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Research Article

## A Review of Formulation and Evaluation of Posaconazole-Loaded Niosomal Gel for Enhanced Topical Antifungal Therapy

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### Abstract

Fungal infections are one of the biggest global health issues and are linked to serious morbidity, especially in people with impaired immune systems. Poor skin penetration, short retention periods, low bioavailability, and frequent dose needs are some of the problems with traditional topical antifungal treatments. Posaconazole is a broad-spectrum triazole antifungal medication that works well against *Aspergillus* and *Candida* species, among other fungal diseases. However, in traditional formulations, its restricted permeability and poor water solubility diminish its therapeutic efficacy. Drug stability, penetration, prolonged release, and targeted administration can all be enhanced by niosomal drug delivery systems, which have shown great promise as nanocarriers. Niosomes are vesicular structures made of cholesterol and non-ionic surfactants that may encapsulate both hydrophilic and lipophilic medications. Posaconazole-loaded niosomes are added to gel systems to improve topical retention and patient compliance. The formulation strategies, preparation methods, optimisation parameters, assessment procedures, therapeutic uses, benefits, drawbacks, and prospects of posaconazole-loaded niosomal gel systems for the treatment of fungal infections are all well covered in this study. A summary of recent developments in topical antifungal systems based on vesicular nanocarriers is also provided. The promise of niosomal gels as efficient substitutes for traditional antifungal formulations is highlighted in this study, which also supports their potential future therapeutic uses.

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**KEYWORDS:** Posaconazole, niosomes, niosomal gel, vesicular drug delivery, nano formulation, topical antifungal treatment, and controlled release are some of the keywords.

## INTRODUCTION

Due to growing resistance, long-term immunosuppressive treatment, diabetic mellitus, cancer chemotherapy, and HIV-related problems, fungal infections have become serious health issues. Millions of people worldwide suffer from superficial fungal diseases such as onychomycosis, candidiasis, and dermatophytosis. Creams, ointments, and lotions are examples of conventional topical antifungal formulations that have low stratum corneum penetration and need frequent application. Both patient compliance and treatment effectiveness are decreased by these restrictions. A second-generation triazole antifungal medication with broad-spectrum efficacy against harmful fungi is posaconazole. It interferes with ergosterol production and the development of fungal cell membranes by inhibiting fungal lanosterol 14 $\alpha$ -demethylase. Posaconazole has strong antifungal properties; its low skin penetration and poor water solubility make formulation difficult. Innovative medication delivery methods have drawn a lot of interest in order to enhance antifungal treatment. Among them, niosomes, which are made of cholesterol and non-ionic surfactants, are potential vesicular carriers. These methods decrease systemic toxicity, increase drug entrapment, improve penetration, and offer prolonged release. Niosome incorporation into gel bases enhances medication retention and topical application even more. The current study addresses the therapeutic importance of posaconazole-loaded niosomal gel systems in the treatment of fungal infections and concentrates on their development and assessment.

## 2. Fungal Infection Overview

Superficial, cutaneous, subcutaneous, and systemic fungal infections are the different categories of fungal infections. While systemic fungal infections damage internal organs and can be fatal in vulnerable people, superficial infections mostly affect the skin, hair, and nails. *Candida albicans*, *Aspergillus fumigatus*, *Trichophyton rubrum*, *Microsporum* species, and *Cryptococcus neoformans* are examples of common fungal infections. Recurrence of infections and resistance to current antifungal medications continue to be significant treatment difficulties. Because topical medication distribution offers localised action with little systemic adverse effects, it is thought to be beneficial for superficial fungal infections. However, medication penetration is severely limited by the skin's barrier function. To get beyond these restrictions, niosomes and other nanocarrier-based technologies are being thoroughly studied.

### Posaconazole as an Agent for Antifungals

Posaconazole has broad-spectrum antifungal action and is a member of the triazole family of antifungal medications. Fungal membrane production is disrupted as a result of the inhibition of cytochrome P450-dependent lanosterol demethylation.

### 1. Posaconazole's benefits include:

- Wide-ranging antifungal properties.
- Effective against resistant fungus species.
- Less harmful than traditional agents.
- Appropriate for both prevention and treatment.

### 2. Posaconazole's drawbacks

- Insufficient solubility in water.
- Insufficient bioavailability.
- Restricted permeability.
- The necessity of changing the formulation.

These difficulties call for the creation of cutting-edge delivery methods that can enhance topical penetration and medication solubility.

### Suitability of Posaconazole for Niosomal Gel Formulation

Posaconazole is a broad-spectrum triazole antifungal medication commonly used to treat fungal infections. However, its therapeutic efficacy is restricted by its low water solubility and inconsistent absorption. Posaconazole's limitations make it a good choice for vesicular drug delivery systems like niosomes.

Niosomal formulations improve the solubility and stability of medications that are weakly water-soluble by integrating them into the vesicle's bilayer membrane. Posaconazole's lipophilicity allows it to be easily entrapped inside the hydrophobic part of the niosomal bilayer, leading to better drug loading and sustained release characteristics.

The addition of posaconazole to a niosomal gel can increase topical administration by improving medication penetration through the skin and local drug retention at the infection site. The gel technology also offers increased contact duration, improved patient compliance, and controlled medication release. Furthermore, niosomes shield the medicine from degradation and mitigate the systemic negative effects associated with traditional antifungal treatment. Posaconazole's physicochemical features, notably its low solubility and lipophilicity, make it an attractive choice for niosomal gel formulations designed to enhance antifungal activity and targeted topical distribution.

### Niosomes - Vesicular Drug Delivery Systems

Niosomes are tiny vesicular drug delivery systems generated by the self-assembly of non-ionic surfactants in an aqueous medium, which is frequently stabilised by cholesterol or other ingredients. They are structurally composed of one or more concentric bilayers that may encapsulate hydrophilic and lipophilic medicines. Hydrophilic medications are confined in the aqueous core, whereas lipophilic drugs are absorbed via the bilayer membrane.

Niosomes have received a lot of interest in pharmaceutical research because of their capacity to increase medicinal efficacy by increasing bioavailability, stability, and controlled drug release. They also lower medication toxicity and enhance targeted distribution to certain tissues or organs. Niosomes

have various benefits over other vesicular systems, such as liposomes, including improved chemical stability, lower cost, simplicity of storage, and easy manufacturing processes. Niosome characteristics are regulated by parameters such as surfactant type, cholesterol content, manufacturing process, and

vesicle size. Because of their biocompatibility and adaptability, niosomes are intensively studied for the delivery of anticancer medications, anti-inflammatory compounds, peptides, vaccines, and cosmetic formulations via diverse routes, including oral, topical, parenteral, and transdermal use. fig 1

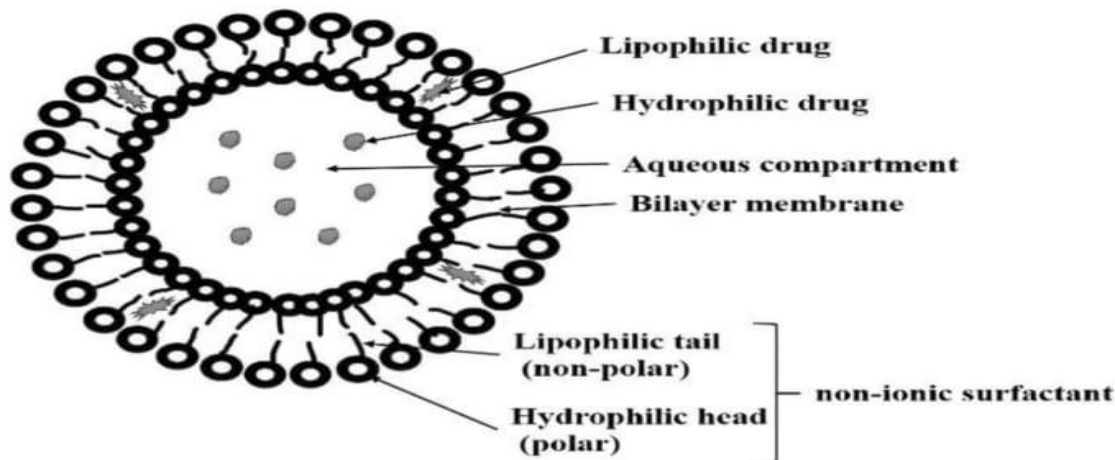


Figure 1: Structure of Niosomes

### Composition of Posaconazole Niosomal Gel

Posaconazole niosomal gel is a vesicular topical drug delivery technology that enhances the solubility, stability, penetration, and therapeutic effectiveness of posaconazole. The formulation is made up of numerous components, including the medication, non-ionic surfactants, cholesterol, charge-inducing agents, aqueous phase, and gelling agents. Each component contributes uniquely to the formulation's development and performance.

#### 1. Posaconazole

Posaconazole is the active medicinal substance contained within the niosomal vesicles. It is a broad-spectrum triazole antifungal that works against a variety of fungal infections. However, posaconazole has low water solubility and absorption, which limit its therapeutic efficacy. Because of its lipophilic nature, the medication may be easily entrapped inside the hydrophobic bilayer of niosomes, resulting in increased solubility, prolonged drug release, and topical penetration.

#### 2. Non-ionic surfactants.

Niosomal formulations primarily use non-ionic surfactants to create vesicles. These surfactants include both hydrophilic and hydrophobic groups, allowing for the spontaneous production of bilayer vesicles in an aqueous environment. Surfactants such as Span 60, Span 40, Tween 60, and Tween 80 are widely utilised. Span 60 is particularly popular because of its high phase transition temperature and ability to improve entrapment efficiency and vesicle stability. The type and concentration of surfactant have a major effect on vesicle size, drug loading, permeability, and release.

#### 3. Cholesterol

Cholesterol is added to the niosomal bilayer to increase membrane stiffness and stability. It lowers the permeability of the vesicular membrane, reducing drug leakage from niosomes. Cholesterol also improves the structural integrity and shelf life of the formulation. The surfactant/cholesterol ratio influences vesicle formation and entrapment efficiency.

#### 4. Charge Inducing Agents

Charge-inducing chemicals are used to increase the physical stability of the niosomal dispersion. These drugs apply a positive or negative charge to the vesicle surface, inhibiting aggregation and fusion via electrostatic repulsion. Dicyetyl phosphate is widely employed as a negatively charged agent, whereas stearylamine provides a positive charge. The addition of these compounds improves dispersion stability and uniformity of vesicles.

#### 5. Aqueous phase.

The aqueous phase hydrates the surfactant-cholesterol combination, allowing vesicle formation. It typically contains phosphate buffer, saline solution, or distilled water. Hydrophilic medications might become trapped inside the aqueous core of the vesicles, whereas lipophilic pharmaceuticals like posaconazole are mostly integrated into the bilayer membrane. The pH and content of the aqueous phase affect vesicle production and stability.

#### 6. Gelling Agents.

The niosomal dispersion is prepared and then combined into a gel foundation for topical administration. Gelling agents like Carbopol 934, Hydroxypropyl methylcellulose (HPMC),

sodium alginate, and xanthan gum are frequently utilised. These ingredients add viscosity, consistency, and spreadability to the formulation. The gel system extends the formulation's residence duration on the skin.

### 7. Additional excipients.

Various extra excipients can be added to increase formulation stability and performance. Preservatives like methyl paraben and propyl paraben prevent microbiological infection. Glycerin and propylene glycol are examples of humectants, which help to keep skin hydrated. pH-adjusting chemicals, such as triethanolamine, are employed to keep the gel's pH within an acceptable range for topical usage.

### Methods of Preparation of Niosomes

Several techniques are employed for the preparation of posaconazole-loaded niosomes.

#### 1. Thin Film Hydration Method

This is the most popular method for producing niosomes. Non-ionic surfactants, cholesterol, and drugs are dissolved in organic solvents like chloroform and methanol. The solvent combination is evaporated under decreased pressure with a rotary evaporator to generate a thin lipid layer on the inner wall of a round-bottom flask. The dried film is subsequently hydrated with an aqueous phase, such as phosphate buffer, while rotating the flask to create multilamellar vesicles. Sonication or homogenization may be used to minimise vesicle size.

#### 2. Ether Injection Method.

Surfactants and cholesterol are dissolved in diethyl ether, which also contains the medication. The organic solution is progressively injected into a heated aqueous phase using a tiny needle. The ether evaporates, forming single-layered niosomal vesicles. This approach often yields big unilamellar vesicles.

#### 3. Reverse Phase Evaporation Method.

Surfactants and cholesterol are dissolved in an organic solvent before being combined with an aqueous medication solution to create a water-in-oil emulsion. The mixture is sonicated, and the organic solvent is extracted at decreased pressure, resulting in the production of niosomes. This approach has a high drug entrapment efficiency.

#### 4. Bubble Method.

The bubble method is a solvent-free approach for producing niosomes. Surfactants and cholesterol are dissolved in an aqueous medium and heated under regulated conditions. Niosomal vesicles are formed when nitrogen gas is fed through a mixture while it is being stirred continuously. This approach avoids the use of hazardous organic solvents.

#### 5. Sonication Method.

Surfactants, cholesterol, and drugs are combined with an aqueous phase before being sonicated using a probe or a bath.

The ultrasonic energy lowers vesicle size, resulting in tiny unilamellar vesicles with a homogeneous distribution.

#### 6. Microfluidization Method.

Microfluidization is the process of mixing two fluid streams at high velocity through microchannels while maintaining regulated pressure. The collision of the streams results in homogenous niosomes with lower particle sizes and improved repeatability.

#### 7. Hand Shaking Method

The hand-shaking technique is comparable to the thin film hydration approach. Surfactants and cholesterol dissolved in organic solvents are manually evaporated to produce a thin film, which is then hydrated with the aqueous phase by gently shaking. This approach is straightforward and cost-effective for laboratory-scale preparation.

#### 8. Proniosome Method.

Proniosomes are dry formulations comprising surfactant-coated carrier materials that are moistened before being used to create niosomes. In comparison to traditional niosomal dispersions, this approach enhances stability, convenience of storage, and handling.

#### 9. Heating Method.

The heating approach involves dispersing surfactants and cholesterol directly in an aqueous medium and heating with continuous stirring until vesicles form. This procedure is straightforward and doesn't require the use of organic solvents.

**Preparation of Posaconazole-Loaded Niosomal Gel**  
Posaconazole-containing niosomal gel is typically made in two steps: first, the niosomal dispersion is created, and then it is incorporated into a gel foundation for topical treatment.

#### 1. Niosomal Dispersal Preparation

Posaconazole is carefully weighed in combination with a suitable non-ionic surfactant, such as Span 60 or Tween 60, and cholesterol in an acceptable ratio. In a round-bottom flask, these components are dissolved in an organic solvent combination consisting of chloroform and methanol. The solvent is then evaporated using a rotary evaporator at low pressure, resulting in the creation of a thin lipid coating on the flask's inner wall.

The dried film is hydrated with an aqueous phase, such as a phosphate buffer solution, at a temperature higher than the surfactant's phase transition temperature. During hydration, mild rotation or shaking creates multilamellar niosomal vesicles that encapsulate the medication. The dispersion is then sonicated or homogenised to minimise vesicle size and create a homogenous niosomal solution.

#### 2. Preparing Gel Base

An appropriate gelling agent, such as Carbopol 934, Hydroxypropyl methylcellulose (HPMC), or sodium alginate, is

continuously stirred into distilled water and allowed to completely hydrate to make a smooth gel basis. Preservatives and other excipients, such as humectants, can be added at this point. To get a clear and stable gel, the pH is adjusted to a desirable range (typically 6-7) with triethanolamine.

### 3. Incorporating Niosomes into Gel

The produced niosomal dispersion is carefully added to the gel foundation while gently swirling to achieve equal distribution of vesicles without causing structural damage. The mixing continues until a uniform niosomal gel is formed. Vigorous stirring is avoided, as it may rupture the vesicles and influence drug entrapment.

### Evaluation Parameters for Niosomal Gel

The niosomal gel containing Posaconazole is tested for various essential characteristics to ensure its appropriateness for topical drug administration, stability, and therapeutic performance.

#### 1. Particle size

This is the average diameter of niosomal vesicles, as assessed by dynamic light scattering. Most studies recommend a size range of 100-300 nm because smaller vesicles have a higher surface area, increased skin penetration, and better drug diffusion across the stratum corneum.

#### 2. Polydispersity index (PDI)

Measures the homogeneity of vesicle size distributions. A low PDI (0.1-0.3) indicates a homogenous system with constant vesicle sizes, which is critical for repeatability, stability, and predictable drug release behaviour.

#### 3. Zeta potential

This metric assesses the surface charge of niosomal vesicles and is an important predictor of physical stability. Values between  $\pm 20$  and  $\pm 40$  mV indicate high electrostatic repulsion between particles, preventing aggregation, fusion, and sedimentation during storage.

#### 4. PH

The gel's pH is adjusted to match that of the skin (5.5-7). This assures that the formulation is non-irritating, biocompatible, and safe for extended topical use without disrupting the skin's natural barrier.

#### 5. Viscosity and Rheology

The gel's consistency and flow behaviour are determined by its viscosity. An appropriate viscosity provides simple application, even spreading, and a sufficient residence duration on the skin. Rheological qualities also impact drug release, with increased viscosity often resulting in slower release.

#### 6. Spreadability

This refers to how quickly the gel spreads over the skin surface with minimum force. Good spreadability provides uniform

administration, improved patient compliance, and consistent dose over the affected region.

#### 7. Entrapment efficiency

This is the percentage of drugs effectively encapsulated within niosomal vesicles. Higher entrapment efficiency is desirable because it indicates more drug loading capacity, less drug waste, and the possibility for prolonged drug release.

#### 9. In vitro drug release

This investigation looks at the rate and pattern of drug release from a formulation over time. Niosomal gels often have a controlled and sustained release profile, allowing therapeutic drug levels to be maintained for a lengthy period of time.

#### 10. Ex vivo skin permeation study

It evaluates the formulation's capacity to enter biological skin membranes using excised skin models. Nanosized vesicles and surfactant-assisted penetration frequently result in enhanced permeability.

#### 11. Stability studies

These studies assess the formulation's performance under various storage circumstances, such as temperature and humidity. Long-term physical and chemical stability is ensured by monitoring parameters such as particle size, zeta potential, and drug content.

#### 12. Antifungal activity

Biological effectiveness is assessed against fungal strains. Improved antifungal action is commonly reported as a result of increased penetration, prolonged release, and improved drug localisation at the infection site.

### Mechanism of Skin Penetration Enhancement

Niosomes improve skin permeability in several ways. Surfactant molecules interact with stratum corneum lipids, altering membrane fluidity and enhancing medication penetration. Vesicles also serve as drug reservoirs, providing continuous release.

The nanosized vesicles enhance interaction with the skin's surface and raise the medication concentration gradient. Incorporation into gel systems extends retention duration at the application location and enhances therapeutic effectiveness.

### Applications of Niosomal Gel Systems.

Niosomal gels are extensively studied for topical and transdermal medication administration. Their applications include the following:

- Antifungal treatment.
- Anti-inflammatory treatment.
- Antibacterial treatment.
- Formulations to treat acne
- Anticancer topical delivery
- Cosmetics and dermatological preparations.

In antifungal treatment, niosomal systems promote medication localisation at infection sites while decreasing systemic side effects.

#### Advantages of Posaconazole-Loaded Niosomal Gel

The main benefits of posaconazole-loaded niosomal gel are:

- Increased drug penetration.
- Better bioavailability.
- Controlled and sustained release.
- Reduced dosing frequency.
- Improved patient compliance

#### Limitations and Challenges

Despite various advantages, niosomal systems have certain limitations:

- Physical instability.
- Vesicle Aggregation and Fusion
- Leakage in storage

#### Recent Advancements in Niosomal Antifungal Systems

Recent research has focused on the creation of sophisticated vesicular systems such as elastic niosomes, proniosomes, transfersomes, and nano-niosomes for improved antifungal treatment. The combination of niosomes, penetration enhancers, and bioadhesive polymers has demonstrated encouraging outcomes. Quality by Design techniques, statistical optimisation, and nanotechnological developments have all enhanced formulation repeatability and medicinal efficacy. Researchers are also looking at ligand-targeted and stimulus-responsive vesicular systems for site-specific drug delivery.

#### Future Perspectives

Future investigations should focus on:

- Clinical assessment of niosomal antifungal systems.

- Large-scale production processes.
- Long-term stability enhancement
- Regulatory approval routes
- Advanced Characterization Techniques
- Use of new biodegradable polymers
- Development of multifunctional nanocarriers.

#### CONCLUSION

Posaconazole-loaded niosomal gel systems are potential nanocarrier-based topical preparations for treating fungal infections. Niosomes enhance medication penetration, stability, controlled release, and targeted administration while minimising systemic adverse effects. Incorporation into gel systems improves patient compliance and topical retention. Continuous improvements in vesicular nanotechnology are expected to aid in the creation of safer and more efficient antifungal treatments. Additional clinical research and industrial scale-up studies are required for the effective commercialisation of niosomal gel formulations.

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