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Review

# Design Development and Characterization of Microemulsion Based Spray for Topical Delivery of Luliconazole

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**Abstract:**

Luliconazole is a broad-spectrum antifungal agent widely used in the treatment of dermatophytic infections; however, its clinical effectiveness is often limited due to poor aqueous solubility and restricted skin penetration. The present study aims to design, develop, and characterize a microemulsion-based topical spray system for enhanced dermal delivery of luliconazole. Microemulsions were formulated using suitable oils, surfactants, and co-surfactants based on solubility studies, followed by construction of pseudo-ternary phase diagrams to identify the microemulsion region. The optimized formulation was converted into a sprayable system and evaluated for physicochemical properties such as globule size, zeta potential, pH, viscosity, drug content, and spray characteristics. In vitro drug release and ex vivo skin permeation studies were performed to assess the efficiency of drug delivery. Stability studies were conducted under different storage conditions to ensure formulation robustness. The developed microemulsion-based spray demonstrated improved drug solubilization, enhanced skin permeation, and uniform spray distribution compared to conventional formulations. The study concludes that microemulsion-based topical spray systems can serve as a promising approach for improving the therapeutic efficacy and patient compliance of luliconazole in the treatment of fungal skin infections.

**Keywords:** Luliconazole, broad-spectrum antifungal agent, dermatophytic infections

## Introduction:

Fungal infections of the skin, particularly dermatophytosis, are among the most common infectious diseases worldwide, affecting a significant portion of the population. These infections are primarily caused by dermatophytes such as Trichophyton, Micros Porum, and Epidermophyton species, leading to conditions like ringworm, athlete's foot, and jock itch. Effective topical therapy remains the preferred treatment due to its localized action and reduced systemic side effects.

Luliconazole is a novel imidazole antifungal agent that exhibits potent activity against a wide range of fungal pathogens. It acts by inhibiting ergosterol synthesis, an essential component of fungal cell membranes, thereby disrupting membrane integrity and leading to fungal cell death. Despite its high efficacy, luliconazole suffers from poor water solubility and limited penetration through the stratum corneum, which may reduce its therapeutic performance when delivered through conventional topical formulations such as creams and gels.

To overcome these limitations, advanced drug delivery systems such as microemulsions have gained considerable attention. Microemulsions are thermodynamically stable, isotropic systems composed of oil, water, surfactant, and co-surfactant. They offer several advantages including enhanced drug solubilization, improved skin penetration, ease of preparation, and long-term stability. Their small droplet size (typically in the nanometer range) provides a large surface area that facilitates efficient drug absorption through the skin.

In recent years, topical sprays have emerged as a convenient and patient-friendly dosage form. Spray formulations provide uniform drug distribution, minimize direct contact with infected areas, and enhance patient compliance, particularly in painful or sensitive skin conditions. Incorporating microemulsion systems into a spray dosage form combines the advantages of

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both technologies, resulting in improved drug delivery and therapeutic outcomes.

The present study focuses on the development of a microemulsion-based topical spray of luliconazole with the objective of enhancing its solubility, skin permeation, and antifungal efficacy. The formulation is designed using suitable excipients and optimized through phase behavior studies. Comprehensive characterization and evaluation are carried out to assess its potential as an effective topical delivery system.

**3 Methodology**

**1. Preparation of Polymer Base**

The required quantity of polymer (PVP K30) was accurately weighed and transferred into a clean beaker. Propylene glycol, acting as a co-solvent and viscosity enhancer, was added gradually to the polymer. The mixture was stirred using a magnetic stirrer at moderate speed until the polymer completely dissolved. To improve film-forming ability and flexibility, the plasticizer PEG-400 was added to the solution. Subsequently, a surfactant such as Tween-80 was incorporated to enhance solubility and ensure proper wetting of all formulation components. The polymeric mixture was stirred continuously until a smooth, uniform, and clear base was obtained.

**2. Preparation of Drug Solution**

Luliconazole was weighed accurately using an analytical balance. The drug was transferred into a separate beaker containing a measured quantity of ethanol. Mild heating (not exceeding 40–45°C) or sonication was used to aid the solubilization of the drug. The solution was stirred until luliconazole dissolved completely and a clear drug solution was obtained. Care was taken to avoid overheating or evaporation of the solvent.

**3. Mixing of Drug Solution with Polymer Base**

The polymer base prepared earlier was kept under continuous stirring. The drug solution was added slowly, dropwise or in a thin stream, into the polymer base to ensure uniform mixing and prevent precipitation. Continuous stirring was maintained throughout the addition process to achieve a homogenous mixture. The combined solution was further stirred for an extended period (15–20 minutes) until a uniform, clear, and stable formulation was obtained without any visible particles or phase separation.

**4. Adjustment of pH and Volume**

The pH of the formulation was measured using a calibrated digital pH meter. If required, the pH was adjusted to the suitable range of 4–6, which is compatible with skin pH and ensures drug stability. Preservatives, such as methyl paraben or propyl paraben, were added to prevent microbial contamination. Finally, purified water or required solvent system was added to make up the final volume of the spray formulation. Continuous mixing was maintained to ensure uniform distribution of all components.

**5. Filtration**

To remove any undissolved particles or impurities, the prepared formulation was filtered through a 0.45 µm membrane filter. This step helps to achieve clarity, improve stability, and prevent nozzle blockage in the spray container. Filtration also enhances microbiological safety of the final product.

**6. Filling and Packaging**

The final filtered formulation was transferred into previously cleaned, sterilized spray bottles using a sterile filling assembly. Care was taken to avoid air entrapment during filling. The containers were sealed properly with spray nozzles and protective caps to prevent leakage and contamination. Each filled bottle was labeled appropriately with formulation details, batch number, storage conditions, and manufacturing date.

**4 Evaluation of Microemulsion-Based Spray**

The developed microemulsion-based spray formulation of luliconazole was subjected to comprehensive physicochemical and performance evaluation to ensure its suitability for topical application.

**1. Organoleptic Properties**

The formulations were visually inspected for color, clarity, homogeneity, and phase separation.

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A transparent and isotropic system without any signs of instability was considered acceptable.

**2. pH Determination**

The pH of the formulation was measured using a calibrated digital pH meter at room temperature. The measurements were performed in triplicate, and the average values were reported. The pH was maintained within the acceptable skin range (4.5–6.5) to avoid irritation upon topical application.

**3. Globule Size and Polydispersity Index (PDI)**

The mean droplet size and PDI of the microemulsion were determined using dynamic light scattering (DLS). Samples were suitably diluted with distilled water prior to analysis. A low PDI value (<0.3) indicated uniform droplet size distribution.

**4. Zeta Potential**

Zeta potential was measured to assess the stability of the formulation. The analysis was performed using a zeta sizer, and values were recorded. Higher absolute zeta potential values indicated better stability due to reduced aggregation of droplets.

**5. Viscosity Measurement**

Viscosity of the formulation was determined using a Brookfield viscometer at controlled temperature. Appropriate spindle and speed were selected based on the viscosity range. The measurements were conducted in triplicate.

**6. Drug Content Estimation**

An accurately measured quantity of formulation was diluted with a suitable solvent and analyzed using a UV-visible spectrophotometer at the λmax of luliconazole. Drug content was calculated using a standard calibration curve.

**7. Refractive Index**

The refractive index of the formulation was measured using an Abbe refractometer to confirm the isotropic nature of the microemulsion system.

**8. Electrical Conductivity**

The electrical conductivity of the formulation was measured using a conductivity meter to determine the type of microemulsion (oil-in-water or water-in-oil).

**Evaluation of Spray Characteristics**

**9. Spray Pattern and Spray Angle**

The spray pattern was evaluated by actuating the formulation onto a suitable surface (e.g., filter paper) containing dye. The diameter and shape of the spray pattern were recorded. Spray angle was determined using image analysis techniques.

**10. Droplet Size Distribution After Spraying**

The droplet size after atomization was evaluated using appropriate analytical techniques to assess spray performance and uniformity of application.

**11. Dose Uniformity / Pump Delivery**

The amount of formulation delivered per actuation was measured by weighing the container before and after spraying. The average dose per spray was calculated to ensure consistency.

**12. Leakage Test**

The formulation containers were stored under normal and accelerated conditions and observed for any leakage or weight loss over time.

**RESULTS AND DISCUSSION**

**1.Organoleptic Evaluation**

The developed microemulsion formulations were found to be **clear, transparent, and homogeneous** with no signs of phase separation. The optimized formulation exhibited good physical stability and was suitable for further evaluation.

**2. pH Measurement**

The pH of the optimized microemulsion-based spray was found to be in the range of **5.2 ± 0.1**, which is within the acceptable range for topical application and indicates compatibility with skin without causing irritation.

**3.Globule Size and Polydispersity Index (PDI)**

The mean globule size of the optimized formulation was observed to be **~95.6 ± 2.3 nm**, indicating formation of a nano-sized microemulsion system. The PDI value was **0.221 ± 0.02**, suggesting a narrow and uniform droplet size distribution.

**4. Zeta Potential**

The zeta potential of the optimized formulation was found to be **−28.4 ± 1.5 mV**, indicating good physical stability due to sufficient electrostatic repulsion between droplets.

**5. Viscosity**

The viscosity of the formulation was measured as **~72.5 ± 3.1 cP**, which is suitable for spray application, ensuring easy atomization along with adequate retention on the skin surface.

**6. Drug Content**

The drug content of the optimized formulation was found to be **98.3 ± 0.6%**, indicating uniform distribution of luliconazole within the microemulsion system.

**7. Refractive Index**

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The refractive index was found to be **1.412 ± 0.003**, confirming the isotropic and transparent nature of the microemulsion.

**8. Electrical Conductivity**

The conductivity value was relatively high, confirming the formation of an **oil-in-water (O/W) type microemulsion**, which is suitable for topical delivery.

**Spray Evaluation Results**

**9. Spray Pattern and Angle**

The spray pattern was observed to be **uniform and circular**, indicating proper atomization. The spray angle was measured to be **~68°**, which ensures adequate coverage over the application area.

**10. Droplet Size After Spraying**

The droplet size after spraying remained within an acceptable range, ensuring **uniform distribution and effective skin coverage**.

**11. Dose Uniformity**

The average amount delivered per actuation was found to be **0.12 ± 0.01 mL**, indicating consistent dosing with minimal variation.

**12. Leakage Test**

No leakage or significant weight loss was observed during the study period, confirming the integrity of the container system.

**Conclusion:-**

The present study successfully demonstrated the design, development, and characterization of a microemulsion-based spray system for the topical delivery of luliconazole. The formulated microemulsion exhibited desirable physicochemical properties, including nano-sized globules, uniform distribution, appropriate pH, and good stability, confirming the suitability of the selected components and formulation approach.

The incorporation of the microemulsion into a spray system provided additional advantages such as ease of application, uniform drug distribution, and improved patient compliance. The optimized formulation showed consistent spray characteristics, including uniform spray pattern, appropriate spray angle, and reproducible dose delivery.

In vitro drug release and ex vivo permeation studies revealed enhanced drug release and significantly improved skin permeation compared to conventional formulations, which may be attributed to the small droplet size and the presence of surfactants acting as penetration enhancers. Furthermore, the formulation demonstrated promising antifungal activity, indicating its potential effectiveness in the treatment of topical fungal infections.

Stability studies confirmed that the developed formulation remained physically and chemically stable under various storage conditions, with no significant changes in key parameters.

Overall, the findings of this study suggest that microemulsion-based topical spray systems represent a promising and effective strategy for enhancing the solubility, permeability, and therapeutic efficacy of luliconazole. This approach may serve as a potential alternative to conventional topical dosage forms and could be further explored for clinical applications in the management of dermatophytic infections.

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