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Formulation and evaluation of cream of eczema with Psoralea Corylifolia.

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ABSTRCT :-

Atopic eczema is an itchy inflammatory skin disease with a chronic relapsing-remitting course; it has increased in prevalence in recent decades and now affects up to 25% of school-aged children in the developed world and up to 10% of adults. Recent advances in understanding the aetiology of eczema have focused interest on skin barrier dysfunction as a common precursor and pathological feature. In addition, genetically determined skin barrier dysfunction (associated with mutations in the gene encoding filaggrin) is known to predispose to multiple systemic atopic diseases. First- line treatments for atopic eczema focus on maintaining and repairing the skin barrier (emollients) and reducing inflammation (topical steroids); allergen and irritant avoidance are also important to achieve disease control. Second and third-line treatments include topical calcineurin inhibitors, ultraviolet light and systemic immunosuppressant therapies of which only ciclosporin is licenced for the treatment of atopic eczema in adults.

Keywords: *psoralea corylifolia, semisolid formulation, eczema*

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 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

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.

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.

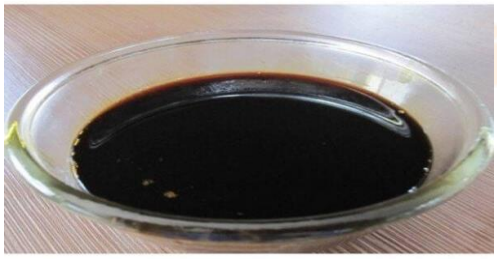
Eczema is a very common skin condition and an important part of atopic condition. It affects all races and ages. It usually begins early in life, even before other atopic conditions such as asthma or hay fever. The key elements in identifying eczema is characteristic scaly rash with severe itching.

According to ayurveda, there are 44 species of Psoralea. Four of these species are exotic and Psoralea corylifolia, which belongs to family Leguminoceae, is widely used in the treatment of skin diseases. The Leguminoceae family has a number of species such as Cassia alata Linn. Pterocarpus santalinus, Pithecellobium dulce Benth, 5 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 6. Essential oil of its fruits shows irritant effects on the skin and mucous membrane.

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 distillation apparatus, at a temperature of 500 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.

Plant Profile:-

Psoralea Corylifolia :-



Psoralea corylifolia, commonly known as babchi, is a popular herb, which has since long been used in traditional Ayurvedic and Chinese medicine for its magical effects to cure various skin diseases This plant is also pharmacologically studied for its chemoprotective, antioxidant, antimicrobial and antiinflammatory properties. This review attempts to highlight the available literature on *P. corylifolia* with respect to its ethnobotany, pharmacognostic characteristics, traditional uses, chemical constituents, and summary of its various pharmacologic activities and clinical effects.

Synoname :- Babchi

- **Biological Source :-** Psoralen and psoralen derivatives are found in plants (Psoralea corylifolia and Ammi majus) and other vegetation such as limes, figs, parsnips, and certain fungi.

- **Family:-** leguminosae

- **Chemical constituents :-** Phytochemical studies indicated that coumarins, flavonoids, and meroterpenes are the main components of P. corylifolia, and most of these components are present in the seeds

- **Properties :-** anti-oxidant, anti-inflammatory, antimicrobial and chemoprotective properties

EXCIPIENT PROFILE :-

1. Liquid Paraffin

- **Source:** Liquid paraffin is a purified mixture of liquid hydrocarbons derived from petroleum.
- **Function:** It is often used as an emollient and lubricant in skincare formulations.
- **Excipient Properties:** Liquid paraffin forms a protective layer on the skin, preventing water loss and providing a smooth texture.
- **Considerations:** Choose a high-quality liquid paraffin, and assess its compatibility with other ingredients.

2. White Beeswax :-

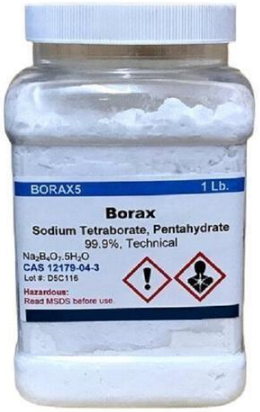
- **Sourse :-** white beeswax derived from a natural source, bee apiaries in North America, that is naturally bleached to a soft, pleasing white color.

- **Function :-** Beeswax is inert with high plasticity. It is insoluble in water and resistant to many acids, but soluble in most organic solvents.
- The melting point of beeswax ranges from 62 to 65°C.

- **Excipient Properties:-** White Beeswax can easily be used in a wide variety of natural bath and body products as well as candle making. Packaged in pastille form for easy handling and measuring, this pure beeswax has a reduced odor when compared to Yellow Beeswax due to a filtration process that removes the color.
- White beeswax is usually more refined and purified, resulting in a higher level of purity

- **Considerations:-** White beeswax is generally considered safe and gentle for use in hair care products.

3. **Borax:-**



- **Source:** Borax, also known as sodium borate, is a boron compound found in nature.

- **Function:** It is often used as an emulsifier, buffering agent, and preservative in formulations.

- **Excipient Properties:** Borax helps stabilize emulsions, control pH, and enhance the preservation of formulations.
- **Considerations:** Use borax within recommended concentrations and consider its pH impact on the overall formulation.

4.Methyl paraben:-

- **Source:** Methyl paraben is a synthetic compound derived from para-hydroxybenzoic acid.
- **Function:** Methyl paraben serves as a preservative. Its primary function is to inhibit the growth of bacteria, mold, and yeast, thus extending the shelf life of the product.
- **Excipient Properties:** Methyl paraben exhibits antimicrobial activity, preventing the spoilage of products by microorganisms.
- **Considerations:** Some individuals may be sensitive or allergic to methyl paraben. It's essential to consider potential reactions.

❖ ROLE OF INGREDIENTS

Sr. no.	Ingredients	Role
1.	Psoralea Corylifolia	Is a popular herb and has anti-oxidant, anti-inflammatory, antimicrobial and chemoprotective properties
2	Liquid Paraffin	Liquid paraffin is commonly used as an emollient and lubricant.
3.	White beeswax	White beeswax are used as thickeners, emulsifiers, and as stiffening agents in cosmetics.
4.	Borex	Borax is used as an emulsifier, buffering agent, and preservative.
5.	Meathyl paraben	Methyl paraben is a preservative commonly used to

		prevent the growth of microorganisms in cream.

PREFORMULATION STUDIES

Pre-formulation studies are crucial steps in the development of a pharmaceutical or cosmetic product. These studies involve the characterization of raw materials and formulation components, researchers gather information and conduct studies to understand the physical, chemical, and biopharmaceutical properties of the active pharmaceutical ingredient (API) and its compatibility with excipients before the actual formulation process begins. This stage helps in designing a stable and effective formulation for further development. For a polyherbal anti-acne cream, which likely involves a combination of herbal extracts, oils, and other ingredients, the pre-formulation studies may include the following:

1. Physicochemical Characterization

- Identification of Active Ingredients: Identify and characterize the active constituents present in each herbal extract to ensure consistency in the formulation.

- Chemical Compatibility: Assess the chemical compatibility of different herbal extracts and other ingredients to avoid potential interactions.

2. Solubility Studies:

- Determine the solubility of active ingredients in various solvents to choose the most suitable vehicle for the cream.

3. Stability Studies:

- Evaluate the stability of individual herbal extracts and the overall formulation under different storage conditions (temperature, humidity, light) to ensure the product's shelf life.

4. Particle Size Analysis:

- Analyze the particle size distribution of powdered herbal extracts to ensure uniform distribution in the cream.

5. Rheological Studies:

- Assess the rheological properties of the cream, such as viscosity and thixotropy, to determine its texture and spreadability.

6. Compatibility with Excipients:

- Check the compatibility of herbal extracts with various excipients, such as emulsifiers, thickeners, and preservatives, to ensure stability and efficacy.

7.Skin Permeation Studies:

- Evaluate the permeation of active ingredients through the skin to understand their bioavailability and optimize the formulation for better skin penetration.

8. Microbiological Analysis:

- Perform microbial testing to ensure the product's safety and establish appropriate preservation methods.

9. Sensory Evaluation:

- Conduct sensory evaluations to assess the cream's appearance, odor, and feel to enhance consumer acceptability.

10. Incompatibility Studies:

- Investigate potential incompatibilities between herbal extracts and other formulation components to avoid any adverse reactions.

11. Quality Control Tests:

- Develop methods for quality control, including assays for active ingredients, to ensure batch-tobatch consistency.

12. Regulatory Compliance:

- Ensure that the formulation complies with regulatory requirements and guidelines for cosmetic products.

FORMULATION TABLE :-

Sr. no.	Ingredients	Quantity
1.	Psoralea Corylifolia	3ml
2.	Liquid paraffin	10ml
3.	White beeswax	3gm
4.	Borex	0.2gm
5.	Methyl parabin	0.02ml
6	Water	3ml

PATIENTS AND METHOD

Collection and Authentication of plant :-

The plant Psoralea corylifolia Linn seeds was collected from the local market. 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 distillation apparatus, at a temperature of 500 C and extraction was carried out using n-hexane as the solvent

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FORMULATION OF THE CREAM :-

Preparation of Aqueous and Oil phase

a. Aqueous Phase :-

Take a beaker, dissolve borax and methyl paraben in distilled water and heat this beaker to 75 ℃ to dissolve borax and methyl paraben and to get a clear solution.

b. Oil Phase :-

Accurate quantity of liquid paraffin and white bees wax are taken in a glass beaker or porcelain dish and heated on water bath to about 70 - 75 ℃ to get molten mass and maintain that heating.

Preparation of cream :-

After preparing oil phase and aqueous phase slowly add this aqueous phase to heated oil phase with continuous stirring. Then add a measured amount of Psoralea Corylifolia extract and stir vigorously until it forms a smooth cream. Then add few drops of rose water as a fragrance.

An oil in water (O/W) emulsion-based cream (semisolid formulation) was formulated.

The oil soluble components (White bees wax 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 paraben 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 and its forms a smooth cream .

Then add few drops of rose water

EVALUATION OF CREAM

The cream was evaluated for its physiochemical parameters pH, physical evaluation, Homogeneity, washability, Irritancy test, phase separation, spreadability, greasiness.

1) Physical Evaluation:

In this test, the cream observed for color, odor, texture, state.

Sr.no	Parameter	Formulation
1.	Color	Faint green
2.	Odor	Characteristic
3.	Texture	Smooth
4.	State	Semisolid

2) Homogeneity:

The formulations were tested for the homogeneity by touch and visual appearance.

3) Irritancy test:

Mark the area (l cm2) on the left-hand dorsal surface. Then the cream was applied to that area and the time was noted. Then it is checked for irritancy, erythema, and edema if any for an interval up to 24 h and reported.

4) Washability:

Small amount of cream was applied on the hand and it is then washed with tap water.

5) Phase separation:

Prepared cream was kept in a closed container at a temperature of 25-100 ^{o}c away from light. Then phase separation was checked for 24 hr. Any change in the phase separation was observed/checked

Sr.no.	Phase	Different room temperature	Stability
1	F1	22°c.	Stable
2	F2	37°c.	Stable
3	F3	Above 45°c.	Unstable/phase separation

7) Spreadability:

The spread ability was expressed in terms of time in seconds taken by two slides to slip off from the cream, placed in between the slides, under certain load. Lesser the time taken for separation of the two slides better the spreadability.

8) Greasiness:

Here the cream was applied on the skin surface in the form of smear and checked if the smear was oily or grease-like.

9) pH:

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 measure .

10) After feel:

Emollience, slipperiness and amount of residue left after the application of a fixed amount of cream was checked.

11) Type of smear:

After application of cream, the type of film or smear formed on the skin was checked.

Result:-

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.

OBSERVATION TABLE:-

Sr No	Parameter	Observed
1.	Color	Light cream

2.	Odour	Characteristic
3.	State	Semisolid
4.	Texture	Smooth
5.	Irritancy	Non-irritant
6.	Spredability	Spreadable
7.	Washability	Easily Washable
8.	Phase Separation	No Phase Separation
9.	pH	8.07

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.

F1	F2	F3
		

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