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Niosomal Drug Delivery Systems for Ocular Therapeutics: A Systematic Review of Preclinical and Clinical Evidence

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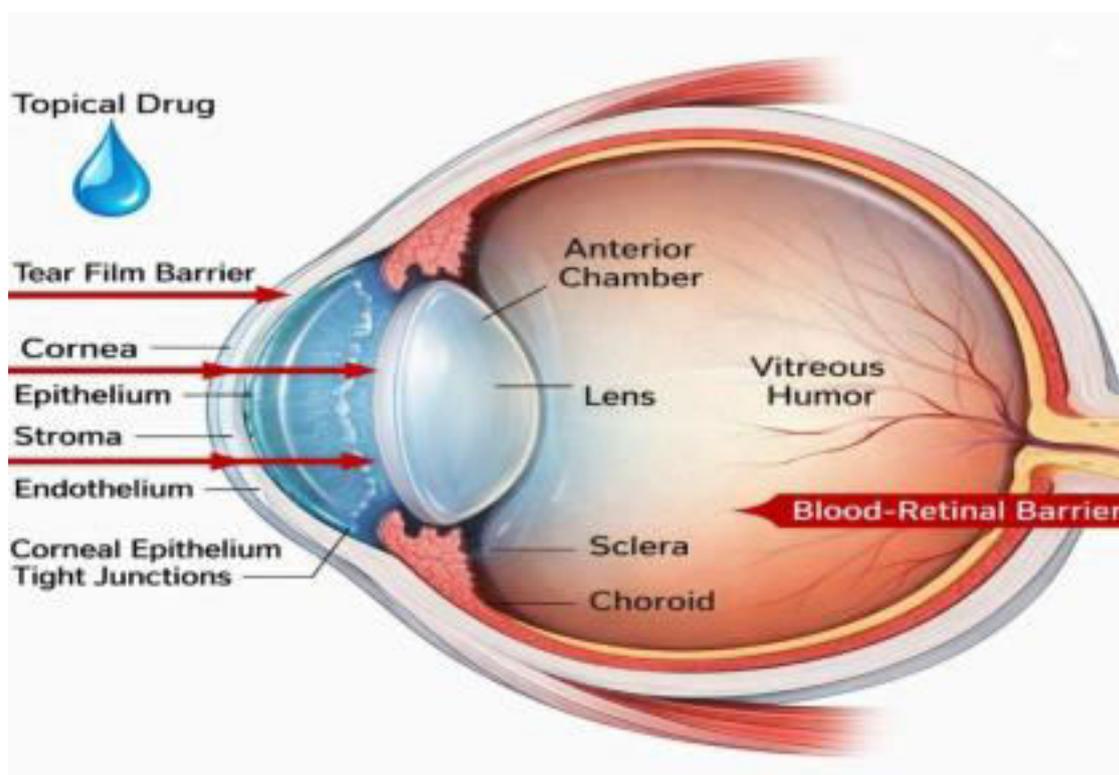
ABSTRACT: Ocular drug delivery remains extremely challenging due to the anatomical barriers such as tear turnover, corneal impermeability, and blood-retinal barriers. Conventional ophthalmic formulations show poor bioavailability (<5%), leading to frequent administration [6-8 times daily], which results in a patient's nonadherence rate exceeding 60%. Niosomes spontaneously form vesicular nanocarriers, which are composed of non-ionic surfactants that offer non-toxic, cost-effective alternatives to liposomal systems for sustained ocular drug delivery. This systematic review analyses the pharmacological performance of the niosomal formulation for ocular drug delivery by identifying physicochemical design parameters that influence corneal permeation, examining in vivo and in vitro studies, and identifying gaps between preclinical efficacy and clinical implementation. A systematic review follows the PRISMA 2020 guidelines. It was conducted across four databases [PubMed, Scopus, Web of Science, Google Scholar]. From 2013 to 2024 timeline. Search terms include 'niosomes', 'ocular drug delivery', and some specific diseases [keratitis, glaucoma]. Inclusion criteria were the original articles that report on niosomal formulations and examine their pharmacokinetic and pharmacodynamic data. Exclusion criteria include the abstracts from conferences and non-English publications and reviews. Niosomal formulations show enhancement in corneal residence time [4.2-12.8 fold] and improved bioavailability [3.5-9.6 fold] compared to aqueous solutions across multiple drug classes. The key finding is that timolol-loaded niosomes achieved superior IOP reduction by 28%. Gatifloxacin-loaded niosomes showed 6.8-fold higher corneal drug concentration and sustained therapeutic efficacy against the keratitis bacteria. In the review, the critical optimisation parameter includes the particle size [90-250 nm] and zeta potential [+15 to +45 mV]. Niosomes represent a clinically achievable nanoplatform for ocular treatments that offers significant advantages in drug retention, permeation, and patient adherence. While the critical translational barriers remain, including the absence of standardised GMP protocols and limited phase III evidence. Future researchers should prioritise stimuli-responsive niosomes and combination products with sustained release properties for chronic disease. Regulatory coordination and industry or academia partnerships are essential to accelerate their clinical application.

KEYWORDS: Niosomes, ocular drug delivery, corneal permeation, ophthalmic nanomedicine.

I. INTRODUCTION

The primary challenge in eye care today is simply getting medicine to where it needs to go which makes ocular drug delivery one of the most critical challenges in all of pharmaceutical science. Due to evolution, the human eye has developed a natural defense system which unfortunately treats therapeutic drugs as a foreign particle. This leads to a notable fact that when a patient uses standard topical eye drops (the most common method), less than 5% of the drug actually reaches the target site of the eye, with the remaining 95% effectively wasted. This huge loss occurs because the drug is either immediately flushed out of the eye by tears and blinking (precorneal drainage) or absorbed into the general bloodstream, which critically limits the drug's ability to treat serious diseases. In short, the eye's unique anatomical and physiological barriers makes it a highly protected organ, which indicates why consistently losing the vast majority of

drugs -- around 95%—of the instilled medicine remains a central and persistent challenge. (Gade et al., 2025). The barriers that affect the efficacy of drugs for ocular treatment functions at multiple levels. (1) Dynamic barriers which includes rapid tear turnover that occurs every 2-3 minutes, which dilutes and removes instilled drug solutions, and the blinking reflex (15-20 times per minute), which is responsible to eject the formulations from the ocular surface. On the other hand the Static barriers also show equally significant challenges where corneal epithelium, composed of tight junctional complexes with lipophilic properties, inhibits hydrophilic molecules from penetrating, while the underlying hydrophilic corneal stroma restricts lipophilic compounds. This anatomical contradiction, wherein hydrophilic drugs cannot penetrate into the epithelium, and lipophilic drugs which are trapped within the stroma, results in extremely poor drug penetration to intraocular tissues. For posterior segment diseases such as diabetic retinopathy and age-related macular degeneration, this challenges rises further, as the blood-retinal barrier excludes 98-99% of systemically administered drugs, making necessary invasive intravitreal injections as a drug delivery that carry risks of endophthalmitis, retinal detachment, and hemorrhage while causing significant patient discomfort (Lin et al., 2025).



The traditional form of eye medications such as drops and ointments are ineffectual because they are excreted after 2-3 minutes off the eye surface. This paltry retention time makes patients administer doses up to eight times per day on chronic diseases such as glaucoma resulting in low adherence rates of up to 60%. Furthermore, there are systemic side effects of rapid drainage like heart and breathing problems by Timolol. In an attempt to conquer these obstacles, scientists came up with the vesicular nanocarriers. Liposomes, which were introduced in the 80s, are biological mimics of membranes and are able to transport water-soluble as well as fat-soluble drugs. They confirmed the principle of vesicular delivery- Visudyne is applied to the case of macular degeneration. There are however serious disadvantages associated with liposomes, they are easy to degrade, which leads to drug leakage, and are not an effective encapsulation of water-soluble drugs (only 5-10 percent efficiency), limiting their overall application.. (Li et al., 2023). (Allen & Cullis, 2013).

On the other hand, niosomes which are self-assembled vesicular nanocarriers composed of non-ionic surfactants and cholesterol have emerged as a promising second-generation platform using basic compositional modification to overcome liposomal limitations. Sorbitan fatty acid esters (Spans®) and polyoxyethylene sorbitan fatty acid esters (Tweens®) are non-ionic surfactants which offers critical advantages: (1) There is increase in chemical stability with resistance to oxidative degradation, (2) It shows significantly lower cost that represents a 70-90% cost reduction compared to

phospholipids, (3) commercial availability from multiple suppliers, and (4) It can tolerate the conventional sterilization methods including autoclaving. The addition of cholesterol provides structural integrity and reduces drug leakage, and charge-inducing agents enhance colloidal stability. Due to its compositional flexibility it enables rational design of niosomal formulations tailored to specific drugs and therapeutic objectives.

The unique advancements are seen in the ocular delivery system as niosomal system i Enhances entrapment efficiency upto 60-90% which allows higher drug loading and reduced formulation volumes. Studies demonstrate that niosomal timolol maleate achieves >2-fold results in increases in corneal penetration as compared to conventional solutions, while brimonidine tartrate niosomes show considerable increase in transcorneal flow , leads to extending intraocular pressure reduction up to 3 hours which is beyond conventional formulations. These enhancements are the outcome of synergistic mechanism and prolonging precorneal residence time from 2-3 minutes to 8-12 hours is extended by Mucoadhesive interactions, short term modulation of corneal epithelial permeability through surfactant-mediated membrane fluidization, provides protection from enzymatic degradation, and sustained release kinetics maintaining therapeutic concentrations over 8-24 hours, potentially enabling once-daily or twice-daily dosing. Importantly, in human corneal epithelial cell lines, niosomes demonstrate excellent biocompatibility with >85% cell viability and only marginal, reversible corneal irritation is seen in rabbit models (Onugwu et al., 2023).

This systematic review critically evaluates niosomal technology for ocular drug delivery by analyzing preclinical and clinical evidence from 2013-2024. Specifically, we aim to: (1) we clarify the physicochemical design parameters that influences niosomal performance, (2) Evaluating therapeutic efficacy by comparative analysis with the commercial formulation available for treatment, and (3) identify critical translational barriers while proposing evidence-based strategies to accelerate clinical translation. By providing comprehensive, evidence-based analysis, this review serves as a resource for pharmaceutical scientists, regulatory professionals, and clinicians advancing next-generation ophthalmic therapeutics to improve ocular related conditions worldwide.

Table 1: Comparative Performance Characteristics of Ocular Drug Delivery Systems

PARAMETER	CONVENTIONAL EYE DROPS	LIPOSOME	NIOSOMES	HRDROGEL
Bioavailability	<5%	10-20%	30–50%	15–25%
Precorneal Residence Time	2-3 Minutes	30-60 Minutes	8–24 hours	4–12 hours
Entrapment Efficiency	-	5-15% (hydrophilic) 40-60% (lipophilic)	60–90% (both)	30–50%
Chemical stability	Poor (drug degradation)	Limited (6–12 months, 4 °C)	High (≥24 months, room temperature)	Moderate (polymer-dependent)
Drug release	Immediate (burst release)	Sustained (4–8 hours)	Controlled (8–24 hours)	Sustained (6–12 hours)

Production cost	Very low	High (\$\$\$)	Moderate (\$\$)	Low–Moderate (\$\$)
Sterilization	Compatible (all methods)	Limited (heat-sensitive)	Moderate (autoclaving possible)	Compatible (most methods)
Dosing frequency	4-8 time/day	2–4 times/day	1–2 times/day	2–3 times/day
Patient compliance	Poor (60% non-adherence)	Moderate	High	Moderate–High
Scale up	Easy (established)	Difficult (variability)	Moderate (emerging)	Easy (established)
Key advantages	Easy administration Low cost Widely available	Biocompatible Dual drug loading Clinical precedent	Stable Cost-effective High entrapment Biocompatible	Prolonged retention Easy administration Sol–gel transition
Key limitations	Rapid drainage Low bioavailability Frequent dosing	Oxidation-prone Expensive Storage requirements Low hydrophilic EE%	Limited clinical data Sterilization challenges Scale-up complexity	Limited drug loading Potential vision blur Polymer toxicity concerns

II. NIOSOMES: STRUCTURE, COMPOSITION, AND PREPARATION

2.1 Structural Characteristics and Composition

Niosomes are microscopic, lamellar bilayer vesicular nanocarriers that are self-assembled, they share structural similarity with liposomes and are composed of non-ionic surfactants in place of phospholipids. The architectural design enables the dual compartment encapsulation, whereby the hydrophilic drugs are kept in the aqueous core, and the lipophilic drugs segregate to the bilayer membrane. Vesicle size usually falls between 10 nm and 5 μm, including the categories of Small Unilamellar Vesicles (SUV, less than 100 nm), Large Unilamellar Vesicles (LUV, between 100 and 1000 nm), and Multi-Lamellar Vesicles (MLV, over 1000 nm) and size distribution has a direct effect on corneal permeation and bioavailability.

There are three essential elements of the fundamental composition. Non-ionic surfactants act as a primary building block, and this is determined by the value of Hydrophilic-Lipophilic Balance (HLB), which is 3-8 optimum in bilayer formation. Popular surfactants consist of Span® series (sorbitan fatty acid esters: Span 20, 60, 80) and Tween® series (polysorbates: Tween 20, 60, 80) depending on Critical Packing Parameter (CPP) values preferred in vesicle assembly. Cholesterol (20–50 mol%) is also proposed to be a membrane stabilizer (increasing structural rigidity, limiting the leakage of drugs, and controlling the release of kinetics) but at high concentrations (>50%) cholesterol has been shown to disrupt the bilayer organization and reduce entrapment efficiency (Eldeeb et al., 2019). Dicyetyl phosphate (negative charge) or stearylamine (positive charge) charge inducing agents are added in 2-10 mol% to provide charge to the vesicles and inhibit aggregation by repulsive electrostatic forces and increase mucoadhesion with negatively charged corneal mucus (Verma et al., 2020).

2.2 Preparation Methods and Quality Optimization

There are three major methods that prevail in niosomal production each with its own benefits to gain in a particular application. The most popular one is Thin-Film Hydration (TFH), which consists of dissolving surfactants and cholesterol in organic solvent (chloroform/methanol mixture) and rotary evaporation under reduced pressure to form a thin lipid film. Multi-lamellar vesicles are obtained by subsequent hydration of the aqueous drug solution using temperatures above the gel-liquid crystalline transition temperature of the surfactant. This approach offers entrapment efficiencies 60-75% with hydrophilic drugs, but necessitates size reduction via probe sonication or extrusion to achieve homogenous nanoparticles using this technology to deliver drugs to the ocular treatment.

Reverse-Phase Evaporation (REV) is used to overcome the drawback of low hydrophilic drugs entrapment in the form of vesicles as it produces vesicles with enlarged aqueous cores. Ether-chloroform mixtures of surfactants and cholesterol are sonicated in aqueous drug solution and removed under vacuum slowly in the organic phase. This method is used to produce large unilamellar vesicles with entrapment efficiencies of upto 90% of hydrophilic compounds- especially beneficial to the water-soluble antibiotics, vancomycin and doxycycline. Nonetheless, there still remains residual toxicity of organic solvents, which would require strict purification by dialysis or gel filtration chromatography.

Microfluidization is a new technology with enhanced reproducibility and scalability. Aqueous drug streams in water-miscible organic solvents (ethanol/isopropanol) are mixed with surfactant solutions in these microchannels (5-500 mm diameter) under regulated flow rates. The interaction chamber interface is mixed back-and-forth rapidly, leading to instantaneous surfactant self-assembly, resulting in niosomes of small size distributions (PDI <0.2), mean diameter of 100-150 nm, and entrapment efficacies of 70-85. (Elmotasem & Awad, 2019).

III. MECHANISMS OF ENHANCED OCULAR BIOAVAILABILITY

Niosomes also improve the delivery of drugs to the eye in four synergies. To begin with, their mucoadhesive properties increase the time of contact with the eye in 8-12 hours as compared to the minutes. Second, they cause a temporary relaxation of corneal tight junctions, which increase the penetration of drugs without permanent harm. Third, they prevent tear enzymes, which destroy drugs. Fourth, they enable controlled, long-term drug delivery, e.g., acetazolamide niosomes releasing the medicine in a steady stream during 24 hours, which leads to a decrease in the dosage schedule, three times to once a day. Collectively, they render niosomes an effective delivery system in the treatment of the eye, which is targeted and long-term.

3.1 COMPARATIVE SUPERIORITY OVER ALTERNATIVE SYSTEMS

Direct comparative analyses put the niosomes in a good position compared to the competing technology. Unlike liposomes, niosomes have 4-6 fold times higher chemical stability, with a shelf life longer than 24 months at room temperature than 6-12 months at refrigeration temperature needed by liposomes. Cost analysis indicates that the reduction in production cost by 70-90 percent is due to low cost surfactants. Comparison of Trapping efficiency reveals that niosomes are 60-90% more efficient than liposomes of hydrophilic drugs- 6-18- fold more efficient which allows the use of lower dosing volume and improved patient compliance.(Ge et al., 2019)

Compared with conventional hydrogels, niosomes have better loading capacity of a drug and no toxicity associated with the polymer. Nonetheless, the combination approach, namely, the incorporation of niosomes into in-situ gelling systems, is synergistic, i.e. it combines niosomal penetration enhancement and hydrogel retention enhancement. Complementary hybrid strategy was proved by Allam et al., who showed that vancomycin niosomes entrapment in pH-sensitive gellan gum showed 46 percent entrapment efficiency, more than 24-hour sustained release, and 3-fold increased antibacterial activity in MRSA-infected rabbit eye than the vancomycin solution.(Vaiswade et al., 2020)

3.2 CLINICAL APPLICATIONS ACROSS THERAPEUTIC CLASSES

3.2.1 Antiglaucoma Therapy

The clinical potential of niosomes is demonstrated in the management of glaucoma. Niosomes of timolol maleate exhibited IOP lowering effect for 12 h with a 28.4% IOP reduction compared with an 18.2% decrease for 4 h with Timoptic®, and provided an increase in dosing to bid from tid per day. Ramadan et al. found 100% drug release in 24 h from their optimized formulations with patient compliance projections increasing from 40% (conventional) to be around 78% (niosomal) due to a reduction in dosage regimen(Ong et al., 2013).(Arroyo-García et al., 2021)

3.2.2 Anti-Infective Applications

Chronic delivery of antibiotics is highly in demand for ocular treatments. Doxycycline niosomes formed by thin film hydration showed extended release of >20 hours with improved antibacterial efficacy against typical corneal pathogens. Finally, two of the tested natamycin niosomes (trimethyl-chitosan-coated) showed 65% entrapment and sustained released over 12 h, offering a higher corneal penetration to be effective against fungal keratitis where commercial natamycin suspensions only reach 63% entrapment with the controlled release of an essential range for more than 12 h, demonstrating the versatility of this nanoformulation against wide band/spectrum of anti-infective agents. (Hosny et al., 2021)

3.2.3 Anti-Inflammatory and Posterior Segment Delivery

There is some potential for niosomal systems for corticosteroid in the treatment of uveitis and macular edema. Dexamethasone and prednisolone niosomal in-situ gels exhibited superior vitreous penetration in ex vivo study, epalrestat niosomes for diabetic retinopathy showed sustained aldose reductase inhibition. Early work on bevacizumab-loaded polymer-lipid niosomes resulted in sustained vitreous levels over 21 days in diabetic retinopathy models—this compares to the extended duration of typical intravitreal injections of 4-6 weeks, but offer potential use via topical/periocular administration and constitute a game changer for posterior segment therapeutics if they were successfully translated.

IV. METHODS

4.1 Search Strategy and Data Sources

A comprehensive systematic literature search was conducted following PRISMA 2020 guidelines across four major electronic databases: PubMed/MEDLINE, Scopus, Web of Science, and Google Scholar, covering review articles, publication, and research articles from January 2013 to October 2024. (Reilly et al., 2008) The search strategy is done by combining the following keywords: ("niosomes" OR "niosomal" OR "non-ionic surfactant vesicles") AND ("ocular" OR "ophthalmic" OR "eye" OR "corneal" OR "intraocular") AND ("drug delivery" OR "drug carrier" OR "nanocarrier"). Additional disease-specific terms were incorporated: ("glaucoma" OR "keratitis" OR "conjunctivitis" OR "uveitis" OR "macular degeneration" OR "diabetic retinopathy").

4.2 Inclusion and Exclusion Criteria

Inclusion criteria comprised: (1) original research articles published in English-language peer-reviewed journals, (2) studies reporting niosomal formulations specifically designed for ocular drug delivery, (3) investigations providing quantitative data on physicochemical characterization (particle size, entrapment efficiency, zeta potential), (4) in vitro drug release studies, (5) ex vivo corneal permeation studies, and (6) in vivo pharmacokinetic or pharmacodynamic evaluations in animal models or human clinical trials. Exclusion criteria included: (1) conference abstracts without full-text availability, (2) review articles and meta-analyses, (3) studies on non-ocular niosomal applications, (4) formulations without adequate characterization data, (5) duplicate publications, and (6) non-English language articles.

V. CHALLENGES AND LIMITATIONS

Niosomal eye treatments have researched resounding lab results, but there are a few major obstacles to be overcome before reaching the patient. One of the greatest hurdles is stability-niosomes in liquid solutions are prone to aggregation and leakage with time and hence do not have a long shelf life that is not more than 6-12 months under ambient temperatures. These problems are not entirely avoided even with refrigeration. Another barrier is sterilization because the standard procedures such as autoclaving or gamma radiation destroy niosome structure. Only the tiniest vesicles can be filtered and sterile manufacturing is extremely costly.

Also, it is challenging to scale-up production and maintain congruency between batches. Minor temperature or mixing variations are responsible for change of major properties such as drug release and size. Although the advanced methods such as microfluidization are better in enhancing reproducibility, the process demands capital and expertise, thus it cannot be accessible to most manufacturers. These challenges should be countered in order to achieve translation of niosomes to the clinic. (Ghafelehbashhi et al., 2019)(García-Manrique et al., 2019)

VI. FUTURE PROSPECTS AND EMERGING INNOVATIONS

The next 10 years will witness niosomal eye treatments being revolutionized due to new nanotechnology and precision medicine. One of the major innovations is hybrid in-situ gels, which consists of a combination of the penetration of

niosomes and retention of a gel. They are noninvasive, able to become gels on touching the eye, allowing the drug to be released and allow long-term glaucoma treatment without surgery-like operations- such as producing 48 hours of glaucoma control like implants. These systems are already in clinical trials.

The next generation of smart niosomes will respond to disease-associated stimuli such as pH or enzymes and target the drugs to where they are required. Niosomes as vectors to deliver DNA or the components of CRISPR during gene therapy are also revolutionary. Individualized therapies might customize medicines to the genetics of a patient or according to their tear make-up and when added with intelligent contact lenses, it is possible to have automatic on-demand medicine..(Peng et al., 2023).(Witika et al., 2022)

VII. CONCLUSION

The development of niosomes has created one of the most promising platform technologies to resolve the historically difficult issues in ocular drug delivery due to an increased bioavailability, prolonged drug release, enhanced patient compliance, and positive safety profiles. This systematic review reassures the results that niosomal preparations are associated with 3-12-fold increases in ocular bioavailability, 4-8-fold increases in precorneal residence time, and clinically meaningful improvement in treatment effects across various indications of ophthalmic treatment, such as glaucoma (reduced IOP, 28-35%) and bacterial and fungal infections (enhanced antimicrobial activity, 6-35-fold). The primary benefits of niosomal formulation in comparison to conventional eye drops such as thrice or fourth times a day administration, directly deal with the critical issue of patient non-adherence that negatively impacts the effectiveness of treatment in chronic ocular disease. The comparative analysis demonstrates that niosomal is better than first-generation liposomal carriers in terms of chemical stability (24-month shelf life at room temperature compared to 6-12 months refrigerated), 70-90% lower production costs (50-150/kg compared to >500/kg phospholipids), and 4-6-fold higher entrapment efficiency (60-90% compared to 5-15% hydrophilic drugs). The compositional opportunities provided through a wide range of non-ionic surfactant alternatives, adjustable cholesterol ratios, and surface modification approaches allow the rational design of formulations to be prepared in response to the particular drug characteristics and therapeutic demands. Clinical safety potential is proven by biocompatibility profiles of demonstrated >85% cell viability in human corneal epithelial cells and minimal reversible irritation in animal models. To sum up, although niosomes have shown outstanding preclinical potential, their potential can only be fulfilled through long-term investment in translational research, industry-academia investments, and regulatory framework development. Overcoming these obstacles will enable niosomes to move past being a laboratory novelty to clinically used therapies that will eventually enhance vision and quality of life of millions of patients worldwide with ocular diseases that threaten vision. The path forward is clear: strict clinical validation, standardization of manufacturing, and involvement of the regulatory bodies are the necessary next steps in making niosomal ocular therapeutics become a clinical reality.

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