



Formulation and Evaluation of pharmaceutical aqueous gel of Rice bran oil for mouth ulcer treatment.

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ABSTRACT:

The current study set out to create and assess an herbal gel using Rice bran oil for the treatment of mouth ulcers. Using varying concentrations of powdered citrus aurantium dulcis and carbopol 934, propylene glycol was used as the gel base to create an herbal gel. Formulations were assessed in relation to different physical properties. The created gel exhibited PH values of 7 to 7.5, was transparent, and was homogenous. Additionally, this formulation displayed appropriate spread ability and extrudability capabilities together with acceptable rheological behavior. Gel had outstanding antimicrobial activity against Escherichia coli and Staphylococcus aureus, according to tests. Based on in-vitro research, it was observed through experimental evidence that powdered flavonoids exhibit substantial antimicrobial and antibacterial activity. This herbal aqueous gel recipe proved reliable, secure, and useful for the treatment of mouth ulcers.

INTRODUCTION:

Mouth ulcers are defined by inflammation and pain in the mucous membrane of the mouth cavity. They are white or yellowish depressions with red margins¹. Mouth ulcers, also known as aphthous stomatitis, are a type of ulcerative disease that affects the oral mucosa and is characterized by repeating ulcers in the throat and oral cavity². Many factors, including biting the inside layer of the cheek, food sensitivities, vigorous tooth cleaning, hormone fluctuations, vitamin shortages, bacterial infections, and illnesses, can result in mouth ulcer³. Treatment of oral ulcers may involve soothing/ antiseptic mouthwashes, such as chlorhexidine mouthwash or povidone iodine mouthwash or usage of antibiotic or anesthetic gel formulations⁴

Gel is a semi-solid formulation consisting of a liquid phase thickened with thickener or gelling component. Topical gel preparations are used for application on skin to achieve optimal cutaneous and percutaneous drug delivery of medicament or local action to certain mucosal surfaces⁵.

Rice bran oil is a kind of vegetable oil that is further pressed or extracted from rice bran produced during rice processing⁶. Rice (*Oryza sativa* L.) is a cereal crop that is grown all over the world. About one-fourth of the world's population uses rice as a dietary source, making it a staple food⁷. Many advantages have been found for RBO, such as cholesterol-lowering⁸, anti-inflammatory⁹, and antioxidant activities¹⁰.

MATERIAL AND METHODS:**Materials:**

Rice bran oil purchased from the local market.

Extraction of rice bran oil:

Rice bran oil is unique among edible oil due to be rich source of commercially and nutritionally important phytochemical such as oryzanol, lecithin, tocopherols and tocotrienols ¹¹.

The extracting process starts with raw material preparation. Rice bran is first screened and then heated by steam at temperature higher than 100 °C to stop lipase hydrolysis in rice bran prior to extraction. RBO is extracted from bran using solvent extraction (hexane) and pressing (screw press or hydraulic press). After extraction, the refining of rice bran oil is required. This is because of the presence of very high amounts of by-products like gums, waxes and free fatty acids in crude RBO. The color of curd RBO is dark greenish brown to light yellow, depending on the condition of bran, extraction method and composition of the bran.

Formulation of gel:

Required amount of Rice Bran Oil dissolve in isopropyl alcohol. The given quantity of propylene glycol with continuous stirring to above solution. In separate beaker take required quantity of carbopol 934 and BHT. Dissolve it in some quantity of water with continuous stirring. Mix solution I into solution II and make up volume with continuous stirring. Lastly add a few drops of flavoring agent such as peppermint Oil.

The composition of gel prepared from the Oil coded as F1, F2 and F3 in tabulated in table 1

Table No. 1: Formulation of Gel

Ingredients	F1	F2	F3
Rice Bran Oil	0.5 gm	0.5 gm	1 gm
Carbopol 934	4 gm	4 gm	4 gm
Isopropyl Alcohol	4 gm	5 gm	5 gm
Propylene Glycol	4 gm	5 gm	5 gm
Butylated Hydroxyl Toluene (BHT)	0.01 gm	0.1 gm	0.1 gm
Purified H ₂ O q.s to produce	100 gm	100 gm	100 gm

Evaluation of microparticles loaded gel

Visual inspection:

The prepared gel was observed for color, odour, and appearance.

Ph:

The pH meter was used to check the pH. About 0.5 gm of the gel was weighed and dissolved in 50.0 ml of distilled water and its pH was measured. The pH of gel formulation was reported in table no 2.

Viscosity:

The viscosity of gel was studied using Brookefield Viscometer. The sample (50 g) was placed in a beaker and was allowed to equilibrate for 5 min before measuring the digital reading using spindle No. 63 at 50 rpm. At this speed, the corresponding reading on the viscometer was noted.

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 a certain load. Lesser the time taken to separate the slide the better spreadability¹². The Spreadability of gel was determined by using the above formula and was reported in table no 2.

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.

The spreadability test showed that F4 batch showed good spreadability compared to other batches as mentioned in the

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. The homogeneity of gel formulation was reported in table no 2

Stability study:

Stability studies were done with open and closed containers. Here, by subjecting the product to room temperature for 1 month¹³.

Extrudability:

The gel formulations were filled in standard capped collapsible aluminium tubes and sealed to the end. The extrudability was determined by pressing the thumb.

Clarity:

The clarity of all the three batches was determined by visual inspection¹⁴.

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.

Antimicrobial activity:

Agar plate media was prepared by adding 28 g of a nutrient agar powder in 1 liter of distilled water heat the mixture and dissolve all components. The dissolved mixture is put in autoclave at 121° C for 15 min, allow cooling but not solidifying. Then inoculated the given microorganism into nutrient agar medium and poured into plates allow until solidified. Then by using the agar well diffusion method, holes about 9 mm diameter in the same medium with a borer. The antimicrobial solution of orange peel extract directly placed in the holes. The plates are incubated and reported in table no 3 and shown in figure 3.

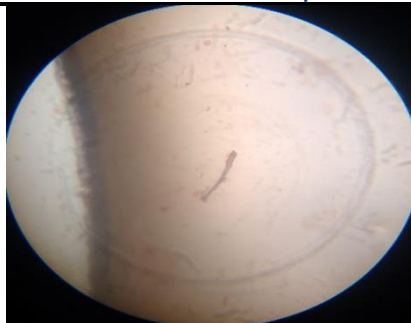


Fig 1: selected E. coli

RESULT AND DISCUSSION:

Formulation was assessed in terms of certain physical parameters. The created gel had a pH range of 7 to 7.5, was transparent, and was homogenous. Additionally, this formulation displayed appropriate spreadability and extrudability qualities along with acceptable rheological behavior.



Fig 2: Prepared gel

Table no.2 Evaluation of microparticles loaded gel

Formulation	Physical appearance	pH	Spreadability	Homogeneity	Extrudability
F1	Whiteish crem	6.7±0.9	5.47 ± 0.01	Good	Good
F2	Whiteish cream	7±0.9	5.66 ± 0.05	Good	Good
F3	Whiteish cream	6.9±0.5	6.41 ± 0.01	Good	Good

Table no.3 Antimicrobial activity of F3

Concentration of gel	Diameter of the inhibition Zone(mm) (zone of clearance) by Rice Bran Oil gel
2 ml	-
4 ml	6 mm
6 ml	8 mm
8 ml	18 mm



(A)

(B)

Fig 3: (A) gel poured with different concentration.

(B) Antimicrobial activity of rice bran oil gel

CONCLUSION:

The formulation of the herbal gel was shown to have significant, therapeutically effective, and acceptable antimicrobial activity. The created herbal aqueous gel formulation was appropriate for treating oral ulcers and was stable, safe, and efficacious.

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