedema or swelling, around the ulcer is another possibility. An ulcer with a keratotic (white, thicker mucosa) edge may result from chronic trauma [10]. Repeated episodes of mouth ulcers may indicate immunodeficiency, due to low levels of immunoglobulins in the oral mucosa. Chemotherapy, HIV, and mononucleosis are all causes of immunodeficiency/immunosuppression and mouth ulcers are a common symptom. Autoimmunity can also result in oral ulcers. An autoimmune response against the epithelial basement membrane called mucous membrane pemphigoid causes desquamation or ulceration of the oral mucosa. An inflammatory autoimmune condition called Behçet's disease may be indicated by a high number of aphthous ulcers. Later on this result in uveitis in the eyes and skin lesions. Vitamin C deficiency can lead to scurvy by preventing wounds from healing and perhaps causing ulcers [11]

### Symptom

- The symptoms of a mouth ulcer depend on the cases, but may include one or more painful sores on part of the mucous membrane lining the mouth.
- Swollen and red mucous membrane around the sores.
- Problems with chewing tooth brushing because of the tenderness.
- Irritation of the sores by salty, spicy or sour foods.
- Irritation of the sores by dentures, orthodontic or mouth splints. On occasions an ulcer may not be sore. This can occur in cause mouth cancer.

**Factors responsible for the mouth ulcers:** Toothpastes and mouthwashes that contain sodium lauryl sulphate, Emotional stress / Psychic stress, Hormonal changes, Nutritional deficiencies, Mechanical trauma, Viral infections, Allergies and sensitivities, Genetics, Infectious agents (both bacterial and viral), Medical condition

### Introduction of gel

Gels are defined as semi rigid systems in which the movement of the dispersing medium is restricted by an interlacing three-dimensional network of particles or solvated macromolecules of the dispersed phase. The word "gel" is derived from "gelatin," and both "gel" and "jelly" can be drawn back to the Latin gel for "frost" and gel are, meaning "freeze" or "congeal." This origin indicates the essential idea of a liquid setting to a solid-like material that does not flow, but is elastic and retains some liquid characteristics. Use of the term "gel" as a classification originated during the late 1800s as chemists attempted to classify semisolid substances according to their phenomenological characteristics rather than

their molecular compositions. At that time, Analytical methods needed to determine chemical structures were lacking.

The USP defines gels (**sometimes called jellies**) as semisolid systems containing either suspensions made up of small inorganic particles, or large organic molecules interpenetrated by a liquid. Where the gel mass contains a network of small separate particles, the gel is classified as a two-phase system. In a two-phase system, if the particle size of the dispersed phase is relatively large, the gel mass is Sometimes called as a magma. Single-phase gels consist of organic macromolecules uniformly circulated throughout a liquid in such a way that no apparent boundaries occur between the dispersed macromolecules and the liquid. In pharmaceutical applications, water and hydro alcoholic solutions are most common. Many polymer gels exhibit reversibility between the gel state and sol, which is the fluid phase containing the dispersed or dissolved macromolecule. However, the formation of some polymer gels is irreversible because their chains are covalently bonded. The three- dimensional networks formed in two-phase gels and jellies are formed by several inorganic colloidal clays. The formation of these inorganic gels is reversible. Gels are generally considered to be more rigid than jellies because gels contain more covalent crosslinks, a higher density of physical bonds, or simply less liquid. Gel-forming polymers produce materials that span a range of rigidities, beginning with a sol and increasing in rigidity to a mucilage, jelly, gel, and hydrogel. Some gel systems are as clear as water, and others are turbid because the ingredients may not be completely molecularly dispersed (soluble or insoluble), or they may form aggregates, which disperse light. The concentration of the gelling agents is mostly less than 10%, usually in 0.5% to 2.0% range, with some exceptions. (12).

### Terminologies Related to Gels

A number of terms are commonly used in discussing some of the characteristics of gels, including imbibition, swelling, syneresis, thixotropic, and aerogel.

**Imbibition** is the taking up of a certain amount of liquid without a measurable increase in volume.

**Swelling** is taking up of a liquid by a gel with a rise in the volume. Only liquids that solvate a gel can cause swelling.

The swelling of protein gels is influenced by pH and the presence of electrolytes. Syneresis happens when the interaction between particles of the dispersed phase becomes so great that on standing, the dispersing Medium is pressed out in droplets and the gel shrinks. It is a form of unpredictability in aqueous and non-aqueous gels. Separation of a Solvent phase is thought to occur because of the elastic contraction of the polymeric molecules; in the swelling process during gel formation the macromolecules become stretched, and the elastic forces increase as swelling proceeds. At equilibrium the restoring force of the Macromolecules is balanced by the swelling forces, determined by the osmotic pressure. If the osmotic pressure decreases, as on cooling, Water may be squeezed out of the gel. The syneresis of an acidic gel from Plant ago albicans seed gum may be decreased by the addition of electrolyte, glucose, and sucrose and by increasing the gum concentration. pH has a marked effect on the separation of water. At low pH marked syneresis occurs, possibly as a result of suppression of ionization of the carboxylic acid groups, loss of hydrating water, and the formation of intermolecular hydrogen bonds. This would reduce the attraction of the solvent for the macromolecule.

**Thixotropic** is a reversible gel-sol formation with no change in volume or temperature, a type of non-Newtonian flow.

**Xerogel** is formed when the liquid is removed from a gel and only the framework remains. E.g., Gelatin sheets, tragacanth ribbons, acacia tears, etc. (12).

### Properties of Gels

1. Ideally, the gelling agent must be inert, safe and cannot react with other formulation constituents.
2. The gelling agent should produce a sensible solid-like nature at the time of storage which is easily broken when exposed to shear forces produced by squeezing the tube, trembling the bottle or at the time of topical application.
3. It should have suitable anti-microbial agent.
4. The topical gel must not be sticky.
5. The ophthalmic gel must be sterile.
6. The apparent viscosity or gel strength increases with an increase in the effective crosslink density of

the gel. However, a rise in temperature may increase or decrease the apparent viscosity, depending on the molecular interactions between the polymer and solvent.

7. They exhibit the mechanical characteristics of the solid state.
8. Each component is continuous throughout the system.
9. There is high degree of attraction amongst the dispersed phase and water medium so the gels remain equally uniform upon standing and doesn't freely settle. **(13,14,15,16)**.

### **Classification of Gels**

Gels can be classified based on colloidal phases, nature of solvent used, physical nature and rheological properties, etc.

- **Based on colloidal phases**

A. Inorganic (Two phase system)

B. Organic (Single phase system)

#### **A. Inorganic (Two phase system)**

If the particle size of dispersed phase is relatively large and form the three-dimensional structure throughout gel, such a system consists of floccules of small particles rather than larger molecules and gel structure, in this, system is not always stable. They must be thixotropic-forming semisolid on standing and become liquid on agitation.

#### **B. Organic (Single phase system)**

These consist of large organic molecules existing on the twisted strands dissolved in a continuous phase. This large organic molecule either natural or synthetic polymers are referred as gel formers, they tend to entangle with each other their random motion or bound together by Vander walls forces.

- **Based on nature of solvent**

#### **A. Hydrogels (Water based)**

A hydrogel is a network of polymer chains that are hydrophilic, infrequently found as a colloidal gel in which water is dispersion medium. They are highly absorbent natural or synthetic polymeric networks. They also have a degree of flexibility likely to the natural tissue, due to their significant water content.

#### **Uses for hydrogels**

1. Sustained-release drug delivery systems
2. Rectal drug delivery and diagnosis
3. Hydrogel-coated wells have been used for cell culture
4. As scaffolds in tissue engineering
5. As environment sensitivity detector
6. Contact lenses (silicone hydrogels, polyacrylamides, polymacon)
7. ECG medical electrode
8. Dressing of healing

**E.g.** Bentonite magma, gelatin, cellulose derivatives, carpooler and poloxamer gel.

#### **B. Organogels (With a non-aqueous solvent)**

An organogel is a non-crystalline, non-glassy thermoreversible solid material composed of a liquid organic phase trapped in a 3D cross-linked network. The liquid can be, E.g., vegetable oil, an organic solvent or mineral oil. The solubility and particle sizes of the structurant are significant characteristics for the elastic properties and firmness of the organogel. Frequently, these systems are based on self-assembly of the structurant molecules.

#### **C. Xerogels**

It is a solid formed from a gel by drying with unrestricted shrinkage. It is frequently retains high porosity (15-50%) and huge surface area (150-900 m<sup>2</sup>/g), along with very small pore size (1-10 nm). When solvent

removed under supercritical conditions, the network doesn't shrink and a highly porous, low-density material known as an aerogel is produced. Heat treatment of a xerogel at higher temperature produces viscous sintering and efficiently transforms the porous gel into a thick glass.

**E.g.** Tragacanth ribbons,  $\beta$ -cyclodextrin, dry cellulose and polystyrene, gelatin sheets and acacia tears.

- **Based on rheological properties**

Usually, gels exhibit non-Newtonian flow properties. They are classified into:

- a. Plastic gels
- b. Pseudo plastic gels
- c. Thixotropic gels

- a. **Plastic gels**

**E.g.** Bingham bodies, flocculated suspensions of Aluminum hydroxide exhibit a plastic flow and the plot of rheogram gives the yield value of the gels above which the elastic gel distorts and begins to flow.

- b. **Pseudo-plastic gels**

**E.g.** Liquid dispersion of tragacanth, sodium alginate, Na CMC, etc. exhibits pseudo- plastic flow. The viscosity of these gels decreases with increasing rate of shear, with no yield value. The rheogram results from a shearing action on the long chain molecules of the linear polymers. As the shearing stress is increased the disarranged molecules begin to align their long axis in the direction of flow with the release of solvent from gel matrix.

- c. **Thixotropic gels**

The bonds between particles in these gels are very weak and can be broken down by shaking. The resulting solution will revert back to gel due to the particles colliding and linking together again (the reversible isothermal gel-sol-gel transformation). This occurs in a colloidal system with non-spherical particles to build up a scaffold like structure.

**E.g.**, Kaolin, bentonite, agar, etc.

### **Based on physical nature**

- a. **Elastic gels**

Gels of agar, pectin, Guar gum and alginates exhibit an elastic behavior. The fibrous molecules being linked at the point of junction by comparatively weak bonds like hydrogen bonds and dipole attraction. If the molecule possesses free -COOH group then additional bonding takes place by a salt bridge of type -COO-X-COO between two adjacent strand networks.

**E.g.**, Alginate and Carbopol.

- b. **Rigid gels**

This can be formed from macromolecule in which the framework linked by primary valence bonds.

**E.g.** In silica gel, silic acid molecules are held by Si-O-Si-O bond to give a polymer structure possessing a network of pores. [17,18,19]

### **Introduction Combretum indicum**

In traditional system of medicine such as Ayurveda and siddha, the main significance is given to the herbal plants. (20) In current situation; the world population is more prone to use herbal medicines day by day. About 60 percent of world population uses the traditional medicinal plant. Due to the rise in pharmacological side effects and the financial load of the modern medical system, interest in traditional medicine is increasing dramatically among the general public, academics, and government.

(21) Up to 80,000 flowering plants are utilized as medicines globally, a huge collection of medicinal plant used in conventional medicine can be found in India.[22].

Chinese **Honeysuckle** (*Quisqualis indica*), is a member of the **Combretacea** family and is also known as Rangoon creeper. It is grown throughout Africa, the Indo-Malay area, and primarily in India (23).In the past, leaves and root fluids and extracts were used as **Anthelmintics** and to treat **Flatulence**. Boils and ulcers can be treated externally with a leaf infusion (24,25). Phytochemical screening yields major classes of constituents: alkaloids, carbohydrates, protein, amino acid, saponins, glycosides,

steroids, tannins, flavonoids and phenolic compounds. Leaves and fruits are reported to be anthelmintic; also used for nephritis. In Amboina, the compound decoction of leaves is used for flatulent abdominal distention. In Bangladesh, used for diarrhoea, fever, boils, ulcers and helminthiasis. Malays use leaf juice as a lotion for boils and ulcers; leaves are applied directly to headaches fruits or seeds have strong anti-helminthic properties that help remove parasitic worms from the body. Gargling with fruit decoction is another way to treat nephropathy. These plants leaves are utilized to relieve fever- induced discomfort].(26)

**MORPHOLOGY**



**Fig No 2 Quisqualis indica**

Combretum indicum is a ligneous vine that grows up to **8 meters in length and 2.5 meters in height**. This plant has elliptical leaves with rounded bases and acuminate tips. This plant grows to a height of 7 to 15 cm, and its arrangement is oriented counter- clockwise. Rangoon creeper has fragrant, tubular flowers that range in colour from white to pink to scarlet. [27] The fruit of the Rangoon creeper is ellipsoidal in shape, measuring between 30 and 35 mm, and it naturally has five noticeable wings. When the fruit reaches maturity, it Taste like almonds.[28]

**Microscopical characters and powder analysis of leaves**

Mayank *et al.* studied the microscopic characters of leaf-like upper epidermis, lower epidermis, parenchymatous cells, colenchymatous cells trichomes, xylem, and phloem. Whole of the midrib filled with collenchymas with different types of trichomes such as covering and glandular. Midrib is almost triangular shows the presence of endodermal layer; it is a single layered, surrounds with vascular bundle, packed with starch grains. Endodermis covers vascular bundle and contains a number of starch grains. Leaf surface (upper and lower surface) study shows the presence of epidermal cells, paracytic stomata, and subsidiary cells. Powder microscopy proved the presence of vessels, covering trichome, glandular trichome calcium oxalate crystals, epidermal cells, paracytic stomata. (29)

Parameters	Result
Vein islet number (1 mm <sup>2</sup> leaf surface)	26.4
Vein termination number (1 mm <sup>2</sup> leaf surface)	52.4
Stomatal number (1 mm <sup>2</sup> leaf surface)	96.32
Stomatal number (1 mm <sup>2</sup> leaf surface)	70.45
Stomatal index	23.8
Palaside ratio	4.36

**Table No. 01**

## AXONOMICAL CLASSIFICATION

- Kingdom: Plantae Division: Magnoliophyta
- Class: Magnoliopsida
- Genus: Combretum
- Family: Combretaceae
- Order: Myrtales
- Species: *C. Indicum*. (30)

## Vernacular Names

- Kannada: - Melati
- Hindi: - Madhu Malti
- Tamil: - Irangun Malli
- Malayalam: - Pullanni
- Telugu: - Rodha Manoharam (31,32)
- **Chemical constituent**

It Leaves mainly contained phytoconstituent Asiatic acid, arjunolic acid, oleanolic acid, benzyl-β-D-xylopyranosyl (1'' →6') β-D-glucopyranoside, nudifloric acid, vanillin, gallic acid, and β-sitosterol, quissqualic acid, mannitol, rutin, trigonelline, vitexin, orientin, isoorientin, D glucose, D- fructose. Flower Pelargonidin 3-glucosides, quissqualic acid, pelargonidin, trigonelline, rutin, gallic acid, quinole carbonitrile, linalool oxides, quercetin and 2,4-dihydro cucurbitacin Seed Stearic acid, palmitic acid, arachidic acid, mannitol, oleic acid, sterol, linoleic acid, myristic acid, citric acid, cyaniding monoglucoside, D- fructose, palmitic acid, and gamma- aminobutyric acid Fruit Trigonelline.(33,34).

Constituent	Pharmacological Activity	Mechanism of Action in Ulcer Pathway
<b>Flavonoids</b> (e.g. quercetin, kaempferol)	Anti-inflammatory, antioxidant, wound healing	Inhibit NF-κB pathway → ↓ TNF-α, IL-6; scavenge ROS → ↓ oxidative stress; enhance fibroblast activity.
<b>Tannin</b>	Astringent, antimicrobial, anti-inflammatory	Precipitate proteins → form <b>protective barrier on ulcer</b> ; reduce microbial colonization and tissue damage.
<b>Alkaloid</b>	Analgesic, anti-inflammatory	Modulate pain receptors and inhibit COX enzymes → ↓ pain and swelling.
<b>Terpenoid</b>	Antibacterial, tissue regeneration	Disrupt bacterial membranes; promote angiogenesis and collagen synthesis
<b>Saponin</b>	Anti-inflammatory, immunomodulatory	Stabilize cell membranes; modulate immune response → ↓ local inflammation
<b>Phenolic compounds</b>	Strong antioxidant, antimicrobial	Neutralize free radicals; prevent infection-induced exacerbation

## Uses

1. The extracts of roots and leaves are also effective as anthelmintic. Leaf juice is used by Malays as a lotion for boils and ulcers.
2. Combretum indicum leaves offer several advantages for mouth ulcer treatment, including their anti-inflammatory properties to reduce swelling and pain, antimicrobial and antioxidant activities to prevent secondary infections and promote healing, and the potential for faster healing of the ulcer site due to increased cicatrization.
3. The presence of flavonoids provides antibacterial and antifungal effects that can prevent or treat secondary infections that may occur in the ulcer.
4. Antioxidants protect cells from damage and contribute to the overall healing process of the ulcerated tissue
5. Herbal medicines, including those containing flavonoids from plants like Combretum indicum, are gaining popularity as patients seek safer and more natural alternatives for managing health issues like mouth ulcers.

## Methodology

### Extraction of combretum indicum leaf

Extraction of combretum indicum leaf is done by condensation method. Firstly, collect a fresh leaf of combretum indicum plant. Then the leaf's are kept under shade drying for 5 to 6 days. The Dried leaf are kept under the Grinder to getting Fine powder. The fine powder dissolve with Ethanol with ratio (35 ml ethanol

+15 ml water) Kept under the condenser for 2 hrs. Then above mix solution are collect and filter it with help of funnel and filter paper. Then the filter are collected. These filter use as extract.

#### 1. Drying



#### 2.Grinding



#### 3.Condensation



#### 4. filtration

#### 5. Extract



## Formulation table

Formulation table the method describes above and the formulae were tabulated in Table 1. Along with control sample gel were prepared by addition of required quantity of Liquorice extract and Holy basil extract to prepare 1%, 2% and mixed mouth ulcer gel respectively.

Ingredient	Quantity	Role
combretum leaf extract	2%	ti-inflammatory Antimicrobial
Carbopol 934	2%	Gelling agent
Propyl paraben	0.01%	Preservative
Methyl paraben	0.0015%	Preservative
Propylene glycol	1.5%	Co-solvent
Triethanolamine	q. s + pH 6.5-7	pH adjustment
Peppermint oil	0.45%	Flavouring agent
Distilled water	Up to 25 ml	Vehicle

Table: composition of mouth ulcer gel formulation. (35)

## Preparation of herbal gel

A precise quantity of Carbopol 934 should be evenly distributed in 15 ml of distilled water by continuous stirring. Set the beaker aside for 30 minutes to let the Carbopol 934 swell. Take 5 ml of distilled water and, in a separate beaker, add the necessary amounts of methyl and propyl parabens by heating in a water bath. Once the solution has cooled, add the propylene glycol. Additional extract was added as needed, and the mixture was thoroughly mixed with the Carbopol 934 gel while being continuously stirred. Finally, the volume was increased to 30 ml by adding the remaining distilled water, and triethanolamine was added drop by drop to create or adjust the necessary mouth skin pH (6.8-7) and to obtain the gel at required consistency. In the end Peppermint oil is added. [36].



## Evaluation parameter

The following criteria were used to assess gels:

### 1. Organoleptic properties

The organoleptic properties of the formulated herbal gel were carefully evaluated to assess its physical appearance and acceptability. Parameters such as colour, odour, and overall appearance were examined. The formulation exhibited a uniform and visually appealing colour, which indicates proper mixing and stability of the ingredients. The odour was found to be pleasant and characteristic of the herbal components used, without any foul or undesirable smell. These organoleptic characteristics are important as they influence patient compliance and overall acceptability of the product. The results suggest that the formulation possesses satisfactory physical properties, making it suitable for oral application.

## 2. Clarity of gel

The clarity of the formulated gel was evaluated by visual inspection to assess its transparency and uniformity. The gel was carefully observed against a clear background under adequate lighting conditions to detect the presence of any suspended particles, turbidity, or phase separation. A clear and transparent appearance indicates proper dispersion of ingredients and good formulation stability. The absence of any visible impurities or cloudiness suggests that the gel is homogeneous and of acceptable quality, which is important for both aesthetic appeal and patient acceptability.

## 3. Measurement pH



The pH of developed gel formulations was determined using digital pH meter. One gram of gel was dispersed in 10 ml of distilled H<sub>2</sub>O and set aside for 2 hour. The pH of the formulation was measured with value provide. The pH of gel formulation was Reported.

## 4. Homogeneity

After placing the gels in the container, they were visually inspected to ensure uniformity and to check for any aggregates or inconsistencies.

## 5. Stability Study

Stability studies were done with open and close container. Here, by subjecting the product to room temperature for two to three weeks.

## 6. Zone of inhibition

## 7. Spreadability test

Spreadability is measured in seconds by the time it takes for two slides to separate from gel placed between them under a specific stress. Faster separation of two slides leads to higher Spreadability. Spreadability is estimated using this

Formula:



Where:

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

M = weight attached to the upper slide. L = the length of the glass slides. T = the time it took to separate the slides

## Result

Sr. No	Parameter	Result
1	Physical evaluation	Colour: - Yellow Odour: - characteristic Consistency: - Good, State:- Semisolid
2	Clarity of gel	Good
3	pH	6.7
4	Homogeneity	Good
5	Stability study	Stable
6	Zone of inhibition	-
7	Spreadability	6 gm.cm/sec

## Conclusion

Now a day's there is a lot of demand for herbal formulations in the market due to their cost effectively and absence of any side effects from above experimental data is clear that gel formulation with herbal ingredients such as *Combretum indicum* leaf has good characteristics viscosity and also possesses a good antimicrobial activity which necessary in the management of mouth ulcer. Natural remedies are more acceptable in the belief. That they are safe with lesser side effects than the synthetic medicine. New herbal Gel formulation has good antimicrobial activity and anti-inflammatory activity so it's stable safe and good for treatment of mouth ulcer.

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