IJBPAS, June, 2023, 12(6): 2673-2681

ISSN: 2277–4998

International Journal of Biology, Pharmacy and Allied Sciences (IJBPAS)

'A Bridge Between Laboratory and Reader'

www.ijbpas.com

DEVELOPMENT AND CHARACTERIZATION OF HERBAL OINTMENT BY USING *PSORALIA CORYLIFOLIA* AND *ALOEVERA* FOR THE TREATMENT OF VITILIGO

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Received 15th July 2022; Revised 20th Aug. 2022; Accepted 5th Oct. 2022; Available online 1st June 2023

https://doi.org/10.31032/IJBPAS/2023/12.6.7190

ABSTRACT

Even in areas where modern medicine is available, the interest on herbal medicines and their utilization have been increasing rapidly in recent years. Plant derived substances and herbal medicines have recently attracted the great interest towards their versatile application, as medicinal plants are the richest source of bioactive compounds used in traditional and modern medicine. The present work is to development and characterization the herbal ointment of *Psoralia Corylifolia* (Bakuchi Oil) and *Aloevera* gel. The ointment base was prepared by using ratio of Beeswax and *Psoralia Corylifolia* in optimum amount to cure vitiligo (Leucoderma). After completion of formulation it was evaluated for its physicochemical parameters like organoleptic characteristics, pH, spreadability, acute skin irritation study. Also the formulation was evaluated for its stability which shows no change in the organoleptic properties, pH, irritancy, spreadability and diffusion study. Thus it could become a media to use the medicinal

properties of *Psoralia Corylifolia* and *Aloevera* gel effectively and easily as a simple dosage form.

Keywords: Vitiligo, *Psoralia Corylifolia*, *Aloevera*, Ointment, Herbal Formulation, Spreadability

INTRODUCTION

Another name of leucoderma is vitiligo. It is a disease of pigmentation **[1]**. The word "leucoderma" means "white skin," which describes the disease. "To be white-skinned." The dermal layers would gradually lose a pigment called melanin, which would cause the white spots **[2]**. White patches on the skin are a result of malfunctioning melanocytes, among other things **[3]**. Use of topical (cream, ointment, oil, etc.) or oral (medicine) psoralens, followed by exposure to UVA radiation in the range of 280-315 nm wavelengths, is the most typical treatment for leucoderma **[4]**. On skin affected by leucoderma, a thin layer of 0.01 percent to 0.1 percent methoxsalen ointment is applied. The skin is exposed to 0.12J/cm^2 to 0.25J/cm^2 UVA after 30 minutes, increasing by 0.12J/cm^2 per week **[5]**. Furanocourmarins like Psoralen are found in *Psoralea Corylifolia* or Bakuchi **[6]**. When exposed to sunlight, psoralen encourages the skin to generate the pigment melanin. By acting as a photo-sensitizer for the start of erythema on the spots of leucoderma, the seeds of *psoralea corylifolia* are thought to enhance amino acid transport through the intestinal mucosa. Under the impact of UV or sunlight, furanocoumarin started the conversion of DOPA (Dihydroxyphenylalanine) to melanin. Free sulfhydryl groups are present in the epidermal tissues **[7]**. These sulfhydryl groups bind to the free copper ions needed by tyrosine in order for it to function **[8]**. *Psoralea Corylifolia* aids in the release of copper that has been sulfhydryl group (SH-group) bound, allowing copper to become free copper and triggering the tyrosinase enzyme to produce melanin.

The objective of the study was a development and characterization in the form of herbal ointment containing *Psoralea Corylifolia* (Bakuchi Oil) and *Aloevera* for the treatment of leucoderma disease.

History

The name "vitiligo" was originally used by Celsus, a Roman physician, in the first century A.D. It is derived from the Latin word "vitilus," which means "calf" **[1]**.

He claims that the disease's white patches resemble the white spots on a spotted calf. Aged diseases like vitiligo are described in the sacred books, the Quran, the Vedas, and

the Bible. Even in traditional Chinese medicine, the illness is referred to as "Bai Dian Feng," "Shewetakusta" in Indian classical atharvaveda, "Kilas" in vinaypitah, and "Bars" and "Phulbehri" in Arabic and Punjabi, respectively **[9]**.

Prevalence

White spots, or vitiligo, affect about 1-2% of the world's population, but the prevalence is reported to be as high as 4% among the small populations of South Asia, Mexico, and the United States. A hospital in Kualalumpur, Malaysia, reported about 2.2% of new cases of the disease between 2003 and 2007 **[10]**.

Epidemiology

Vitiligo is a common depigmented skin disease with an estimated prevalence of 0.5-2% of the world's adult and child population. One of the earliest and largest epidemiological studies reported was conducted on Bornholm, Denmark in 1977, with vitiligo reportedly affecting 0.38% of the population. Vitiligo affects ethnic groups and people of all skin types unfavorably. However, the geographical difference seems to be large **[11]**.

Pigment Biochemistry

Melanin is the most important skin pigment. It is synthesized by specialized cells called melanocytes. Melanin is formed by a series of oxidation reactions involving the amino acid tyrosine in the presence of tyrosinase (an enzyme). Melanocytes synthesize melanin within membrane-gated organelles called melanosomes, which are then translocated to surrounding keratinocytes by dendrites. Each epidermal melanocyte secretes melanosomes to approximately 40 keratinocytes (1:40) nearby, and this population is termed the 'epidermal melanin unit'. Consequently, the type (eumelanin/pheomelanin) and amount of melanin synthesized by melanocytes and its distribution in surrounding keratinocytes determine the actual color of healthy skin.

The melanin formation process involves four major steps. ¬

- Development of melanocyte progenitor cells (melanoblasts) and their migration from the neural crest to peripheral sites.
- Differentiation of melanocytes into melanocytes.
- Survival and proliferation of melanocytes.
- Melanosome formation and melanin production. All four steps are important for normal melanin biosynthesis, and impaired melanin pathways cause skin depigmentation or hyperpigmentation **[1]**.

Treatment

This research focuses on combination therapy with the herbal medicine psoralen, *Psoralea corylifolia*, and exposure to UV light. Patients with vitiligo have areas of completely white skin. PUVA or phototherapy is a combination of psoralen and exposure of the skin to UV light. PUVA (UVA is longwave radiation and UVB is shortwave radiation) can cause some repigmentation, especially in facial vitiligo and black patients. The results of other body parts and Caucasian patients are less encouraging. Treatment is usually twice a week for 2 years. Nevertheless, complete repigmentation cannot be guaranteed and may recure **[12]**.

Mechanism of Action for Vitiligo (Leucoderma):

The drug has a purely local effect and appears to have a specific effect on the arterioles of the capillary plexus, which have been dilated to increase plasma in this area.

The skin becomes red and melanoblasts (pigments of clear cells) are stimulated. In vitiligo, melanoblasts do not function properly and become mandexate pigments when stimulated by drugs and gradually spread to white vitiligo patches **[13, 14]**. The phytochemically evoked covalent bond of the active ingredient to the pyrimidine base is also involved in its therapeutic effect. Photon co-generation includes a thymine dimer adduct on the contralateral DNA strand. Psoralen is used to treat low-pigmented skin diseases such as vitiligo because it is known to be inserted into DNA that forms mono and di-adducts in the presence of long-wavelength UV light **[15]**.

MATERIALS AND METHODS

Bees wax & *Psoralia Corlifolia* (Bakuchi Oil) Ratios:

Bees wax and ***Psoralia Corlifolia*** (Bakuchi Oil) weigh accurately 1:1 ratio of 1 gm of bees wax & 1 ml bakuchi oil. As it 1:4 ratios, 1 gm of bees wax & 4 ml *Psoralia Corlifolia Oil* (*P. Corylifolia Oil*). To melted each china dish of bees wax & *P. Corylifolia* (Bakuchi Oil) using a double boiler. Bees wax was heated in china dish at 70°C & then add the *P. Corylifolia* (Bakuchi Oil) and mixed it. To cooled the mixture &pour in to the beaker. Ratios of Beeswax and *Psoralia Corlifolia* (Bakuchi Oil) shown in **Table 1**.

Table 1: Ratio of Bees wax & *Psoralia Corlifolia* (Bakuchi Oil)

Ratios	Hard	Semi solid	Melt speed
1:1	Firm	Yes	Slow
1:2	No	Yes	Average
1:3	No	Medium	Fast
1:4	No	No	Very fast

MATERIALS

Table 2: List of Excipients with Functions

List of Excipients	Functions of Excipients
Bees wax	Used as a stiffening agent
Liquid paraffin	Used as an emollient
Glycerin	Used as a moisturizer
Methyl paraben	Used as a preservative
Propyl paraben	Used as a preservative
Psoralia Corlifolia (Bakuchi Oil)	Used as a drug
Aloevera	Used as a drug

METHOD

Beeswax and liquid paraffin were separately heated to 70 ° C in a porcelain dish. Methylparaben and propylparaben were mixed separately. Liquid paraffin was added dropwise to the beeswax with constant stirring. Then add Bakuchi oil and a moisturizer such as *aloevera* gel or glycerin to the ointment base with constant stirring.

Table 3: Formulation of Herbal Ointment

Sr. no.	Drug *(Psoralia Corlifolia)*	Bees wax	Liq. paraffin	*Aloevera* Gel	Glycerin	Water	Methyl Paraben	Propyl Paraben	Inference
F1	5ml	5gm	1ml	2gm	2ml	-	0.01	0.01	Ointment base was not prepared
F2	5ml	5gm	2ml	3gm	2ml	-	0.01	0.01	Ointment base was not spreadable
F3	5ml	5gm	3ml	4gm	2ml	-	0.01	0.0	Ointment base was not soft
F4	5ml	5gm	4ml	5gm	2ml	4ml	0.01	0.01	Lumps was produced & stability issue
F5	5ml	5gm	5ml	5gm	2ml	3ml	0.02	0.02	Lumps was produced & stability issue
F6	5ml	5gm	5ml	5gm	2ml	2ml	0.02	0.02	Lumps was produced
F7	5ml	5gm	5ml	5gms	2ml	1ml	0.02	0.02	Lumps was produced
F8	5ml	5gm	5ml	5gm	2ml	-	0.02	0.02	Ointment base was prepared

CHARACTERIZATION OF HERBAL OINTMENT

All ointments produced were characterized with respect to parameters such as appearance, odor, color and pH values, Spredability, skin irritation studies and stability.

Organoleptic properties all blank formulations (i.e., active-free formulations) and drug-filled formulations were tested for

physical appearance, color, texture, phase separation, and uniformity. These properties were evaluated by visual observation. We tested homogeneity and texture by squeezing a small amount of prescribed cream and gel between the thumb and index finger. The consistency of the formulation and the presence of coarse particles were used to assess the texture and uniformity of the formulation. Immediate feel (including stiffness, roughness and greasiness) was also evaluated **[16, 17]**.

pH value

About 2.5 g of the total formulation was placed in a dry beaker and 50 mL of water was added. The beaker containing the ointment was heated to 50-70°C on a water bath. The ointment pH was determined using a pH meter. Determinations were made in triplicate and the average of the three measurements was recorded **[18]**.

RESULT& DISCUSSION

Organoleptic properties **Table 3** shows the sensory properties of the ointment formulation, including physical appearance, color, texture, phase separation, homogeneity and immediate skin feel. The results showed that the ointment was aesthetically pleasing, had a smooth texture, was all homogeneous, and had no evidence of phase separation. All formulations were light brown in color and aromatic odor.

pH value

The pH of all formulations was found to be between 6.80 + 0.152 and 7.02 + 0.174, which is within the range. The pH of all formulations is within the normal pH range of the skin.

Spreadability

Ease of spread Spreadability is expressed as the time (in seconds) it takes for two slides to slide off the gel when placed between the slides in the specified load direction. An excess amount of sample was placed between the two slides and a defined amount of weight was placed on these slides to compress the slides to a uniform thickness [16]. Added a 70 g weight and recorded the time required to separate the two slides. Spredability was calculated using the formula.

S = M.L/T

Where, M = wt. tied to the upper slide, L = length of glass slides,

T = time taken to separate the slides.

In the F8 batch, Spreadabaility was performed 3 times and was found to be in the range 173.6 to 180.2.

Acute skin irritation test

The primary skin irritation test was performed on male albino rats weighing

approximately 150-200 g. A set of 6 rats were used in the study of each formulation. Animals were maintained with standard pet food and free access to water. Animals were bred under standard laboratory conditions. The dorsal hair on the back of the rat was cut one day before the study. 50 mg of different formulations were applied to a 1 cm area of intact skin of different animals. After applying the formulation to rat skin, the animals were returned to their cages. After 48 hours of exposure, the formulation was removed. The test site was wiped with tap water to remove any remaining residue. We reviewed unwanted skin changes, namely color changes and skin morphological changes. Skin irritation tests showed no signs of redness or dryness.

Stability Study

All formulations developed have undergone accelerated stability testing for approximately 5 weeks. Room temperature was maintained according to (ICH Guideline 1993). There is no change in color, pH, spreadability or skin irritation during the stability test.

CONCLUSION

Herbal ointment preparations are made using herbs and are further evaluated by various evaluation parameters such as organoleptic properties, pH value, spreadability, acute skin irritation, stability study of herbal preparations, and good results were obtained.

ACKNOWLEDGMENTS

Authors are thankful to Dr. Subhash University, Junagadh for their necessary facilities and constant support to successfully completion of this research work.

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