WWW.IJRPR.COM

International Journal of Research Publication and Reviews

Journal homepage: www.ijrpr.com ISSN 2582-7421

Formulation And Evaluation of Psoriasis Disease

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ABSTRACT:

Psoriasis (PsO) is a common, systemic, chronic, inflammatory disease characterized by key clinical symptoms, including itching, pain, and scaling. Psoriasis is the most common chronic autoimmune disease. The objective of the present study was to formulate herbal cream that consists of Aloevera, turmeric extract and Nigella sativa extract used in treating Psoriasis. Various phytochemical identification tests were carried out using reagents. DPPH (2, 2- diphenyl-1-picrylhydrazyl) free radical scavenging assay was carried out to confirm antioxidant activity. Coconut oil, Olive oil and Vitamin E oil were used in the formulation which provides different pharmaceutical activities. Phytoconstituents present in the herbal extract were identified by Liquid Chromatography-Mass Spectroscopy (LC-MS) studies. Evaluation studies were carried out for prepared cream. LC-MS studies concluded that various herbal constituents were identified and it concludes that active constituents responsible for treating psoriasis were present in the obtained extract and also possessed antioxidant activity. Psoriasis is a chronic inflammatory skin disease characterized histologically by hyperproliferation and aberrant differentiation of epidermal keratinocytes.[3] Psoriasis is a common, chronic, recurrent, immune-mediated inflammatory disorder of skin. Although conventional topical and systemic therapies yield remission for a while, they carry a risk of many side effects that limit the long term use of these agents and the disease recurs generally in a short period of time after cessation of therapy.[6] Psoriasis is an autoimmune condition with the most significant and far-reaching consequences for humans. In order to cure psoriasis, an herbal ethosomal cream was developed.

KEYWORDS: Nigella sativa, Turmeric, Aloevera, Herbal cream, Anti psoriasis.

NEED OF INVESTIGATION:

1. Limitations of Current Treatments:

Conventional treatments (like corticosteroids, biologics, and immunosuppressants) may have significant side effects, including skin thinning, increased infection risk, and liver toxicity.
Some patients develop resistance or reduced effectiveness over time.

2. Growing Interest in Natural and Alternative Therapies:

Many individuals with chronic skin conditions prefer natural or herbal remedies due to perceptions of safety and holistic benefits.

There is a high demand for complementary therapies with fewer side effects.

3. Evidence of Anti-inflammatory and Antioxidant Activity in Herbs:

Ingredients like Nigella sativa, aloe vera, turmeric, etc., have demonstrated anti-inflammatory, antimicrobial, and antioxidant properties.
These effects are relevant to psoriasis, which involves immune dysregulation, inflammation, and oxidative stress.

AIM AND OBJECTIVE:

AIM:

To formulate and evaluate a stable, effective herbal cream using natural ingredients such as Nigella Sativa oil, turmeric and Aloe vera gel for the management of psoriasis.

OBJECTIVES:

1. To select and incorporate herbal ingredients with known anti-psoriatic, anti-inflammatory, Moisturizing, and skin-healing properties (e.g., Nigella sativa oil, Aloe vera gel, turmeric Extract).
2. To develop a suitable cream base that enhances the delivery and stability of active herbal Ingredients without causing irritation.
3. To formulate a herbal cream using optimized concentrations of the selected ingredients.
4. To evaluate the physicochemical properties of the cream, including: pH Spreadability Viscosity Stability Homogeneity
5. To assess the in vitro and/or in vivo efficacy of the herbal cream for anti-inflammatory and Skin-soothing effects relevant to psoriasis.
6. To conduct skin irritation or compatibility testing to ensure the product is safe for use on Sensitive skin.

7. To compare the herbal formulation with standard or marketed anti-psoriatic creams, if Applicable.

INTRODUCTION:

Psoriasis is a chronic autoimmune human skin disorder that is characterized by excessive proliferation of keratinocytes, scaly plaques, severe inflammation, and erythema. Treatment of psoriasis causes its remission after finishing the treatment or only relieves the patient's condition. Moreover, psoriasis is often accompanied by other diseases, such as depressive illness, cardiovascular disease, and a seronegative arthritis known as psoriatic arthritis. [3] Psoriasis is a common, chronic, recurrent and immunemediated inflammatory disorder characterized by circumscribed, red, thickened plaques with an overlying silver white scale. Although the prevalence of psoriasis varies depending on ethnicity, approximately 2% of the world's population suffers from this disease. Herbal formulations are receiving more concentration in public because of their high-quality properties and less side effects. Additionally it also provides the skin with necessary nutrients and required moisture (Mali AS, et al. 2015). The herbal cream is basically water in oil type of emulsion. The natural ingredients chosen for preparation of herbal cream are turmeric, papaya, aloe-vera, tulsi, and neem. The choice of these ingredients is based on their individual properties.[7] Psoriasis is categorized by different clinical manifestations and each class of psoriasis is characterized by examine the mild, moderate to severe symptoms on skin. These symptoms generally include the white or red colour of irregular skin; the patches are commonly itchy and scaly to the skin.1 Psoriasis skin is evaluated by itching, red scalps, white scales and rashes are developed on the skin.[11]

Causes of Psoriasis:

Genetic factors:
In our body genes play an important role to control everything in the body, from height to eye colour. The normal function of cells in the body is controlled by genes, so it is important to work genes normally. Around 10% of the normal population has predisposed the genes to psoriasis; but from 10% only 1-3% of the populations develop psoriasis. Also families with some history ofpsoriasis have been more likely to develop psoriasis.

Environmental factors:
Many environmental factors are generally causing psoriasis. These factors activate genes to produce psoriasis. Some of the responsible factors related to the environment are established below.

Infections:
Streptococcal throat infection, tonsillitis on the throatand some other skin related infection may harm the skin and that can result in produce guttate (small, salmonpink droplets).

Stress:
Stress is very common and it can cause mental illness which may affect the body to produce many products. The stress enhances the inflammatory response to our skin. According to researchers it is the important factor for stress induced psoriasis.

Medication:
Ace-inhibitors, Beta-blockers, Lithium, Synthetic Antimalarial medications, Quinidine, Indomethacin, NSAIDS, Interferons etc. So, the group of these medications can activate the disease condition.

Life style:
Our skin is a major part of the body and also it is the major organ of our body, it works as a protective tool from external harms on the body. So, due to less awareness regarding personal care in our daily life style which include diet, exercise, sleep and obesity, air pollution, more alcohol consumption, smoking. Consuming alcohol in small or extra amounts may enhance the production chances of psoriasis and continuously smoking can also make the disease worse.

Other factors:
Cold weather, Obesity, Folate and vitamin B12 deficiency [6]

Causes:
1] Red patches on skin. 2] Dry, Cracked skin
3] Itching, Burning to the skin 4] Thickened or Ridged nails 5] Flaky scalp
6] Skin pain or sensitivity

Types of Psoriasis:

1. Chronic plaque Psoriasis
Among different types of psoriasis, the most common one is plaque psoriasis or psoriasis vulgaris. Almost 85 percent ofpeople with psoriasis have plaque psoriasis which is characterized by thick red patches of skin, often with a silver or white flaking layer.

Figure 1. Plaque psoriasis

2. Guttate Psoriasis

Streptococcal infection like pharyngitis or perianal infection classically triggered a distinct variant of psoriasis called guttate psoriasis which is more common in kids and adolescents than adults. In this case, patients severely present small drop like lesions which respond well to topical treatments and phototherapies [6].

Figure 2. Guttate psoriasis

3. Flexural Psoriasis

The quality of life of a psoriatic patient may be impaired considerably by facial and flexural psoriasis. This type of psoriasis is an extrapolative marker indicating a poor prediction of psoriasis. Facial and flexural psoriasis cannot be considered as dissimilar disease entities but rather as site differences.

Figure 3. Flexural psoriasis

4. Erythrodermic Psoriasis

Erythroderma is a scaly erythematous dermatitis that involves 90% or more of the cutaneous surface. The most mutual dermatoses underlying erythroderma are psoriasis and eczema. Erythroderma may be also caused by cutaneous T cell lymphomas [8].

Figure 4 Erythroderma psoriasis

5. Pustular Psoriasis

The patients who are suffering from pustular psoriasis or related pustular diseases may genetic abnormalities which impair the function of crucial players of the innate skin immune system. Detection of these irregularities has changed the paradigm of these diseases recently.

Figure 5. Pustular psoriasis

6. Palmoplantar Psoriasis

Plaque psoriasis that involves the palms and soles is characterized as palmoplantar psoriasis. This type of psoriasis is a challenge for dermatologists that is difficult to be treated with topical and systemic therapies.

Figure 6 Palmoplantar psoriasis

7. Scalp Psoriasis

Scalp psoriasis can affect patients' lives harmfully and is often resistant to the treatment that is not been a major focus of a scientific study. The activity of secukinumab of patient-reported outcomes of scalp psoriasis is evaluated by this analysis.

Figure 7 Scalp psoriasis

8. Nail Psoriasis

About 80% patients with psoriasis are likely to develop nail psoriasis as a result of the conditions of their nails as nails are considered epidermal appendages. Psoriasis can cause nail disorders of two patterns.

Figure 8. Nail psoriasis

DRUG PROFILE

1. *ALOEVERA*

BOTANICAL NAME: Barbaloin

SYNONYM: Aloe Indica Royle, Aloe Vulgaris Lam

FAMILY: Asphodelaceae

CHEMICAL CONSTITUENTS: Aloevera contains more than 75 different compounds, including vitamin, enzymes, minerals, Sugars, Anthraquinones.

TAXONOMICAL CLASSIFICATION:

Kingdom – Plant

Order- Asparagales **Family -** Asphodelaceae **Genus**- Aloes
Species – Aloe Barbadensis miller

USES:

1. Antiinflammatory and immunomodulatory effect

2. Antimicrobial properties
3. Digestive health
4. Oral or Dental care

Figure 9. Aloevera

2 CURCUMIN:

BOTANICAL NAME: curcuma longa

SYNONYMS: curcuma domestica, turmeric.

CHEMICAL CONSTITUENTS: curcumin I ($C_{21}H_{20}O_6$, diferuloylmethane, 94%), curcumin II ($C_{20}H_{18}O_5$, demethoxycurcumin, 6%) and curcumin III ($C_{19}H_{16}O_4$, bis-demethoxycurcumin, 0.3%)]

TAXONOMICAL CLASSIFICATION: curcuma longa

Kingdom- plantae

Order- Zingiberaceae

Family-Zingiberaceae(ginger family)

Genus- curcuma

Species – curcuma longa

USES:
1. Antiinflammatory action
2. Antioxidant
3. Wound healing
4. Regulation of keratinocyte proliferation

Figure 10. curcumin

3. KALONJI:

BOTANICAL NAME: nigella sativa

SYNONYMS: black seed, mangrail.

CHEMICAL CONSTITUENTS: thymol, thymoquinone,cymene,carvacrol.

TAXONOMICAL CLASSIFICATION:

Kingdom- plantae

Order- ranunculales.

Family-ranunculaceae butter cup family

Genus- Nigella

Species – Sativa

USES:

1. Antiinflammatory effect
2. Antioxidant properties
3. Antimicrobial Action
4. Immunomodulatory

Figure 11. Nigella sativa

EXCIPIENT PROFILE

Excipient	**Use**
Aloevera gel	Moisturizing agent, skin healing
Turmeric	Antiseptic, antiinflammatory
Nigella sativa oil	Antimicrobial, antiinflammatory
Cocoa butter	Moisturizing agent
Stearic acid	Emulsifying agent, thickening agent
Cetyl alcohol	Stabilizer
Olive oil	Moisturizing agent
Vit E oil	Antioxidant
Coconut oil	Moisturizing agent
Methyl paraben	Preservative
Distilled waer	Vehicle

1. COCOA BUTTER:

Cocoa Butter (Theobroma oil) is a natural fat obtained from cocoa beans and is widely used in pharmaceutical and cosmetic formulations. Here's a detailed excipient profile of cocoa butter.

Synonyms: Cacao butter, Theobroma oil

Source: Natural fat extracted from cocoa beans

Appearance: Pale yellow

Odor: Mild, characteristic chocolate-like aroma

Pharmaceutical Uses

- **Topical formulations:** Creams, lotions, ointments, lip balms
- **Suppository base:** Ideal for rectal and vaginal suppositories (melts at body temperature)
- **Emollient –** Softens and soothes the skin

Fig. 9 cocoa butter

2: STEARIC ACID:

Stearic acid is a type of saturated fatty acid that is commonly found in both animal and plant fats.
It appears as a waxy, solid substance at room temperature and has the chemical formula $C_{18}H_{36}O_2$.

Synonym: *C18 fatty acid*

Source: *typically derived from plant fats (eg. Palm or Coconut oil) or animal fats.*

Appearance: *white waxy solid*

Odour: *slightly oily*

Pharmaceutical Uses:

In cosmetics and skincare: As an emulsifier, thickener, and stabilizer in creams and lotions. In soaps: Helps harden the bar and improve lather.
In pharmaceuticals and supplements: As a lubricant or binder. In industrial products: Used in rubber, candles, and plastics.

Figure 10. Stearic acid

3. ***COCONUT OIL:*** coconut oil is extracted from kernel of mature coconuts from coconut palm.

Synonym: methyl 4 hydroxybenzoate

Source: Blueberries

Appearance: semisolid or semisolid at RT.

Odour: mild, sweet

Pharmaceutical uses:

- Moisturizer and emollient: soothes dry scaly or irritated skin.
- Ointment base: act as carrier or base for active ingredient in cream, lotion and balms.
- Wound healing: Virgin coconut oil has been shown to promote healing and reduces inflammation in minor cuts and burns.
- Ayurvedic medicine: used for oil pulling, massage.

Figure 11. Coconut oil

PLAN OF WORK:

1) Literature Survey
2) Selection of Herbal drug
3) Determine Active Constituent of Herbal drug
4) Selection of Excipients
5) Selaction of Material and Equipments
6) Preparation of Formulation

LITURATURE SURVEY:

1. **Walunj jayashri et al, (2024**) Psoriasis is an inflammatory skin disease characterized by scaling ant inflammation (pain, Swelling, heat and Redness) resulting in thick, redskin with silvery scales. These spots may be itchy or Painful.Psoriasisis now treated with Systemic, local treatment and light therapy. These treatments have Some negative and potentially fatal side effects.
2. **Linn Y K et al, (2014**) Psoriasis is a common, chronic, recurrent, immune-mediated inflammatory disorder of skin. Although conventional topical and systemic therapies yield remission for a while, they carry a risk of many side Effects that limit the long term use of these agents and the disease recurs generally in a short period of Time after cessation of therapy. An increasing number of psoriatic patients are using herbal products as a Treatment to control their disease with less side effects.
3. **Dhyani A. et al, (2023)** Herbal cosmetics are products that are used to improve one's look. The goal of the research was to develop a herbal cream for moisturizing, nourishing, Whitening, and treating various skin diseases. Curcuma longa (Turmeric powder), Carica papaya (Papaya), Aloe barbadensis (Aloe-vera leaves), Azadirachta indica (Neem leaves), and Ocimum sanctum (Tulsi leaves) are some of the basic drugs used to make the cream.
4. **Sethi et al, (2009)** In the present research an attempt has been made to develop antipsoriatic cream using combination of herbs like neem, sarsaparilla, bakuchi and daruhaldi. Psoriasis is an inflammatory disease of skin characterized by well defined erythematous plaque with large adherent silvery scales.
5. **Rajasree et al, (2022)** To prepare an herbal ointment using an ethanolic extract of Berberis aristata and assess the anti-psoriatic effectiveness of the finished product. We were able to make multiple Ointments that were each categorized as F-1, F-2, and F-3 by adding varying concentrations of Stearic acid and cetyl alcohol by learning about various formulation types, such as oil in water.

MATERIAL AND METHOD

HERBS USED:
Aloevera- Soothing agent, Moisturizing agent
Curcumin- Anti Inflammatory agent, Antioxidant protection
Nigella Sativa- Antimicrobial agent, Anti Inflammatory agent

INGREDIENTS:
Cocoa Butter Stearic
Acid
Olive oil
Coconut oil
Cetyl alcohol
Vitamin E oil
Methyl paraben
Distilled water

METHOD OF PREPARATION:

Extraction: Steps carried out in the preparation of psoriasis herbal cream were as follow

- Aloevera leaves, cut leaf, blend and extract gel and store
- Curcumin (3gm), alcohol (15ml) kept in air tight container (5 days) for maceration (Alcoholic Extract Preparation).

Figure 12. extraction

Figure 13. Ingredients

1. **Prepare the oil Phase:** In a heat-resistant beaker, Add Cocoa Butter, steric acid, cetyl alcohol, coconut oil, Vit E oil, Olive oil. Gently heat the oil phase. mixture to 75°C in a double boiler or water bath, Stirring occasionally Completely until the waxes are completely melted and the mixture becomes uniform.

Figure 12. oil phase

2. **Prepare the water Phase:** Add the Methyl paraben(preservative), ethylamine, dissolve curcumin extract, Aloevera extract, Nigellla sativa oil add water upto Quantity sufficient.Stir well to ensure it dissolves. Heat to 75°C.

Figure 13. Water phase

3. **Combine the phases:** Slowly pour the oil phase into the water phase while ' continuously an stirring or using immersion blender to form an emulsion. Blend well until the cream thickens and becomes Smooth and uniform using an immersion blender can' help ensure that aloevera gel, nigella sativa oil and Curcumin powder are evenly distributed throughout the cream. the mixture Should be free of lumps.

Figure 14. combine phase

4. **Cool down Phase:** Once the mixture has cooled to below 40°C and stir gently to incorporate these ingredients.

figure 15. cooling phase

5. Storage: Transfer the finished cream into a Sterilized jar or container for storage. Store in cool, dry place.

Figure 16. storage

FORMULATION TABLE:

Ingredient	Use	F1	F2	F3
Aloevera gel	Moisturizing agent, skin healing	2ml	2ml	3ml
Turmeric	Antiseptic, antiinflammatory	1gm	3gm	2gm
Nigella sativa oil	Antimicrobial, antiinflammatory	3ml	2ml	2ml
Cocoa butter	Moisturizing agent	3gm	3gm	3gm
Stearic acid	Emulsifying agent, thickening agent	3gm	3gm	3gm
Cetyl alcohol	Stabilizer	1ml	2ml	2ml
Olive oil	Moisturizing agent	2ml	2ml	1ml
Vit E oil	Antioxidant	1ml	1ml	1ml
Coconut oil	Moisturizing agent	1ml	2ml	2ml
Methyl paraben	Preservative	3gm	2gm	1gm
Distilled waer	Vehicle	Q. S.	Q.S.	Q. S.

EVALUATION PARAMETERS:

Evaluation of Psoriasis herbal cream includes following parameters:

Determination of organoleptic properties - The appearance of the cream was judged by its color, pearlscence and roughness and graded.
pH - The pH meter was calibrated and measured the PH by placing in the beaker containing 20mg of the cream
Homogeneity- test was done by physical touch with hands.

Appearance - The appearance of the cream was found by observing its color, opacity. etc.

Determination of emolliency - Emolliency slipperiness and amount of residue left after the application of fixed amounts of cream was checked.

Smear Type - The test was conducted after the application of cream on the skin the smear formed was oily or aqueous in nature

Washability - The removal of the cream applied on skin was done by washing under tap water with minimal force to remove the cream.

Irritancy Test - The cream was applied on left hand dorsal side surface of 1 sq.cm and observed in equal intervals upto 24hrs for irritancy, redness and edema.

Accelerated Stability Studies - Accelerated stability studies were performed on all the formulations by maintaining at room temperature for 20 days with constant time interval During the stability studies the parameters like homogeneity, viscosity, physical changes, pH and type of smear were studied.

CONCLUSION

This study explored making best treatment for psoriasis by adding herbal ingredients like Aloevera, Turmeric, Nigella sativa. These herbs are known for supporting treat psoriasis, reduce Skin irritation, improve in cell growth and easing skin burning and to reduce red patches on skin. The cream is tested by applying on th skin by texture, appearance, stabiliyyand safety. Among all The samples formulation formulation 3 (f3) performed the best.
It has yellowish colour and pleasant odour, acidic pH, good consistency and was safe for topical Use without skin irritation and side-effects.
Herbal products are more suitable than those based on chemicals. Pre-clinical and clinical trials are required to gain a better understanding of its effectiveness. This study emphasizes the Potential of using natural ingredients in skincare products and encourages further exploration in this area.

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