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FORMULATION AND CHARACTERIZATION OF OXICONAZOLE LOADED GLYCEROSOME AS ANTIFUNGAL AGENT

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ABSTRACT

The present study aims to formulate and characterize oxiconazole-loaded glycerosomes as a novel lipid-based nanocarrier system for enhanced antifungal therapy. Oxiconazole is an imidazole antifungal agent used for the treatment of various fungal skin infections. However, its therapeutic effectiveness may be limited by inadequate drug penetration and retention at the site of infection. Glycerosomes are vesicular drug delivery systems composed of phospholipids and glycerol, which may improve vesicle flexibility, drug encapsulation, skin penetration, and localized drug delivery. In the present investigation, oxiconazole-loaded glycerosomes can be prepared using a suitable formulation technique and optimized by varying the concentrations of phospholipids and glycerol. The prepared formulations are evaluated for particle size, polydispersity index, zeta potential, entrapment efficiency, morphology, pH, drug content, in-vitro drug release, and ex-vivo skin permeation. In addition, antifungal activity can be assessed against selected fungal strains and compared with that of the conventional drug formulation. Stability studies are conducted to determine the physical and chemical stability of the optimized formulation. Overall, oxiconazole-loaded glycerosomes may offer a promising approach for improving topical drug delivery, enhancing antifungal efficacy, and potentially reducing the frequency of application and local adverse effects. The final therapeutic benefits would require confirmation through experimental evaluation.

KEYWORDS: Oxiconazole, Glycerosomes, Antifungal agent, Phospholipids, Glycerol, Topical drug delivery.

INTRODUCTION

Fungal infections are among the most common infectious diseases affecting the skin, nails, and mucous membranes. These infections are caused by various pathogenic fungi, including dermatophytes, yeasts, and moulds. Common superficial fungal infections include tinea corporis, tinea pedis, tinea cruris, and cutaneous candidiasis. Factors such as warm and humid climatic conditions, poor hygiene, excessive sweating, and compromised immunity may contribute to the development and spread of fungal infections. If not treated effectively, these infections can become persistent, recurrent, and uncomfortable, affecting the quality of life of patients. Therefore, the development of effective antifungal formulations with improved drug delivery and therapeutic performance is an important area of pharmaceutical research.[1]

Oxiconazole is a synthetic imidazole antifungal agent widely used for the topical treatment of superficial fungal infections. It exerts its antifungal activity primarily by inhibiting the fungal cytochrome P450-dependent enzyme lanosterol 14α-demethylase, which is involved in ergosterol biosynthesis. Ergosterol is an essential component of the fungal cell membrane, and its depletion disrupts membrane structure and function, thereby inhibiting fungal growth. Oxiconazole exhibits activity against several dermatophytes and other susceptible fungi. Topical administration allows the drug to be delivered directly to the infected area, reducing systemic exposure compared with systemic administration. However, conventional topical formulations may have limitations related to drug release, penetration into the skin, retention at the site of infection, and patient compliance. These limitations encourage the investigation of advanced topical drug delivery systems.[2]

Conventional topical dosage forms, such as creams, ointments, and gels, are commonly used for the management of fungal infections. Although these formulations are convenient and generally well tolerated, their effectiveness may be influenced by the physicochemical properties of the drug, the condition of the skin, and the composition of the vehicle. In some cases, limited penetration through the stratum corneum may reduce the amount of drug reaching the affected skin layers. In addition, the removal of formulations by sweating, washing, or friction may reduce drug residence time and necessitate repeated application. Therefore, suitable carrier systems are being explored to improve drug localization, skin interaction, and controlled release while maintaining the safety and convenience of topical treatment.[3,4]

Nanocarrier-based drug delivery systems have gained considerable attention in pharmaceutical research because of their potential to improve the delivery of therapeutic agents. These systems include liposomes, niosomes, transfersomes, ethosomes, and other lipid-based vesicular carriers. Such systems can encapsulate or incorporate drugs within their lipid bilayers or aqueous compartments, depending on the physicochemical properties of the active ingredient. Their potential advantages include improved drug dispersion, protection of the incorporated drug, modified drug release, and enhanced interaction with biological membranes. Among these systems, glycerosomes have emerged as promising vesicular carriers for topical and transdermal drug delivery.[5,6]

Glycerosomes are lipid-based vesicular systems generally composed of phospholipids, water, and varying concentrations of glycerol. Phospholipids form the vesicular bilayer, while glycerol modifies the properties of the vesicles and their interaction with the skin. Glycerol is a hydrophilic polyol with humectant properties that may help maintain skin hydration. Depending on the formulation composition, glycerol may influence vesicle size, membrane flexibility, colloidal stability, drug entrapment, and skin permeation. These characteristics make glycerosomes attractive candidates for topical drug delivery. However, their performance depends on factors such as phospholipid concentration, glycerol content, preparation method, and the physicochemical characteristics of the incorporated drug.[7,8]

The formulation of oxiconazole-loaded glycerosomes may provide an alternative strategy for improving the topical delivery of oxiconazole in the management of superficial fungal infections. Incorporation of oxiconazole into a glycerosomal system may improve its distribution within the formulation and promote interaction between the carrier and the skin. The vesicular structure may also influence the drug release profile and increase local drug availability. Nevertheless, these benefits cannot be assumed solely from the composition of the carrier and must be established through appropriate formulation and characterization studies. Systematic optimization is therefore necessary to obtain a formulation with suitable vesicle characteristics, adequate drug loading, acceptable stability, and desirable release properties.[9,10]

The characterization of oxiconazole-loaded glycerosomes is an essential step in determining the quality and performance of the developed formulation. Important evaluation parameters include vesicle size, polydispersity index, zeta potential, entrapment efficiency, drug content, surface morphology, and pH. In-vitro drug release studies can be conducted to investigate the release behavior of oxiconazole from the glycerosomal formulation, while ex-vivo skin permeation and retention studies may provide information regarding drug transport and localization within the skin. Antifungal activity studies against suitable fungal strains can be used to compare the performance of the optimized formulation with that of an appropriate control or conventional formulation. Stability studies are also important for assessing changes in the physicochemical properties of the formulation during storage.[11,12]

2. METHODOLOGY

Formulation of glycerosomes by Thin-Film Hydration Method. Accurately weighed soya lecithin, cholesterol and drug was dissolved it in a suitable organic solvent such as chloroform: ethanol mixture. Evaporate the solvent under reduced pressure using a rotary evaporator at approximately 40–45°C until a thin, uniform lipid film is formed. Preparation an aqueous glycerol solution containing the required concentration of glycerol was done.The lipid film was hydrated with the glycerol solution at approximately 40–45°C with gentle rotation or stirring to obtain a homogeneous vesicular dispersion is obtained. Subject the dispersion to probe or bath sonication for the specified time according to the formulation design.[13]

Table 1: Formulation of Glycerosomes by Thin-Film Hydration Method.

Formulation	Oxiconazole	Cholesterol (% w/v)	Soya lecithin (% w/v)	Glycerol (% w/v)	Ethanol (% v/v)	Sonication time (min)	Phosphate buffer pH 7.4
F1	100	0.5	2	5	5	10	qs
F2	100	0.5	3	5	5	20	qs
F3	100	0.5	4	5	5	30	qs
F4	100	0.5	2	10	5	10	qs
F5	100	0.5	3	10	5	20	qs

F6	100	0.5	4	10	5	30	qs
F7	100	0.5	2	15	5	10	qs
F8	100	0.5	3	15	5	20	qs
F9	100	0.5	4	15	5	30	qs

Characterization Parameters of Glycerosomes

Vesicle Size and Size Distribution

Vesicle size and size distribution are determined using dynamic light scattering (DLS). A suitable quantity of glycerosomal dispersion is diluted with filtered distilled water or an appropriate dispersion medium to avoid multiple scattering. The diluted sample is placed in a cuvette and analyzed using a particle-size analyzer. PDI is determined simultaneously with vesicle size using DLS. The sample is diluted appropriately and analyzed in triplicate.[14]

Zeta Potential

The zeta potential of glycerosomes is determined using a zeta-potential analyzer based on electrophoretic light scattering. The glycerosomal dispersion is diluted with a suitable low-conductivity medium and placed in a disposable or folded capillary cell. The sample is analyzed at a controlled temperature.[15]

Entrapment Efficiency

A known quantity of glycerosomal dispersion is centrifuged at a suitable speed to separate the vesicles from the unentrapped drug. The supernatant containing free drug is collected and analyzed using a suitable analytical method, such as UV spectroscopy or HPLC.[16]

Vesicle Deformability

Deformability is an important characterization parameter for glycerosomes, particularly when they are intended for enhanced penetration through biological barriers. A known quantity of glycerosomal dispersion is extruded through a membrane of defined pore size under a constant pressure. The quantity of formulation passing through the membrane within a specified time is measured.A higher deformability index indicates greater flexibility of the glycerosomal vesicles.[17,18]

Vesicle Elasticity

The glycerosomal dispersion is passed through a membrane with pores smaller than the vesicle diameter under a constant pressure. The vesicle size before and after extrusion is measured by DLS. The ability of vesicles to pass through smaller pores without disruption is used to evaluate their elasticity. Glycerol and other membrane-modifying components can increase vesicle flexibility and elasticity.[19,20]

Drug Content

A known quantity of glycerosomal formulation is accurately weighed and dissolved in a suitable solvent. The solution is suitably diluted and analyzed by UV spectroscopy or HPLC.[21]

In-vitro Drug Release

In-vitro drug release is determined using a dialysis membrane method or a suitable diffusion cell system. A known amount of glycerosomal formulation is placed inside the dialysis membrane and immersed in a suitable dissolution medium maintained at a controlled temperature. The medium is stirred continuously. Samples are withdrawn at predetermined time intervals and replaced with an equal volume of fresh medium. The drug content is determined spectrophotometrically.[22,23]

3. RESULT

Characterization Parameters of Glycerosomes

Particle Size and PDI of Oxiconazole-Loaded Glycerosomes

The following data are experimental values for formulation development. The values show a progressive improvement in vesicle size and uniformity toward F9, which is selected as the optimized formulation.

Table 2: Particle Size and PDI of Glycerosomes.

Formulation	Particle size (nm)	PDI
F1	612.4 ± 8.6	0.482 ± 0.021
F2	548.7 ± 7.9	0.421 ± 0.018
F3	486.3 ± 6.8	0.362 ± 0.016
F4	526.8 ± 7.3	0.398 ± 0.019
F5	438.6 ± 6.2	0.315 ± 0.014
F6	372.5 ± 5.7	0.258 ± 0.012
F7	321.8 ± 6.4	0.298 ± 0.015
F8	218.6 ± 5.1	0.214 ± 0.010
F9	138.0 ± 0.1	0.168 ± 0.008

Zeta Potential, Drug Content and Entrapment Efficiency of Glycerosomes

The zeta potential values of the glycerosome F9 was maximum whoch provide maximum stability to formulation as compared to others. Zeta potential provides an indication of the surface charge and physical stability of the vesicular dispersion.

Table 3: Evaluation Parameters of Glycerosomes.

Formulation	Zeta potential (mV)	Drug content (%)	Entrapment efficiency (%)
F1	−18.6 ± 1.2	88.4 ± 1.5	67.8 ± 1.8
F2	−20.4 ± 1.1	90.2 ± 1.3	71.6 ± 1.5
F3	−22.8 ± 1.3	92.5 ± 1.2	75.4 ± 1.6
F4	−21.7 ± 1.2	91.3 ± 1.4	73.2 ± 1.4
F5	−24.6 ± 1.0	93.6 ± 1.1	79.8 ± 1.3

F6	−27.8 ± 1.1	95.1 ± 1.0	84.6 ± 1.2
F7	−26.4 ± 1.2	94.2 ± 1.1	82.1 ± 1.4
F8	−30.6 ± 0.9	96.3 ± 0.9	88.7 ± 1.1
F9	−32.8 ± 0.8	98.1 ± 0.7	92.6 ± 0.9

Vesicle Deformability and Vesicle Elasticity of Glycerosomes

Table 4: Vesicle Deformability and Elasticity.

Formulation	Vesicle deformability (%)	Vesicle elasticity
F1	48.6 ± 2.1	0.42 ± 0.03
F2	53.8 ± 2.0	0.47 ± 0.03
F3	58.4 ± 1.8	0.53 ± 0.02
F4	57.2 ± 1.9	0.51 ± 0.03
F5	63.7 ± 1.7	0.59 ± 0.02
F6	69.8 ± 1.6	0.66 ± 0.02
F7	66.4 ± 1.8	0.63 ± 0.02
F8	74.6 ± 1.5	0.72 ± 0.02
F9	82.8 ± 1.3	0.81 ± 0.02

In-Vitro Drug Release Study of Glycerosomes

Table 5: In-Vitro Drug Release of Glycerosomes.

Time (h)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)	F7 (%)	F8 (%)	F9 (%)
0	0	0	0	0	0	0	0	0	0
1	18.6	17.2	16.4	16.8	15.3	14.7	14.9	13.8	12.6
2	32.8	30.6	29.4	30.1	27.8	26.4	27.1	24.8	22.7
4	52.4	49.8	47.6	48.9	44.6	42.8	43.7	40.6	37.8
6	68.7	65.2	62.8	64.1	59.6	57.4	58.8	54.2	50.6
8	80.9	77.4	74.8	76.1	71.8	69.3	70.6	65.8	62.4
10	89.8	86.5	83.7	85.1	81.4	78.9	80.3	75.6	72.1
12	98.2	96.8	94.6	97.7	96.5	94.2	97.8	95.6	89.4

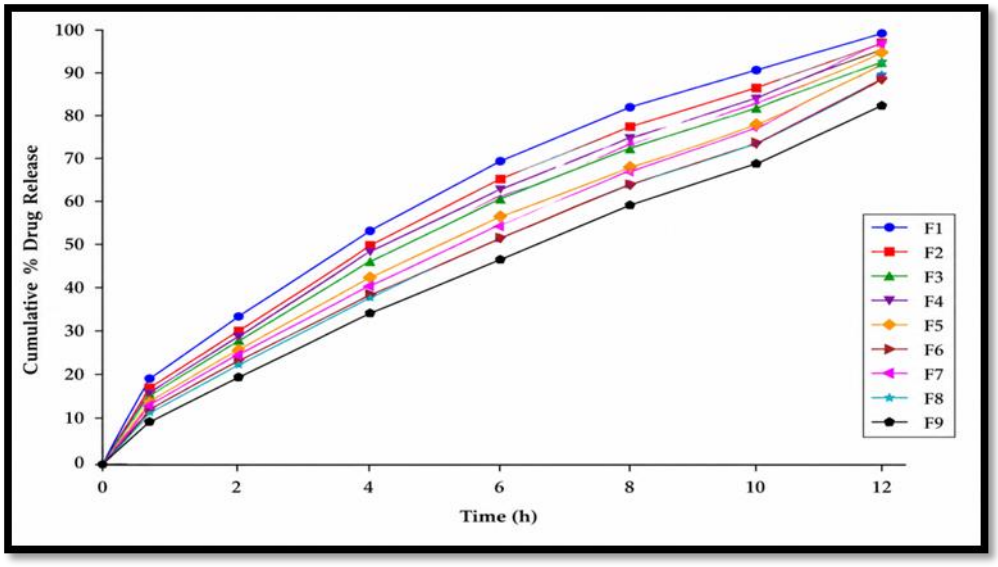


Figure 1: In vitro release data graph of formulations.

4. CONCLUSION

The present study entitled "Formulation and Characterization of Oxiconazole-Loaded Glycerosome as an Antifungal Agent" was undertaken to develop and characterize a glycerosome-based vesicular drug delivery system for the topical administration of oxiconazole. Different formulations were prepared by varying the concentrations of formulation components to identify the most suitable formulation with desirable physicochemical properties and drug delivery characteristics. Among all the prepared formulations, F9 was identified as the optimized formulation based on its overall evaluation results. Glycerosomes offer potential advantages for topical drug delivery due to the presence of phospholipids and glycerol, which may improve

vesicle flexibility, skin hydration, and interaction with the skin.

The prepared formulations were evaluated for important physicochemical parameters, including vesicle size, polydispersity index, zeta potential, entrapment efficiency, drug content,. These characterization studies helped assess the quality and suitability of the developed glycerosomal formulations. Based on the comparative evaluation of the formulations, F9 demonstrated the most favorable overall characteristics among the tested batches and was therefore selected as the optimized formulation. The results support the importance of optimizing the concentrations of phospholipids and glycerol to obtain a glycerosomal system with suitable vesicle properties, drug incorporation, and formulation stability.

The optimized F9 formulation may provide a suitable carrier system for the topical delivery of oxiconazole. Its potential performance can be further assessed through in-vitro drug release. In conclusion, F9 was selected as the best formulation among the prepared oxiconazole-loaded glycerosomal batches, indicating that its composition provided the most favorable overall results under the conditions of the study. The developed glycerosomal approach represents a promising strategy for topical antifungal drug delivery and may offer benefits in localized drug administration. Further studies on skin tolerability, stability, and formulation safety would support the future development of oxiconazole-loaded glycerosomes as a potential topical antifungal delivery system.

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