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FORMULATION AND EVALUATION OF TOPICAL GEL CONTAINING *MIMOSA PUDICA* AND *PROSOPIS CINERARIA* EXTRACTS

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Abstract: *Mimosa pudica* L. (*chui-mui*) is a creeping annual or perennial herb of Fabaceae - Mimosoideae family. *Prosopis cineraria* L. (Druce) (*Khejri*), is a small tree of Fabaceae family. Ethanolic extracts of *M. pudica* and *P. cineraria* possess antileprotic activity against *Mycobacterium leprae*. An herbal topical gel containing *M. pudica* and *P. cineraria* extracts was developed that can be used in the treatment of leprosy. Four gel formulations (F1-F4) were prepared using Carbopol 974P, Carboxy Methyl Cellulose (CMC) and Hydroxy Propyl Methyl Cellulose (HPMC) as the gelling agents. Evaluation of all the prepared gels was performed taking a marketed Dapsone 5% w/w gel as the standard.

Keywords: *Mimosa pudica*, *Prosopis cineraria*, Leprosy, Carbopol, CMC, HMPC, Gel

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INTRODUCTION

More than 25% of the pharmaceutical products used around the world contain plant based ingredients. Yet only a small percentage of the plants have been evaluated for their potential medicinal use [1].

Mimosa pudica L. commonly called as touch me not, humble plant or *chui-mui*, is a creeping annual or perennial herb of Fabaceae - Mimosoideae family [2]. It is found in tropical and sub-tropical parts of India. Leaves of *M. pudica* show rapid movement when they are stimulated by touch or heating. They also show very slow, periodical movement called as nyctinastic movement which is controlled by a biological clock [3]. The entire plant of *M. pudica* is considered to possess medicinal properties and used traditionally in the treatment of various disorders including bilious fever, leprosy, leucoderma, dysentery, inflammation, vaginal and uterine complaints, asthma and whooping cough [4].

Prosopis cineraria L. (Druce) or *Khejri*, is a small tree of Fabaceae family. It grows in dry and arid regions of India, mainly in Rajasthan, Haryana, Punjab, Gujarat, and Uttar Pradesh. It is the State tree of Rajasthan. Leaves and pods of this plant are extensively used as fodder for cattle, camels and goats. Pods of the plant called as "Sangri" have nutritious value and is considered as dry fruit of desert. It is one of the main ingredients of classic Rajasthani dish "Panchkuta" [5], [6]. *P. cineraria* is traditionally used in the treatment of asthma, bronchitis, dysentery, leucoderma, leprosy, muscle tremors, snakebite, rheumatism, inflammations, piles and other skin problems [7], [8].

Ethanolic extracts of *M. pudica* and *P. cineraria* were found to possess *in-vitro* antileprotic activity against *Mycobacterium leprae* [9]. The present study was aimed to develop an herbal topical gel containing *Mimosa pudica* and *Prosopis cineraria* extracts that can be used in the treatment of leprosy.

MATERIALS AND METHODS

Plant collection, authentication and preparation of extracts

Whole plant of *Mimosa pudica* L. was collected from Gungun Nursery, Chopasani Housing Board, Jodhpur (Raj.). Bark of the *Prosopis cineraria* L. (Druce) was collected from Pal Village, Jodhpur (Raj.). Their taxonomical identification and authentication were done by Dr. Vinod Maina, Joint Director, Botanical Survey of India, Arid Zone Regional Center, Jodhpur (Raj.). Roots of *M. pudica* and bark of *P. cineraria* were washed with distilled water and air dried at room temperature under shade. The dried roots of *M. pudica* and dried bark of *P. cineraria* were extracted individually with ethanol using continuous hot percolation (soxhelation)

method. The obtained extracts of *M. pudica* and *P. cineraria* were subjected to phytochemical screening.

Chemicals

Analytical grade Carbopol 934, Carbopol 974P, carboxy methyl cellulose (CMC), hydroxy propyl methyl cellulose (HPMC), oleic acid, glycerin, triethanolamine, methyl paraben and propyl paraben of Loba Chemie Pvt. Ltd., Mumbai were used in the development of the topical gels.

Preparation of topical gels [10], [11]

The topical gels were developed by using ethanolic extracts of *Mimosa pudica* and *Prosopis cineraria* in equal quantities (1:1 ratio). Carbopol 934, Carbopol 974P, carboxy methyl cellulose and hydroxy propyl methyl cellulose were used as the gelling agents. The gelling agent was dispersed with 50 ml of purified water in a beaker with continuous stirring at 500 rpm. Methyl paraben and propyl paraben were dissolved in 5 ml of purified water by heating on water bath and then mixed with the dispersed gel. Extracts, glycerine and oleic acid were added slowly to the above mixture with continuous stirring and remaining quantity of purified water was added to it. Triethanolamine was added drop by drop in sufficient quantity to it with gentle and uniform stirring to obtain the gel of required consistency [12], [13], [14]. Composition of the topical gel formulations is given in Table 1.

Table 1: Composition of topical gel formulations (F1-F4)

S. No.	Ingredients	Quantity taken (gm or ml)			
		(F1)	(F2)	(F3)	(F4)
1.	Ethanolic extract of *Prosopis cineraria*	2.5	2.5	2.5	2.5
2.	Ethanolic extract of *Mimosa pudica*	2.5	2.5	2.5	2.5
3.	Carbopol 934	1.0	--	--	--
4.	Carbopol 974P	--	1.4	--	--
5.	Carboxy methyl cellulose	--	--	1.8	--
6.	Hydroxy propyl methyl cellulose	--	--	--	2.0
7.	Glycerine	3.5	3.5	3.5	3.5
8.	Oleic acid	2.5	2.5	2.5	2.5

9.	Methyl paraben	0.15	0.15	0.15	0.15
10.	Propyl paraben	0.30	0.30	0.30	0.30
11.	Triethanolamine	q.s.	q.s.	q.s.	q.s.
12.	Purified water	q.s.	q.s.	q.s.	q.s.
Total quantity		100 gm	100 gm	100 gm	100 gm

Evaluation of the topical gel formulations

Evaluation tests of all the prepared gels (F1-F4) were performed taking a marketed Dapsone 5% w/w gel as the standard [15], [16]. Physical parameters, pH, viscosity, consistency and spreadibility of all the gel formulations were tested [17], [18].

Physical evaluation: All the gel formulations were tested for physical parameters viz. colour, odour and homogeneity.

Measurement of pH: The pH values of gel formulations were determined using digital pH meter. The measurement of pH of each formulation was done in triplicate and the average pH value was calculated.

Viscosity: Viscosity of the gel should be such that the preparation can be easily removed from the container and can be easily applied to the skin. The measurement of viscosity of the prepared topical gels was done with Brookfield viscometer (model LV-DV-II). Viscocity was determined using spindle no. S-95 at 30 rpm.

Consistency: Consistency of the gels was measured using the penetrometer instrument which comprises a penetrating object (needle), reading scale, stop watch and level reader. The gel was uniformly filled is a container without entrapping any air bubble into it. The filled containers were stored at room temperature for 24 hrs. The gel container was then placed on the base of the penetrometer with mouth of the container open. With the help of the level reader it was ensured that the surface of gel was perpendicular to the penetrating object (needle). Tip of the needle was set just touching the surface of the sample. The needle was then released and held free for 5 seconds. The depth of penetration of needle in the sample was measured. The test was carried out in triplicate for each gel and the average of three readings was recorded as consistency or hardness of the gel.

Spreadibility: Spreadibility was determined by an apparatus which consists of a wooden block provided by a pulley at one end [19], [20]. A ground glass slide was fixed on this block and another glass side of the same dimensions was placed over this slide. About 2 gm gel was applied between the two slides. A 1 kg weight was placed on the top of the upper slide for 5 min. to provide a uniform film of the gel between them. Excess of the sample was scrapped off from the edges. The upper slide was then pulled with 100 gms. of weight placed in a pan tied to the upper slide. The time (in sec.) required by the top slide to cover a distance of 10 cm was noted down. Spreadibility was calculated by the following formula:

$S = M \times L / T$

Where,

S : Spreadibility (gm.cm/sec);

M : Weight tied to the upper slide (gm);

L : The length covered by the upper slide (cm); and

T : The time taken for upper slide to travel the specified length (sec)

Stability study

The gel formulation F1 was subjected to accelerated stability study [21], [22]. Gel was filled in the collapsible tubes and stored at 40°C ± 2°C/ 75% RH ± 5% RH for 3 months and studied for physical parameters, pH, viscosity, spreadibility and consistency.

RESULT AND DISCUSSION

For the evaluation of the prepared gel formulations (F1-F4), various tests viz. physical evaluation, pH, viscosity, spreadibility and consistency were conducted. Dapsone 5% w/w gel was taken as the standard in all of the tests. Results of the evaluation tests and stability study are shown in Table 2 and Table 3 respectively.

The developed gel formulations (F1-F4) were brownish yellow in color, translucent in appearance and showed good homogeneity with absence of lumps. The pH of the gel formulations was near to the pH of the skin, hence they can be applied on the skin without causing any discomfort. The test values of viscosity, consistency and spreadibility indicate that the gels can be easily removed from the container and applied on the skin. The gel formulation F1 appeared more clear and transparent as compared to F2, F3 and F4 formulations. Test results of the formulation F1 were found closer to the test results of the standard Dapsone 5% w/w gel. Gel formulation F1 was found stable at 40°C ± 2°C/ 75% RH ± 5% RH after 3 months.

Table 2: Evaluation of the gel formulations

Test Parameters	F1	F2	F3	F4	Dapsone 5% w/w gel
Colour	Brownish yellow	Brownish yellow	Brownish yellow	Brownish yellow	Yellowish
Odour	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
Homogeneity	Homogenous	Homogenous	Homogenous	Homogenous	Homogenous
pH*	6.8 ± 0.06	6.2 ± 0.0	7.3 ± 0.1	7.4 ± 0.17	6.9 ± 0.06
Viscosity (cps)*	4655 ± 0.58	5088 ± 1.0	5374 ± 1.15	5410 ± 1.53	4650 ± 1.15
Consistency/ Penetration depth (cm)*	4.2 ± 0.35	3.3 ± 0.42	3.1 ± 0.89	2.7 ± 0.23	4.4 ± 0.61
Spreadibility (gm.cm/sec)*	34.89 ± 0.71	30.36 ± 1.64	22.23 ± 0.49	19.49 ± 0.57	32.97 ± 0.62

*Mean of triplicate determinations; All values are Mean ± Standard Deviation

Table 3: Stability testing of F1 gel at 40°C ± 2°C/ 75% RH ± 5% RH

Test Parameters	Initial	At 3rd Month
Colour	Brownish yellow	Brownish yellow
Odour	Characteristic	Characteristic
Homogeneity	Homogenous	Homogenous
pH*	6.8 ± 0.06	6.8 ± 0.17
Viscosity (cps)*	4655 ± 0.58	4657 ± 1.53
Consistency/ Penetration depth (cm)*	4.2 ± 0.35	4.1 ± 0.15
Spreadibility (gm.cm/sec)*	34.89 ± 0.71	34.12 ± 1.37

*Mean of triplicate determinations; All values are Mean ± Standard Deviation

CONCLUSION

Due to increasing drug resistance and side effects of the synthetic drugs, herbal formulations have growing demand in the market. Four gel formulations comprising *Mimosa pudica* and *Prosopis cineraria* extracts were developed, which can be used topically in the treatment of leprosy. Out of the four formulations the gel F1 showed better results as compared to the gels F2, F3 and F4. Test results of all the developed topical gel formulations were found comparable with the test result of the standard gel formulation i.e. Dapsone 5% w/w gel.

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