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Formulation And Evaluation of Herbal Emulgel for Treatment of Psoriasis

Research Article

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Abstract

One of the most prevalent skin conditions in humans, psoriasis is thought to have strong genetic roots. It is characterized by abnormal keratinocyte differentiation and excessive development, however with the right treatment, it is completely curable. The development of psoriatic plaques is associated with environmental triggers and other factor such as streptococcal infection, physical trauma (such as tattoos and surgical incisions), smoking and alcohol abuse, as well as certain medications such as antidepressant drugs, anti-hypertensive drugs, anti-cytokine medication. The formulation goal is to develop an emulgel infused with a combination of herbs such as Neem oil, Coconut oil and Aloevera gel, that can help to alleviate the symptoms of Psoriasis and also to cure the condition. The prepared gel formulations were evaluated for pH, viscosity, drug content uniformity, physical characterization, phytochemical screening and by also evaluating it's effect on psoriasis affected skin. Aloevera and neem oil, and coconut oil containing emulgel exhibited the drug content within the optimum range 87.56%-90.45% which concluded efficient drug loading in the formulation.

Keywords: Psoriasis, Emulgel, Aloevera, Neem oil, Coconut oil.

Introduction

One of the most prevalent skin conditions in humans, psoriasis is thought to have strong genetic roots. It is characterized by abnormal keratinocyte differentiation and excessive development, however with the right treatment, it is completely curable (1).The development of psoriatic plaques is associated with environmental triggers and other factor such as streptococcal infection, physical trauma (such as tattoos and surgical incisions), smoking and alcohol abuse, as well as certain medications such as antidepressant drugs, anti-hypertensive drugs, anti-cytokine medication (2).

Psoriasis is a chronic, genetically influenced, remitting and relapsing scaly and inflammatory skin disorder that affects 1 to 3 percent of the world's population. For best treatment, specific immune therapeutics are necessary for the unique auto inflammatory process of generalized pustular psoriasis (GPP). Clarifying the immune processes and genetic variations (especially those pertaining to the IL-36 signaling axis) that contribute to illness pathogenesis can improve our comprehension of the immune responses, the course of the disease, and the resolution of inflammation. (1,3).

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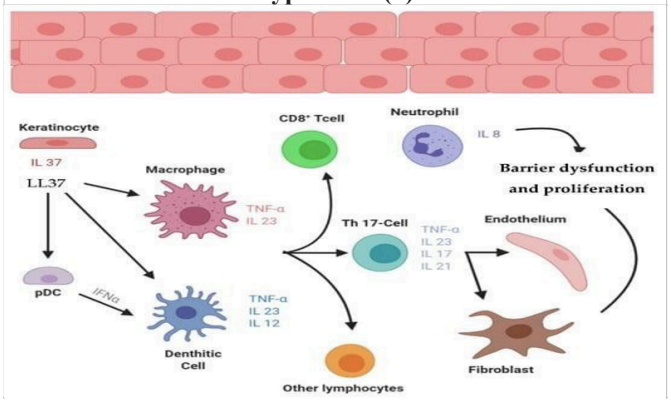
The study of the pathophysiology of psoriasis has significantly advanced our understanding of skin biology in general. Over the last fifteen years, advances in our knowledge of the pathophysiology of psoriasis have resulted in very successful, targeted therapies that have given us a better understanding of the pathophysiology of chronic inflammatory illnesses that are dominated by the IL-23/Th17 axis. (4)

Pathogenesis of Psoriasis

Figure 1: Plaque-type psoriasis pathogenesis principal hypothesis (5)



Activation of the adaptative immune response through T cell subsets drives the maintenance phase of psoriatic inflammation. Two distinct mechanisms contribute to the proliferation of keratinocytes in the epidermis: inflammation caused by TNF-α, IL-17, and IFN-γ, and LL-37 complexing with DNA to increase the synthesis of type I IFNs. By generating LL-37, proinflammatory cytokines (TNF-α, IL-1β, and IL-6), chemokines, and S100 proteins, all of these mediators

further sustain keratinocyte activation and spread chronic inflammation. When taken as a whole, these encourage keratinocyte growth and the synthesis of AMPs and chemokines, which in turn encourage the recruitment of neutrophils and maintain skin inflammation. The primary hypothesis on the development of plaque-type psoriasis is illustrated in Figure 1. Plaque-type psoriasis is characterized by the TNFα–IL-23–Th17 inflammatory cascade. Hematopoietic cells, including CD8+ T cells (Tc17), invariant NKT cells, γδ T cells, non-T non-B lymphocytes (also known as type 3 innate lymphoid cells), and neutrophils, are among the cell types that produce the various forms of IL-17. IL-17A-F cytokines control inflammatory reactions [20]. It has been established that a receptor that may be activated by two distinct cytokines, IL-17A and IL-17F, with IL-17A having a larger effect, mediates the most significant signaling in psoriasis. (5,6).

New comorbidities related to Psoriasis

a) Psoriatic Arthritis

Alibert in 1818 observed the occurance of simultaneous Arthritis and Inflammatory Joint Disease in patients of Psoriasis. The arthritis was discovered as a different form i.e. a distinct one from Rheumatoid Arthritis. The major difference between the Rheumatoid and Psoriatic Arthritis was the absence of (RF) Rheumatoid Factor, lack of B-cell activation and also the presence of HLA- B27 and a continuous of enthesitis (7). Since some medical professionals believed that psoriasis was a chronic wound-healing reaction, a subsequent model emphasized the possible involvement of fibroblasts. By this theory, fibroblasts activated in the dermis were viewed as the genesis of psoriatic plaques as by driving keratinocyte proliferation . Defects in neutrophils have been proposed. Mast cells have been noted to have increased interferon-gamma (IFN-γ) in psoriatic patients (8).

b) Osteoporosis

Bone microarchitecture change resulting in decreased strength is called as osteoporosis which came out as a recent comorbid condition related to Psoriasis. Current advancement in the research described the involvement of certain cytokines such as Interferon-gamma, TNFalpha and Interleukin-6. The research suspected that the patient of Psoriasis (9).

c) Chronic Obstructive Pulmonary Disease

COPD affects approximately 10% of the population and encompasses chronic obstructive bronchitis and emphysema. Th-1 and Th-17 cells are disrupted in psoriasis, and IL-1, IL-6, IL-8, and TNF-α are elevated along with systemic inflammation markers including C-reactive protein (CRP). Both of these cytokines and CRP are elevated in COPD and are linked to the severity of the illness. Moreover, sputum and bronchoalveolar lavage fluid from COPD patients had elevated levels of neutrophils, TNF-α, IL-6, and IL-8.40 IL-17, which is already linked to psoriasis through the Th-17 response, was recently linked to lung conditions like COPD (6,9).

d) Obstructive sleep apnea

In addition to daytime symptoms brought on by excessive sleepiness, OSA is a common type of sleep disorder that affects 2-4% of the general population. It is characterized by recurrent episodes of partial or complete obstruction of the upper airway during sleep, which causes intermittent hypoxia and frequent awakenings. OSA patients have inflammation of the upper airways, as well as increased oxidative stress and systemic inflammation indicated by elevated levels of TNF- α, IL-6 and C-reactive protein (5,9).

Table 1: Marketed formulations for the treatment of Psoriasis

Sr.no.	Chemical Constituents	Adverse effects
1	Triamcinolone (Trianex)	itching, scaling, severe redness, soreness, or swelling of the skin. Blistering, burning, crusting, dryness, or flaking of the skin, irritation, redness and scaling around the mouth
2	Clobetasol (Clobex)	High doses or long-term use of clobetasol can lead to thinning skin, easy bruising, changes in body fat (especially in your face, neck, back, and waist), increased acne or facial hair, menstrual problems, impotence, or loss of interest in sex.
3	Coal tar based shampoos (Neutrogena T-Gel and MG217 Psoriasis Medicated Conditioning Shampoo)	Skin/scalp irritation or staining of skin/hair (especially in patients with blonde, bleached, dyed, or gray hair) may occur
4	DHS Tar lotion and shampoo, Doak Tar lotion and shampoo	DHS Tar lotion and shampoo, Doak Tar lotion and shampoo long term use can cause tar acne.
5	Calcipotriol (Cal) and Betamethasone dipropionate (BDP)	Calcipotriol can cause itching, stinging, dryness, and rash, while BDP can lead to thinning of the skin, stretch marks, and skin infections.

Tachyphylaxis, more often observed local cutaneous NB in the face and intertriginous areas include purpura, folliculitis, acne, striae distensiae, telangiectasia, and skin atrophy could make co-existing dermatoses worse: tinea, perioral dermatitis, and roseacea could result in contact dermatitis.Systemic (rare): glaucoma, cataracts, Cushing's disease, femoral head osteonecrosis, and HPA axis support (10).

Use of Neem oil in the treatment of Psoriasis

Neem possesses anti-inflammatory, antibacterial, analgesic, antiviral, antifungal, immune modulatory and antioxidant activities which substantiate its use as skin therapy. Various novel formulations and associated

patents that improved the permeability of neem based products across skin could be found in literature (11). An indigenous medication consisting of an aqueous extract of Neem leaves was tested in 50 cases of uncomplicated psoriasis under a conventional coal tar regimen in a double-blind clinical drug trial. Patients who took the medication in addition to coal tar responded more quickly and effectively than those who took a placebo, and no adverse effects were observed during the trial period (11).

Use of Aloevera gel in treatment of Psoriasis

Aloevera pulp is made up of 98.5% water and 1.0–1.5% proteins, organic acids, enzymes, phenolic compounds, polysaccharides, and minerals. Hepatoprotective, immunosuppressive, anti-diabetic, analgesic, anti-inflammatory, and antioxidant qualities are all present in aloe vera gels and extracts. The preclinical and clinical benefits of A. vera in the treatment of psoriasis have been shown in many research. Antioxidant, antinociceptive, and anti-inflammatory effects have also been reported. Aloe vera modulates immune response by activating macrophages with an increase in lymphocyte response to alloantigens, releasing nitric oxide and cytokines, and activating the maturation of immature dendritic cells. A double-blind, placebo-controlled, randomized study was conducted to assess the potential adjuvant activity and tolerability of an Aloe vera extract in a hydrophilic cream for the treatment of psoriasis vulgaris. For four weeks, the interventions were applied topically three times a day for five days in a row. Patients were clinically assessed once a week up to 16 weeks, and afterward followed up once a month for the following 8 months (12).

Use of coconut oil in the treatment of Psoriasis

Fatty acids also have skin-soothing benefits for treating psoriasis. Coconut oil might help soften the skin, due to containing lauric, capric, and caprylic acids, which are all types of fatty acid. Lauric acid also has antimicrobial activity, which helps to reduce the risk of skin infections and irritation. The biggest benefit of the oil is its ability to moisturize the scalp. In fact, it's sometimes used as a conditioner to hydrate dry scalp and skin. This possibility brings hope to people experiencing dry scales that itch relentlessly (13).

Method of Preparation

Collection of Aloevera

Aloevera was collected from the herbal garden. It was cleaned properly with sterile water to remove the yellowish fluid. The sap was scraped out of aloevera leaves. The fibers were broken down uniformly by mechanical stirrer at 4000 rpm for 1 hour. It was filtered out and strained using the muslin cloth. The filtrate was refrigerated and stored until it's use. Neem oil was purchased from an online store that was manufactured and marketed by Baidyanath.

Preparation of standard solution

1 ml of aloevera gel and neem oil were weighed accurately and each were dissolved in methanol in separate volumretric flask, sonicated, filtered and analyzed.

Formulation table

Method of preparation of emulgel

The gel base (aqueous phase) was prepared by dispersing carbopol in a mixture of propylene glycol and distilled water. Triethanolamine was added dropwise until the pH of the solution becomes 7.6 suitable for skin. The aloevera gel was added to the mixture dropwise and the solution was placed on a magnetic stirrer.On the other hand the oil phase was prepared when neem oil is added to the mixture of coconut oil and PEG (Polyethylene Glycol). A small quantity of methyl paraben was added to water and heated until it completely dissolved. The methyl paraben was then added to the aqueous phase. A small quantity of Propyl paraben was added to the oil phase. Both aqueous and oil phase was heated on a hot plate maintaining the temperature upto 50 degree Celsius. The oil phase was added dropwise to the aqueous phase. 1% of Zinc oxide was added to the prepared solution. The prepared emulgel was placed on a magnetic stirrer for 3 hours. The prepared gel was then filled into a containor, labelled and refrigerated.(14,15)

Table 2: Formulation table of emulgel formulation

Sr. No.	Ingredients	F1	F2
1	Aloevera(ml)	40	40
2	Neem oil (ml)	3.5	3.5
3	Coconut oil (ml)	4.0	4.0
4	Carbopol (gm)	1.0	2.0
5	Triethanolamine (ml)	1.0	1.0
6	Propylene glycol (ml)	7.5	7.5
7	Polyethylene glycol (ml)	10	10
8	Methyl Paraben(gm)	1.0	1.0
9	Propyl Paraben(gm)	1.0	1.0
10	Zinc Oxide(gm)	1.0	1.0
11	Water(ml)	q.s	q.s

Evaluation of the herbal components

Characteristic of neem oil and aloevera gel used

The characteristics such as physical state colour, odour and taste were checked and the results are depicted into table no.3 (15,16).

Construction of Calibration curve

Calibration curve of aloevera and neem oil: Preparation of standard solution: 1 ml of aloevera gel and neem oil were weighed accurately and each were dissolved in methanol in separate volumetric flasks .

Evaluation of the formulation

Physical characteristics of the emulgel

Physical appearance

Physical parameters such as colour and appearance were checked visually and the results are depicted in the table 3.

Determination of the pH

The developed formulations were evaluated for pH using a digital pH meter (Elico LI 617), the pH meter probe was immersed in the formulation for 5 minutes and then the readings were taken.

Spreadability test

Two glass plates of 5x20 cm and a weight of 30 gm were used for the study. About 100 mg of the test formulation was placed over one glass plate. Then the second glass plate was placed over the first glass plate in such a way that the formulation is sandwiched between the 2 glass plates. An extra weight of about 10gm was placed over the sandwiched glass plate for uniform spreading, then after five minutes, the diameter of the spread formulation was measured using as scale. An average of these readings were taken.

The formula for calculating the spreadability of a gel is

S=M x L/T where ;

S : spreadability

M: the weight in the pan, tied to the upper slide

L: Is the length moved by the glass slide T: Is the time taken to separate the slide completely from each other (17).

Viscosity determination

The viscosity of is an important factor to determine the rheological properties of the emulgel. The viscosity of emulgel can be determined by using the Brookfield Viscometer at 25 degree Celsius. The measurement over the whole range of speed setting from 10 rpm to 100 rpm with 30 sec between two successive speed (17).

Drug content determination

Each formulation was weighed 1ml accurately and transferred into a 10 ml of volumetric flask and volume was made up by using methanol as a solvent. The content was filtered out using a suitable filter paper and sonicated for 5 minutes 0.1 ml of solution was taken up from the above mixture and again the dilution was made upto 10 ml by using a volumetric flask.1 ml filtrate was taken and the drug content was estimated by using UV/Visible Spectrophotometer at 250 nm for neem and 205 nm for aloe.

Results and Discussion

Evaluation of the herbal components use formulation

Physical Characteristics of neem oil, aloevera gel

The physical characteristics such as colour, odour and taste of neem oil and aloevera gel were observed and the results were stated in table no.3

Table 3: Characteristics of herbal components

Sr. no.	Characteristic	Observation (Neem oil)	Observation (Aloevera gel)
1	Physical State	Liquid	Semisolid
2	Colour	Brown	Translucent
3	Odour	Pungent	No odour
4	Taste	Bitter	Characteristic

Construction of Calibration Curve

The construction of calibration curves of neem oil and aloevera in methanol were constructed so that the absorbance results collected through experimentation could be directly converted into concentration by extrapolating through the linearity range.

Figure 3: Calibration curve of neem oil in methanol at 250 nm

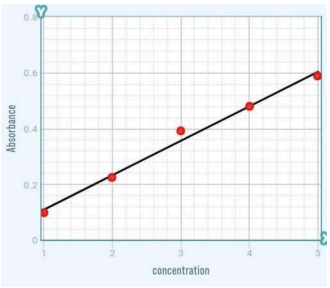
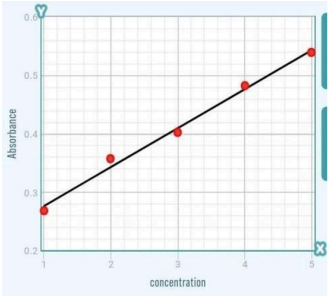


Figure 4: Calibration curve of aloevera gel in methanol at 205nm



Evaluation of the formulation

Figure 5: Formulation batch F1 and F2

Table 4: Characteristics of herbal components

Sr. No.	Physical Characteristics	Batch F1	Batch F2
1	Physical State	Semisolid	Semi-solid
2	Colour	Creamish brown	Creamish
3	Texture	Smooth	Smooth
4	Odour	Slightly pungent	Slightly
5	pH	6.88±0.88	6.95±0.97
6	Viscosity(cps)	4600±1.08	4097±1.12
7	Spreadability (gm cm/sec)	11.97±0.95	11.34±1.02
8	Drug Content	90.34%±1.14	91.48%±1.04
9	Phase Separation	Not observed	Not observed
10	Flocculation	Not observed	Not observed

Emulgel formulation

The emulgels were prepared by incorporation method. Polyethylene glycol and Propylene glycol were used as surfactants, coconut oil and neem oil were used as oil phase and water was used as external phase. To prepare the emulgel formulation oil phase was incorporated into the aqueous phase and then mixed by stirring continuously using magnetic stirrer. Samples in which no signs of phase separation, flocculation and sedimentation were visually observed and were selected as stable formulations. The emulgel prepared showed other physical characteristics such as physical state, colour, texture, odour as stated in table 4.

Physical characterization of Emulgel formulation

- **pH determination:** The pH values of 2 developed formulae was in the range 5-6 which is considered acceptable to avoid risk of irritation upon application to the skin and the results are tabulated in table no 4.
- **Viscosity determination:** The viscosity of the emulgel formulation was in the range 1,134-21,000 centipoises (cps) which is also considered acceptable as it displays the excellent rheological properties of a formulation, the results are tabulated in table no.4
- **Spreadability:** Spreadabilty is very important because it shows the behavior of the emulgel that comes out of the tube. The spreadability values shown in the table no. shows that all the polymers used gave gels spreadable with a little shear. The diameters of the extended circle ranged from 11.97 and 11.34 gm cm/sec for formulation F1 and F2. The data in the table no.4 revealed that increase in the spreadability was always associated with decrease in concentration of gelling agent

Conclusion

In this study, aloevera and neem oil containing emulgel was developed as a carrier for topical delivery containing the combination of different herbal drugs was successfully formulated.The emulgel was prepared by incorporation method using Carbopol as a gelling agent and surfactants such as Polyethylene glycol and propylene glycol and zinc oxide was also added for UV protection.The magnetic stirrer and sonicator showed to be a simple and efficient techniques for mixing and size reduction, it was concluded that the system exhibited uniformity and enhanced diffusion rate due to these techniques and the parameters effecting performance of the formulation were optimized.The emulgel was characterized by a pH range of 5-6 which was concluded as an optimized pH range to avoid irritation on skin surface.The viscosity of the formulation F1 and F2 shown optimized range for the excellent rheological properties of the formulation. The spreadability values characterized that the prepared emulgels are easily spraeadable with the application of little shear, it was concluded that the spreadability values are within the optimized range of 11-12. The emulgel exhibited the drug content within the optimum range 87.56-90.45% which cocluded efficient drug loading in the formulation.It was also observed that no phase separation and flocculation was exhibited by the formulation which showed that the formulation exhibits optimized uniformity. It was also concluded that formulation batch F2 was developed, as low viscosity was exhibited by formulation batch F1, the viscosity was improved by increasing the concentration of Carbopol as mentioned in table no. 1.It was also observed that introduction of the coconut oil to the formulation affected the gel's strength, gelling point and oil binding capacity of the formulation and also improved the viscosity of the formulation.

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