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Formulation and Evaluation of the Polyherbal Gel Prepared Using Carbopol 934 for Treating Skin Diseases in Comparison with Ointment Using Emulsifying Ointment.

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Short Communication

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ABSTRACT

Present study deals with Topical Drug Delivery system composed of polyherbals including Neem, Tulsi, Aloe and Fenugreek which are having Antifungal and Antibacterial activity in the form of gel, were formulated using gelling agent as Carbopol 934 and was compared with ointment prepared by taking same herbal drugs using emulsifying ointment base B. P. The gels and ointments were evaluated for various physicochemical parameters like pH, viscosity, spreadability, skin irritation test and microbial evaluations. Among the various formulations prepared for each of the gel and ointment, increasing concentrations of each of the herbal extracts were used from 1 to 10% w/w and thereof these compositions having concentrations 2 to 5% w/w give best results as per the preliminary studies of appearance, viscosity, spreadability and uniformity. Microbial evaluation of the gel showed that greater diffusion and inhibition was observed for gel formulation composed of 5% herbal extract.

INTRODUCTION

Effectiveness of the topical application mainly depends on its rate and extent of drug release from the base. Fungal infections are often topical than systemic. Gels are also upcoming recently due to ease of application and better percutaneous absorption. Present gel formulation is herbal formulation that includes herbal extracts of neem^[1], aloe, tulsi and fenugreek which have cure for dermatitis, allergies, eczema, abscesses.

Objective

To formulate a gel with precise spreadability, smoothening and effective release of medicament. The gel is also targeted towards the synergistic effect of neem and tulsi which have antibacterial and antifungal activities. The gel is also expected to give emollient activity due to presence of aloe. The gel was compared with ointment made using emulsifying ointment base B.P. which had same proportions of herbal drug extracts.

EXPERIMENTAL METHODS

Extract preparation

Herbal materials were grinded and were subjected to methanolic extraction using a soxhlet extractor. Concentrated extracts were then used for formulation of the gel.

Extracts were added with glycerine in proportion of 50:50, 70:30, and 90:10 parts by volume. Sodium lauryl sulphate was used as surfactant in concentrations of 1, 2.5, 5% w/w of extracts. Carbopol 934 was used at concentrations of 0.1, 0.2, 0.3, 0.4, 0.5% w/w of extracts. Gels were added increasing order of each extract ranging from 1% to 10% w/w. Triethanolamine was used as a neutralizer to set the pH of gel at 7.4. Benzoic acid was used as preservative. Thus for ointment formulations similar process was carried out by mixing parts of extracts with emulsifying ointment base B.P.

Preparation of Gel

Carbopol 934 was dissolved in a mixture of glycerin and sodium lauryl sulphate at 80-85 °C on a water bath with constant stirring. The mixture was cooled to 40 °C. Extract was gradually added to the above mixture with stirring at 2000 rpm (Remi-Mixture) to obtain mucilaginous consistency. The stirring speed was reduced as the consistency increased. During the process of gel formulation excess air bubble entrapment was observed. An attempt to reduce air bubble entrapment by cooling the gel to 4-10 °C with stirring successively resulted in a transparent gel without air bubbles.

Table No 1: Formulation of gels

Content	Gel 1	Gel 2	Gel 3
Carbopol 934	0.3 %	0.3 %	0.3 %
Triethanolamine	q.s.	q.s.	q.s.
Benzoic acid	0.2 %	0.2 %	0.2 %
Sodium lauryl sulphate	2.5 %	2.5 %	2.5 %
Glycerin	1.3 %	1.3 %	1.3 %
Water(to produce 100 g)	q.s	q.s	q.s
Each Herbal extract	3 % v/v	4% v/v	5% v/v

Evaluation of gel

The gels were evaluated for pH, viscosity, spreadability, skin irritation test, microbial evaluation and stability.

pH determination

pH of the gel was determined using Equip-tronic digital pH meter.

Viscosity

Viscosity was measured by Brookfield Viscometer [2] which measures the shearing stress on a spindle rotating at a definite, constant speed while immersed in the sample.

Spread-ability

Spreadability of an ointment was measured by apparatus described by Multimer et al [3]. An excess of gel sample was placed between the two glass slides and a 1000g weight was placed in slides for 5 minutes to compress a sample to uniform thickness. Weight (80 gm) was added to the pan. The time required to separate the two slides was taken as a measure of spreadability.

It was calculated using the formula

$$S = m. l / t.$$

Where S is spreadability, m is weight tied to upper slide, l is the length of glass slide and t is time taken.

Skin irritation test

Test was performed on rabbit by applying 1g of formulation on 9cm² area. Gel 1g taken on 9 cm² cotton wool and was applied on the back of the rabbit. Then aqueous solution of 1 ml containing 0.8% formalin (irritant) soaked in 9 cm² cotton wool firmed with adhesive plaster. The animal was observed for 7 days for any sign of edema and erythma.

Microbial evaluation

The microbial evaluation was carried out using in Cup and Plate method for all the formulations of gels and ointments. The bacterial strains used in the study were both gram positive and gram negative bacteria such as *Escherichia coli* (strain no. NICM 2256 NCTC 9002), and gram positive organism are *Staphylococcus aureus* (strain no. NCIM 2079 ATCC no. 6538). Antifungal activity was performed using fungal strains such as *Candida albicans* and *Aspergillus niger*. The plates for antibacterial test were incubated at 37 °C for 24 hours while plates for antifungal tests were incubated at 37 °C for 48 hours and their zones of inhibition were measured.

Stability studies

Formulated gel preparations were kept at different temperature conditions such as 27°C (room temperature), 8 ± 1°C (refrigerator temperature) and 45 ± 2°C, at 75 ± 5% relative humidity for the span of one month. The following parameters such as pH, viscosity and microbial evaluation were studied.

RESULTS AND DISCUSSIONS

The viscosity of gels was increased with the increase in Carbopol content which may be due to the increase in formation of three dimensional cross linking structure of gel, as expected. All formulations were found to be non irritant except gels with 5% SLS.

Sodium lauryl sulphate when used in 1, 2.5% had better effects, of which 2.5% SLS had excellent results. The pH of the gels were found to be suitable for skin application. Spreadability of gel formulations decreased with increase in polymer concentration. Stability study shows satisfactory results within 14 days period and showed change in pH within next 14 days.

Table No 2: Evaluation of gels

Formulation	Viscosity (centipoises)	pH	Spreadability (gm.cm/ sec)
Gel1 (F1)	7500	7.1	67
Gel 2 (F2)	7800	7.3	54
Gel 3 (F3)	7900	7.3	46

Table 3 shows formulation F3 with greater inhibition against selected microbial strains. Zone of inhibition for ointments was found less as compared to gels.

Table No 3: Antibacterial and Antifungal activity

Formulations	<i>Escherichia coli</i>	<i>Staphylococcus aureus</i>	<i>Aspergillus niger</i>	<i>Candida albicans</i>
	Zone of inhibition in mm			
Gel 1 (F1)	7	5	6	4
Gel 2 (F2)	9	6	7	7
Gel 3 (F3)	10	8	9	8
Ointment 1	4	3	4	2
Ointment 2	5	3	4	4
Ointment 3	5	4	7	6

CONCLUSION

The most satisfactory formulation was F3. From results it is observed that gels are free of irritation and have better antimicrobial activity than ointments. The zone of inhibition shows its release is better in gel than ointment. Thus polyherbal gel made from carbopol 934 can be used for treating skin diseases.

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