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Formulation and Evaluation of Pharmaceutical Gel Using Piper Betle (Betel Leaf) Powder for Mouth Ulcer Treatment

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Abstract: The study focuses on developing an herbal gel formulation using Piper betle (betel leaf) powder for the treatment of mouth ulcers. Gels are widely used due to their semi-solid consistency and localized drug delivery capability. The use of herbal ingredients such as betel leaf, curcumin, and peppermint oil aims to enhance safety, reduce side effects, and improve patient compliance compared to synthetic formulations. The formulation was evaluated based on physical appearance, pH, spreadability, homogeneity, and extrudability. Results indicated a stable, greenish gel with good physical properties and antimicrobial potential. The study supports the viability of herbal gels as effective, economical alternatives for mouth ulcer treatment

Keywords: Betel leaves, Herbal gel, Mouth ulcer

I. INTRODUCTION

Gels are semi-solid systems with a liquid phase enclosed in a three-dimensional matrix of polymers (either synthetic or natural gum) that has a high level of chemical or physical cross-linking. Aqueous colloidal suspensions of hydrated versions of insoluble medications are called gels. Gels contain more liquid than magma.[1,3,4]The most popular method of treating ulcers is gel. Since the main purpose of gels is to treat mouth ulcers, it seems unlikely that herbal gels, despite their superior efficacy and safety over synthetic ones, will be well-liked by customers in the current market.[2,5]A more drastic strategy for making herbal gel more widely used would be to alter customer expectations by emphasizing safety and effectiveness.



Fig no-1: Gel





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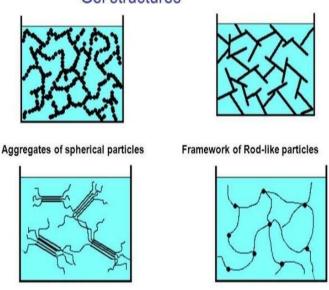
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Structure of Gel:- The network structure of the gel and product is determined by the nature of the and the type of oil used for the coupling. Single or small macromolecules may be arranged in spherical or evenly spaced clusters inside a single hydrocolloid product. Getting these goods ready in gel wax. [6]

Gel structures



Physical gel with crystalline junctions
Chemical gel -covalent junctions

Fig no-2: Structure of gel.

Advantages of gel:-[7]

- They have a limited effect and few negative effects.
- Their patient compliance is good.
- To ensure slow and sustained absorption, they are administered topically.
- They have minimal adverse effects and a confined effect.

Disadvantages of gel:- [8,9]

- Gels work more slowly and last longer.
- Additives or gelators could irritate skin.
- The gel dries out due to solvent loss in the formulation.
- In certain gels, flocculation results in an unstable gel.

Ideal Topical Gel Properties:- [10]

The following characteristics are excellent for a gel

- It should be uniformly transparent.
- It should have a steady nature and be inert.
- The skin and other regions where it is applied shouldn't be irritated by it.

Oral ulcer

Ulcers are painful blisters that appear inside the mouth. They're generally red or unheroic. They're different from cold blisters, which appear on the external lips and are caused by a contagion[11]To treat mouth ulcers, synthetic andsemi-synthetic specifics similar as steroidal andnon-steroidalanti-inflammatory drugs, original anesthetics, original anesthetics, and antibiotics and antiseptics are recommended. The most common treatments are topical steroids, but

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dragged use of these specifics can have major side goods, including immunosuppression, osteoporosis, hyperglycemia, gastrointestinal diseases, and adrenal insufficiency.[12]



Fig no -3: Mouth Ulcer

Causes:

- a) Injury: injuries to the tongue or cheek, burns or wounds from eating or drinking, or damage from a toothbrush or dentures.
- b) food allergies: eating certain foods like chocolate or spicy or acidic foods, or stopping smoking.
- c) drug reactions: toothpaste containing sodium lauryl sulfate.
- d) Other factors: a weakened immune system, changes in hormones, tension, worry, or lack of sleep Situations Diseases including chronic inflammatory bowel disease or cold sore viruses like the herpes simplex virus.[13]

Types of oral ulcers:[14]

Depending on the quantity and size of lesions,

1. Minor ulcer:

These typically decay in 1 to 2 weeks and are 2 to 8 mm wide.

2. Major ulcers:

These are big, deep, and typically have an uneven or elevated border.

3. Herpetiform Wounds:

These wounds are a collection of tiny, pinhead-sized wounds.

4. Conditions That Cause Ulceration:

Mouth sores are fairly prevalent and are mostly caused by accidents like broken teeth, fillings, or unsuitable dentures.

Benefits of Betel Leaves:

- Anti diabetic agent
- ❖ Anti cancer agent
- Anti microbial agent
- ❖ Anti asthmatic agent

Materials

1) Betel leaves: Locally, betel leaves were gathered from the medical theater. Clean the leaves with irrigated water. Using an applicable grinder admixture, air- dried leaves were base into a fine greasepaint. operation in expression comes next.











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Fig no-4:Betel Leaves Powder

- 2) Carbopol (934): Carbopol also known by the generic name Carbomer is a synthetic polymer derived from cross-linking of poly(acrylic acid).
 - Molecular Formula:C5H10O2.
 - Molecular Weight: 102.13 g/mol.
 - Supplier Name:Sahyadri s.s.
- 3) Methyl Paraben: It is produced by the methanol esterification of p-hydroxybenzoic acid in the presence of sulfuric acid.
 - Molecular Formula:C8H8O3,
 - Molecular Weight:152.15 g/mol
- 4) Propylparaben: Propylparaben is a natural substance found in vegetables and fruits like flaxseeds, barley, and grapes.
 - Molecular Formula: C10H12O3
 - Molecular Weight: 180.2 g/mol
- 5) Triethylamine: Triethanolamine is produced from the reaction of ethylene oxide with aqueous ammonia.
 - Molecular Formula:C6H15NO2
 - Molecular Weight: 149.19
- 6) Curcumin: Curcumin is a bright yellow chemical produced by plants of the Curcuma longa species.
 - Molecular Formula:C12H20O6
 - Molecular Weight: 368.37
- 7) Peppermint oil: Peppermint oil is the essential oil taken from the flowering parts and leaves of the peppermint plant.
 - Molecular Formula:C10H20O
 - Molecular Weight: 965.5





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Formulations Table:

Sr no	Name of the ingredients	Quantity (gm)	Used
1	Carbopol 934	2.5	Gelling agent
2	Propylene glycol	2	Co-solvent
3	Methyl paraben	0.01	Preservatives
4	Propylparaben	0.01	Preservatives
5	Triethylamine	q.s	For adjust PH, Antioxidant, Polyphenols.
6	Betel leaves Powder	2	Antiviral compound and anti-inflammatory compounds
7	Curcumin extract	2	Antiseptic,Antimicrobial.
8	Peppermint oil	1	As a flavour
9	D.W	25 ml	Vehicle

Formulation of gel:

Dispersed Carbopol 934 in Distilled water

\$\delta\$ 5 ml water Methyl and propyl paraben

\$\delta\$ Heated on water bath

\$\delta\$ After cooling add propylene glycol

\$\delta\$ Betel leaves powder mix in above mixture

\$\delta\$ Mixed all ingredients and flavor add into Carbopol 934 properly

\$\delta\$ Volume made up to 20 ml with distilled water

\$\delta\$



Continuous stirring triethanolamine added drop wise (Adjust pH 6.8-7)

Fig no-5: Formulation Of Gel.





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Evaluation parameters:

- 1. Visual appearance (Clarity):-The produced gels were examined for color, clarity, texture, transparency, and the presence of any grit. This parameter as a whole shows how the formulation looks.
- a) Physical evaluation:-Physical attributes like color, fragrance, and consistency were visually inspected.
- b) Color:-The color of the formulation was ascertained by eye inspection. Consistency was assessed by putting the product on the skin.
- c) Odour:-The formulation's scent was evaluated by mixing the gel with water and sniffing the combination.
- 2) PH:-The pH was measured using a pH meter. After weighing and dissolving roughly 0.5 grams of the gel in 50.0 milliliters of distilled water, the pH of the mixture was determined.
- 3) Spreadability:-The duration in seconds it takes for two slides to separate from gel positioned between them when subjected to a specific stress is known as spreadability. The spreadability improves with less time spent separating the slide.

The formula for calculating spreadability is $S = M \times L / T$ where,

M = is the higher slide's weight. L = is the glass slide length.

T = is the amount of time needed to split the slides.

When compared to previous batches, the F4 batch demonstrated good spreadability, according to the spreadability test.

- 4. Homogeneity:-Following production, each gel is visually examined to determine its homogeneity.
- 5. Extrudability:-Typical capped collapsible aluminum tubes were filled with the gel formulations and sealed at the end. Using the thumb, the extensibility was assessed.

Result

Sr.No	Evaluation Test	Result
1	Colour	Greenish
2	Odour	Characteristics
3	PH	6.8
4	Homogeneity	Good
5	Spreadability	15
6	Extrudability	Good

6. Stability study:-Both open and closed containers were used in the stability tests. Here, a stability study was reported after the product was left at room temperature for a month.

Open container	Close container
Not stable	Stable

II. CONCLUSION

The primary goal is to create an herbal oral mouth ulcer gel that would not only treat the ulcer but also lessen its discomfort, irritation, and adverse effects. The results show that guava and betel leaves can be used to make an herbal mouth ulcer gel that can be used to treat ulcers. The aforementioned study concludes that all initial testing and stability tests recommended the use of herbal mouth ulcer gel with consumer compliance and economy.

Herbal formulations are in high demand these days because they are inexpensive and have no negative side effects. It is evident from the experimental findings above that a gel formulation containing herbal compounds like curcumin and betel has good qualities and antimicrobial action.









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