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Development and Evaluation of a Novel Herbal Anti-Ulcer Gel Formulation Incorporating Bauhinia Racemosa Extract

Mr. Aditya Rajesh Jakhad[1], Mr. Mayur Sakharam Gangurde[2], Miss. Sonali Rajendra Shejole[3], Mr. Raj Hemant Dode[4]

[1]B. Pharm Student, SVS Institute of Pharmacy, Mungase, Malegaon.
[2]Assistant Professor, Department of Pharmacognosy), SVS Institute of Pharmacy, Mungase, Malegaon.
[3]B. Pharm Student, SVS Institute of Pharmacy, Mungase, Malegaon.
[4]Assistant Professor, Department of Pharmaceutics, SVS Institute of Pharmacy, Mungase, Malegaon.

ABSTRACT

This research paper focuses on the development and testing of an anti-ulcer gel containing Bauhinia Racemosa extract that is specifically designed for the treatment of mouth ulcers. The study's goal is to overcome the limits of current treatment choices by offering a natural and effective alternative for people suffering from mouth ulcers. The research aims include developing an anti-ulcer gel based on Bauhinia Racemosa extract, assessing its efficacy and safety, and adding to existing knowledge on ulcer treatment. The gel formulation combines Bauhinia Racemosa's distinct phytochemical composition, including flavonoids, tannins, and saponins, which are thought to have anti-inflammatory, antibacterial, and wound-healing activities. The anti-ulcer gel's efficacy will be evaluated using a variety of criteria, including pain reduction, ulcer healing promotion, and relief of oral discomfort associated with mouth ulcers. Safety and tolerability will be extensively investigated to guarantee that there are no negative side effects. The study will also investigate the probable processes by which the gel exerts its anti-ulcer properties. The anti-ulcer gel's effectiveness will be determined by comparing it to existing conventional therapies for mouth ulcers. The long-term impact and recurrence rates of mouth ulcers treated with the gel will also be studied. The purpose of this research is to contribute to the scientific literature on natural products for the treatment of mouth ulcers by making evidence-based recommendations for the use of anti-ulcer gel in clinical practice. The study will also highlight topics for future research and development of natural products for treating mouth ulcers. This research report aims to improve the quality of life for those suffering from mouth ulcers by offering a safe, effective, and natural treatment option.

KEYWORDS: Mouth Ulcers, Anti-Ulcer Gel, Bauhinia Racemosa, Phytoconstituents.

1.0 INTRODUCTION

Mouth ulcers, also known as aphthous stomatitis, are a type of ulcerative disease that affects the oral mucosa and is marked by recurrent oral and throat ulcers.[1] There are several common causes of mouth ulcers, including biting the inner layer of the cheek, dietary allergies, and trauma, scrubbing one's teeth, hormonal fluctuations, nutritional shortages, bacterial infections, and illnesses.[2] Mouth ulcer treatment

options include the use of antibiotic or anaesthetic gel formulations, as well as calming and antiseptic mouth washes like povidone iodine or chlorhexidine mouthwash.[3] Formulations that are semi-solid consist of gels with a liquid phase that are subsequently thickened with additional ingredients. Topical gels are designed to be applied to the skin or specific mucosal surfaces to facilitate local medication action or percutaneous drug uptake.[4] Numerous Indian medicinal plants are associated with a range of pharmacological properties due to the diverse classes of phytochemicals they contain. These herbal substances offer a fantastic substitute for traditional synthetic medications, which have a lot of adverse effects.[5]

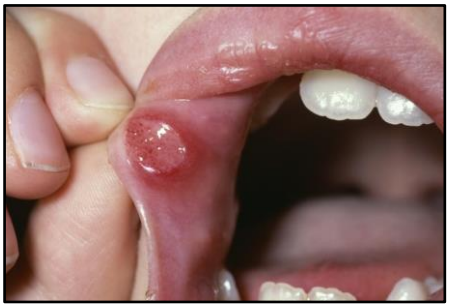

Fig. 1.1 : Aphthous stomatitis

Natural materials, including microbes, plants, animals, and minerals, are used to make medicines that treat illnesses. Additionally, new medications are being created. Within the Fabaceae family, the genus Bauhinia has more than 200 flowering plants with a pantropical range. Leaves of Bauhinia Racemosa commonly called as Bidi leaf tree, belonging to family Fabaceae, are very commonly used in skin care products.[6] They are rich in phytoconstituents such as triterpenoids (Lupeol), steroids (β-sitosterol), coumarins (scopoletin and scopolin), flavonoids (kaempferol and quercetin), and stilbenes (resveratrol). Natural molecules generated from plants, like flavonoids, terpenoids, steroids, and others, have drawn a lot of interest recently because of their many pharmacological characteristics, which include antioxidants. The heartwood yielded pacharin, a derivative of dibenzoxepin. As a result, in the current study, this plant's hydroalcoholic extract have been added to gel formulation that may be utilised to treat mouth ulcers, a disease linked to microbial invasion.[7]

Fig. 1.2 : Leaves of Bauhinia Racemosa

2.0 Materials and Methods

2.1. Collection of Materials

The leaves of Bauhinia racemose were collected from the medicinal garden and authenticated from Department of Botany, MSG College, Malegaon. Carbopol 934 was procured from Pharmaceutics lab, SVS IOP, Mungase. All the other excipients were of analytical grade.

2.2. Preparation of Extract :

The leaves of bauhinia racemosa were washed and air dried. Dried leaves were powdered using the mixer

grinder. The extraction was done using the Soxhlet extractor using hydro-alcohol as a solvent. The Soxhlet extractor was set up by placing the thimble in the main chamber, adding a suitable hydroalcoholic solvent mixture (ethanol : water 70:30 v/v) in the round-bottom flask, and condenser was connected. The solvent mixture in the round-bottom flask was heated using a heating mantle, ensuring that the solvent vapours condense and drip into the thimble containing the plant material. After the extraction was completed, The round-bottom flask containing the extracted compounds was removed and the solvent was evaporated using a water bath to obtain the crude extract and was collected in an air tight container.[8]

Fig. 2.1 : Extraction By Soxhlet Apparatus

2.3. Phytochemical screening :

The above prepared extract was subjected to preliminary phytochemical screening tests to identify the presence of various components, by using different tests and reagents. The required phytoconstituents for the anti-ulcer activity in mouth ulcers are Flavonoids (Quercetin, Kaempferol) and Triterpenoids (Lupeol), For detecting their presence in our extract, two types of chemical tests were performed.

2.3.1. For Flavonoids :[9]

Shinoda Test: Add a few pieces of magnesium ribbon to the extract, followed by the dropwise addition of concentrated hydrochloric acid. The appearance of a red, orange, or pink colour indicates the presence of flavonoids.

2.3.2. For Triterpenoids :[10]

Salkowski Test: Dissolve the extract in chloroform and add a few drops of concentrated sulfuric acid. The formation of a reddish-brown colour at the interface indicates the presence of triterpenoids.

2.4. Formulation of Gel :

The Carbopol-934 was dissolved in distilled water and kept aside for hydration. In a separate container, the required amount of Triethanolamine was mixed with the remaining water. The Triethanolamine solution was slowly added to the Carbopol dispersion with continuous stirring until a smooth and homogenous gel is formed. Required amount of Plant extract, Glycerin, and Propyl Paraben was weighed and mixed in Carbopol gel until a uniform distribution is achieved. The final gel formulation was transferred to suitable container for storage and further evaluation.[11]

Table 2.1 : Formulation Table For Anti-Ulcer Gel

Ingredients	Formulation Code		
	B1	B2	B3
API Extract (ml)	2.0	2.0	2.0
Carbopol 934 (mg)	700	840	560
Triethanolamine (ml)	0.50	0.48	0.52
Glycerin (ml)	1.6	2.0	1.2
Propyl Paraben (mg)	40	40	40
Chocolate Essence	q.s.	q.s.	q.s.
Distilled Water (ml)	15	15	15

3.0 Evaluation of Gel :

3.1. Visual appearance :

The prepared gels were tested for colour, clarity, texture, transparency and presence of any gritty particles.

3.2. pH Determination :

The pH of herbal gel formulations was 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.

3.3. 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.

3.4. 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

Spreadabilty of gel formulations were reported

3.5. Viscosity :

The viscosity of all the prepared formulations were analysed by the Brookefield's viscometer LVDVE with helipath , using spindle number 96 at 10 rpm.

3.6. Anti-Microbial Activity :

The gel formulation was evaluated for its antimicrobial activity against relevant oral pathogens. The antimicrobial activity of the gel was assessed using the agar diffusion method. Petri dishes were inoculated with cultures of Streptococcus mutans, Lactobacillus acidophilus, and Candida albicans, representing common oral pathogens.[12]

3.7. Stability Studies:

The gel formulation was subjected to accelerated stability testing to evaluate its physical and chemical stability over time. The gel samples were stored under controlled conditions of temperature (40°C) for a period of 3 months. At predetermined time intervals (30, 60, and 90 days), the samples were evaluated for various parameters, including appearance, pH, viscosity, and microbial quality.[13]

4.0 Result and Discussion :

4.1. Collection and authentication of plant :

The collected leaves of Bauhinia racemosa were identified and authenticated by Dr. J.T. Jadhav Department of Botany, MSG College, Malegaon and the Authentication number is MSG/PG/BOT-99-06/03/2024.

4.2. Phytochemical Screening :

The extract was tested for the presence of phytoconstituents such as Flavonoids (Quercetin, Kaempferol) and Triterpenoids (Lupeol). The results for respective phytoconstituents were recorded as positive.

Table 4.1 : Phytochemical Investigation of Extract

Test	Observation	Inference
Shinoda Test (Flavonoids)	Pink Coloured Appeared	Flavonoids are Present
Salkowski Test (Triterpenoids)	Reddish-Brown Colour Appeared	Triterpenoids are Present

4.3. Formulation of Herbal Gel :

Three batches of herbal anti-ulcer gels were formulated by varying the herbal ingredients in each of the formulation.

Batch 1 **Batch 2** **Batch 3**

4.4. Evaluation of Gel :

Evaluations were conducted on all prepared gel compositions with respect to physical appearance, pH, homogeneity, spreadability, and viscosity.

The observation shows that the gel had an exquisite appearance and a smooth texture. All of the produced batches had pH values between 6.5 and 7.0. Every gel exhibited good spreadability. Every prepared gel exhibited good homogeneity and was lump-free. The developed plans were far more straightforward and understandable. All of the produced batches had excellent viscosities that were within the range. Batch 2 was found to be the best batch.

Table 4.2 : Results For Evaluation Parameterse

Formulation	Physical Appearance			pH	Homogeneity	Spreadability (cm)	Viscosity (cp)
	Colour	Texture	Clarity				
B1	Brownish	Smooth	Turbid	6.72	Homogenous	6.2	258
B2	Brown	Smooth	Clear	6.50	Homogenous	6.8	275
B3	Brownish	Rough	Turbid	6.87	Homogenous	6.5	292

4.5. Anti-Microbial Activity :

The antimicrobial activity of the gel was assessed using the agar diffusion method. Out of all the 3 batches prepared, B2 gel containing the hydroalcoholic extract showed the highest zone of inhibition both against C. albicans and E. coli.

4.6. Stability Studies For B2 Formulation :

Table 4.3 : Stability Studies Data for Anti-Ulcer Gel

Formulation Code	Time Period	Stability Parameters			
		Appearance	pH	Viscosity	Microbial Quality
B2	Initial	Smooth and Homogenous	6.4	275	Pass
	10 Days	No Change	6.4	277	Pass
	20 Days	No Change	6.2	276	Pass
	30 Days	No Change	6.2	270	Pass

Conclusion

The development and evaluation of the anti-ulcer gel formulation containing flavonoids and triterpenoids from Bauhinia Racemosa extracts has yielded highly promising results by leveraging the plant's inherent anti-inflammatory and wound healing properties. The superior performance of the B2 formulation, as evidenced by the comprehensive testing regimen, highlights the significant therapeutic value of this Bauhinia-based product. This research paves the way for the further exploration and commercialization of B. racemosa-derived healthcare solutions that could benefit both rural communities and the wider public.

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