

Formulation and Evaluation of Herbal Antiulcer Gel

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Abstract: Background: Aphthous stomatitis or mouth ulcers is the most common condition that we encounter. Clinically the lesions are single or multiple superficial and deep sealed and are associated with microbial invasions. Aim: This study was conducted with the aim of evaluating the effectiveness of herbal drugs for treatment of Aphthous stomatitis. Materials and Methods: In the research work, mouth ulcer gels were formulated incorporating the ethanolic extracts of as Neem, Amla and Liquor ice using carbopol 934 as the gelling agent. three batches were formulated by varying the concentration of the herbal ingredients (F1 to F3) the prepared formulations were evaluated for various parameters like physical appearance, pH, Spreadability, Homogeneity and antimicrobial activity against fungi and bacteria. The antimicrobial activity was also compared with a marketed gel formulation. Results and Discussion: All the prepared formulation using different concentration of plant extract showed the pH values in between 6.1 ± 0.2 to 7.0 ± 0.1 . The spreadability values ranged between the 6.0 to 8.0 cm. Out of all the formulations, formulation F2 containing all the three herbal extracts showed a good spread ability and very promising antimicrobial activity comparable with a marketed gel. Conclusion: Thus stable, effective gels containing herbal ingredients for management of mouth ulcers can be developed.

Keywords: Aphthous stomatitis, herbal treatment, antimicrobial activity, mouth ulcer gel, ethanolic extracts

1. Introduction

Aphthous stomatitis or mouth ulcer is an ulcerative condition that is related to the oral mucosa and is characterized by repeating ulcers in the throat and oral cavity. 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 anaesthetic gel formulations Semi - solid formulations include gel having a liquid phase which is then thickened by other components. Topical gels are intended for the application on skin or to certain mucosal surfaces for local action or percutaneous penetration of medicament preparations. A large number of Indian medicinal plants are attributed with various pharmacological activities as they contain diversified classes of phytochemicals. As the conventional synthetic drugs suffer from a numerous side effects, these herbal ingredients provide a good alternative.

Leaves of Neem commonly called as Azadirachtaindica, belonging to family Meliaceae, are very commonly used in skin care products. They are rich in phytoconstituents such as 6 - desacetylnimbinene, nimbandiol, nimbolide, ascorbic acid, n - hexacosanol and amino acid, 7 - desacetyl - 7 - benzoylazadiradione, 7 - desacetyl - 7 - benzoylgedunin, 17 - hydroxyazadiradione and nimbiol. The mechanism involved in production of antiulcer activity of the plant is due to its antioxidant, antiinflammatory, mucus secreting, cytoprotective or healing activities. Reported pharmacological activities of the plant are hypoglycemic, hypolipidemic, wound healing, immunomodulatory, antifungal and hepatoprotective. It is traditionally used for

mouth ulcer treatment.⁶ Leaves of Azadirachtaindica, commonly called as neem, belonging to family Meliaceae, are rich in several phytoconstituents such as nimbin, nimbidin, nimbolide, and limonoids, quercetin and sitosterols. They have very strong antibacterial, antifungal and anti - inflammatory activity⁷ and are quite commonly used for oral and dental treatments. Leaf of *Emblia officinalis* Linn, called as Amla, belonging to family Phyllanthaceae, is a common herb known for its wide variety of pharmacological activities such as diuretic, laxative, liver tonic, refrigerant, stomachic, restorative, anti - pyretic, hair tonic, ulcer preventive and for common cold, fever; as alone or in combination with other plants. Pharmacological activities of *Emblia officinalis* Linn could be attributed due to the presence of the phytoconstituents such as ellagic acid, gallic acid, emblicanin A and B, phyllembin, quercetin, and ascorbic acid. Thus in the present research work, the ethanolic extracts of these plants have been incorporated in gel formulations which could be used for the management of mouth ulcers, a condition that is associated with microbial invasion. Root of *Glycyrrhizaglabra* Linn, called as Liquorice, belonging to family Fabaceae, is a common herb known for its wide variety of pharmacological activities such as antibacterial, antioxidant, antimalarial, antispasmodic, anti - inflammatory and anti - hyper glycaemic properties. Liquorice root contains triterpenoids, polyphenols, and polysaccharides. Flavonoids account for the yellow root color. The principal glycoside, glycyrrhizin, exists in content of 7% to 10%, depending on cultivation practices. The isoflaveneglabrene and the isoflavaneglabridin, found in the roots of liquorice, are phytoestrogens.

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Figure 1: Neem



Figure 2: Amla



Figure 3: Liquorice

2. Materials and Methods

2.1 Collection of materials

The leaves of *Azadirachta indica*, *Emblica officinalis* Linn, *Glycyrrhizaglabra* Linn were collected from the Local Area of Sangli & Kolhapur. Carbopol 934 was procured from Arti Chemicals, Mumbai. All the other solvents were of analytical grade.

2.2 Preparation of extracts

The Powder of Neem leaves was macerated with ethanol 95% for 3 days and separated by centrifugation at 3000 rpm to obtain the ethanolic extract of neem. The leaves of *Azadirachta indica* and *Emblica officinalis* Linn were dried to retain the phytoconstituents and macerated separately with ethanol and separated by centrifugation to obtain ethanolic extract of *Glycyrrhizaglabra* Linn and ethanolic extract of *Azadirachta indica* (EEZ) respectively. All the extracts were stored at room temperature.

2.3 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.

2.4 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 *Azadirachta indica*, *Emblica officinalis* Linn and *Glycyrrhizaglabra* Linn 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. Three formulations (F1 to F3) of the herbal gel were prepared.

3. Evaluation of Gel

3.1 Visual appearance

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

3.2 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.

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:

$$S = M L / T$$

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 in Table.

3.6 Antimicrobial activity

The antimicrobial activity of all three gel formulations and a marketed moth ulcer gel was carried out by well diffusion method. Two microbial cultures *Candida Albicans* (fungi) and *E - coli* (bacteria) were used. 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. For the antifungal activity, the plates of the sabouraud dextrose agar media were prepared. Each plate was inoculated with an aliquot (0.1 ml) of the fungal suspension which was spread evenly on the solid media. After 15 min, the wells with 6 mm diameter were made by using sterile cork borer and filled with 0.5g of gel formulations. All the plates were incubated at 27 °C for 5 - 7 d and then the diameter of the zone of inhibition was recorded. Triplicates were carried out for each extract against each of the test organism

4. Result and Discussion

4.1 Phytochemical screening

The preliminary quantitative phytochemical investigations of plant extracts are as shown in Table 1 Thus, the three extracts contain varied types of phytoconstituents which might be responsible for their antimicrobial activity.

4.2 Formulation of herbal gel

Seven formulations of herbal gels were formulated by varying the herbal ingredients in each of the formulation as shown in Table 2

4.3 Evaluation of gel

All the prepared gel formulations were evaluated for parameters such as physical appearance, pH, homogeneity, spread ability and viscosity. The observation reveals that the gels were having smooth Texture and were elegant in appearance. The pH of all prepared gels was found to be in range of 6.5 - 7.0. All the gels showed good spread ability. Also from the above data it was observed that increase the concentration of plant extract increases the spread ability. All the prepared gels showed good homogeneity with absence of lumps. The developed preparations were much clear and transparent. The viscosity of all the developed gels was found to be excellent and within the range. The results are shown in Table 3.

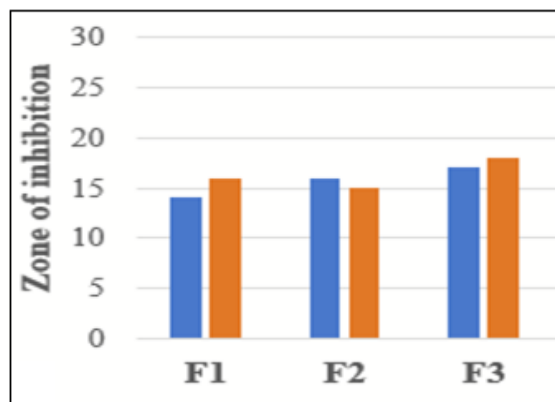


Figure 3: Antimicrobial activity of gel formulations

Table 1: Phytochemical Investigation of extracts

Sr. no	Phytochemical constituents	Emblica officinalis Linn	Azadirachtaindica	Glycyrrhizaglabra Linn
1.	Carbohydrates	-	-	-
2.	Proteins	+	-	-
3.	Amino acids	+	-	-
4.	Glycosides	-	-	+
5.	Flavonoids	-	+	+
6.	Alkaloids	-	+	+
7.	Tannins	-	+	+
8.	Saponins	+	+	+
9.	Phenolic compounds	+	+	+
10.	Steroids	+	+	+

+ Present – absent

Table 2: Formulation of herbal gels

Sr. no	Ingredients	F1	F2	F3
1.	Emblica officinalis Linn	4	-	4
2.	Azadirachtaindica	-	3	3
3.	Glycyrrhizaglabra Linn	-	3	3
4.	Carbopol 934 (g)	20	20	20
5.	Methyl paraben (g)	0.2	0.2	0.2
6.	Propyl paraben (g)	0.1	0.1	0.1
7.	Propylene glycol (ml)	2	2	2
8.	Water (ml) upto	30	30	30

Table 3: Various parameters of prepared gel formulations

Formulation	Physical appearance			pH	Homogeniety	Spreadability (g. cm/sec)	Viscosity (cps)
	Colour	Texture	Clarity				
F1	Green	Smooth	Clear	6.20±0.04	Homogenous	6.9±2.31	128900 1.96
F2	Green	Smooth	Clear	6.84 ±0.08	Homogenous	6.35±1.96	1350002.00
F3	Greenish brown	Smooth	Clear	6.77± 0.03	Homogenous	8.17±2.38	1955001.23

Data represented S. D (n=3)

4.4 Antimicrobial activity

The antimicrobial activity was studied using the well diffusion method. Out of all the formulations, F3 gel containing the all the three ethanoic extracts showed the highest zone of inhibition and it was comparable with the marketed Hiora gel formulation, both against *C. albicans* and *E. coli*. The result is shown in Figure 3.

5. Conclusions

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 Amla, neem and Liquorice has good characteristics, viscosity and also possesses a good antimicrobial activity which is necessary in the management of mouth ulcers.

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