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THERAPEUTIC EVALUATION OF CANNABIDIOL NANO-CREAM IN UVB-INDUCED PSORIASIS RAT MODEL

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ABSTRACT

Psoriasis is a chronic inflammatory skin disease characterized by hyperproliferation of keratinocytes, immune cell infiltration, and erythematous plaques. This study aimed to evaluate the therapeutic efficacy of a cannabidiol (CBD) nano-cream in a UVB-induced psoriasis rat model. The nano-cream was formulated using a nanoemulsion-based system to enhance dermal delivery and sustained release of CBD. Characterization studies confirmed optimal pH, viscosity, spreadability, and high drug content. The anti-psoriatic potential was assessed by evaluating histopathological changes, Psoriasis Area Severity Index (PASI), and epidermal thickness in Wistar rats exposed to UVB radiation. Results demonstrated that the CBD nano-cream significantly reduced inflammation, erythema, and epidermal hyperplasia compared to control groups. The findings support the potential of CBD nano-cream as a promising topical therapeutic approach for the treatment of psoriasis.

Key words: Cannabidiol, Psoriasis, Nano-cream, UVB-induced model, Topical delivery, Wistar rats

1 INTRODUCTION

Psoriasis is a persistent autoimmune dermatological disorder typified by dysregulated keratinocyte hyperproliferation and a pronounced inflammatory milieu, afflicting a substantial portion of the global population and frequently necessitating prolonged therapeutic regimens. Although conventional pharmacological interventions—particularly topical corticosteroids such as Clobetasol propionate—demonstrate substantial efficacy in attenuating symptomatic manifestations, their extended utilization is frequently associated with deleterious cutaneous and systemic side effects[1-3]. As such, a paradigm shift toward the exploration of safer, phytotherapeutic alternatives is garnering increased scientific and clinical interest.

Cannabidiol (CBD), a non-psychoactive phytocannabinoid derived from *Cannabis sativa*, has emerged as a compelling candidate owing to its multifaceted pharmacodynamic properties, including potent antioxidative, anti-inflammatory, and emollient effects[2]. Furthermore, its interaction with the cutaneous endocannabinoid system underscores its potential in modulating immune responses and epidermal homeostasis pertinent to psoriatic pathophysiology. Nonetheless, the intrinsic physicochemical limitations of CBD—namely, its hydrophobicity and chemical instability—pose significant challenges for its effective incorporation into dermal drug delivery systems.[4-8]

Advancements in nanotechnological methodologies offer a viable resolution to these challenges, particularly through the development of nanoemulsion-based topical vehicles, which enhance CBD's solubility, augment percutaneous penetration, and ensure sustained release at the target site.[5,7-8] In this study, high-energy emulsification techniques were employed to fabricate CBD-loaded nano-creams with optimal colloidal stability and uniform nanoscale dispersion. Rigorous physicochemical characterization, antioxidative profiling, and in vivo anti-psoriatic efficacy studies

were undertaken to establish the therapeutic validity of the formulation.[9-10]

The resultant findings elucidate the potential of nanostructured CBD formulations as innovative and efficacious alternatives to conventional psoriasis therapies. These nano-carrier systems present a harmonized balance between therapeutic potency and safety, marking a significant advancement in the realm of chronic inflammatory dermatologic therapeutics.

2 MATERIALS AND METHODS

2.1 Materials

The drug Cannabidiol was purchased from HempCann Solutions Pvt Ltd. Polyvinayl alcohol, Sodium lauryl sulphate, ethanol were purchased from Sigma-Aldrich, Mumbai.

2.2 Method

2.2.1 Formulation of cannabidol nanocream

Cannabidol nanocream was prepared using a high-energy emulsification method involving high-shear stirring with a mixer. The process began by mixing cetyl alcohol with Cannabidol and stirring the mixture at 350 rpm on a hotplate stirrer set to 55°C for 30 minutes. Concurrently, methyl paraben and propyl paraben were dissolved in distilled water and heated on a hotplate until fully dissolved, then allowed to cool. Tween 80 and propylene glycol were added to the cooled paraben solution and stirred with a magnetic stirrer at 350 rpm for 30 minutes. This water phase was gradually poured into the oil phase, and the resulting mixture was stirred at 2000-3000 rpm for 8 hours to form a thick emulsion. The emulsion was then homogenized with a mixer for 30 minutes. Finally, a few drops of rose-scented perfume were added, and the mixture was blended thoroughly with a mixer to achieve a homogeneous cream mass. (Table 1)

Table 1: Formulation of Cannabidol Nanocream

Materials	F1	F2	F3	F4	F5
Cannabidol	-	2	4	6	8
Tween 80	30	30	30	30	30
Propylene glycol	5	5	5	5	5
Cethyl alcohol	0.5	0.5	0.5	0.5	0.5
Methylparaben	0.1	0.1	0.1	0.1	0.1
Propylparaben	0.05	0.05	0.05	0.05	0.05
Distilled Water	100ml	100ml	100ml	100ml	100ml

2.2.2 Preparation of Cannabidol Cream

The oil phase, consisting of 14% stearic acid and 0.2% cetyl alcohol, is melted over a water bath and poured into a hot mortar. This mixture is then combined with 10% cannabidol in the hot mortar and stirred until homogeneous. For the water phase, dissolve 0.1% methylparaben, 10% glycerin, and 1% TEA in the remaining distilled water. Heat this mixture on a water bath until fully dissolved, then allow it to cool. Gradually pour the cooled water phase into the oil phase in the hot mortar, mixing continuously until a homogeneous cream mass forms. Finally, add a few drops of rose-scented perfume and stir until evenly distributed.

2.2.3 Volunteer irritation test

Cosmetics were applied behind the ear and left for 24 hours. Observations were made for any changes, such as redness, itching, or roughness of the skin.

2.3 Anti-Psoriasis Activity

2.3.1 Mouse-tail model for psoriasis

All procedures of the study were conducted in accordance with the guidelines set by the CPCSEA and an approved IAEC protocol number (IAEC-17-019). Fifteen male Swiss albino mice were allowed to acclimatize for 5 days and were randomly assigned to three groups: six mice in Group I (standard group, treated with Clobetasol propionate 0.05% cream), six mice in Group II (Cannabidol NLC-loaded cream), and six mice in Group III (placebo control).

The samples were applied locally to the tails at a rate of 2-5 mg per animal, uniformly to the proximal part of the tail. A plastic cylinder was placed over the tail and fixed with adhesive tape to ensure a contact time of 2 hours. After this period, the cylinders were removed, and the tails were wiped with cotton. The mice were treated once daily for 2 weeks.

Two hours after the last treatment, the animals were sacrificed, and the tails were fixed in 10% buffered formalin and processed for histopathology. Longitudinal sections of about 5 μm thickness were prepared, stained with hematoxylin-eosin, and permanent slides were prepared for evaluation. The sections were examined under a light microscope to observe alterations in epidermal thickness, elongation of ridges, and orthokeratosis. The animals were also observed for mortality, clinical signs, and changes in body weight.[11-14]

2.4 Rat Ultraviolet Ray B Photo Dermatitis Model for Psoriasis

Healthy male Sprague Dawley rats weighing 150-200 grams were kept in a 12-hour light/12-hour dark cycle at a temperature of 20.4 to 23.8 °C and a relative humidity of 36 to 61%. The rats were provided with food and reverse osmosis water treated with ultraviolet light ad libitum. All procedures were conducted in accordance with the guidelines set by the CPCSEA and an approved IAEC protocol number (IAEC-17-009).

The study design included three groups: Group I (6 animals) received 2-5 mg/kg of Clobetasol propionate 0.05% cream as the standard treatment, Group II (6 animals) received 2-5 mg/kg of Cannabidol loaded cream, and Group III (3 animals) received 2-5 mg/kg of placebo cream. The hair on the dorsal skin of the rats was clipped and carefully shaved. An area of 1.5 x 2.5 cm on one side of the flank was irradiated for 15 minutes (1.5 J/cm²) at a vertical distance of 20 cm with UV-B lamps, resulting in biphasic erythema.

After 72 hours, the test anti-psoriatic cream, standard cream, and placebo cream were applied topically at 2-5 mg/rat on the irradiated site once daily. The irradiated rats were sacrificed on day 11 after UV-B irradiation using CO2 anesthesia. Skin biopsies were immediately taken, fixed in 10% formalin, and embedded in paraffin. Tissue sections (4 μm thick) were stained with hematoxylin and eosin and examined under a light microscope to observe alterations in epidermal thickness, elongation of ridges, and orthokeratosis. The study also evaluated mortality, clinical signs, and body weight changes. Data were analyzed using one-way ANOVA followed by Dunnett's Multiple Comparison test.[11, 13-15]

3 RESULT AND DISCUSSION

3.1 Results of The Irritation Test on Volunteers

The irritation test for nanocream and cream preparations was conducted on 12 volunteers according to specified requirements. The preparations were applied to the back of the volunteers' ears and left for 24 hours. The volunteers were divided into two groups: 6 volunteers received nanocream with a 10% canola oil concentration, and the other 6 received cream with a 10% canola oil concentration. Neither the nanocream nor the cream showed any signs of primary or secondary irritation, such as redness, itching, or skin roughening, after 24 hours. Thus, it can be concluded that both the nanocream and cream preparations are safe to use.

3.2 Ani-Psoriasis Activity

3.2.1 Mousetail model for psoriasis

Advanced anti-psoriatic studies were conducted on animal models to evaluate and compare the safety and efficacy of a nanoparticulate anti-psoriatic cream loaded with AE, PE, and CE cream versus Clobetasol propionate 0.05% cream. These studies utilized the mouse tail method for topical applications in psoriasis.

Compared to the normal control group, the mice treated with the standard drug (Clobetasol propionate 0.05% cream) and the test drug (Cannabidol based nanocream) showed a significant reduction in epidermal thickness of the tail skin. Based on these results, it can be concluded that both the standard and test drug formulations may possess potential anti-psoriatic activity. (Figure 1)

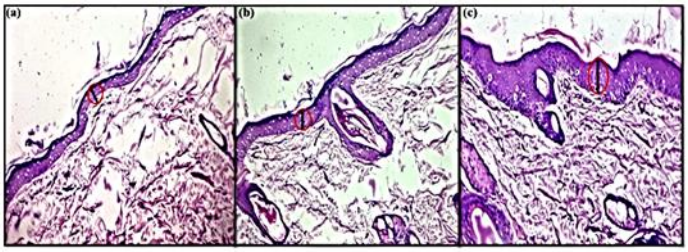

Figure 1: Histopathology of mice tail skin for, a) Standard Group I, b) Test group II, c) Placebo group III

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3.3 Rat Ultraviolet Ray-B Photodermatitis Model for Psoriasis

The Rat Ultraviolet Ray-B photodermatitis model was used to evaluate the antipsoriatic potential of a anti-psoriatic cream compared to Clobetasol propionate 0.05% cream. Compared to the normal control group, the rats treated with the standard drug (Clobetasol propionate 0.05% cream) and the test drug (Cannabidol loaded nanocream) exhibited a significant reduction in epidermal thickness and inflammatory changes. Based on these results, it can be concluded that both the standard and test drug formulations have potential anti-psoriatic activity. (Figure 2)

4 CONCLUSION

This study provides compelling evidence that the CBD-loaded nano-cream is an effective topical treatment for managing psoriasis symptoms. The formulation demonstrated desirable physicochemical properties such as appropriate pH, high spreadability, viscosity suitable for skin application, and nearly complete drug entrapment. The sustained release profile observed in vitro ensured prolonged drug availability at the site of action, which is crucial for chronic conditions like psoriasis.

In vivo studies further confirmed the therapeutic efficacy of the CBD nano-cream in a UVB-induced psoriasis rat model. There was a significant improvement in clinical symptoms, with a notable reduction in erythema, scaling, and skin thickness. Histopathological examination revealed a decrease in epidermal hyperplasia and inflammatory cell infiltration in treated animals compared to disease controls. These findings underline the anti-inflammatory and antiproliferative action of CBD when delivered in a nano-formulated cream.

Overall, the research highlights the potential of CBD nano-cream as a novel and effective strategy for topical psoriasis therapy. Given the favorable outcomes observed in preclinical studies, future research should aim at evaluating the long-term safety, stability, and clinical efficacy in human trials to pave the way for therapeutic application in dermatology.

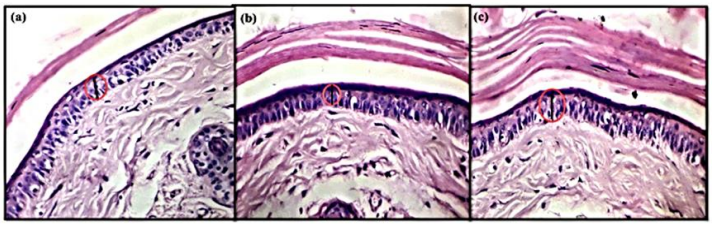

Figure 2: Histopathology of Rat Skin for, a) Standard group I, b) Test group II, c) Placebo group III

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