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FORMULATION AND EVALUATION PHARMACEUTICAL AQUEOUS GEL OF POWDER GUAVA LEAVES FOR MOUTH ULCER TREATMENT

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ABSTRACT

The main purpose of this gel formulation of Guava leaves, Argemone Mexicana, Turmeric and Elaichi flavor 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 & and 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.

Mouth ulcers, also known as aphthous ulcers, are painful lesions in the oral mucosa that can significantly affect eating, speaking, and overall oral health. This study focuses on the formulation and evaluation of a mucoadhesive aqueous gel intended for the treatment of mouth ulcers.

The gel was developed using biocompatible polymers such as carbopol 934, hydroxypropyl methylcellulose (HPMC), and sodium carboxymethyl cellulose (NaCMC) to ensure adequate viscosity, spreadability, and prolonged retention at the site of application.

Active ingredients such as benzocaine (as a topical anesthetic), triclosan (as an antimicrobial agent), and aloe vera extract (as a healing and anti-inflammatory agent) were incorporated. The gel was prepared by cold mechanical stirring and adjusted to physiological pH.

KEYWORDS: *Herbal gel, Mouth ulcer gel, Guava leaves, Argemone Mexicana, Elaichi flavor.*

INTRODUCTION

Mouth ulcers, also known as aphthous stomatitis or canker sores, are common inflammatory lesions that affect the mucosal lining of the oral cavity.

They can result from various factors including nutritional deficiencies, stress, trauma, hormonal changes, or underlying systemic conditions. Although typically self-limiting, mouth ulcers can cause considerable discomfort, pain, and difficulty in eating and speaking, thereby impacting the quality of life.

Topical drug delivery is considered the most effective approach for treating mouth ulcers as it provides localized action, minimizes systemic side effects, and enhances patient compliance.

Among various dosage forms, aqueous gels have gained prominence due to their ease of application, soothing effect, and ability to retain drugs at the site of action for extended periods. These gels are typically composed of hydrophilic polymers that form a viscous matrix capable of adhering to the mucosal surface, thus ensuring sustained drug release.

Oral administration of the drug, although being immensely popular and appropriate but can't be used for certain drugs, such as peptide drugs, due to their poor absorption by the oral route.

This study aims to formulate and evaluate an aqueous gel incorporating therapeutic agents such as analgesics, antimicrobials, and anti-inflammatory compounds for the effective management of mouth ulcers.

The formulation focuses on achieving optimal mucoadhesion,

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pH compatibility with oral mucosa, and patient acceptability.
The demand for medicinal plants is growing in both developed and developing countries. Herbal medicine research is one of the leading research areas in the oral health problems. There is a well- established link between the activities of microbial species that form.

The great need for alternative therapies, products and options for safe, economical and effective oral contraceptives stems from an increase in the incidence of diseases especially in developing countries, an increase in resistance to pathogenic bacteria in the current use of chemotherapeutics and antibiotic opportunistic infections in vulnerable people, and economically considered economics in developing countries In addition, allopathic medicine is very expensive and expensive in developing country like India and has limited success in preventing and treating oral and oral disease. Therefore, herbal remedies used in traditional.

medicine and other products continue to be regarded as one of the best alternatives to synthetic and natural. remedies. The current research is related to the use of Herbal Guava Leaves and Argemone Mexicana in the treatment of oral ulcers in a medical gel.

Mouth ulcers are yellowish or whitish depression with red margination in mucus lining of mouth cavity, characterized by inflammation and pain.

Based on clinical status, mouth ulcer patients can be categorized into three groups: minor, major and herpitiform, Etiology is unknown or often misunderstood; its diagnosis is largely based on clinical signs.

However some factors like psychological stress, topical trauma, microbial infections, genetics, nutritional derangements, immunological, hormonal changes, allergies and medications are considered important factors as etiology of mouth ulcerations.

Topical steroids viz. triamcenolon and prednisolon are most frequently used treatments but they have some serious side effects on continuous application like adrenal insufficiency, immuno-supression, hyperglycemia, gastrointestinal osteoporosis, disturbance, Moreover commercially available etc.

formulations containing synthetic and semi-synthetic active agents are complained of local irritation, staining of teeth, burning sensation, etc, due to high alcohol concentration and presence of some organic compounds (3).

Mouth Ulcer
An oral ulcer (also called a mouth ulcer or mucosal ulcer) is an ulcer that occurs in the mucous. membranes of the mouth. They are painful round or oval ulcers that form in the mouth, especially Lyon inside the cheeks or lips.

Mouth sores, also known as aphthous sores, can be painful when we eat, drink or brush our teeth. Common causes of mouth sores include a lack of nutrients like iron, vitamins especially B12 and C, poor oral hygiene, disease, depression, indigestion, mechanical damage, food intolerance, hormonal imbalance, skin disease etc.

A mouth ulcer is a fracture or fracture of the mucous membrane, located in the middle of the mouth. It is usually yellow or white and usually looks like pressure on the mouth which is a mucous membrane

.
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 ar very common and are mainly due to injuries such as improper dentures, broken teeth, or filling.

- **Factors responsible for the mouth ulcers:**

Toothpastes and mouthwashes that contain sodium lauryl sulfate, Emotional stress/Psychic stress, Hormonal changes, Nutritional deficiencies, Mechanical trauma, Viral infections, Allergies and sensitivities, Genetics, Infectious agents (both bacterial and viral), Medical

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AQUEOUS GEL

GAUVA LEAVES

PLAN OF WORK

1. Literature Review

Study of pathophysiology, and treatment options for mouth ulcers.

Analyze previous formulations and therapeutic agents used in oral gel preparations.

2. Selection of Active Ingredients

Choose suitable therapeutic agents (e.g. antimicrobial, anti-inflammatory). Examples: Benzocaine, Chlorhexidine, Triclosan, Aloe vera, Amlexanox, etc.

3. Selection of Gel Base and Excipients

Select appropriate polymers for gel formation (e.g., Carbopol 934, HPMC, NaCMC). Choose suitable co-solvents, preservatives, pH adjusters, and flavoring agents.

4. Pre-formulation Studies

Evaluate drug-excipient compatibility.

Determine solubility, stability, and required concentration of each component.

5. Formulation of Aqueous Gel active drug(s) and other excipients.

Adjust pH and viscosity as needed for oral mucosal compatibility.

6. Evaluation of the Gel

Physical appearance (color, clarity, homogeneity)

pH measurement, Viscosity, Spreadability, Drug content uniformity, Mucoadhesive strength Stability studies (short-term accelerated)

7. Data Analysis

Analyze results statistically.

Compare formulations to identify the most effective and stable formulation.

REVIEW ON LITERATURE

1. The formulation and evaluation of a pharmaceutical aqueous gel for mouth ulcer treatment, as explored by Das SK, Das V, Gulati AK, and Singh VP, focuses on developing an Aqueous gel utilizing natural ingredients known for their therapeutic properties.in **2019**.
2. Jain NK, Roy R, Pathan HK, et al., Formulation and Evaluation of Polyherbal Aqueous Gel from Psidium guajava, Piper betel and Glycerrhiza glabra Extract for Mouth Ulcer Treatment. Research Journal of Pharmacognosy and Phytochemistry, **2020**;
3. Nikita Shahare, Shailendra Chouhan, and G.N. Darwhekar have contributed to the field of pharmaceutical aqueous gels, particularly focusing on their application in treating mouth ulcers. Their review article, titled *"Herbs Used in Treatment of Mouth Ulcer: A Review,"* was published in the *International Journal of Pharmacognosy and Chemistry* in **2021**. This comprehensive review examines various herbal remedies and their effectiveness in managing mouth ulcers.
4. Thawkar MM, Kosalge SB, and Urade PK This article provides an overview of pharmaceutical gels, discussing their types, formulation strategies, and roles in drug delivery systems. This review focuses on the formulation aspects of pharmaceutical gels, highlighting the advantages.**2021**.
5. Madaan, T. Manjula, and M. Soni, published in the *Journal of Fundamental & Comparative Research* in **2022**. It discusses the therapeutic potential of natural ingredients, such as extracts from *Citrus aurantium dulcis* (orange peels), in creating effective topical gels.
6. Development and Evaluation of In Situ Gel Formation for Treatment of Mouth Ulcer" by Nikita Harekrishna Gurav and Prerana Shantinath Husukale, published in the *Turkish Journal of Pharmaceutical*

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Sciences in June **2023**.This study focuses on the development and evaluation of in situ gels for treating mouth ulcers using choline salicylate and borax as model drugs.

7. Harshada B. Tribhuvan, Sapana S. Mhaske, Vaishnavi G. Wayal, Priti R. Pawar, and Prof. Kajal Walunj The study emphasizes the use of herbal ingredients known for their therapeutic properties, such as anti- inflammatory and antimicrobial effects.**2023**.
8. Ghuge AS and Khandre RA. However, their work titled "Formulation and Evaluation of Mouthwash Using Guava Leaves for Aphthous Ulcer Treatment" focuses on developing a herbal mouthwash utilizing guava leaf extract for treating aphthous ulcers.**2024**.

AIM

To develop a stable, effective, and patient-friendly aqueous gel formulation containing therapeutic agents for the treatment of mouth ulcers, and to evaluate its physicochemical properties, drug release By ensuring that the drug reaches its intended target in a controlled manner, TDDS improves the therapeutic index and reduces the dosage required for effective treatment. Delivering the drug directly to the ulcer site for localized action. Providing pain relief,anti- inflammatory, and healing effects. Evaluating safety, stability, and patient acceptability.

OBJECTIVES

1. Reduction of Systemic Side Effects.
2. Control Drug Release.
3. Target specific sites.
4. Safe, effective, and stable formulation
5. pain relief,
6. promote healing,
7. reduce the duration of mouth ulcers.
8. Reduce discomfort due to oral ulcer.
9. Improve absorbtion
10. Easily Apply
11. Reduce irritation.

MATERIAL & METHODS

1. CHEMICAL REQUIREMENTS

Sr. NO	Name Of Ingridients	Quantity(gm)	Used
1.	Carbopol 934	2.5gm	gelling agent
2.	Propylene glycol	2ml	Co-solvent
3.	Methyl Paraben	0.015gm	Preservatives
4.	Propyl Paraben	0.01gm	Preservatives
5.	Triethanolamine	q.s	for adjust pH
6.	Guava leaves powder	2gm	Antioxidant, polyphenols, antiviral compounds and antiinflammatory compounds
7.	Curcumin Extracts	2ml	Antiseptic
8.	Clove oil	1ml	As Flavour
9.	A. Maxicana latex extract	1ml	Antimicrobial
10.	Distilled water	25ml	Volume makeup

2. INSTRUMENTS REQUIREMENTS

Sr.no	Apparatus Name
1.	Beaker
2.	Glass Stirrer
3.	Measuring Cylinder
4.	PH Meter/Paper
5.	Water Bath

METHODS

1. **Weighing of Ingredients**

All ingredients were accurately weighed using a digital balance.

2. **Preparation of Gel Base**

Carbopol 934 (1–2%) was slowly dispersed in distilled water with constant stirring to avoid clumping. The dispersion was allowed to swell for 24 hours for complete hydration.

3. **Incorporation of Other Ingredients:**

Glycerin and preservatives were dissolved in a small quantity of water and added to the hydrated gel base.

The active drug was dissolved or dispersed (depending on solubility) in the base.

4. **Neutralization and Gel Formation:**

Triethanolamine was added dropwise to the formulation to adjust the pH to 6.5–7.0, promoting gel formation.

5. **Mixing and Homogenization**

The entire mixture was stirred using a mechanical stirrer to ensure uniform distribution and smooth gel consistency.

6. **Filling and Storage**

The gel was transferred into clean, labeled containers and stored at room temperature for further evaluation.

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FORMULATION OF GEL

Dispersed Carbopol 934 in Distilled water

↓

5ml water+ Methyl and propyl paraben

↓

Heated on water bath

↓

After colling add propylene glycol

↓

Guava leaves powder mix in above mixture

↓

Volume made up to 20ml with distilled water

↓

Mixed all ingredients and elaichi flavour add into Carbopol 934 properly.

↓

Continuous stirring triethanolamine added dropwise. (Adjust pH 6.8-7)

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Prepared Gel

EVALUATION OF GEL

1. **Physical appearance**: Physical parameters such as appearance and colour were checked.
2. **Microscopic analysis**: The microscopic study by the optic microscope with magnification of 10 & 40 for uniformly gel texture & bubbles.
3. **Clarity of gel**; The clarity of gel was determine by visual inspection.
4. **Homogeneity**: Gel formulations were tested for homogeneity by visual inspection after the gels have been set in to the container.
5. **Stability study**: Stability studies were done with open and close container. Here, by subjecting the product to room temperature for 1 month.
6. **pH determination**: The pH of developed gel formulations was determined using digital pH meter. 1gm of gel was dissolved in 100 ml distilled water and kept aside for 2 hours. The measurement of pH of each formulation was done in triplicate and average values are calculated.
7. **Spread ability**: Spreadability was determine by apparatus which consists of a wooden block, which was provided by a pulley at one end. By this method spreadability was measured on the basis on slip and drag characteristics of gels. An excess of gel (about 2gm) under study was placed on this ground slide.
   The gel was then sandwiched between this slide and another glass slide having the dimension of fixed ground slide and Spreadability was determined by the apparatus provided with the hook. A one kg weighted was placed on the top of the two slides for 5 min. to expel air and to provide a uniform film of the gel between the slides. Excess of the gel was scrapped off from the edges. The top plate was then subjected to pull of 80 gm.With the help of string attached to the hook and the time (in sec.) required by the top slide to cover a distance of 7.5 cm be noted.
8. **Gel Strength**: Gel strength was determined by the time in seconds required by the weight to penetrate in the gel. A Sample amount of 5 gm of each of the optimize batches was taken and 3.5 gm weight was placed on the surface of gel. The time in seconds required by the weight to penetrate 0.5 cm in the gel.
9. **Viscosity**: Viscosity was determined by using Brookfield viscometer. Formulated gels were tested for their rheological behaviors at 250C. The measurement was made over range of speed from 10rpm to 100rpm with 30seconds between 2 successive speeds and then in a reverse orders.
10. **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 0.5 gm of gel from each batches add in to this hole. Plates were then incubated at 270C for 48 hr. The zone of inhibition (diameter in mm) developed.

RESULT & DISCUSSION

The results of evaluation parameter in vitro study shown in table below:

1. Organoleptic Evaluation

Colour	Yellowish white
Odour	Characteristics
Homogeneity	Good

From the above mention results in table, it is clearly shows that prepared gel formulation have good appearance. The gel formulation have good homogeneity.

2.Stability Study

Open Container	Closed Container
Not Stable	Stable

One month stability study was done with open and Stable 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

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means the form of instability in aqueous gels.

3. **Other Evaluation Parameters**

Sr.no	Type of Evaluation	Result
1.	Spread ability	4±0.1
2.	pH	6.8±0.5
3.	Gel Strength	38±0.7
4.	Viscosity	3.115±0.15

From the above table it is clearly show that the pH of formulated gel was found in suitable range. The spreadability show that with increasing viscosity of formulation spreadability decreases and vice-Versa. Gel strength of gel was found in suitable range.

CONCLUSION

From the mentioned results, it was concluded that the prepared gel formulations are in good appearance with suitable pH range.

Formulated gel have good homogeneity, proper gel strength & spread ability. The gel is neither too thick nor too thin. The all formulated gels are found to be stable in closed container as compared to open container.

The formulation showed the antibacterial and antifungal activities against Staphylococcus aureus and Candida albicans. Argemone Mexicana latex extract shows antimicrobial activity against S. aureus. Therefore, the study concluded that the natural remedies are more acceptable & they are safer with minimum side effects than synthetic preparations.

Thus, the data presented in this study, it was concluded that the formulated gel of powdered Guava Leaves, argemone Mexicana with Clove flavor possesses a significant therapeutically efficacious & have suitable vehicle for drug delivery. Thus, the formulated gel is suitable for treatment of mouth ulcer.

The formulation of pharmaceutical aqueous gels for mouth ulcer treatment offers a promising approach due to its ease of application, localized drug delivery, and prolonged retention time at the site of action. Incorporating herbal or synthetic active agents into a gel base enhances therapeutic efficacy while minimizing systemic side effects.

Evaluation parameters such as pH, viscosity, spreadability, mucoadhesiveness, and drug release profiles confirm the suitability of aqueous gels for oral mucosal applications.
Overall, aqueous gel formulations represent an effective, patient-friendly, and clinically viable option for managing mouth ulcers.

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