Review Article

Microemulgel-Based Topical Delivery of Luliconazole and Calamine for Tinea Pedis: A Comprehensive Review

Abinesh P H*[1], Kenneth N, Annis Bala Priya M[2], Bhasith Raihan S H[2], Dona Catherine L[2], Muniyappan S[2], Shamini R[2], Kenneth N[3]

[1]Assistant Professor, Department of Pharmaceutics, Immanuel Arasar College of Pharmacy, Nattalam, Tamilnadu, India.

[2]B. Pharm Student, Immanuel Arasar College of Pharmacy, Nattalam, Tamilnadu, India.

[3]Principal, Department of Pharmacy Practice, Immanuel Arasar College of Pharmacy, Nattalam, Tamilnadu, India.

***Corresponding author's E-mail:** abinesh406@gmail.com

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ABSTRACT

Tinea pedis is one of the most common superficial fungal infections worldwide and is primarily caused by dermatophytes such as *Trichophyton rubrum* and *Trichophyton interdigitale*. Conventional topical antifungal formulations often exhibit limitations including poor drug solubility, inadequate skin penetration, and reduced patient compliance. Microemulgel systems have emerged as promising topical drug delivery platforms that combine the enhanced solubilization and permeation properties of microemulsions with the favourable rheological characteristics of gels. This review highlights the formulation rationale and therapeutic potential of a luliconazole–calamine microemulgel for the management of tinea pedis. Luliconazole, a broad-spectrum imidazole antifungal agent, inhibits lanosterol 14α-demethylase, thereby disrupting ergosterol biosynthesis and fungal cell membrane integrity. Calamine provides complementary antipruritic, soothing, and protective effects that help alleviate symptoms associated with fungal infections. The incorporation of luliconazole into a microemulgel system enhances drug solubility, improves skin permeation, and facilitates sustained drug release, while the gel base improves spreadability and patient acceptability. Critical formulation parameters including pH, viscosity, particle size, polydispersity index, zeta potential, spreadability, drug content analysis, and in vitro drug release are discussed. Overall, the luliconazole–calamine microemulgel represents a promising topical delivery approach with the potential to improve therapeutic efficacy, symptom relief, and patient compliance in the treatment of tinea pedis.

Keywords: Tinea pedis, Luliconazole, Calamine, Microemulgel, Topical drug delivery, Antifungal therapy.

INTRODUCTION

Superficial fungal infections of the skin are among the most common dermatological disorders and are primarily caused by dermatophytes, yeasts, and non-dermatophyte fungi that infect keratinized tissues. Tinea pedis (athlete's foot) is one of the most common superficial fungal infections worldwide and is predominantly caused by *Trichophyton rubrum* and *Trichophyton interdigitale*. The infection commonly develops in warm and moist environments and is characterized by symptoms such as pruritus (itching), erythema (redness), scaling, and fissuring of the skin. If left untreated, tinea pedis may spread to adjacent areas and can predispose patients to secondary bacterial infections. Early diagnosis and appropriate antifungal therapy are essential for effective management and prevention of complications[1,2].

Topical drug delivery systems, particularly gels, offer several advantages over oral administration, including localized drug delivery, improved patient compliance, and avoidance of first-pass metabolism. However, traditional topical agents like ointments and creams have drawbacks such as discomfort and stability issues. Gels, defined as semisolid formulations, are increasingly used in managing skin diseases due to their efficacy and safety. They enable localized drug delivery but have limitations in incorporating hydrophobic drugs. Combining microemulsions with gels can overcome this limitation, enhancing drug absorption and stability. Recent research focuses on formulating microemulsion-based gels for effective topical delivery of drugs[3,4,5].

Luliconazole is an optically active imidazole antifungal agent known for its broad-spectrum antifungal activity, particularly against pathogenic fungi such as dermatophytes. Its mechanism of action involves the inhibition of lanosterol 14α-demethylase, which is a crucial enzyme in the ergosterol biosynthesis pathway. By interfering with this biosynthesis process, luliconazole effectively disrupts the formation of ergosterol, a vital component of fungal cell membranes, thereby exerting its antifungal effects[6].

Calamine is commonly used in dermatological products for its protective and soothing effects. It possesses astringent, antipruritic, mild antiseptic, soothing, and protective properties, making it effective for treating various skin conditions. Combining calamine with luliconazole can provide antifungal activity and symptomatic relief. Additionally, using these agents in a microemulgel system enhances drug solubility, stability, skin penetration, and retention, improving therapeutic efficacy and patient acceptability[7].

This review provides a comprehensive overview of luliconazole–calamine microemulgel as a promising topical drug delivery system for the management of tinea pedis. It discusses the aetiology and treatment of tinea pedis, the principles and advantages of microemulsion and microemulgel systems, the therapeutic roles of luliconazole

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and calamine, and the evaluation parameters used to assess formulation performance, stability, and therapeutic efficacy.

TINEA PEDIS

Tinea pedis, commonly known as athlete's foot, affects approximately 3% of the global population at any given time. This fungal infection is believed to have become prevalent in the late nineteenth and early twentieth centuries due to the increasing popularity of occlusive footwear, which creates a suitable environment for the fungi to thrive. Statistically, tinea pedis is more frequently observed in men compared to women and is relatively rare among children. The infection typically targets the lateral toes, with a particular propensity for the interdigital space between the fourth and fifth toes, where the conditions are conducive to fungal growth[1].

Etiology

Tinea pedis is predominantly associated with dermatophytes, particularly *Trichophyton rubrum* and *Trichophyton interdigitale* being the most prevalent pathogens. The specific organisms involved can vary based on geographic regions, local climate, and sociocultural factors. Other fungi that can cause tinea pedis, though less commonly, include *Epidermophyton floccosum*, *Trichophyton tonsurans*, *Trichophyton soudanense*, *Trichophyton violaceum*, and *Microsporum audouinii*. Additionally, certain non-dermatophyte moulds, such as *Neoscytalidium hyalinum, Neoscytalidium dimidiatum, Scopulariopsis brevicaulis*, and species of *Fusarium*, have been observed as contributors to the infection, albeit at a lower frequency. In rare instances, tinea pedis has also been linked to *Cylindrocarpon lichenicola* and various *Candida* species, which are classified as yeasts. Overall, while dermatophytes dominate the aetiological landscape of tinea pedis, the involvement of non-dermatophyte fungi and yeasts illustrates the complexity of this common fungal infection[1,8].

Pathophysiology

The pathophysiology of tinea pedis involves the invasion and colonization of keratinized tissues by dermatophytic fungi. The causative fungi produce enzymes such as proteases and keratinases that digest keratin, thereby facilitating penetration into keratinized tissues. The fungal hyphae invade the stratum corneum and spread outward through the keratin layer. The infection generally remains confined to the superficial cornified layers of the skin because these fungi are unable to penetrate deeper tissues in immunocompetent individuals. Inflammatory responses result in accelerated epidermal turnover and scaling. Furthermore, the fungal cell wall contains mannans that suppress the host immune response, reduce lymphoproliferative activity, and decrease keratinocyte proliferation. Reduced keratinocyte turnover limits the shedding of infected skin, thereby prolonging the infection. Warm and moist conditions, particularly excessive sweating, further enhance fungal growth and persistence[1,2,8].

Clinical Manifestations

Tinea pedis is classified into four distinct clinical types: interdigital, hyperkeratotic (moccasin type), vesiculobullous, and ulcerative, each characterized by specific patterns of skin manifestations.

1. **Interdigital Tinea Pedis:**

   It is the most prevalent type, particularly in adult males, presenting with maceration, desquamation, and fissuring between the toes.

2. **Hyperkeratotic (moccasin-type):**

   It is the second most common form of tinea pedis, manifesting as diffuse scaling and erythema on the sole and medial aspect of the foot.

3. **Vesiculobullous (inflammatory):**

   It is characterized by pruritic vesicles and bullae against an erythematous background on the dorsal surface of the foot.

4. **Ulcerative Tinea Pedis:**

   It is a rare condition associated with rapidly spreading interdigital erosions and ulcers, which are more severe than those found in vesiculobullous tinea pedis[1].

Diagnosis

The diagnosis of tinea pedis is primarily based on clinical examination; however, laboratory confirmation is often required to establish a definitive diagnosis. This is typically achieved through potassium hydroxide (KOH) wet-mount examination of skin scrapings, allowing for the visualization of septate fungal hyphae. While effective, KOH cannot identify specific dermatophyte species or assess fungal viability. Fungal culture is the gold standard for determining the causative organism, though it is labor-intensive and takes 7-14 days for results. Newer methods such as reflectance confocal microscopy and multiplex polymerase chain reaction (PCR) demonstrate high sensitivity and rapid detection of fungal pathogens, but are limited by costs and availability[1].

Treatment

1. **General measures:**

Several preventive measures are recommended for tinea pedis. Patients should keep feet clean and dry, wear breathable footwear, and avoid sharing shoes. Good hygiene and regular drying of interdigital spaces are crucial. Disinfecting footwear and socks can prevent reinfection, as dermatophytes can survive in shoes. Antiseptic or antifungal powders may be used to manage moisture, and treatment for hyperhidrosis is recommended[1].

2. **Topical antifungal therapy:**

Topical antifungal therapy is essential for the treatment of localized tinea pedis, typically administered once or twice daily for 1–6 weeks. Both azoles and allylamines are effective, often outperforming placebo. Common side

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effects include pruritus and burning, and poor compliance can lead to relapses; adherence may improve with once-daily dosing. Antifungal resistance can arise from non-dermatophyte mould infections or genetic mutations. Future research is expected to focus on new formulations for better drug delivery[1].

3. Systemic antifungal therapy:

Systemic antifungal therapy is recommended for severe or resistant tinea pedis, particularly in immunocompromised patients and those with onychomycosis. Dosage and duration of oral antifungals depend on infection severity and patient factors. While commonly used agents show similar efficacy, newer therapies may offer better effectiveness and tolerability. Combining topical and systemic antifungals can enhance cure rates in difficult cases[1].

TOPICAL DRUG DELIVERY SYSTEM

Topical drug delivery systems are pharmaceutical formulations designed to deliver drugs to the skin or mucosal surfaces for localized therapeutic effects. They are primarily classified into two categories: external and internal topical formulations. External formulations are directly applied to the skin through methods such as spreading or spraying to treat specific diseased areas. Internal formulations are intended for application to mucous membranes, including oral, vaginal, and rectal tissues, to achieve localized therapeutic action. This classification is important for optimizing drug delivery, improving treatment efficacy, and minimizing systemic side effects[9].

Topical drug delivery systems offer several advantages, including the avoidance of first-pass metabolism and gastrointestinal incompatibilities. They provide site-specific drug delivery, enhance patient compliance, and facilitate self-administration. Furthermore, they are suitable for drugs with short biological half-lives and narrow therapeutic indices. An additional advantage is the ease of discontinuing therapy whenever necessary by removing the formulation from the application site[10].

Despite their widespread use, conventional topical formulations such as ointments, creams, and lotions have certain disadvantages. Their sticky or greasy nature may cause discomfort during application and reduce patient acceptability. These formulations often require rubbing due to their lower spreading ability and may also be associated with stability-related issues[10].

Classification of topical drug delivery systems

Topical drug delivery systems allow for drug administration via the skin and can be classified into solid, semisolid, and liquid formulations. Recent advancements include microemulsions, nanoemulsions, liposomes, transdermal patches, and microemulgels, all of which improve drug permeation and therapeutic effectiveness[3].

Skin as a target site for drug delivery

Skin is one of the largest organs of the human body and performs several essential functions while serving as the first line of defense against external factors. The skin also has the ability to absorb topically applied drugs; therefore, its acceptance as an ideal route for drug delivery is increasing for a variety of drug molecules[9,11].

Structure of Skin

The skin is composed of three major layers: the epidermis, dermis, and subcutaneous tissue (hypodermis). Each layer possesses distinct structural and functional characteristics that influence the permeation and absorption of topically applied drugs[9,11].

Epidermis

The epidermis is the outermost skin layer that functions as a protective barrier. It comprises stratified squamous epithelial cells and is avascular, consisting of five layers: stratum corneum, stratum lucidum, stratum granulosum, stratum spinosum, and stratum basale. The stratum corneum is crucial for regulating drug penetration through the skin[9,11].

Dermis

The dermis, beneath the epidermis, consists of papillary and reticular layers, containing proteins such as collagen and elastin that improve skin strength and elasticity. It also houses hair follicles, glands, and blood vessels, which are essential for supplying oxygen and nutrients to the epidermis and are crucial for thermoregulation, wound healing, and skin repair[9,11].

Subcutaneous Tissue (Hypodermis)

The subcutaneous tissue, or hypodermis, is the skin's deepest layer, situated beneath the dermis. Composed mainly of adipose and connective tissue, it offers cushioning and mechanical protection, acts as an energy reserve, and assists in maintaining body temperature through insulation[9,11].

Penetrability of the skin

The penetration of topically applied drugs through the skin requires the drug molecules to traverse multiple skin layers before reaching the target site or systemic circulation. The primary pathways of skin penetration include intercellular, transcellular, and follicular routes[12,13].

1. **Intercellular pathway:** This is the most common route of drug permeation, where drug molecules diffuse through the lipid matrix present between adjacent cells of the stratum corneum.
2. **Transcellular pathway:** In this route, drug molecules pass directly through the epithelial cells by crossing both cellular and lipid domains.
3. **Follicular pathway:** Drug molecules penetrate through hair follicles and associated sebaceous glands,

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providing an alternative route that can bypass portions of the stratum corneum barrier[12,13].

Role of stratum corneum barrier

The stratum corneum is the outermost layer of the epidermis and serves as the primary barrier to drug permeation through the skin. It consists of keratinized corneocytes embedded within a lipid matrix, often described as a "brick-and-mortar" structure. This barrier protects the body from external environmental factors and prevents excessive water loss. However, it also limits the penetration of many therapeutic agents, making effective transdermal and topical drug delivery challenging. Therefore, various formulation strategies, including microemulsions and microemulgels, are developed to enhance drug permeation across the stratum corneum and improve therapeutic efficacy[14].

MICROEMULSION

Microemulsions are thermodynamically stable, optically clear, isotropic dispersions of two immiscible liquids, such as oil and water, stabilized by an interfacial film of surfactants, often in combination with co-surfactants. They are characterized by nanosized droplets, typically ranging from 10 to 100 nm in diameter, which contribute to enhanced drug solubilization, improved skin permeation, and increased bioavailability[13,15].

Microemulsions are classified into three types based on their composition:

a. **Oil-in-water (O/W) microemulsions:** Oil droplets dispersed in a continuous aqueous phase.

b. **Water-in-oil (W/O) microemulsions:** Water droplets dispersed in a continuous oil phase.

c. **Bicontinuous microemulsions:** A system in which both oil and water form continuous phases separated by a surfactant film[13,14].

Components of microemulsion

Microemulsions are stable systems composed of four key components: oil phase, aqueous phase, surfactant, and co-surfactant. The selection of these components significantly influences the stability, solubilization capacity, and drug delivery performance of the system.

Oil phase: The oil phase is responsible for solubilizing lipophilic drugs and enhancing their permeation through the skin. Commonly used oils include mineral oil, oleic acid, isopropyl myristate, and various vegetable oils, selected based on drug compatibility and solubility.

Aqueous phase: The aqueous phase generally consists of water or buffer solutions, which support the dissolution of hydrophilic drugs and aid in drug release from the system.

Surfactant: The surfactant is a key component that reduces interfacial tension between the oil and water phases and stabilizes the microemulsion by forming a flexible interfacial film.

Co-surfactant: The co-surfactant, often a short-chain alcohol or glycol, works synergistically with the surfactant to further reduce interfacial tension and increase the flexibility of the interfacial layer, thereby facilitating microemulsion formation[13,15].

MICROEMULGEL

Microemulgels are advanced topical drug delivery systems formed by incorporating a microemulsion into a gel matrix. They combine the advantages of both microemulsions and gels, enabling the effective delivery of hydrophilic as well as lipophilic drugs. The nanosized droplets present in the microemulsion enhance drug solubility, skin permeation, and bioavailability by providing a large surface area for absorption. Incorporation into a gel base improves formulation stability, spreadability, and ease of application[5,15,16].

Advantages of microemulgel

- Improves the solubilization of lipophilic drugs.
- Improves drug permeation through the skin due to the presence of nanosized droplets.
- Increases drug bioavailability by facilitating better absorption at the site of application.
- Provides controlled and sustained drug release.
- Improves formulation stability compared to conventional microemulsions.
- Suitable for the delivery of both hydrophilic and lipophilic drugs[4,5].

Formulation considerations of microemulgel

Selection of oil phase: The oil phase is essential for solubilizing lipophilic drugs and affecting their permeation through the skin. Common oils used include oleic acid, isopropyl myristate, mineral oil, and vegetable oils, chosen for their drug solubility, compatibility, and penetration-enhancing properties.

Selection of surfactant: Surfactants lower the interfacial tension between oil and water, aiding stable microemulsion formation. Non-ionic surfactants such as Tween 80, Tween 20, and Span 80 are favored for their low toxicity and compatibility with topical formulations.

Selection of co-surfactant: Co-surfactants enhance interfacial film flexibility and aid in forming stable microemulsions, with common examples being ethanol, propylene glycol, polyethylene glycol, and isopropanol.

Selection of gelling agent: Gelling agents such as Carbopol 934, Carbopol 940, hydroxypropyl methylcellulose (HPMC), and xanthan gum are used to transform microemulsions into microemulgels, enhancing viscosity, spreadability, and patient acceptability[4,5,15].

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LULICONAZOLE

Luliconazole is classified as a Biopharmaceutics Classification System (BCS) Class II drug, characterized by low aqueous solubility and high permeability. As a novel imidazole antifungal agent, it marks a significant advancement in antifungal therapy. Luliconazole provides a potent and targeted treatment option for dermatophytosis, demonstrating broad-spectrum activity and favourable pharmacokinetic properties. These attributes position it as a potential first-line treatment for various dermatophyte-related infections[6].

Mechanism of action

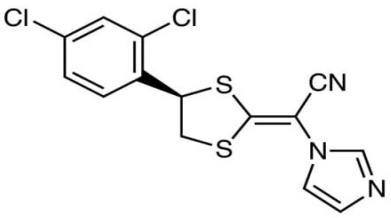

Figure 1: Structure of Luliconazole.

The chemical structure of luliconazole is shown in Figure 1. Luliconazole exerts its antifungal activity by inhibiting the enzyme lanosterol 14α-demethylase, which plays a crucial role in the biosynthesis of ergosterol, a major component of fungal cell membranes. Inhibition of this enzyme results in decreased ergosterol production, leading to disruption of fungal cell membrane integrity, increased membrane permeability, and leakage of essential intracellular components. Consequently, fungal growth is inhibited, ultimately resulting in fungal cell death[17].

Pharmacokinetics

Luliconazole demonstrates minimal systemic absorption when administered topically, with studies indicating very low plasma concentrations between 0.063 and 0.090 ng/mL. The maximum concentration (Cmax) observed is approximately 0.314 ng/mL after repeated applications, with steady-state levels achieved by day 8, reflecting limited systemic accumulation. Luliconazole exhibits high lipophilicity (log P ~4.07) and poor aqueous solubility, which facilitate its retention in the stratum corneum and further diminish systemic exposure. These pharmacokinetic factors contribute positively to its safety profile as a topical antifungal treatment[18].

Uses

Luliconazole is a topical imidazole antifungal agent primarily used to treat superficial skin fungal infections, especially dermatophytosis (e.g., tinea pedis, tinea corporis, tinea cruris). It targets pathogens such as *Trichophyton rubrum* and *Epidermophyton floccosum*, with some efficacy against *Candida*. Its low minimum inhibitory concentrations make it effective for recurrent or resistant cases, and it is convenient for patients due to its once-daily application and minimal systemic absorption[19].

ROLE OF CALAMINE IN DERMATOLOGICAL THERAPY

Calamine is a well-established dermatological agent widely used for the management of various skin disorders due to its soothing, protective, and mild anti-inflammatory properties. It is primarily composed of zinc oxide with a small proportion of ferric oxide, which contributes to its characteristic pink colour and therapeutic activity[7,20].

Calamine exhibits antipruritic action, helping to relieve itching and reduce discomfort associated with inflammatory skin conditions. It is commonly used in conditions such as eczema, dermatitis, urticaria, chickenpox, acne, herpes, allergic skin reactions, insect bites, and minor skin irritations[7,20].

The therapeutic benefits of calamine are attributed to its ability to form a protective barrier over the skin surface, thereby reducing irritation, preventing scratching, and minimizing the risk of secondary infections. In addition, it provides mild astringent and drying effects, which are useful in the management of oozing and inflamed lesions[7].

Calamine is considered safe for both paediatric and adult use and is commonly incorporated into lotions and topical formulations. Its zinc oxide and ferric oxide constituents work together to provide enhanced protective and soothing effects, contributing to improved dermatological outcomes[7].

RATIONALE FOR COMBINING LULICONAZOLE AND CALAMINE IN A MICROEMULGEL FOR TINEA PEDIS

Tinea pedis, a prevalent superficial dermatophytic infection caused predominantly by *Trichophyton rubrum*, *Trichophyton interdigitale*, and *Epidermophyton floccosum*, is clinically characterized by intense pruritus, interdigital maceration, erythema, scaling, and weeping lesions, necessitating a therapeutic approach that addresses both the causative organism and the associated symptomatic burden. Luliconazole, a novel imidazole antifungal, exerts potent fungicidal activity against the responsible dermatophytes by inhibiting lanosterol 14α-demethylase (CYP51), thereby disrupting ergosterol biosynthesis and compromising fungal cell membrane integrity. However, luliconazole alone does not alleviate the pronounced pruritus, maceration, and inflammatory symptoms characteristic of tinea pedis. Calamine, composed of zinc oxide and ferric oxide, complements luliconazole through its well-established antipruritic, astringent, and drying properties, effectively reducing interdigital moisture and maceration, which are critical predisposing factors for fungal persistence and reinfection. Additionally, zinc oxide supports skin barrier repair in fissured lesions and prevents secondary bacterial superinfection, a frequent complication of interdigital tinea pedis. Incorporating both actives into a microemulgel vehicle enhances percutaneous penetration of lipophilic luliconazole into the hyperkeratotic stratum corneum of the feet, while providing a soothing, non-greasy, and patient-compliant formulation, thus representing a rational dual-action therapeutic strategy for tinea pedis.

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PREPARATION OF MICROEMULGEL

The preparation of microemulgel involves three main steps, as illustrated in Figure 2:

1) Creating a microemulsion by mixing an oil phase, aqueous phase, surfactant, and co-surfactant for either an oil-in-water or water-in-oil system

2) Preparing a gel base by dispersing a gelling agent in water and adjusting the pH

3) Incorporating the microemulsion into the gel base while stirring continuously to achieve a homogeneous mixture[4,15].

Figure 2: Schematic Representation of Microemulgel Formation.

EVALUATION PARAMETERS

Physical Appearance: Physical appearance is evaluated for colour, clarity, homogeneity, consistency, and phase separation to assess the physical stability and uniformity of the formulation[15].

pH Determination: The pH of microemulgel formulations is generally determined using a calibrated digital pH meter. An appropriate pH range is essential to ensure skin compatibility and reduce irritation risk during topical application[4,15].

Viscosity Measurement: Viscosity is assessed using a Brookfield viscometer to evaluate the rheological behaviour, consistency, spreadability, and structural integrity of the formulation[4,15].

Particle Size, Polydispersity Index (PDI), and Zeta Potential: The mean droplet size, polydispersity index (PDI), and zeta potential are typically determined using dynamic light scattering (DLS) techniques. These parameters provide important information regarding colloidal stability, size distribution, and surface charge of the formulations[15].

Spreadability: Spreadability is evaluated to determine the ease with which the formulation can be applied and uniformly distributed over the skin surface. Good spreadability contributes to enhanced patient compliance and therapeutic effectiveness[4,15].

Drug Content Analysis: Drug content is usually determined using analytical techniques such as UV–Visible spectrophotometry or High-Performance Liquid Chromatography (HPLC) to ensure uniform drug distribution and dosage accuracy[4,15].

In Vitro Drug Release Study: In vitro drug release studies are performed using Franz diffusion cells to evaluate the release behaviour and permeation characteristics of the drug from the microemulgel formulation[4,15].

CONCLUSION

Luliconazole–calamine microemulgel represents a promising and rationally designed topical drug delivery system for the effective management of tinea pedis. The microemulgel platform successfully addresses the solubility limitations of luliconazole while enhancing skin penetration, drug retention, and formulation stability. The inclusion of calamine provides complementary antipruritic and soothing benefits, offering both aetiological and symptomatic relief in a single formulation. Comprehensive evaluation parameters confirm its physicochemical suitability and therapeutic potential. Overall, this combination microemulgel system offers a promising alternative to conventional topical antifungals, warranting further preclinical and clinical investigation to establish its complete efficacy and safety profile.

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