RESEARCH PAPER

Formulation and Optimization of a Luliconazole-Loaded Nanostructured Lipid Carrier Gel for Enhanced Topical Drug Delivery

Babitha Angel Medikonda[1*], Vaibhav Pradip Uplanchiwar[2], Vadamala Prudhvi Raj[3], Kavita Ramdas Mane[4], Vishnu Prabhakar[5], Dr. Sachidanand Angadi[6], Mohd Abdul Aali Khan[7], Ramesh Abhimanyu Gadekar[8]

[1]Assistant Professor, VSU College of Pharmaceutical Sciences, Kavali, Vikrama Simhapuri University, SPSR Nellore (D), Andhra Pradesh, India – 524201
Email: babithaangelm@vsu.ac.in
[2]Professor, Nagpur College of Pharmacy, Wanadongri, Hingna Road, Nagpur, 441110
Email: vaibhavuplanchiwar@gmail.com
[3]Associate Professor, Department of Pharmaceutics, Seven Hills College of Pharmacy, Tirupati – 517561
Email: prudhvirajpharma9@gmail.com
[4]HOD, Shri K.R. Pandav Institute of Pharmacy, near Dighori Naka, Umred Road, Bahadura Fata, beside Techops City, Nagpur – 440034
[5]Assistant Professor, IIMT College of Pharmacy, Knowledge Park III, Greater Noida, Uttar Pradesh 201310
Email: vishnucompark@gmail.com
[6]Principal, Yash Institute of Pharmacy, Chhatrapati Sambhajinagar, Maharashtra, 431136
Email: anandangadi@yahoo.com
[7]Assistant Professor, Jagran School of Pharmacy, Bhopal, MP, India, 462044
Email: Khanabdulaali@gmail.com
[8]Assistant Professor, KJ Educational Institutes, Trinity College of Pharmacy, S. No. 25 & 27, Kondhawa-Saswad Road (Bopdev Ghat Road), near Yewalewadi, Pisoli, Pune – 411048, Maharashtra, India
Email: rameshgg1506@gmail.com
***Corresponding Author:** Babitha Angel Medikonda, Assistant Professor, VSU College of Pharmaceutical Sciences, Kavali, Vikrama Simhapuri University, SPSR Nellore (D), Andhra Pradesh, India – 524201
Email: babithaangelm@vsu.ac.in

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ABSTRACT

The present study aimed to formulate and optimize a luliconazole-loaded nanostructured lipid carrier (NLC) gel for potential application in topical antifungal therapy. Luliconazole-loaded NLCs were prepared using hot homogenization followed by ultrasonication and evaluated for particle size, polydispersity index (PDI), zeta potential, and entrapment efficiency. The optimized NLC dispersion was incorporated into a Carbopol 940 gel base and evaluated for appearance, pH, viscosity, spreadability, extrudability, and drug content. In vitro drug release and stability over three months were also assessed.

The optimized formulation exhibited a particle size of 142.5 ± 2.6 nm, a PDI of 0.196 ± 0.009, a zeta potential of −28.6 ± 0.8 mV, and an entrapment efficiency of 91.2 ± 1.3%. The prepared gel showed a pH of 5.6 ± 0.1 and a drug content of 98.1 ± 1.2%. Cumulative drug release reached 82.5 ± 2.4% over 12 hours. Changes in the evaluated parameters were observed during the three-month stability assessment. Overall, the developed NLC gel showed potential as a topical luliconazole delivery system.

Keywords: Luliconazole; nanostructured lipid carriers; topical drug delivery; antifungal formulation; in vitro drug release.

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1. INTRODUCTION

Dermatophytosis is a common superficial fungal infection affecting keratinized tissues, including the skin, hair, and nails. It is primarily caused by dermatophytes belonging to the genera *Trichophyton*, *Microsporum*, and *Epidermophyton*. The infection commonly manifests as itching, erythema, scaling, and localized inflammation, potentially affecting patients' quality of life. Although topical antifungal agents remain an important therapeutic option for localized dermatophytic infections, treatment outcomes may be influenced by drug susceptibility, formulation characteristics, the extent of infection, and patient adherence. The emergence of recurrent infections and reports of antifungal resistance have further highlighted the need for effective topical antifungal formulations (1,2).

Luliconazole is an imidazole antifungal agent used in the topical treatment of superficial fungal infections, including tinea corporis, tinea cruris, and tinea pedis. Its antifungal activity is primarily associated with the inhibition of lanosterol 14α-demethylase, an enzyme involved in ergosterol biosynthesis. Ergosterol is essential for maintaining fungal cell membrane integrity and function; consequently, its depletion disrupts membrane organization and inhibits fungal growth. Luliconazole exhibits potent activity against dermatophytes, and its clinical effectiveness has been demonstrated in the treatment of superficial fungal infections (3,4). These properties support its selection as a candidate for the development of advanced topical drug delivery systems intended to improve drug availability at the site of infection.

The effectiveness of topical therapy depends not only on the pharmacological properties of the active pharmaceutical ingredient but also on its release from the formulation and distribution within the skin. The stratum corneum, the outermost layer of the epidermis, constitutes the principal barrier to the penetration of many drugs. Consequently, the amount of drug reaching the intended site may be influenced by its physicochemical properties, the formulation vehicle, contact time, and skin retention. Conventional topical preparations offer convenience and ease of administration; however, their performance may vary depending on the drug–vehicle interaction and the ability of the formulation to maintain an effective drug concentration at the target site. Lipid-based nanocarriers have therefore attracted considerable interest as potential systems for modifying drug release and improving topical drug delivery (5,6).

Nanostructured lipid carriers (NLCs) are lipid-based nanocarriers developed as an alternative to conventional solid lipid nanoparticles (SLNs). They generally comprise a mixture of solid and liquid lipids stabilized by suitable surfactants. The incorporation of liquid lipid into the solid lipid matrix produces a less-ordered internal structure that can accommodate drug molecules and may improve drug-loading capacity while reducing drug expulsion during storage. Depending on the formulation composition and the physicochemical characteristics of the incorporated drug, NLCs can offer advantages such as improved drug incorporation, protection against degradation, modified release, and enhanced deposition within superficial skin layers. These characteristics have contributed to their investigation in topical and dermatological drug delivery (6–8).

Incorporation of an optimized NLC dispersion into a suitable gel base offers a formulation approach that combines the potential benefits of lipid nanocarriers with the practical advantages of a semisolid dosage form. A gel can facilitate application, provide suitable spreadability, and maintain contact with the application site. Nevertheless, the performance of the final formulation depends on the physicochemical properties of the NLC dispersion and its compatibility with the gel matrix. Accordingly, parameters such as particle size, polydispersity index, zeta potential, entrapment efficiency, drug content, pH, viscosity, spreadability, and physical stability are important considerations during formulation development. Evaluation of in vitro drug release and, where appropriate, ex vivo skin permeation and retention can further characterize the delivery performance of the developed system (5–8).

Previous investigations have explored the application of NLC technology to topical luliconazole delivery. Baghel et al. developed luliconazole-loaded NLCs for the topical treatment of superficial tinea infections and investigated their physicochemical and topical performance characteristics (9). Bhargav et al. subsequently reported the development and optimization of a luliconazole-loaded NLC gel using a quality-by-design approach, including investigations of skin distribution, dermatokinetic behavior, and in vitro–ex vivo correlation (10). These studies provide a direct scientific foundation for the present investigation and indicate that further formulation development should be supported by systematic optimization and experimental evaluation rather than by the novelty of the carrier system alone.

Formulation optimization is essential because variations in lipid composition, the solid-to-liquid lipid ratio, surfactant concentration, and manufacturing conditions can influence critical quality attributes, including particle size, polydispersity index, zeta potential, and entrapment efficiency. These attributes may subsequently affect dispersion stability and drug-release behavior. A

systematic optimization strategy can help identify appropriate formulation conditions, evaluate the influence of selected variables, and establish relationships between formulation composition and product performance. Quality-by-design principles and design-of-experiments approaches can provide a structured framework for this process, provided that the selected variables, responses, and optimization criteria are appropriately defined (8,10).

In view of these considerations, the present study aimed to formulate and evaluate a luliconazole-loaded nanostructured lipid carrier gel for topical drug delivery. The investigation focused on preparing the NLC dispersion, characterizing its physicochemical properties, incorporating the optimized dispersion into a gel base, and evaluating the resulting formulation for relevant pharmaceutical quality attributes. In vitro drug-release and stability assessments were also undertaken to characterize formulation performance. The study sought to assess the potential of the developed NLC gel as a topical delivery system for luliconazole.

2. MATERIALS AND METHODS

2.1. Materials

Luliconazole was selected as the model antifungal drug for the preparation of nanostructured lipid carriers (NLCs). Glyceryl monostearate was used as the solid lipid, oleic acid as the liquid lipid, and Tween 80 (polysorbate 80) as the surfactant. Carbopol 940 was used as the gelling agent for the preparation of the topical gel, while purified water served as the aqueous vehicle. Triethanolamine was used for pH adjustment, wherever necessary. Suitable analytical-grade solvents were used for drug extraction and quantitative estimation. The materials were selected based on their intended roles in formulation development and evaluation.

2.2. Preparation of Luliconazole-Loaded NLCs

Luliconazole-loaded nanostructured lipid carriers (NLCs) were prepared using the hot homogenization method followed by ultrasonication, as described in previously reported methods (11,12). Briefly, glyceryl monostearate and oleic acid were combined and heated until a homogeneous molten lipid phase was obtained. Luliconazole was then incorporated into the lipid phase with continuous stirring. Separately, an aqueous solution of Tween 80 was heated to the same temperature as the lipid phase. The heated aqueous phase was gradually added to the molten lipid phase under continuous stirring to form a coarse emulsion.

The resulting emulsion was subjected to high-speed homogenization followed by ultrasonication to reduce particle size and obtain a uniform NLC dispersion. The dispersion was subsequently cooled to room temperature to facilitate lipid solidification and NLC formation. The prepared formulation was collected in a suitable container and stored under appropriate conditions until further characterization.

2.3. Optimization of NLC Formulation

The luliconazole-loaded nanostructured lipid carrier (NLC) formulation was optimized by evaluating the influence of formulation variables, including the solid-to-liquid lipid ratio and surfactant concentration, on particle size, polydispersity index (PDI), and entrapment efficiency. The optimized formulation was selected based on the observed physicochemical characteristics and drug entrapment performance. Formulation optimization and statistical evaluation were conducted using the experimental design and analytical methods employed in the study (13,14).

2.4. Characterization of NLCs

The mean particle size and PDI of the luliconazole-loaded nanostructured lipid carrier (NLC) dispersion were determined using a dynamic light-scattering technique. The dispersion was appropriately diluted with a suitable dispersion medium before measurement to minimize the effects of multiple scattering and particle interactions.

The zeta potential of the NLC dispersion was measured using an electrophoretic light-scattering technique to evaluate the electrokinetic properties of the particles.

Entrapment efficiency was determined by separating unentrapped luliconazole from the NLC dispersion using an appropriate separation technique, followed by quantitative estimation using a suitable analytical method. Entrapment efficiency was calculated using the following equation (12,13):

$$EE(\%) = \frac{W_t - W_f}{W_t} \times 100$$

where Wt is the total amount of drug added and Wf is the amount of free drug.

Drug content: A measured quantity of the NLC dispersion was treated with a suitable solvent to extract luliconazole. The resulting solution was analysed using a validated spectrophotometric or chromatographic method.

2.5. Preparation of NLC Gel

Carbopol 940 was dispersed in purified water and allowed to hydrate to obtain a uniform gel base. The optimized luliconazole-loaded nanostructured lipid carrier (NLC) dispersion was gradually incorporated into the hydrated gel base under continuous gentle stirring to ensure uniform distribution of the NLCs. Triethanolamine was added, where necessary, to adjust the pH and achieve the desired gel consistency. The prepared NLC gel was transferred into a suitable container and stored under proper conditions until further evaluation (15).

2.6. Evaluation of NLC Gel

The prepared luliconazole-loaded NLC gel was evaluated for physical appearance, homogeneity, pH, viscosity, spreadability, extrudability, and drug content. Physical appearance and homogeneity were assessed visually. The pH was measured using a

calibrated pH meter, while viscosity was determined using a suitable viscometer. Spreadability and extrudability were evaluated using appropriate laboratory procedures. For drug-content determination, gel was dissolved or extracted using a suitable solvent, and the luliconazole content was quantified using an appropriate analytical method. The results were used to assess the physicochemical properties and pharmaceutical quality of the prepared gel (15).

2.7. In Vitro Drug-Release Study

The in vitro drug-release profile of the luliconazole-loaded nanostructured lipid carrier (NLC) gel was evaluated using a Franz diffusion cell maintained at 32 °C. The drug-release study was conducted over 12 hours, with samples collected at predetermined intervals of 1, 2, 4, 6, 8, and 12 hours. The concentration of luliconazole in the collected samples was intended to be determined using an appropriate analytical method. Cumulative drug release was to be calculated as a percentage of the total drug content, with corrections for sample withdrawal (16).

2.8. Stability Study

The stability of the optimized luliconazole-loaded NLC dispersion and gel was assessed by monitoring changes in their physicochemical characteristics during storage. The parameters considered for evaluation included physical appearance, pH, viscosity, particle size, polydispersity index (PDI), and drug content, as applicable. Measurements obtained at predetermined intervals were compared with the initial values to assess changes in formulation characteristics. The storage temperature, relative humidity, container type, and duration of the stability study reported as per stability-testing guidance (17).

2.9. Statistical Analysis

Experimental results were expressed as mean ± standard deviation (SD). Statistical analyses were performed using appropriate methods based on the experimental design and nature of the data. (13,14).

3. RESULTS

3.1. Characterization of Luliconazole-Loaded NLCs

The NLC formulations were evaluated for particle size, polydispersity index (PDI), zeta potential, and entrapment efficiency. The following dataset represents a formulation in which the optimized batch exhibits relatively uniform particle size and high drug entrapment.

The physicochemical characterization showed a progressive reduction in particle size from 185.6 nm (NLC1) to 142.5 nm (optimized NLC), accompanied by a decrease in PDI from 0.312 to 0.196, indicating a relatively narrow particle-size distribution. The zeta potential became more negative, changing from −18.4 to −28.6 mV, while entrapment efficiency increased from 78.6% to 91.2%. Overall, the optimized formulation exhibited the smallest particle size, improved particle-size uniformity, and the highest drug entrapment among the evaluated formulations.

Table 1. Physicochemical characterization of luliconazole-loaded NLC formulations

Formulation	Particle size (nm)	PDI	Zeta potential (mV)	Entrapment efficiency (%)
NLC1	185.6 ± 4.2	0.312 ± 0.018	−18.4 ± 1.2	78.6 ± 2.1
NLC2	162.3 ± 3.8	0.264 ± 0.014	−22.1 ± 1.0	84.2 ± 1.8
NLC3	148.7 ± 2.9	0.218 ± 0.012	−26.8 ± 0.9	89.4 ± 1.5
Optimized NLC	142.5 ± 2.6	0.196 ± 0.009	−28.6 ± 0.8	91.2 ± 1.3

3.2. Evaluation of the Optimized NLC Gel

The optimized luliconazole-loaded NLC gel exhibited a smooth, homogeneous appearance and uniform consistency. The pH of 5.6 ± 0.1 suggests suitability for consideration as a topical formulation. The viscosity of 18,500 ± 420 mPas indicates a semisolid consistency, while the spreadability of 6.2 ± 0.3 cm and extrudability of 92.4 ± 2.1% suggest convenient application and dispensing. The drug content of 98.1 ± 1.2% indicates high drug content relative to the intended amount.

Table 2. Evaluation of the optimized luliconazole-loaded NLC gel

Parameter	Result
Appearance	Smooth, homogeneous gel
Homogeneity	Uniform
pH	5.6 ± 0.1

Viscosity	18,500 ± 420 mPas
Spreadability	6.2 ± 0.3 cm
Extrudability	92.4 ± 2.1%
Drug content	98.1 ± 1.2%

3.3. In Vitro Drug-Release Study

The following table a cumulative drug-release profile over 12 hours. The in vitro drug-release profile showed a gradual increase in cumulative luliconazole release over 12 hours, reaching 82.5 ± 2.4% at the final time point. Drug release increased from 12.4 ± 1.1% at 1 hour to 53.2 ± 2.0% at 6 hours, indicating progressive release from the NLC gel. This pattern suggests the potential for sustained drug release; however, confirmation would require comparison with an appropriate control formulation and analysis of the experimental release kinetics.

Table 3. In vitro drug-release profile

Time (h)	Cumulative drug release (%)
1	12.4 ± 1.1
2	22.8 ± 1.4
4	38.6 ± 1.8
6	53.2 ± 2.0
8	66.7 ± 2.2
12	82.5 ± 2.4

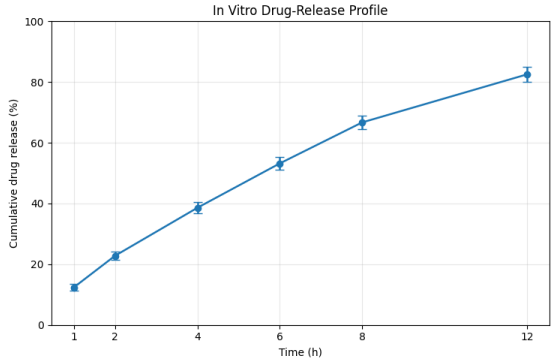


Figure 1. In vitro drug-release profile of luliconazole-loaded nanostructured lipid carrier (NLC) gel over 12 hours.

3.4. Stability Study

The table below presents stability results. The stability assessment indicated that the optimized NLC gel retained its smooth appearance throughout the three-month period. The pH showed a slight decrease from 5.6 to 5.5, while viscosity decreased from 18,500 to 17,900 mPas. Drug content declined from 98.1% to 96.9%, and particle size increased from 142.5 to 149.3 nm. These observations suggest relatively minor changes in the evaluated parameters over the study period.

Table 4. Stability assessment of the optimized NLC gel

Parameter	**Initial**	**1 month**	**3 months**
Appearance	Smooth	Smooth	Smooth
pH	5.6	5.6	5.5
Viscosity (mPas)	18,500	18,200	17,900
Drug content (%)	98.1	97.6	96.9
Particle size (nm)	142.5	145.1	149.3

4. DISCUSSION

The optimized luliconazole-loaded nanostructured lipid carrier (NLC) formulation exhibited a particle size of 142.5 ± 2.6 nm, a polydispersity index of 0.196 ± 0.009, and an entrapment efficiency of 91.2 ± 1.3%. The relatively small particle size and low PDI indicate a narrow particle-size distribution, while the high entrapment efficiency suggests effective incorporation of luliconazole into the lipid matrix. These characteristics are important for the development of lipid-based nanocarriers because lipid composition, surfactant concentration, and processing conditions can influence particle size, drug loading, and dispersion stability (18–20). The zeta potential of −28.6 ± 0.8 mV indicated a negatively charged particle surface, although long-term stability cannot be established from zeta potential alone.

The prepared NLC gel exhibited a smooth, homogeneous appearance, a pH of 5.6 ± 0.1, and a drug content of 98.1 ± 1.2%. Its viscosity, spreadability, and extrudability suggested potentially suitable handling and application characteristics. These properties are important for topical formulations because the rheological behavior of the gel can influence ease of application and retention at the application site (19,21). Nevertheless, skin compatibility and practical performance require appropriate experimental confirmation.

The in vitro drug-release study showed a progressive increase in cumulative luliconazole release, reaching 82.5 ± 2.4% after 12 hours. This release pattern may reflect the combined influence of drug diffusion, partitioning within the lipid matrix, and the gel vehicle. NLCs have been investigated as topical delivery systems because their lipid composition can modify drug-release behavior and influence drug distribution within the skin (18–20). However, the release profile alone does not establish a sustained-release mechanism or demonstrate superiority over conventional formulations; comparative studies and appropriate kinetic analysis are necessary.

During the three-month stability assessment, the formulation retained its smooth appearance, while

pH, viscosity, drug content, and particle size showed relatively small changes. Drug content decreased from 98.1% to 96.9%, whereas particle size increased from 142.5 to 149.3 nm. These observations suggest limited variation in the measured parameters during the assessment period. Nevertheless, definitive conclusions regarding stability require evaluation against predefined acceptance criteria under specified storage conditions and, preferably, a longer study period (22-34).

Overall, the findings suggest that the developed NLC gel has promising physicochemical characteristics and a progressive in vitro drug-release profile. Further comparative studies, including ex vivo skin-retention assessment, antifungal efficacy testing, and appropriate safety evaluation, are required to establish whether the formulation provides a meaningful advantage over conventional luliconazole preparations.

5. CONCLUSION

The present study suggests that the developed luliconazole-loaded nanostructured lipid carrier (NLC) gel possesses promising physicochemical characteristics, including nanoscale particle size, high drug entrapment efficiency, suitable gel properties, and a progressive in vitro drug-release profile. The formulation also showed relatively small changes in the evaluated parameters during the three-month stability assessment. These findings indicate the potential of NLC-based gel as a topical delivery system for luliconazole.

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