Volume 2, Issue 2, 2023, Page 156-163

International Journal of Pharma Research and Technology

Formulation and Evaluation of Mouth Ulcer Gel by Using Active Herbal Ingredients

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Abstract

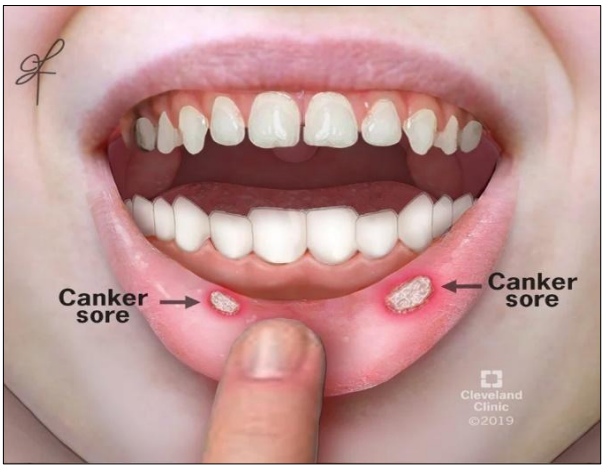
Mouth ulcers often cause pain and irritation of the sores by salty, spicy and sour food items and may cause discomfort while healing occurs due to the use of chemical formulations. This project focuses on the preparation of a herbal mouth ulcer healing gel because of better cultural acceptability, better compatibility with human body and lesser side effects. The gel was prepared by using extract of liquorice root and ethanolic extract of aloe vera. The developed formulations are homogenous and having pH range 6.8 to 7.0. Formulation showed acceptable rheological behaviour with applicable Spreadability and Extrudability properties. Anti- fungal studies of formulations showed very capable against *Candida albicans* comparable with a marketed gel. Therefore, developed formulations have potential to treat mouth ulcers.

Keywords: Mouth Ulcer, Homogenous, Sprediability, Herbal Gel, Liquorice, Ethanolic Extract

Introduction

Mouth ulcers are painful and typically small lesions that develop in your mouth or at the base of your gums. They can make eating, drinking, and talking uncomfortable. Types of mouth ulcers include canker sores and the sores caused by hand, foot, and mouth disease. Mouth ulcers are rarely contagious and usually go away after 1 to 2 weeks, even without treatment. If you get a mouth ulcer that is large, is extremely painful, or lasts for a long time without healing, seek the advice of a doctor or dentist. While mostly harmless, mouth ulcers can be extremely uncomfortable and make it difficult for some people to eat, drink, and brush their teeth. Mouth ulcers range in size, and the exact symptoms of the mouth ulcer will depend on what type of ulcer a person has. 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. Treatment of mouth ulcers may include soothing/ antiseptic mouthwashes, such as *Chlorhexidine* mouthwash or *povidone* iodine mouthwash or use of antibiotic or *anesthetic* gel formulations.

It has been observed that plant drugs constitute 25% of total drugs in developed countries such as United States, while in fast developing countries like China and India the contribution is above 80%. Thus, the economic importance of medicinal plants in India is much more than rest of the world. These countries contributes two third of the plants used in modern system of medicine and the indigenous systems of medicine provides health care system of rural population. Liquorice is the dried peeled or unpeeled roots and stolons of *Glycyrrhiza glabra* Linn, Family: leguminosae. This plant has been used for its medicinal property for more than 4000 years. Leaves of *Aloe barbedensis* commonly called as aloe vera, belonging to family Asphodelaceae, are very commonly used in skin care products. They are rich in phytoconstituents such as amino acids, anthroquinone, enzymes, hormones, lignin, minerals, salicylic acid, saponins, sterols, sugars, vitamins The mechanism involved in production of antiulcer activity of the plant is due to its antioxidant, anti-inflammatory, mucus secreting, cytoprotective or healing activities.



Material and Methods

Collection and authentication of plant materials

The liquorice was purchased from local market. The leaves of aloe barbadensis were collected from medicinal garden and authenticated from Pharmacognosy department KYDSCT'S cop, Sakegaon. All the other solvents were of analytical grades.

Preparation of plant extracts

Extraction of glycyrrhizic acid from liquorice root

GA was extracted by using the method of maceration with slight modification in the method described in literature. For this purpose, drug (licorice roots) powders were macerated with the solvent mixture of acetone and dilute nitric acid for 2 h. The contents were filtered and additional20 ml of acetone was added to the marc and warmed gently. The contents were filtered and filtrate was obtained. To this filtrate sufficient volume of dilute ammonia solution was added till precipitation of ammonium glycyrrhizinate is completed. The precipitate

was collected and washed with 5 ml of acetone, dried and collected.

Preparation of Aloe vera extracts

The juice of Aloe leaves was macerated with ethanol 95% for 3 days and separated b y centrifugation at 3000 rpm to obtain the ethanolic extract of aloe (EEA). All the extracts were stored at room temperature.

Phytochemical screening

All the above prepared extracts were subjected to preliminary phytochemical screening tests to identify the presence of various components, by using different tests and reagents.

Formulation of gel

A sufficient amount of Carbopol 934 was soaked in distilled water overnight, and then mixed with distilled water with continuous stirring using a mechanical stirrer. Another solution containing varying concentrations of EEA, GAE and the required quantity of methyl paraben and propyl paraben were added with continuous stirring. Propylene glycol was also added to the solution. This prepared solution was further mixed with Carbopol 934 solution thoroughly with continuous stirring, volume was made up to 30ml with water and the pH was adjusted by addition of triethanolamine to obtain gel of required consistency. Five formulations of herbal gel were prepared.

Formulation of Gel

Ingredients	Quantity in gm or ml				
	F1	F2	F3	F4	F5
Liquorice root extract (GAE)	2	4	-	-	3
Aloe vera extract (EEA)	-	-	2	4	3
Carbopol 934	20	20	20	20	20
Methyl parabens	0.2	0.2	0.2	0.2	0.2
Propyl parabens	0.1	0.1	0.1	0.1	0.1
Propylene glycol	2	2	2	2	2
Triethanolamine	q.s	q.s	q.s	q.s	q.s
Peppermint oil	q.s	q.s	q.s	q.s	q.s
Distilled water	q.s to 30 ml	q.s to 30 ml	q.s to 30 ml	q.s to 30 ml	q.s to 30 ml

Evaluation parameters

Phytochemical screening of GA

Phytochemical screening of GA was performed for the identification of phytoconstituents present.

Test for saponins (foam test)

The extract was dissolved with 20 ml of distilled water and stirred for 15 minutes. The formationof 1cm layer of foam for a period of time showed the presence of saponins.

Tests for flavonoids

With sodium hydroxide*:* Extract was mixed with 1 ml of sodium hydroxide solution. Blue to violet color indicates the presence of anthocyanins, yellow to orange color shows the presence of flavonones and yellow color indicates flavones.

Fehling's test

On the water bath, Extract was kept. To which Fehling solution A and B were mixed. Brick red precipitate showed the presence of reducing sugars.

pH determination

The extract was dissolve in 10 ml of distilled water for evaluating the pH. The pH was determined using digital pH meter. The pH was measured in triplicate. Evaluation of the physicochemical characteristics Physical appearance

The prepared herbal mouth gel was visually inspected for color, texture, homogeneity, and clearness within 24 h after preparation. It shows acceptable appearance and hence selected for further analysis.

Measurement of pH

The pH of herbal mouth gel formulations were determined by using digital pH meter (Lab line Digital PH Meter). 1 gm of gel was taken and dispersed in 10 ml of distilled water and keep aside for two hours.

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. Homogeneity of gel formulation was reported in Table no.6

Viscosity

The measurement of viscosity of the formulated gel was determined by Brookfield Viscometer RVDV Model using spindle no. 64 at 25°C. The gels were rotated at speed 50, 60 & 100 rpm speed, the results are shown in table no.

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 slideL = length of glass slides

T = time taken to separate the slides

Spreadability of gel formulations were reported in Table

Anti-bacterial activity

The antibacterial activity of the prepared gel formulations was performed by agar well diffusion method. The plates of the nutrient agar media were prepared. Each plate was inoculated with an aliquot (0.1 ml) of the bacterial suspension which was spread evenly on the surface of the medium of the plate. After 15 min, wells with 6 mm diameter were made with the help of a sterile cork borer in the solid medium and filled with 0.5g of gel. All the plates were incubated at 37 ◦C for 24 h. The antibacterial activity was assessed by measuring the diameter of the zone of inhibition (ZOI) in mm. Triplicates were carried out for each extract against each of the test organism.

Result and Discussion:

Phytochemical screening of GAE

The tests performed for phytochemical screening showed the presence of flavonoids and saponins in the extract (GAE) as shown in Table. 2

Table No.2: Phytochemical screening of GAE

Sr no.	Test	Observation	Result
1.	Test for saponins (foam test)	Persistent foam is observed	Present
2.	Tests for flavonoids With sodium hydroxide	Yellow color	Present
3.	Fehling's test	Brick red precipitate	Present

pH determination of extract

Table No.3 : pH of the GA extract

Sr no.	pH	Mean ± SD
1	5.6	5.56 ± 0.05
2	5.6	
3	5.5	

Physical evaluation of herbal gel:

Table No.4 : Physical evaluation of gel formulations:

Formulations	Color	Consistency	Odour	Clarity
F1	Yellowish Brown	Good	Characteristics	Clear
F2	Yellowish Brown	Good	Characteristics	Clear
F3	Greenish	Good	Characteristics	Clear
F4	Greenish	Good	Characteristics	Clear
F5	Greenish Brown	Good	Characteristics	Clear

Measurement of pH of herbal gel

Table No.5: pH of gel formulations

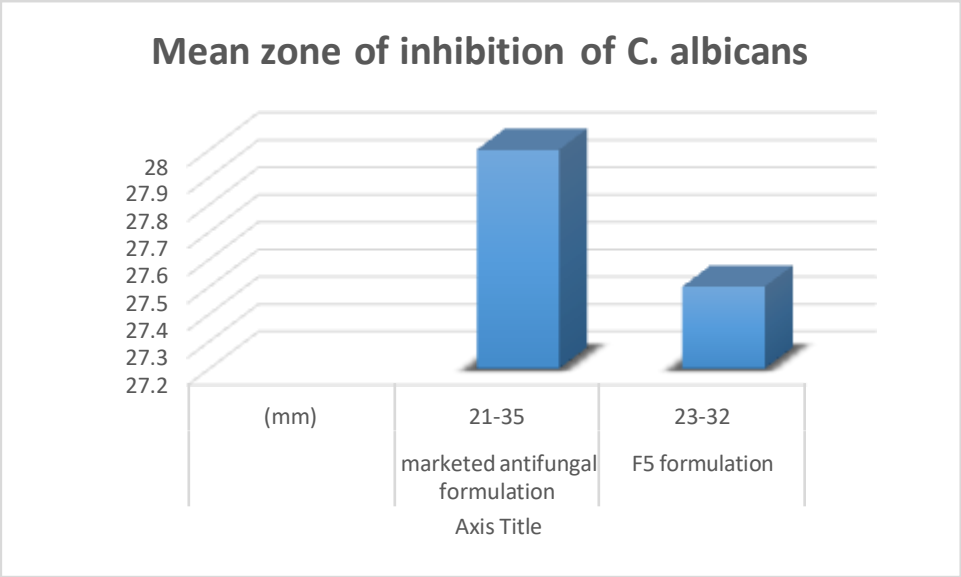
Formulations	pH	Homogeneity	Viscosity cps	Spreadability (g.cm/sec)
F1	6.9	Homogenous	12925	23.2
F2	6.9	Homogenous	12200	23.8
F3	7.0	Homogenous	13813	24.6
F4	6.9	Homogenous	13540	24.4
F5	6.8	Homogenous	13910	25.8

The acceptable pH values of the formulations were in the range of 6.5–7.0. The spreadability of formulations ranged from 23.2 to 25.8 (g.cm/sec). All formulations viscosity was found to be between 12200 Cps to 13910 Cps All formulations found to be homogenous.

Anti-bacterial activity

The antifungal activity of the tested F5 formulations was found to be equal to that of the reference standard. It was observed that the plain formulation used in the study exhibited no antifungal activity. The selected F5 formulation showed that there is no significant difference in the zone of inhibition with the gel formulation in comparison to the reference standard at P <0.05, against *C. albicans*. The result is shown in table.

Formulations	Range of Zone of inhibition (mm)	Mean zone of inhibition of C. albicans
marketed antifungal formulation	21-35	28
F5 formulation	23-32	27.5



Conclusion

Herbal formulations are in increasing demand nowadays in the market due to their less side- effects and cost effectiveness than the synthetic formulations. The natural ingredients are easily known to the people than the synthetic drugs so people can move towards herbal formulations. In the present study we can develop the mouth ulcer gel using extracts which are prepared from herbal ingredients which can be easily available. From the above experimental data it is clear that gel formulations with herbal ingredients such as liquorice and aloe vera which are having its own antimicrobial activity has possesses all the characteristics such as homogeneity, pH, viscosity and good antibacterial activity which is necessary in the treatment of mouth ulcers.

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