

Topical Emulgel Systems in Dermatological Therapy: A Review of Tolnaftate and Loratadine Combination.

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Abstract

Dermatological disorders such as superficial fungal infections are frequently associated with allergic symptoms including pruritus, erythema, and inflammation, necessitating an effective and patient-friendly topical therapeutic approach. Conventional topical dosage forms like creams, ointments, and gels often exhibit limitations related to poor drug penetration, greasiness, and reduced patient compliance. Emulgel systems have emerged as a promising novel topical drug delivery platform that combines the advantages of both emulsions and gels, offering improved stability, enhanced drug release, and better skin permeability, particularly for hydrophobic drugs. Tolnaftate, a widely used antifungal agent, is effective against dermatophytes, while loratadine, a second-generation antihistamine, provides relief from allergic manifestations without causing sedation. The combination of tolnaftate and loratadine in an emulgel formulation offers a dual-action therapeutic strategy by simultaneously targeting fungal infection and associated allergic symptoms. This review highlights the concept, advantages, and formulation aspects of emulgel-based topical delivery systems, with particular emphasis on the physicochemical properties, mechanism of action, and dermatological relevance of tolnaftate and loratadine. Additionally, formulation considerations, methods of preparation, evaluation parameters, and therapeutic potential of the combined emulgel system are discussed. The review aims to provide comprehensive insights into the development of tolnaftate–loratadine emulgels as an effective, safe, and patient-compliant topical therapy for dermatological conditions.

Keywords: Emulgel, Loratadine & Tolnaftate, Combination drugs

I. INTRODUCTION

Dermatological disorders constitute a significant global health concern, with superficial fungal infections such as dermatophytosis, candidiasis, and tinea infections being among the most common conditions affecting the skin, hair, and nails.^[1] These infections are frequently associated with allergic manifestations including pruritus, erythema, inflammation, and irritation, which can considerably impair patient comfort and quality of life.^[2] In many cases, fungal skin infections trigger or exacerbate hypersensitivity reactions, necessitating therapeutic approaches that address both the infectious and allergic components simultaneously.^[3]

Topical drug delivery is widely preferred for the management of localized dermatological conditions due to its ability to deliver drugs directly to the site of action while minimizing systemic exposure and adverse effects.^[4] However, conventional topical dosage forms such as creams, ointments, and gels suffer from several limitations, including poor penetration through the stratum corneum, instability, greasiness, and reduced patient compliance.^[5] Additionally, these formulations may be inadequate for delivering hydrophobic drugs efficiently, resulting in suboptimal therapeutic outcomes.^[6]

To overcome these drawbacks, novel topical delivery systems have been explored, among which emulgel formulations have gained considerable attention. Emulgels combine the advantages of emulsions and gels, offering improved drug solubilization, enhanced skin penetration, better stability, and superior patient acceptability.^[7] They are particularly suitable for incorporating lipophilic drugs and achieving controlled drug release at the application site.^[8]

The combination of an antifungal agent such as **tolnaftate** with an antihistaminic drug like

loratadine in a topical emulgel formulation provides a rational therapeutic approach for managing fungal infections accompanied by allergic symptoms. Tolnaftate effectively inhibits fungal growth, while loratadine alleviates itching and inflammation associated with allergic responses, thereby improving overall therapeutic efficacy and patient compliance.^[9]

The objective of this review is to provide a comprehensive overview of **topical emulgel systems in dermatological therapy**, with a specific focus on the formulation, evaluation, and therapeutic potential of **tolnaftate–loratadine combination emulgels**. The review aims to summarize current research findings, highlight formulation considerations, and discuss future prospects for dual-action topical therapies.^[10]

II. Overview of Topical Drug Delivery Systems :

Topical drug delivery provides localized therapy, achieving high drug concentration at the site of action while reducing systemic exposure. ^[11] It avoids first-pass metabolism and improves patient compliance due to easy application ^[12]. However, the stratum corneum poses a significant barrier, limiting drug penetration ^[13]. Novel carriers such as emulgels and nanocarriers enhance permeation and retention in the skin ^[14].

Advantages of topical drug delivery :

- Topical drug delivery bypasses hepatic first-pass metabolism and gastrointestinal degradation, thus improving the bioavailability of the applied drug ^[15].
- Topical application is generally non-invasive and painless, making it more acceptable and comfortable for patients ^[16].
- This route enhances patient compliance and adherence because formulations like gels, creams, and patches are easy to apply and require less frequent dosing ^[16].
- Topical delivery can achieve controlled and sustained drug release at the target site, improving therapeutic outcomes ^[17].
- The use of topical systems is particularly advantageous for drugs with narrow therapeutic windows or short biological half-lives, as they maintain consistent local drug levels ^[17].

III. Emulgel as a Novel Topical Drug Delivery System

Definition and Concept of Emulgel

An emulgel is a *gellified emulsion* formed by incorporating a pre-prepared emulsion into a gel base, combining the properties of both emulsion and gel ^[18]. This dual nature allows emulgels to deliver hydrophobic and hydrophilic drugs effectively through the skin by harnessing both gel consistency and emulsion dispersal systems ^[18]. Emulgels are considered an advanced form of topical drug delivery because they overcome limitations of conventional gels and creams for poorly soluble drugs ^[19].

Advantages of Emulgels over Conventional Gels, Creams, and Ointments

Emulgels exhibit *dual controlled drug release*, prolonging therapeutic action due to the combined mechanisms of gel and emulsion systems ^[18]. They offer a *non-greasy and easily spreadable texture*, which improves patient comfort and compliance compared with ointments and heavy creams ^[18]. Emulgels demonstrate better stability and lower phase separation than standard emulsions, ensuring uniform drug distribution ^[20]. Their formulation can enhance the *penetration of hydrophobic drugs* through the skin by incorporating the drug in the oil phase of the emulsion ^[20]. Emulgels typically have a pleasing appearance, are transparent, and are easily washed off, making them cosmetically acceptable for dermatological use ^[21].

Types of Emulgels (O/W and W/O)

Emulgels can be classified as **oil-in-water (O/W)** or **water-in-oil (W/O)** depending on the emulsion type used before gellation ^[19].

In **O/W emulgels**, oil droplets are dispersed in a continuous aqueous phase, ideal for delivering lipophilic drugs ^[19].

In **W/O emulgels**, water droplets are dispersed in a continuous oil phase, which can be more occlusive and suited for certain therapeutic goals ^[19].

Mechanism of Drug Release and Skin Penetration

Drug release from emulgels occurs through *diffusion from the gel network* followed by partitioning from the emulsion phase to the skin surface ^[18].

Penetration of the drug across the stratum corneum may be enhanced by the oil phase and surfactants in the emulsion, which can disrupt lipid packing in skin layers ^[21].

The gel matrix prolongs contact time with the skin, allowing sustained release and improved absorption compared with simple gels or creams [18].

Rationale for tolnaftate and loratadine combination

• Need for dual-action therapy in dermatological conditions

Dermatological conditions such as fungal infections often present with both infection and associated symptoms like pruritus and inflammation that are not always fully addressed by antifungal therapy alone [22].

Antifungal monotherapy like tolnaftate effectively inhibits fungal growth on the skin but does not directly alleviate histamine-mediated itching or allergic symptoms [23].

Antihistamines such as loratadine target peripheral histamine H₁ receptors, reducing itching and erythema associated with allergic skin conditions [24].

• Benefits of antifungal–anti-allergic combination

Combining an antifungal agent with an antihistamine can simultaneously address the cause of infection and symptomatic discomfort, potentially leading to improved overall patient outcomes [24][25].

Dual therapy may reduce the need for additional systemic antihistamine use and may decrease reliance on oral medications for symptomatic relief [24].

Such combinations may enhance patient compliance by **reducing the total number of medications a patient must use** in cutaneous fungal conditions with pruritic components [24].

• Synergistic therapeutic effects

Although direct clinical trial data on tolnaftate–loratadine combinations are limited, evidence from other drug combination approaches suggests that pairing agents with **different mechanisms of action can produce additive or synergistic benefits** for complex conditions [25]. In dermatological practice, combining agents with complementary actions—antimicrobial plus symptomatic relief—can result in **faster resolution of symptoms and improved quality of life** for patients [24][25].

Drug profile

Tolnaftate

• Chemical structure and physicochemical properties

Tolnaftate is a synthetic thiocarbamate antifungal agent with the chemical formula C₁₉H₁₇NOS and a molecular weight of approximately 307.4 g/mol [26]. Its IUPAC name is O-2-naphthyl methyl(3-methylphenyl)thiocarbamate, appearing as a white to off-white solid powder that is highly lipophilic and sparingly soluble in water [26].

Mechanism of antifungal action

Tolnaftate inhibits the fungal enzyme squalene epoxidase, disrupting ergosterol biosynthesis, which weakens fungal cell membranes and leads to fungicidal or fungistatic effects [27].

• Spectrum of activity

Tolnaftate is active against dermatophytes such as *Trichophyton*, *Epidermophyton*, and *Microsporum* species, but it is less effective against *Candida* species [27].

• Pharmacokinetics and topical suitability

After topical application, tolnaftate exhibits negligible systemic absorption, making it suitable for treating localized superficial fungal infections like tinea pedis, tinea corporis, and jock itch [26].

Loratadine

• Chemical structure and physicochemical properties

Loratadine is a second-generation tricyclic antihistamine with a benzocycloheptapyridine core, less lipophilic than first-generation antihistamines, which reduces CNS penetration [28].

• Mechanism of anti-allergic action

It acts as a selective inverse agonist at peripheral histamine H₁ receptors, blocking histaminemediated allergic responses such as pruritus and erythema [29].

• Role in dermatological therapy

Loratadine is used to relieve itching and allergic symptoms in urticaria and allergic dermatitis, and it can inhibit histamine-induced inflammatory actions on skin cells [30].

• Pharmacokinetics and topical relevance

Although loratadine is usually administered orally, its peripheral selectivity and long-acting active metabolite desloratadine support its potential for dermatological use in localized antiallergic effects [28][31].

Formulation Considerations for Tolnaftate–Loratadine Emulgel

Selection of Oils, Emulsifiers, and Gelling Agents

Selection of suitable oils such as light liquid paraffin, castor oil, or isopropyl myristate is important to solubilize poorly water-soluble drugs

and form the oil phase of the emulsion [32]. Non-ionic surfactants like Tween 80 or Span 20 are commonly used as emulsifiers to stabilize O/W or W/O systems and maintain droplet integrity [32]. Gelling agents such as Carbopol 940, HPMC, and sodium CMC are used to provide structure, viscosity, and stability to the final emulgel formulation [33].

Choice of Penetration Enhancers

Penetration enhancers such as oleic acid, clove oil, menthol, and eucalyptus oil are incorporated to temporarily disrupt the stratum corneum lipid barrier and facilitate drug transport into the skin [34].

Ideal penetration enhancers should be non-toxic, non-irritating, and pharmacologically inactive while being compatible with both drug and excipients [34].

pH Adjustment and Skin Compatibility

The pH of an emulgel formulation should be adjusted to approximate the natural skin pH (about 4.1–5.8) to minimize irritation and maintain barrier function [34].

Triethanolamine (TEA) is often used to adjust the pH and induce polymer uncoiling for gel formation, particularly with Carbopol systems [34].

Drug–Excipient Compatibility Studies

Pre-formulation studies such as FTIR, DSC, and stability screening help confirm that the active drugs and excipients do not interact adversely, ensuring formulation stability and drug efficacy [35].

Methods of Preparation of Emulgel

- **Preparation of emulsion phase:** The oil and aqueous phases are heated and mixed with appropriate surfactants until a stable emulsion forms [32].
- **Gel base preparation:** Gelling agents like Carbopol are hydrated and neutralized (often with TEA) to form a uniform gel matrix [34].
- **Incorporation of emulsion into gel:** The prepared emulsion is gradually mixed into the gel base under gentle stirring to avoid phase separation [32].
- **Homogenization techniques:** Mechanical or high-speed homogenization ensures a uniform emulsion droplet size distribution and stable emulgel formulation [32].

Evaluation Parameters of Emulgel Formulations

Physical Appearance and Homogeneity

The emulgel should have a smooth, uniform appearance without phase separation or grittiness, indicating good formulation stability [36].

pH Determination

pH is measured to confirm compatibility with skin pH, reducing the likelihood of irritation upon application [36].

Viscosity and Rheological Behavior

Viscosity and rheology (shear thinning behavior) influence spreadability and retention on the application site and are evaluated using viscometers [36].

Spreadability and Extrudability

Spreadability (measured by glass slide methods) and extrudability assess ease of application and uniform drug distribution across the skin [36].

Drug Content Uniformity

Drug content analysis ensures that the active drugs are evenly dispersed throughout the emulgel [36].

In Vitro Drug Release Studies

In vitro release studies using Franz diffusion cells help determine drug release kinetics, which should be sustained and controlled [36].

Skin Permeation and Retention Studies

Skin permeation and retention tests quantify how much drug penetrates and remains within skin layers, informing therapeutic effectiveness [36].

Antifungal Activity Evaluation

Antifungal activity is assessed using methods such as agar diffusion tests against dermatophytes to confirm efficacy [36].

Anti-Allergic / Anti-Inflammatory Evaluation

Anti-allergic effects can be evaluated via in vitro or ex vivo assays measuring inflammatory markers or histamine response [32].

Stability Studies

Stability studies under varied environmental conditions monitor changes in appearance, pH, viscosity, and drug content over time [32].

Clinical Significance of Tolnaftate–Loratadine Emulgel

- **Improved patient compliance:** The non-greasy, easy-to-apply emulgel enhances compliance relative to conventional ointments or creams [32].
- **Enhanced therapeutic efficacy:** Controlled release and improved penetration of combined antifungal and anti-allergic agents can improve clinical outcomes [32].

- **Reduced dosing frequency:** Sustained drug release minimizes the need for frequent application, improving adherence [36].
- **Minimized systemic side effects:** Localized delivery limits systemic absorption, reducing the risk of systemic side effects seen with oral antihistamines [36].

Safety and Regulatory Considerations

- **Skin irritation and sensitization studies:** Preclinical testing such as patch tests or animal studies is essential to confirm that the formulation does not cause erythema, edema, or sensitization [37].
- **Regulatory guidelines for topical combination products:** Regulatory frameworks generally require evidence of safety, efficacy, and quality for combination topical products prior to approval [38].
- **Quality control requirements:** Robust quality control is necessary, including tests for microbial limits, physical properties, and stability to meet pharmacopeial standards [38].

Challenges and Limitations

- **Stability issues**
Emulgels are prone to physical instability such as phase separation, creaming, and drug precipitation, which can affect shelf life and therapeutic efficacy [39].
Chemical stability of active ingredients like tolnaftate and loratadine can be compromised due to hydrolysis, oxidation, or photodegradation during storage [40].
- **Scale-up and manufacturing concerns**
Scaling up laboratory formulations to industrial production can be challenging due to difficulties in maintaining uniform droplet size, viscosity, and homogeneity in large batches [41]. Maintaining consistency in emulgel rheology and spreadability while using high-shear homogenization and large mixing equipment is another critical concern [42].
- **Drug interaction risks**
In combination formulations, interactions between active drugs and excipients may lead to reduced bioavailability, precipitation, or altered release profiles [43].
Proper preformulation compatibility studies, such as FTIR, DSC, and stability testing, are essential to minimize drug–excipient or drug–drug interactions [44].

Future Prospects

- **Personalized dermatological therapy**
Emerging approaches in personalized dermatology may allow tailored emulgel formulations with drug combinations and concentrations optimized for individual patient profiles [45].
- **Enhanced permeation techniques**
Incorporation of nanocarriers, liposomes, and chemical penetration enhancers in emulgels may improve drug delivery through the stratum corneum and achieve targeted action [46].
- **Clinical translation and commercialization**
Continued research and regulatory approval of nano- and multi-drug emulgels could accelerate clinical adoption and commercialization, improving patient adherence and therapeutic outcomes [45].

IV. CONCLUSION

- Tolnaftate–loratadine emulgel is a promising dual-action topical therapy that combines antifungal and anti-allergic effects in a single formulation. This system offers advantages such as sustained drug release, enhanced skin penetration, improved patient compliance, and minimized systemic side effects.
Novel formulation approaches, including the use of nanocarriers and advanced polymers, can further enhance therapeutic efficacy and stability.
Future directions include personalized dermatological therapy, clinical translation of nanoemulgels, and broader commercialization of combination topical systems.
Overall, Tolnaftate–loratadine emulgel represents a versatile and effective strategy for the management of dermatological conditions requiring simultaneous antifungal and anti-allergic treatment.

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