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## Evaluation of a Novel Herbal Formulation in the Treatment of Eczema with *Psoralea Corylifolia*

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**Background:** We studied the efficacy of an herbal semisolid formulation, prepared from hexane extract of seeds of *Psoralea Corylifolia*, which has anti-inflammatory and antimicrobial properties, in the treatment of eczema.

**Methods:** Extraction of seeds of *Psoralea Corylifolia* was done in Soxhlet apparatus using hexane as the solvent. Furthermore, Oil in Water (O/W) cream was formulated with a stearic acid base and was evaluated for various parameters like pH, viscosity, rheology, etc. This cream was then utilized for the treatment of eczema.

**Results:** The formulation was effective in treating eczema in this open clinical trial. Thirty patients suffering from eczema were treated for 1 month, out of whom twenty five completed the study. The patients recovered from their symptoms using the cream twice daily and were assessed every week for 1 month. It was observed that the symptoms score reduced at the end of 2 weeks onwards. At the end of the study, the symptom score for eczema reduced from  $6.367 \pm 1.098$  to  $0.333 \pm 0.279$  for length of the lesion, from  $1.333 \pm 0.994$  to  $0.165 \pm 0.087$  for exudation rate, and from  $2.567 \pm 0.504$  to  $0.165 \pm 0.132$  for the rate of itching.

**Conclusion:** The plant *Psoralea Corylifolia* has been used in treatment of various skin disorders, and the present research concluded that this plant could be effectively used for the treatment of eczema.

**Keywords:** *psoralea corylifolia*, semisolid formulation, eczema, herbal medicine

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### INTRODUCTION

Herbal medicine, as a major part of traditional medicine, has been used in medical practice since antiquity and is a common element of ayurvedic, homeopathic, and naturopathic medicine. World health organization (WHO) notes that 74% of the plant derived medicines are used in modern medicine, in a way that their modern application directly correlates with their traditional use as herbal medicines by native cultures<sup>1</sup>. WHO estimates that 65–80% of the world's population uses traditional medicines as their primary form of health care and about 85% of traditional medicines involve the use

of herbal preparations. The global market of herbal drugs at present is approximately \$ 600 billion<sup>2</sup>.

Dermatology is an essential part of general medicine, since the skin is not by any means foreign to the body which it covers. Diseases of the skin are a common occurrence. They account for a great deal of misery, suffering, incapacity and economic loss. The skin is a protective covering of the body. On average, it covers a surface area of 2 square meters. In its intact state, the skin is a strong barrier, impenetrable to life threatening microorganisms and resistant to chemicals and harmful UV rays<sup>3,4</sup>. Drugs are applied topically to the skin mainly for their local action. Although the

topical route can also be used for systemic drug delivery, percutaneous or transdermal absorption of drug is generally poor and erratic. Topical drug absorption takes place through sweat glands, hair follicles, sebaceous gland and the stratum corneum.

According to ayurveda, there are 44 species of *Psoralea*. Four of these species are exotic and *Psoralea corylifolia*, which belongs to family Leguminosae, is widely used in the treatment of skin diseases. The Leguminosae family has a number of species such as *Cassia alata* Linn., *Pterocarpus santalinus*, *Pithecellobium dulce* Benth,<sup>5</sup> possessing antimicrobial activity which is already reported. Triterpenoid is a major constituent of all the above-mentioned species, which has a good anti-inflammatory activity. Literature survey reveals that the selected plant contains furanocoumarins which has been isolated and characterized<sup>6</sup>. Essential oil of its fruits shows irritant effects on the skin and mucous membrane. It has distinct stimulatory action on voluntary muscles in high concentrations<sup>7</sup>. Bakuchiol, one of the major constituents, has been shown to have a prominent cytotoxic activity. The anthelmintic activity of *Psoralea corylifolia* seeds is clinically proved on flatworms and roundworms<sup>8</sup>.

Eczema is a very common skin condition and an important part of atopic condition. It affects all races and ages. It usually begins early in life, even before other atopic conditions such as asthma or hay fever. The key elements in identifying eczema is characteristic scaly rash with severe itching<sup>9</sup>.

## PATIENTS AND METHODS

### Collection and Authentication of plant

The plant *Psoralea corylifolia* Linn. was collected from the local region of Nagpur district. The plant

specimen was dried and its herbarium sheet was prepared and authenticated from the Department of Botany, Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur.

The seeds from the authenticated wild plants were collected and air dried in shade, under normal environmental conditions and then subjected to size reduction to get coarse powder. Such powdered material of *Psoralea* seeds were charged into the soxhlet apparatus, at a temperature of 50°C and extraction was carried out using n-hexane as the solvent. The herb extract ratio was found to be 250 mg for 500g of the herb used.

### Formulation of the cream

An oil in water (O/W) emulsion-based cream (semisolid formulation) was formulated. The emulsifier (stearic acid) and other oil soluble components (White bees wax, Stearyl alcohol, Cetyl alcohol, Mineral oil and Hexane extract of seeds of *Psoralea corylifolia*) were dissolved in the oil phase (Part A) and heated to 75°C. The preservatives and other water soluble components (Methyl paraban, Propyl paraban, Triethanolamine, Propylene glycol and water) were dissolved in the aqueous phase (Part B) and heated to 75°C. After heating, the aqueous phase was added in portions to the oil phase with continuous stirring until cooling of emulsifier took place<sup>10,11</sup>. The formula for the cream is given in Table 1.

### Evaluation of the cream

The cream was then evaluated for the following physical parameters:

#### (a) Formulation Properties

The formulation properties of the cream were

**Table 1.** Formula for cream

PART A (Oily Phase)		PART B (Aqueous Phase)	
Ingredients	% w/w	Ingredients	% w/w
Stearic acid	2.5%	Propylene glycol	5.0%
White bees wax	1.5%	Triethanolamine	2.0%
Stearyl alcohol	5.0%	Methyl paraban	0.01%
Cetyl alcohol	6.5%	Propyl paraban	0.04%
Mineral oil	5.0%	Water	Upto 100%
<i>Psoralea corylifolia</i> extract	5.0%		

studied by visual appearance and characteristics.

- a. State - Semisolid.
- b. Color - Orange
- c. Odor - Characteristic.
- d. Appearance – Homogenous

### (b) pH of the Cream

The pH meter was calibrated using standard buffer solution with a pH of 7.4 and 9.2. About 0.5g of the cream was weighed and dissolved in 50.0 ml of distilled water and its pH was measured <sup>12</sup>.

### (c) Viscosity

Viscosity of the formulation was determined by Brookfield Viscometer at 100 rpm, using spindle no 7.

### (d) Rheological behavioral of the cream

The rheological property was determined to know the flow behavior of formulation. The viscosity at different rpms was measured using Brookfield viscometer. The rheological behavior of the formulation was studied by taking 100g of the cream in the beaker. The rate of shear was increased gradually from minimum to maximum and corresponding dial reading was noted; then, the rate of shear was decreased gradually to the lowest value and the dial reading was recorded. The graph was plotted between percent torque and viscosity to determine type of flow <sup>13</sup>. The Pseudo plastic behavior of the cream is shown in Figure 1.

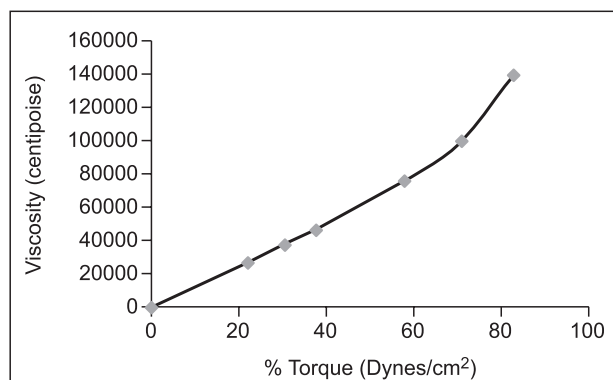


Figure 1. Pseudo plastic behavior of cream

### Franz Cell diffusion study

The phosphate buffer with a pH of 6.8 was used for the *in-vitro* drug release studies as a receptor medium. The formulated cream (5g) was accurately weighed and placed in the donor part of the Franz diffusion cell and a semi permeable cellulose membrane with a molecular cut off point of 1000. The cell body was filled with degassed phosphate buffer, pH=6.8. The receptor phase was stirred thoroughly by a constantly spinning bar magnet at 100rpm. Intervals of 20, 40, 60, 80, 100 and 150 min were chosen for sampling time, and samples were analyzed for drug content spectrophotometrically at 258 nm <sup>14</sup>. In spectroscopic assay, the amount of the absorbed drug is determined. In this case, the extract present in the formulation was absorbed at 258 nm, which showed the release pattern of cream. The release pattern of the formulated cream is illustrated in Figure 2.

### Patient Study

Cream prepared from the hexane extract of the seeds of *Psoralea corylifolia* was prescribed to 30 patients suffering from eczema, under the supervision of a chief medical officer at the Department of Shalya Tantra, Government Ayurvedic Hospital, Nagpur. This study was approved by Ethical Committee. The animal work was done in Sharad Pawar College of Pharmacy, Nagpur.

About 30 patients received the therapy. The cream topically used twice or three times a day for one month. Most of the patient responded to one course of treatment. No significant side effects were reported. Before giving the drug to

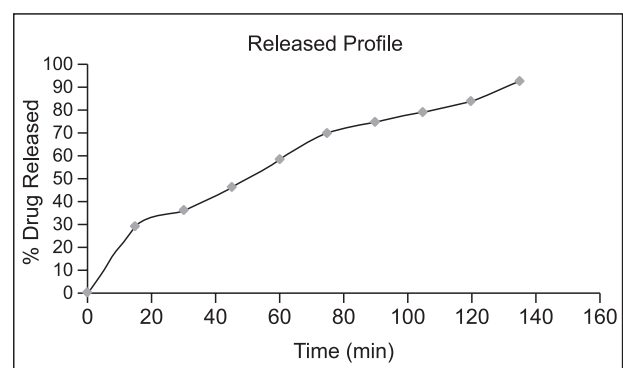


Figure 2. Cumulative percent release of drug

the patients, the detailed history of each patient was recorded in a case record form which was specially prepared for the purpose of the study and all the factors were documented on the first day examination as well as on the days of successive periodic visits. Consent form was sign by the patient before prescribing cream.

This formulation was compared with the Placebo preparation, in which the formulated cream contained all the ingredients except for the hexane extract of *Psoralea Corylifolia*.

The parameters considered for the evaluation were:

- Largest length of the lesion
- Rate of exudation
- Rate of itching

**Statistical analysis**

To assess the results of the study, both objective and subjective findings were recorded before, during and after completion of the treatment. The most leading clinical feature of the patients (measurable) was considered as the objective parameter for analysis. This parameter was the largest size of the lesion <sup>15</sup>.

Other parameters which could not be measured were considered as subjective parameters, such as exudates and pain or itching sensation. The reduction in signs and symptoms of eczema on the 28<sup>th</sup> day was found to be significant. For statistical analysis of the result, measurable parameters were selected and their mean and standard deviation was calculated. The results were prepared using the data obtained via ANOVA.

**RESULT**

Extraction of the seeds of *Psoralea Corylifolia* was done successfully using hexane as the solvent. Creams are non greasy, rinsable, non staining and are mostly preferred by patients. They cling to the surface of application unlike fluid systems, which run off the desired area and streak. Moreover, they also cause less dryness and burning. For these reasons, a O/W cream was selected as a dosage form. Also, the hexane extract of the seeds had solubility in part A, i.e. the oily phase, whereas the other ingredients were soluble in aqueous phase or part B.

**Table 2.** Evaluation Parameters of cream

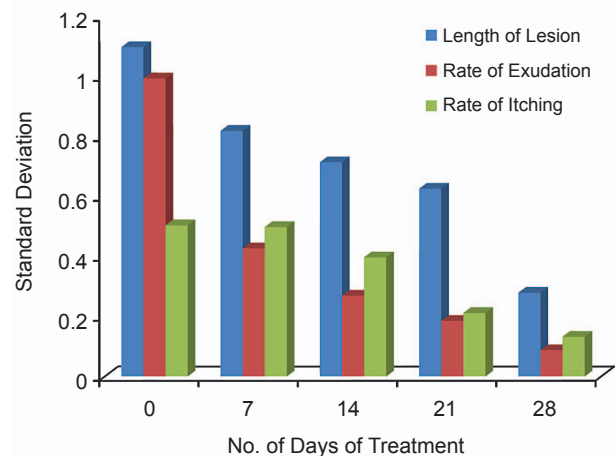
pH	Viscosity ( in cps)
5.8	27085
5.6	27088
5.9	27090

Evaluation of the cream was done for different parameters which were all within the normal limits. The pH of the cream was found to be in range of 5 – 6 which is good for skin pH. The viscosity of was cream was in the range of 27080 – 27090 cps which indicates that the cream is easily spreadable by small amounts of shear (Table 2). Rheological behavior of the cream was studied and the graph confirmed that the cream had pseudo plastic flow behavior. The drug release pattern was studied by Franz diffusion method to find out the percentage of the drug release of the cream which was found to be 94%

Finally, a clinical trial was conducted on 30 patients suffering from eczema in which all the parameters and signs of the disease were healed in a period of 4 weeks. There were 21(3%) male

**Table 3.** Changes in the parameters of the eczema in patients

Follow-up week	Group (n = 30)		
	Length of the lesion	Exudation rate	Rate of Itching
	Mean ± SD	Mean ± SD	Mean ± SD
0 week	6.367 ± 1.098	1.333 ± 0.994	2.567 ± 0.504
1 <sup>st</sup> week	4.533 ± 0.819	0.566 ± 0.427	1.533 ± 0.498
2 <sup>nd</sup> week	2.538 ± 0.714	0.300 ± 0.269	0.466 ± 0.397
3 <sup>rd</sup> week	1.322 ± 0.626	0.211 ± 0.185	0.234 ± 0.211
4 <sup>th</sup> week	0.333 ± 0.279	0.165 ± 0.087	0.165 ± 0.132



**Figure 3.** Effect of treatment of parameters on patients





**Figure 4.** Effect of *Psoralea corylifolia* cream with stearic acid base on patient

and 9(30%) female patients, 14(46.6%) patients were 17-40 years, 6(20%) were 41-60 years, 8(26.6%) were above 65 years and 2(6.6%) were 0-6years.

The placebo formulation was used for treating patients with eczema but the recovery was not good compared to the cream containing *Psoralea* extract.

The results of the statistical data showing recovery of patients from the symptoms of eczema are presented in Figure 3 and Table 3. Figure 4 shows the comparative effect of the cream on patients suffering from eczema before and after treatment.

## DISCUSSION

*Psoralea corylifolia* Linn. (Leguminoceae) is well known for its medicinal value in Indian traditional system of medicine and in ayurvedic preparations<sup>16,17</sup>. In the present work, it was decided to extract and formulate a dosage form and utilize it for treating Eczema.

There is growing demand for herbal cosmetics in the global market; therefore, we tried to make an herbal cream containing the extract of *Psoralea Corylifolia* in the concentration of 5%. As a matter of fact, we attempted to formulate creams containing *Psoralea* extract in different concentrations (from 1% to 5% and more) but we found out that only the cream containing 5% *psoralea* extract was stable and concentrations above 5%, i.e. 6% or more, were not stable and resulted in the breakdown of the emulsion. Therefore, 5% *psoralea* extract was found to be suitable for the formulation. Our study indicated that the developed herbal formulation containing the extract of *Psoralea Corylifolia* in the

concentration of 5% was comparatively better than those formulations with higher concentrations after evaluating the parameters of the cream<sup>18</sup>.

Literature survey reveals that the plant possesses a broad spectrum of biological activities<sup>16,19</sup>. Also, the plant is widely used in the treatment of skin diseases. This plant has been used for psoriasis and leucoderma. Therefore, we decided to try it in Eczema. We conducted a trial on 30 patients suffering from Eczema and found that all the parameters and signs of the disease were healed in a period of 28 days.

Various topical formulations like gels and creams containing *psoralea* are available in the market. These formulations are used for some skin disorders such as leucoderma and psoriasis but they are not used for eczema. The formulation of the cream containing n -hexane extract of *psoralea*, which we tried to prepare, has not been available before and our attempt gave successful results.

Based on our research, it could be concluded that the plant possesses a broad spectrum of biological activities. Also, the plant is widely used in the treatment of skin diseases. The patient study which was done in the present work for Eczema showed that the *Psoralea* seed oil could be effectively used in the treatment of eczema, in addition to psoriasis and other skin disorders.

It is suggested that various constituents of this extract become separated using different separation techniques to evaluate and study other activities of the plant. It is very likely that the pure form of these isolated constituents possess prominent anti inflammatory, analgesic and anti microbial activities, which justifies their use in the treatment of various skin disorders. This can lead to development of new potent compounds with significant activity. Furthermore, *In - vivo* studies of the formulation are recommended.

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