

Formulation and Evaluation of Betel Leaf Powder Loaded Mouth Ulcer Gel

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Abstract: *The main purpose of this gel formulation of Betel leaves, Turmeric was to relieve pain and discomfort due to oral ulcers. As we know there are different types of sores in the mouth that cause inflammation and pain. The most common oral ulcers are Local trauma & Aphthous Stomatitis. Now many over-the-counter medications are essential to staying in primary health care because of the positive response and the most effective treatment with the least amount of side effects. Herbal medicines are still the backbone of almost 75-80% of the world's population, especially in developing countries, in primary health care due to better adherence to the human body, cultural acceptance and less side effects. They are found mainly in tropical and subtropical regions of India, the Americas and Africa, where they occur in various countries. The gel contains the main ingredients Guava Leaves Powder, A. Mexicana, Elaichi & Carbopol 934 as a gelling agent & Propylene glycol as a co-solvent. Another ingredient Haldi acts as an antiseptic. The formulated gel was tested for different parameters such as physicochemical parameters (pH, viscosity, distribution ability, etc.), inhibition area, etc. The gel is homogeneous mixture that shows the pH 6.8. This herbal gel was stable at room temperature protected from any germs and thus safe for use on mouth sores.*

Keywords: Herbal gel, Mouth ulcer gel, Betel leaves.

I. INTRODUCTION

A gel is a semi solid system of at least two constituents, consisting of a condensed mass enclosing and inter penetrated by a liquid. Gels and jellies are composed of small amount of solids dispersed in relatively large amount of liquid, yet they possess more solid-like than liquid-like character. Gels are Semi-Solids systems in which a liquid phase is contained within a 3-D polymer Matrix (consisting of natural or synthetic gum) having a high degree of physical or chemical cross-linking. Gels are aqueous colloidal suspensions of the hydrated forms of insoluble medicament. Gel is the most common form of ulcer treatment. Gels are primarily been products aimed at curing the mouth ulcer in the present scenario, it seems improbable that herbal gel, although better in performance and safer than the synthetic ones, will be popular with the consumers. There is an increasing demand of herbal gel for maintaining and curing mouth ulcer, but synthetic gel, may include a number of harmful toxins which can produce severe side effect. Global interest toward Herbal cosmetic is rising because of safety, as a product or home-made formula. Components are added to gel primarily for maintaining stability and drug concentration. Herbal formulations are considered as alternative to synthetic gel but formulating gel using completely natural raw material is a difficult task. The gels are having many advantages such as:

- a) Gel can avoid gastrointestinal drug absorption difficulties caused by gastrointestinal pH.
- b) Gels are having property to avoid enzymatic activity and drug interaction with food and drinks.
- c) They can substitute for oral administration of medication when the route is unsuitable.
- d) They can avoid the first pass effect, that is, the initial pass of drug substance through the human body.
- e) They avoid systemic and portal circulation following gastrointestinal absorption.
- f) Gels are not deactivated by liver enzymes because the liver is bypassed.
- g) They are non-invasive.
- h) They have good patient compliance.
- i) They are applied over skin for slow and prolonged absorption.

- j) Gels have also been applied in pharmacy to some viscous suspension for oral use for example Aluminum hydroxide gel.
- k) They have localized effect with minimum side effects.(1)



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.

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

Anemia, Leukemia, Neutropenia, Other white cell dyscrasias.

5. Rheumatoid disease

Lupus erythematosus, Bechet's syndrome, Sweets syndrome.

6. Gastrointestinal disorder

Celiac disease, Crohns disease, Ulcerative colitis.

7. Drugs

Cytotoxic agents, Nicorandil, Other.(2)



Types of oral ulcers:

Based on the size of the lesions and the number,

1. Minor ulcer:

These are about 2-8mm wide and usually rot in 10 days to 2 weeks.

2. Major ulcer:

These are large and deep, usually with a raised or irregular border.

3. Herpetiform Wounds:

This type of wound is a group of small wounds that have the size of a pinhead.

4. Ulcerative Conditions:

Sores in the mouth are very common and are mainly due to injuries such as improper dentures, broken teeth, or filling.(3)

Betel Leaf : In India, since ancient times betel leaf is used in religious rituals as it is considered auspicious. Betel leaf is a heart-shaped, deep green colour leaf that belongs to the family of Piperaceae. The scientific name of betel leaf is "*Piper betle*".

Benefits of Betel Leaves :

- Anti diabetic agent
- Lowers high cholesterol levels
- Anti cancer agent
- Anti microbial agent
- Helps in Wound healing
- Anti asthmatic agent
- Helps to overcome Depression
- Improve oral health
- Gastro protective activity
- Anti-malarial agent (4)

Materials and Methods:-

Betel leaves were collected locally from the medicinal garden. With rinsed water clean the leaves. Air dried leaves were grinded to a fine powder in a suitable grinder mixture. Followed by usage in formulation.



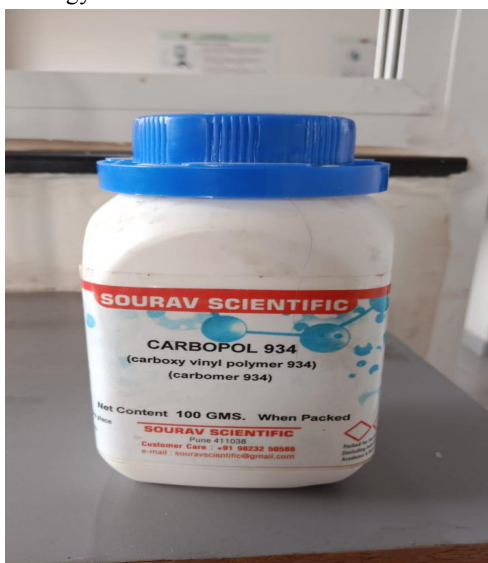
Formulation Table :-

Sr. No	Name Of Ingredient	F ₁ (gm)	F ₂ (gm)	F ₃ (gm)	Category
1	Carbopol 934	2.5	2	3	Gelling Agent
2	Propylene glycol	2	2.5	1	Co-solvent
3	Methyl Paraben	0.015	0.01	0.015	Preservative

4	Propyl Paraben	0.01	0.015	0.01	Preservative
5	Triethanolamine	q.s	q.s	q.s	For adjust pH
6	Betel leaf powder	2	1.8	2.5	Antibacterial, antiseptic
7	Curcumin Powder	1	1.2	0.5	Antiseptic
8	Menthol flex	1	1	1	As Flavor
9	Distilled Water	25ml	25ml	25ml	-

Excipient Profile :

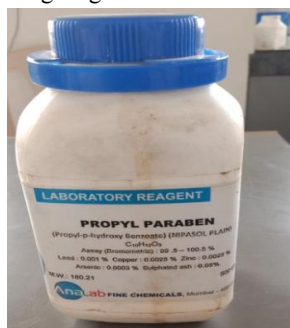
1. Carbopol (934) : Carbopol (934) is highly cross-linked with excellent stability at high viscosities, which confers excellent bio adhesive and viscoelastic properties. Some studies have evaluated the toxicity of this type of polymer and demonstrated low toxicity and low irritant potential. It exhibits short flow properties and a creamy sensory profile, and is therefore well suited for use as a rheology modifier in lotions and creams.



2. Methylparaben Significance : Methylparaben is frequently used as a preservative in cosmetics to prevent the growth of bacteria and mold in products that would otherwise be susceptible to microbial growth. It is a broad spectrum antimicrobial agent that is effective.

Combinations of methyl and propylparabens are commonly employed to achieve better antimicrobial results. Parabens antimicrobial activity is generally considered to be pH-independent under values of 8.0 where they are fully undissociated.

3. Propylparaben Significance : Propylparaben is the benzoate ester that is the propyl ester of 4-hydroxybenzoic acid. Preservative typically found in many water-based cosmetics, such as creams, lotions, shampoos and bath products. Also used as a food additive. It has a role as an antifungal agent and an antimicrobial agent



4. Triethanolamine : Triethanolamine, or TEA is a viscous organic compound that is both a tertiary amine and a triol. It is a colorless compound although samples may appear yellow because of impurities. Triethanolamine is found in sunscreen lotions, liquid laundry detergents, dishwashing liquids, general cleaners, hand sanitizers, polishes, metalworking fluids, paints, shaving cream and printing ink. (5)



5. Curcumin : Curcumin is a natural compound found in turmeric products. Curcumin is thought to be responsible for many of turmeric's health benefits.

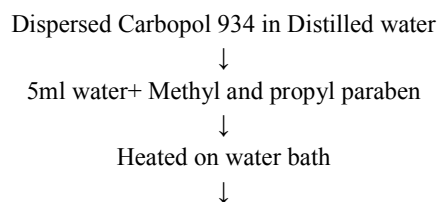
Clinical research suggests curcumin offers the following benefits:

- Has antioxidant properties
- Reduces inflammation
- Supports brain health
- Supports heart health (6)



7. Menthol flex : Is a substance naturally found in mint plants, such as peppermint and spearmint. It gives a cooling sensation and is often used to relieve minor pain and irritation. Menthol is added to products as a flavoring agent.

Formulation of gel :-



After colling add propylene glycol
↓
Betel leaves powder mix in above mixture
↓
Mixed all ingredients and flavor add into Carbopol 934 properly
↓
Volume made up to 20ml with distilled water
↓
Continuous stirring triethanolamine added drop wise (Adjust pH 6.8-7)



Evaluation of gel :

1. Visual appearance- (clarity)

Color, 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 color, smell, and consistency

3. Colour

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

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

4. Odour

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

5. pH

Measurement of pH : The pH of herbal gel formulations were determined by using digital pH meter. 1 gm of gel was taken and dispersed in 10 ml of distilled water and keep 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

6. Homogeneity

All developed 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.

7. Spreadability

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

Spreadability of gel formulations were reported.



Sr.no.	Type of Evaluation	Result
1.	Colour	Greenish
2.	Odour	Characteristic
3.	pH	6.8
4.	Homogeneity	Good
5.	Spreadability	21

8. Stability study:

Stability studies were done with open and close container. Here, by subjecting the product to room temperature for 1 month.

Open container	Close container
Not stable	Stable

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 the contraction of gel by separating out of liquid. Syneresis, it means the form of instability in aqueous gels.

Determination of Zone inhibition:

The antibacterial and antifungal activity of formulated gel were carried out by Cup-plate method. There are S. aureus and Candida albicans culture used. The test was performed using the agar well diffusion Prepared nutrient brought and poured in to sterile petri plates and kept for drying and cooling. After that each bacterial culture were spread by micron wire loop. A sterile cork borer 6 mm diameter was used to drill holes 4 mm deep. Then 0.5gm of gel from each batches add in to this hole. Plates were then incubated at 27°C for 48 hr. The zone of inhibition developed.



The gel formulation shows antibacterial and antifungal activity against *S. aureus* and *Candida albicans*.

II. RESULT AND DISCUSSION

The prepared gel formulations were evaluated for parameters such as physical appearance, pH, homogeneity, stability, spreadability. The observation reveals that the gels were having smooth texture and were elegant in appearance. The prepared gel showed good homogeneity with absence of lumps. Hence the developed formulation were much clear and transparent.

III. CONCLUSION

The main aim of this project to formulate herbal oral mouth ulcer gel that will cure mouth ulcer and reduce pain and irritation. As seen from the results, it is possible to formulate herbal mouth ulcer gel by using betel leaves which is useful to hill the lesion present while mouth ulcer so I prepared this formulation.

Nowadays there is a lot of demand for herbal formulations in the market due to their cost effectivity and absence of any side effects. From the above experimental data it is clear that a gel formulation with herbal ingredients such as betel and curcumin has good characteristics and Antimicrobial activity.

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