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Review Article

Tiny Droplets Big Impact: Emerging Nanoemulsion Strategies for Enhanced Nail Penetration in Onychomycosis Therapy

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ABSTRACT

Onychomycosis remains a persistent fungal infection of the nail due to the dense keratin structure and low permeability of the nail plate, which restrict the effectiveness of conventional topical therapies. Although oral antifungal agents such as terbinafine and itraconazole are widely prescribed and demonstrate favorable clinical outcomes, their long treatment duration, potential adverse effects, drug interactions, and issues related to patient adherence often limit their use. Consequently, considerable attention has been directed toward developing advanced topical drug delivery systems capable of improving antifungal penetration through the nail barrier. Nanoemulsions have emerged as promising carriers because of their nanosized droplets, large surface area, and enhanced drug solubilization properties. This review examines the role of nanoemulsion-based formulations in the treatment of onychomycosis, with emphasis on formulation characteristics, physicochemical behavior, stability considerations, and their application in transungual drug delivery. Various antifungal agents, including terbinafine, itraconazole, ciclopirox, and amorolfine, have been incorporated into nanoemulsion systems, often in combination with natural oils and keratolytic permeation enhancers. Available evidence indicates that these formulations improve nail hydration, facilitate drug diffusion through keratinized tissues, and provide prolonged drug release at the site of infection. Enhanced antifungal activity has also been observed against difficult-to-treat and resistant fungal species. Experimental studies consistently report superior nail penetration and fungal inhibition compared with conventional topical preparations, while clinical investigations suggest improved therapeutic outcomes, faster recovery, and increased patient acceptability. Despite challenges such as formulation instability, sensitivity to storage conditions, and susceptibility to microbial contamination, nanoemulsion-based delivery systems represent a promising strategy for improving the topical management of onychomycosis and may contribute to the development of more effective and patient-friendly antifungal therapies.

Keywords: Antifungal drug delivery, Nail permeability, Nanoemulsion, Onychomycosis, Topical nanotechnology, Transungual delivery.

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INTRODUCTION

Onychomycosis, which causes 20-40% of all illnesses that are referred to as onychopathies and roughly 30% of cutaneous mycotic infections, is a widespread illness that affects 5.5% of people globally (Akhter *et al.*, 2024). Fingernail onychomycosis can cause pain, discomfort, and loss or impairment of tactile functions. Toenail dystrophy can make it difficult to walk, exercise, or wear properly fitting shoes. Furthermore, onychomycosis causes negative physical and psychological repercussions (Hadi *et al.*, 2024). Yeasts, which used to be thought of as pollutants, are now more widely acknowledged as pathogens in fingernail diseases. Candida parapsilosis, Candida tropicalis, and Candida krusei are responsible for the remaining 70% of cases, with Candida albicans accounting for the balance. As seen among housewives, farmers, and fishermen, long-term exposure to dampness and chemicals, such as detergents, as well as compromised local immunity resulting from trauma, leads to CO, together with Candida paronychia. A main or secondary disease can be Candida. In cases of severe immune suppression, its function as a primary pathogen is almost always apparent in conditions like HIV infection and Chronic Mucocutaneous Candidiasis (CMC). On the other hand, secondary invasion by Candida occurs at the nail complex in cases of PVD, malnourishment,

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and compromised local immunity. It is well known that the keratin in nail polish creates an ideal environment for the growth of virulent Candida strains (Alessandrini *et al*., 2020). Clinical signs of onychomycosis include Distal and Lateral Subungual Onychomycosis (DLSO), Proximal Subungual Onychomycosis (PSO), Superficial White Onychomycosis (SWO), Endonyx, and Total Dystrophic Onychomycosis (TDO).

Lateral and Distal Subungual Onychomycosis

The most common medical condition associated with moving the fingers and toenails together is DLSO. The yeast enters through the lateral and distal deep nail cavities, extends closest toward the developing nail stream after invading the horny layer of the hyponychium and/or nail tissue, and then passes through the opaque underside of the nail plate. Clinical manifestations include subungual hyperkeratosis and onycholysis. It serves as a mycotic reservoir for fungal growth. T. rubrum is the most prevalent causative species, followed by T. tonsurans, T. mentagrophytes, and Epidermophyton floccosum. rubrum causes "one hand, two feet" tinea syndrome, a unique clinical pattern in DLSO in which the fungus spreads from the palmar and plantar surfaces of the hands and feet (Pereira-Leite *et al*., 2025). T. mentagrophytes var. interdigitale causes chronic dermatophytosis syndrome, which begins as tiny, 1 mm-sized plantar vesicles and collarettes over the soles, which are home to a large number of hyphae (Gupta *et al*., 2023).

Nanoemulsions

The nanoemulsion is an innovative drug delivery system that has gained significant importance in recent years due to its ability to address the challenges of traditional formulations, particularly for complicated infections such as onychomycosis (Bencherif *et al*., 2009). They are colloidal dispersions comprising two immiscible phases, often water and oil, stabilised by co-surfactants and surfactants, and which exist in a droplet size range of 20 to 200 nanometres (Mishra *et al*., 2019). In contrast to macroemulsions, nanoemulsions are highly kinetically stable, transparent, and feature excellent droplet sizes, which increase drug solubility, stability, and the ability to penetrate biological barriers (ElSherif *et al*., 2017). Their special features make them very useful for topical use, as enhanced permeation is required. The issue of targeting the delivery of antifungal agents to within the dense keratinised plate of the nail and retaining high concentrations of drugs at sites of infection for extended durations, where the efficacy of therapy is enhanced, is dual beneficial in the case of onychomycosis, particularly with nanoemulsions (See in Table 1) (Chaurasia, 2024).

Pathophysiology and Challenges in Treating Onychomycosis

Pathophysiology of Onychomycosis

Is a chronic mycological contamination affecting the nail unit, including the nail dish, nail bed, and surrounding tissues. The development of onychomycosis is closely associated with both the pathogenic characteristics of fungi and the complex structure of the nail unit (Pugazhendhi *et al*., 2020). The nail plate acts as a strong protective barrier because it is composed mainly of densely packed keratin. This keratinized structure restricts the penetration of therapeutic agents and also limits immune defence mechanisms (Leung *et al*., 2019; Pabale *et al*., 2022). These enzymes destroy the nail matrix and cause structural damage, including thickening, brittleness, discolouration, and a distorted nail plate. The most common cause of onychomycosis is dermatophytes (primarily Trichophyton rubrum and Trichophyton mentagrophytes), which account for most cases worldwide (Atram *et al*., 2022) (shown in Figure 1).

Challenges in Treating Onychomycosis

The development of antifungal therapy for onychomycosis remains challenging due to physiological and pharmacological barriers. The nail plate is a compact, closely packed keratin fiber that serves as an effective barrier to drug penetration. This restricts the penetration of topical antifungal agents into the infected nail bed, resulting in subtherapeutic drug levels at the site of infection. Nail growth is very slow, which increases the treatment time. The growth rate of toenails is about 1-2 mm each month, so it can take 12-18 months for the whole nail to be replaced, which is one reason the course of treatment is quite long. A large range of causative fungi may also develop as biofilms in the nail structure. Biofilms also shield fungal cells from antifungal agents and the immune system, leading to persistent infections and treatment failure.

Components and Formulation Strategies

The nanoemulsion formulation will need three key components: the oil phase, the surfactant/co-surfactant system, and the aqueous phase (Winnicka *et al*., 2012). Lipophilic antifungal agents are transported through the oil phase, and this increases their solubility and bioavailability. Advanced topical therapies for onychomycosis: Nanoemulsions (NEs) and nanoemulgels are excellent methods for treating onychomycosis, using submicron-sized droplets that can improve drug solubility and absorption across the keratinised nail plate. These systems, which incorporate oils, surfactants, and gelling agents, provide superior drug concentration and sustained release compared with conventional therapies, thereby reducing systemic toxicity (See Table 2) (Prajapati *et al*., 2025).

METHODS OF PREPARATION OF NANOEMULSIONS

With droplets typically between 20 and 200 nm, nanoemulsions are thermodynamically or kinetically stable colloidal dispersions composed of oil, water, a detergent, and, frequently, a co-surfactant. Both high-energy and low-energy emulsification methods can be used to prepare them, depending on the formulation requirements and the physicochemical properties of the components. These preparation methods influence droplet size, stability, drug loading capacity, and permeation efficiency. The commonly used preparation techniques are summarised below.

High-Energy Emulsification Methods

These techniques use mechanical devices to generate intense disruptive forces that break coarse emulsions into nano-sized droplets.

High-Pressure Homogenization

This technique involves applying extremely high pressure while passing the coarse emulsion through a small opening (500-5000 psi). The intense shear stress, cavitation, and turbulence reduce droplet size to the nanometre range, resulting in a uniform and stable nanoemulsion. Ultrasonication uses ultrasonic waves generated by a probe sonicator. The audio cavitation produced during sonication causes microbubbles to form and collapse, breaking larger droplets into smaller nanoscale droplets. Microfluidization: This technique employs a microfluidizer in which two streams of coarse emulsion collide at high velocity in microchannels. The strong shear forces and impact reduce droplet size, producing highly stable nanoemulsions with a narrow size distribution.

Low-Energy Emulsification Methods

Low-energy methods count on the impulsive formation of nanoemulsions through changes in system composition or temperature. Phase Inversion Temperature (PIT) Method. This method uses temperature-induced phase inversion of non-ionic surfactants. When the temperature changes, the surfactant's affinity for the oil and water phases shifts, leading to the formation of nanosized droplets. In the Stage Inversion Arrangement (PIC) method, the regular addition of water to a mixture of oil, surfactant, and co-surfactant leads to phase inversion and the spontaneous formation of nanoemulsions. The spontaneous emulsification method involves mixing oil, surfactant, and co-surfactant with an aqueous phase under gentle stirring.

Nanoemulsions can be prepared by means of either high-energy or low-energy methods (see Table 3).

Mechanism of Drug Delivery Through the Nail Plate

The success of antifungal treatment in onychomycosis is, in the most significant part (Figure 2), caused by the capacity of the medication to penetrate the dense and keratinised nail plate to reach the infection area under the nail plate (Sherje *et al*., 2018). The nail plate, due to its strong, non-absorbent nature, presents significant challenges to drug penetration into the skin; hence, conventional topical medications are less useful (Sarode *et al*., 2024; Jafari *et al*., 2021). Nanoemulsions, owing to their small droplet size and engineered surface features, have demonstrated the potential to overcome these obstacles by promoting more effective drug delivery through the nail plate (Kumar *et al*., 2011). There are three main routes through which drugs penetrate the nail: the interpleural, intercellular, and transcellular pathways. The transcellular path: Drugs enter the nail plate directly through keratinised cells (Langaroudi *et al*., 2019).

The nanoemulsion droplet size (nanoscale) is also significant in improving transdermal drug delivery (Khan *et al*., 2024). Droplets with diameters between 20 and 200 nm would have high surface-to-volume ratios. Smaller droplets also spread more widely, resulting in a more even distribution and longer contact with the nail plate, which is paramount for drug release (Padrilah *et al*., 2024).

Table 1: Etiological groups of fungi causing onychomycosis.

Group	Causative Organisms	Key Features	Role in Onychomycosis	References
Dermatophytes	Trichophyton rubrum, Trichophyton mentagrophytes	Keratinophilic fungi invade keratinised tissues (nail, skin, hair).	The most common cause (60-70% of cases) is usually chronic, slowly progressive infections.	(Westerberg *et al*., 2013a)
Yeasts	Candida albicans, Candida parapsilosis	Opportunistic fungi are part of normal flora infections favoured by immunosuppression or chronic moisture.	Responsible for 20-25% of cases; more frequent in fingernails, often with paronychia.	(Westerberg *et al*., 2013a)
Non-Dermatophyte Moulds (NDMs)	Scopulariopsis brevicaulis Fusarium species Aspergillus species	Environmental saprophytes; not primarily Keratinophilic but can colonise or infect damaged nails.	Cause 10-15% of cases; often linked to trauma, pre-existing nail disease, or immunosuppression.	(Westerberg *et al*., 2013b)

Enhanced Efficacy and Reduced Toxicity

The key advantage of nanoemulsions is that they allow the dramatic enhancement of the efficacy of antifungal drugs (Shah *et al*., 2012). The droplets that are too small will enable drugs to enter the depth of the layers that include the nail bed, which docks a colony of the fungus, and this gives close contact with the surface of the nail. The outcome of this further penetration is greater local drug dosing, which helps more efficiently eradicate infections, including Trichophyton rubrum and Candida species (Shahbaz, n.d.; Song *et al*., 2020).

Stability, Scalability, and Patient Compliance

Small emulsions have high kinetic stability, which does not permit the degradation and phase separation of drugs. Alternatively, due to their stability, the substances have an extended shelf life and can therefore be easily marketed (Akhter *et al*., 2024). They are also simple to administer due to their non-greasy texture and low viscosity, which increases patient compliance, which is crucial in the long-term management of onychomycosis (Gupta *et al*., 2010). From a production standpoint, nanoemulsions can be sized using standard high-energy techniques. Tiny fluidisation to

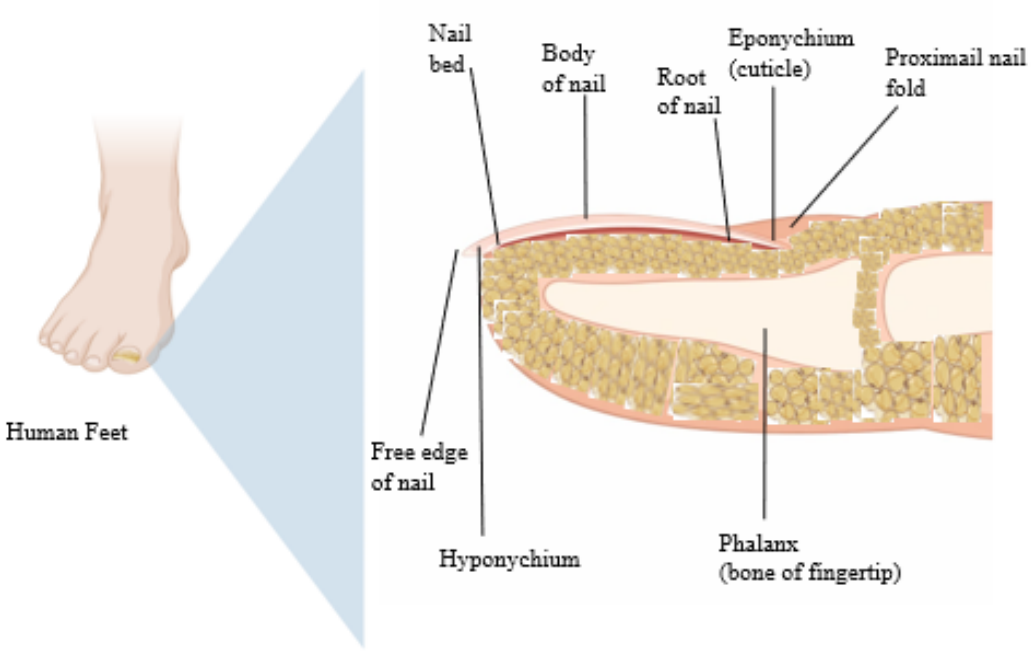

Figure 1: Anatomy of the Nail.

Table 2: Components and Their Roles in Nanoemulsion Formulations for Onychomycosis.

Component	Examples	Role in Formulation
Oil Phase	Medium-chain triglycerides, isopropyl myristate, essential oils (e.g., tea tree oil)	Enhances solubility and bioavailability of lipophilic drugs; influences droplet size and drug release rate.
Surfactant	Tween 80, Span 20, Cremophor EL	Reduces surface and interfacial tension; promotes uniform mixing of oil and water; improves solubility of poorly water-soluble drugs.
Co-surfactant	Ethanol, propylene glycol, polyethene glycol	Further reduces interfacial tension; increases flexibility and stability of the interfacial film.
Aqueous Phase	Purified water, buffer solutions	Provides a medium for hydrophilic excipients; maintains pH for formulation stability.
Penetration Enhancers	Urea, thioglycolic acid, salicylic acid	Softens and hydrates the nail plate; enhances drug permeability and bioavailability.
Stabilisers/ Antioxidants	Vitamin E, Butylated Hydroxytoluene (BHT)	Prevents phase separation, aggregation, and drug precipitation; prolongs shelf-life and maintains stability.

Table 3: Methods of Preparation for Nanoemulsion Formulations.

Method	Type	Principle	Advantages	Limitations
High-Pressure Homogenization	High-energy	Uses high pressure to force coarse emulsion through a narrow gap, breaking droplets into nanoscale sizes.	Produces uniform droplets; scalable for industrial production.	Requires expensive equipment; generates heat, which may degrade sensitive drugs.
Microfluidization	High-energy	Employs microchannels where two streams collide at high velocity, creating nanosized droplets.	High stability; excellent droplet size control.	High cost; energy-intensive process.
Ultrasonication	High-energy	Utilises ultrasonic waves to create cavitation forces that reduce droplet size.	Simple, cost-effective for small-scale production; good for heat-sensitive drugs.	Limited scalability; potential contamination from probe erosion.
Spontaneous Emulsification	Low-energy	Relies on diffusion of oil into the aqueous phase under controlled conditions, leading to droplet formation.	Easy to perform; no special equipment needed.	Droplet size may be larger and less stable than high-energy methods.
Phase Inversion Temperature (PIT)	Low-energy	Emulsion formation occurs by changing temperature, which alters surfactant solubility and causes phase inversion.	Produces fine droplets; energy efficient.	Limited to non-ionic surfactants; sensitive to temperature variations.
Solvent Evaporation/Diffusion	Low-energy	Organic solvent containing oil phase diffuses/evaporates, leading to nanosized droplets in the aqueous medium.	Good for encapsulating lipophilic drugs; simple procedure.	Requires removal of organic solvents; potential residual toxicity.

Table 4: Marketed Antifungal Formulations for Onychomycosis.

Brand Name	Active Drug	Dosage Form	Concentration	Manufacturer	Key Features
Efinaconazole (Jublia®)	Efinaconazole	Topical solution	10%	Bausch Health	Low surface tension improves penetration into the nail plate.
Tavaborole (Kerydin®)	Tavaborole	Topical solution	5%	Sandoz	Boron-based antifungal with good nail permeability.
Ciclopirox (Penlac®)	Ciclopirox	Nail lacquer	8%	Sanofi	Broad-spectrum antifungal used for mild infections.
Amorolfine (Loceryl®)	Amorolfine	Nail lacquer	5%	Galderma	Inhibits fungal sterol biosynthesis.
Terbinafine (Lamisil®)	Terbinafine	Oral tablet / topical	250 mg	Novartis	Systemic therapy has a high cure rate.
Itraconazole (Sporanox®)	Itraconazole	Oral capsule	100 mg	Janssen	Pulse therapy is commonly used in severe infections.

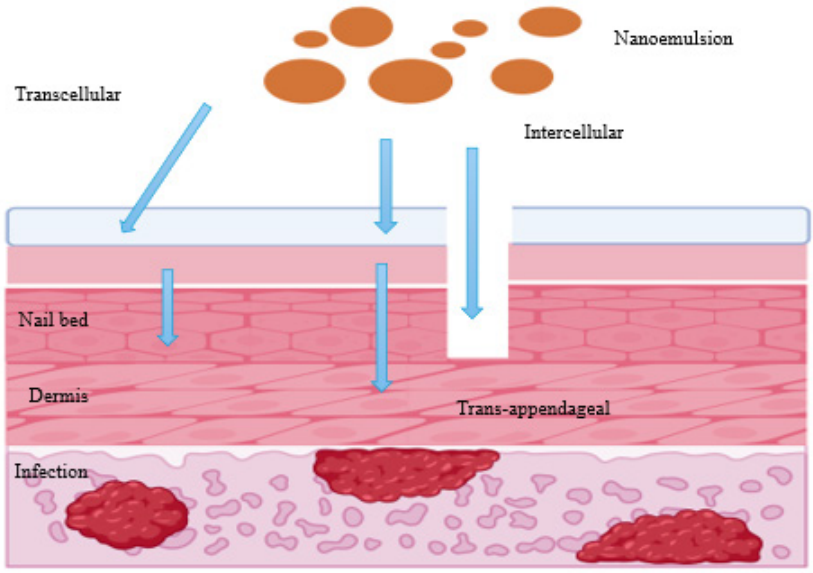

Figure 2: Mechanism of Drug Delivery Through the Nail Plate.

Table 5: Recent Nano-Drug Delivery Systems (Nano-DDS) Investigated for Onychomycosis.

Drug	Nano-DDS Type	Key Components	Study Type	Major Findings	References
Amorolfine	Solid Lipid Nanoparticles (SLN)	Stearic acid, bile salts	*In vitro* and *ex vivo*	1.6-fold higher nail permeation and improved antifungal activity.	Ahmed *et al.*, 2025
Voriconazole	Nanostructured Lipid Carriers (NLC)	Solid + liquid lipids	*Ex vivo* permeation	Higher drug retention in nail models compared to free drug.	Rocha *et al.*,
Terbinafine	Liposomal film formulation	Phospholipids	*In vivo* study	Improved antifungal activity and sustained drug release.	Tuncay *et al.*,
Luliconazole	Liposomal nail lacquer	Liposome vesicles + lacquer base	In vitro	Enhanced nail permeation and antifungal activity.	Chouhan *et al.*,

guarantee a constant degree of product quality (Daphne Nguyen *et al.*, 2025).

Formulation Challenges

Although there are many potential applications for nanoemulsions, there are a number of barriers to their widespread adoption (Kabanov *et al.*, 2009). Even if nanoemulsions are kinetically stable, phase separation may still take place under difficult storage circumstances, which is a serious problem. The choice of surfactants and co-surfactants is critical, as they should avoid irritating the nail or surrounding skin while not irritating the skin (Bhaskar *et al.*, 2025).

FUTURE PROSPECTS AND LIMITATIONS

Because they can enhance the solubility of medications, promote deeper penetration into the nails, and enhance antifungal properties, nanoemulsions have high potential for the treatment of onychomycosis. In the future, these studies are likely to focus on the development of multifunctional nanoemulsions containing antifungal drugs either in combination with stimuli-responsive carriers or with sustained-release carriers or with natural bioactive components for longer activity and reduced number of doses.

Marketed Antifungal Formulations for Onychomycosis

The marked preparation and patent are seen in Table 4.

Recent Nano-Drug Delivery Systems (Nano-DDS) Investigated for Onychomycosis

In vitro and *in vivo* studies on DDS related to Onychomycosis are shown in Table 5.

CONCLUSION

Onychomycosis remains a significant global health problem due to its frequency, its chronicity and its difficult treatment. The thick keratinised nail plate makes it a formidable barrier to the efficacy of standard class antifungal medicine given topically. Oral antifungals are effective; however, they often have systemic adverse effects and long treatment regimens, which control patient adherence and increase the risk of relapse. Furthermore, the rising incidence of medicinal resistance to antifungal drugs makes the treatment of this illness more challenging. Therefore, there is a grave need for innovative ways of drug delivery that can overcome these limitations. These formulations enhance the stability of the drug, solubility and permeability through biological barriers such as the hard nail plate.

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ABBREVIATIONS

BHT: Butylated Hydroxytoluene; **CMC:** Chronic Mucocutaneous Candidiasis; **CO:** Candida Onychomycosis; **DDS:** Drug Delivery Systems; **DLSO:** Distal and Lateral Subungual Onychomycosis; **HIV:** Human Immunodeficiency Virus; **NDMs:** Non-Dermatophyte Moulds; **NEs:** Nanoemulsions; **NLC:** Nanostructured Lipid Carriers; **nm:** Nanometres; **O/W:** Oil-in-Water; **PIC:** Phase Inversion Composition; **PIT:** Phase Inversion Temperature; **psi:** Pounds per Square Inch; **PSO:** Proximal subungual onychomycosis; **PVD:** Peripheral Vascular Disease; **SLN:** Solid Lipid Nanoparticles; **SWO:** Superficial White Onychomycosis; **TDO:** Total Dystrophic Onychomycosis.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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