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A SYSTEMATIC REVIEW ON DEVELOPMENT AND EVALUATION OF NOVEL NANO FORMULATIONS FOR OCULAR DRUG DELIVERY SYSTEM

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ABSTRACT

Nanotechnology integration has led in significant improvements in ocular medicine administration. Even though numerous standard dose forms are employed, shorter bioavailability and retention durati on continue to be a serious concern in the ocular drug delivery system. In addition, a number of other barriers exist that affect. The drug's solubility and permeability are reduced as a result of It has a short er residence duration on the ocular surface. The application of nanotechnology could be the most effe ctive solution to these issues. The field of all nanocarriers has showed considerable potential in offerin g precise medicine delivery to the ocular tissues.

Compact size, biocompatibility, and surface modification improve medication solubility, lengthen release, and increase bioavailability. Nanotechnology also makes it easier to implant medicinal molec ules to treat a number of eye conditions such as infections, macular degeneration, and glaucoma. The goal of these improvements is to remove barriers and issues in the ocular medication delivery system. This review emphasises how nanotechnology can change the delivery of ophthalmic drugs, potentially leading to more effective and patient friendly therapies for eye illnesses.

Keywords: Nanotechnology, Nanocarriers, Ocular drug delivery, Glaucoma

INTRODUCTION :

Drugs and other foreign particles are almost impossible for the human eye to penetrate due to its intricate anatomy, physiology, and biochemistry.

Therefore, creating an ocular drug delivery system continues to be an intriguing and challenging problem for formulation and development specialists.The basic goal of creating an ocular medication delivery system is to overcome the eye's natural barriers, resulting in high therapeutic efficacy while avoiding irreversible tissue damage.Short retention times and constraints on corneal epithelial permeability typically limit the efficiency of ophthalmic preparations.Frequent blinking (6to15 times/min), high tear turnover (0.5to2.2 μL/min), nasolacrimal discharge, and ineffective conjunctival absorption all contribute to high precorneal clearing rates. Furthermore, the modest retention volume (~30 μL) of the conjunctival sac typically results in less medication being transmitted through the cornea or scleral membrane. This article seeks to provide a comprehensive summary of recent advances in lipid nanocarrierbased ocular medication delivery techniques **[1]**.Another goal of the paper is to emphasise the growing importance of these nanosystems. when managing disorders affecting the front and back of the eye. Understanding the anatomical and physiological barriers in the ocular area, the biochemical pathways in the ocular tissues, and the drug transfer across the ocular epithelial surface are critical for designing effective ocular administration systems **[2]**.

The Significance of Ocular Drug Delivery:

The eyes, as the windows to the soul, also serve as gatekeepers for therapeutic interventions.

Ocular drug delivery holds paramount importance in the therapy of a spectrum of eye problems, ranging from basic illnesses like glaucoma and conjunctivitis to more complicated disorders such as macular degeneration and diabetic retinopathy. Unlike systemic drug delivery, where the bloodstream acts as a robust circulatory system, the ocular environment demands tailored approaches to ensure drug bioavailability, sustained release, and targeted action **[3]**.

Anatomical and physiological characteristics of the human eye

The aqueous humour, cornea, conjunctiva, iris, ciliary body, and lens are located in the anterior chamber of the human eye, whereas the vitreous humour, retina, sclera, choroid, and optic nerve are located in the posterior chamber.The endothelium, stroma, and epithelium are the three layers that make up the cornea.Narrow, flattened epithelial cells create tight interjunctional complexes known as zonula occludens distal to Bowman's membrane.These layers serve as barriers to

the spread.100 times more lipid is present i n the outermost 6–7.

layered epithelium and the innermost simpl e squamous sheet of the endothelium layer t han in the intermediate stroma or substantia propria.

Dense, closely spaced collagen fibrils arran ged in lamellar or orthogonal layers compri se the bulk of the stroma.The collagenrich, somewhat translucent matrix between the c ornea's stroma and endothelium is called th e basement membrane, sometimes referred to as Descemet's membrane.Directly beneat h the epithelium, which is mainly made up of collagen fibersa vital protein that gives t he cornea structural stabilityis the Bowman' s membrane**[4]**. The aqueous humour of the anterior and posterior segments preserves i ntraocular pressure, while the ciliary body s ecretes a translucent, gelatinous fluid to fill the vitreous chamber.

A schematic representation of the main regi ons and several ocular pathways of the hum an eyeis presented in **Figure 1**.

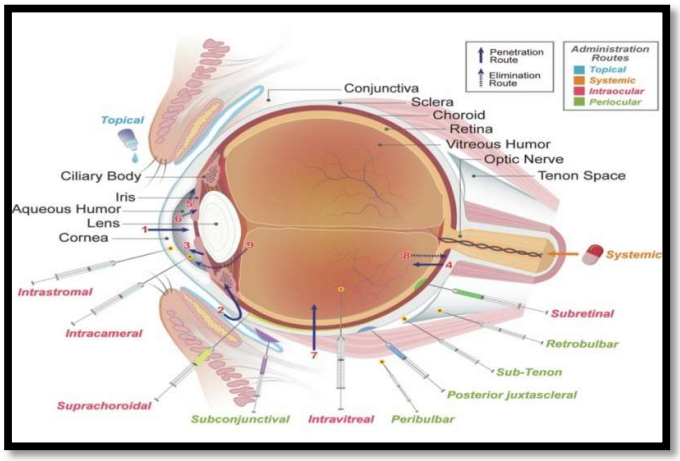

Figure 1: A schematic representation of the main regions and several ocular pathways of the human eye

DRUG TRANSPORT MECHANISM

When a drug is administered topically to the culdesac, it can penetrate the intraocular tis sues through the corneal membrane or diffu se through the sclera and conjunctiva in a n oncorneal fashion in addition to disorders li ke uveitis and glaucoma that impact the ant erior part of the eye.

Topical treatment is preferable for surface i nfections and inflammation because of its b enefits, which include hepatic metabolism, prevention of systemic absorption, and con venience of drug delivery.Topical solutions' ocular bioavailability has been shown to be only 5to10% due to limited drug penetratio n into the inner tissues of the eyes**[5]**.reachi ng the desired medication concentration is problematic.

Especially in the rear region. Compared to t he noncorneal method, most therapeutic dru gs are absorbed largely through transcellula r transport via the corneal epithelial membr

ane and stroma.Surface area, diffusivity, co ncentration gradient, pKa, and an optimum log p value of 1 to 3, which is also compara ble to other biological membranes, are the p hysicochemical properties of actives that go vern the corneal permeability.The stroma of the cornea is highly hydrophilic and cornea l epithelial cells have a tendency to act as a drug depot, releasing drugs into it.

This would provide a ratelimiting membran e barrier for extremely hydrophobic medica tions, while permitting the entry of polar m edications with molecular weights up to 50 kDa.As a result, the degree of ionisation, li pophilicity, solubility, and molecular size al l have a significant impact on how well a dr ug penetrates and is accessible to the eyes.T he irisciliary body expresses a number of dr ug transporters from the ATPbinding casset te family, as well as several proteins associ ated with multidrug resistance and solute ca rrier families**[6]**.

According to studies, the irisciliary body ha s a drug transporter that stops drugs from di ffusing enters the watery humour from the blood andbeing aggressively removed from it, lowering the drug's ocular bioavailability. Trauma, vascular disorders, inflammation, and intraocular surgery can all cause chang es to the bloodaqueous barrier.These chang es could compromise the eye's equilibrium and membrane integrity.Medication deliver y to the anterior part of the eye is impeded by three factors: the corneal membrane and the anterior bloodaqueous barrier are static, the conjunctival blood flow, lymphatic drai nage, and tear turnover are dynamic, and th e metabolism is slow.Merely lipid transfer or exchange to the cellular or subcellular m embrane, fusion with the plasma membrane , adsorption to the ocular surface via weak hydrophobic or electrostatic forces, and end ocytosis by phagocytic cells of the reticuloe ndothelial cells are some of the ways that li pid nanoparticles can carry pharmaceuticals **(Figure 2)**.

Small molecules (less than 500 Da) can be delivered intravitreously to the vitreous hu mour; however, extended use of this techni que of drug delivery might cause retinal iss ues and raised intraocular pressure.

While very invasive methods of gene transf er, including subretinal injection, have their benefits, they can also cause a variety of co mmon problems, including as intraocular pr essure, vitreous haemorrhage, retinal detach ment, recurrence of submacular haemorrha ge, and postoperative development of choro idal neovascularization**[7]**.

Popular periocular drug delivery techniques that give medications directly to posterior ocular regions while lowering the risk of en dophthalmitis and retinal damage include s ubconjunctival, intrascleral, subTenon's retr obulbar, and peribulbar injections.

To increase the precorneal residence durati on and corneal penetration of medications, various methods can be employed, includin

g eye drops, hydrogels, in situ gels, nanopar ticles, nano micelles, polymeric ocular inse rts, implants, dendrimers, nanosuspensions, and microneedles. Thus, ocular bioavailabi lity is increase **[8]**.

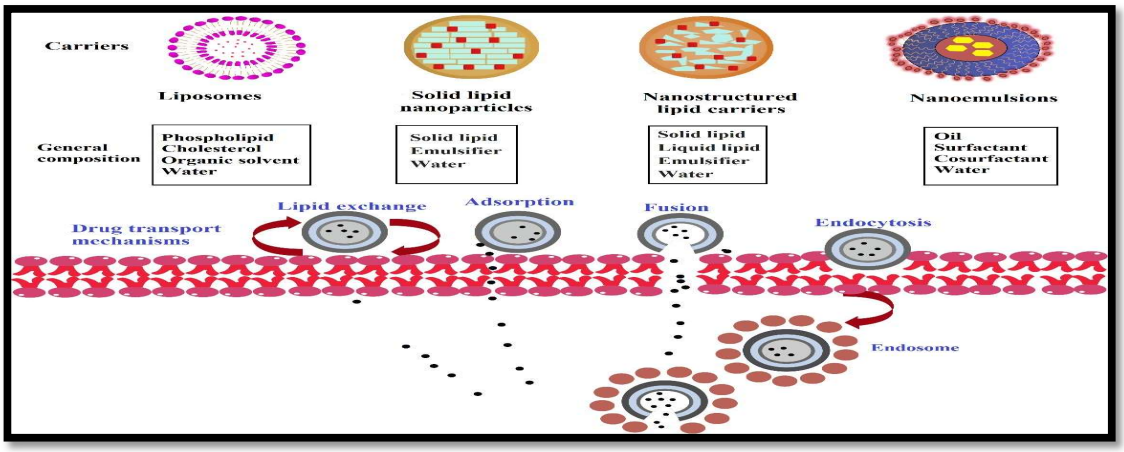

Figure 2: Drug transport mechanism in human eye

NANOCARRIERS FOR OCULAR DRU G DELIVERY

Nanocarriers, with its submicron particle si ze and unique physicochemical properties, can be an effective technique of delivering active substances to precise locations. For a range of drug delivery applications, nanoca rriers are often made of materials that disso lve in particulate matter or combined with l igands that are particular to a given target. They can encapsulate several active formul ations from different sources by employing a range of preparation techniques.

Nanoparticles are frequently Used in the cr eation of novel medication delivery technol ogies that allow active chemicals.to pass pa st many**[9]**.

The ocular area has physiological barriers. After the medication has been endocytosed by the cornea's epithelial cells, these nanoc arriers can also function as a depot or reser voir for the drug's gradual release. This hel ps to decrease rapid medication loss caused by nasolacrimal discharge and tear turnover. Furthermore, nonionic surfaceactive formul ation components that inhibit pglycoprotein activity in epithelial cells and open the cor nea's tight junction may improve ocular bio availability.anytime the posterior area of th e eye is addressed. They can avoid recurrin g medication administration by serving as a control release mechanism**[10]**. Drugs can be dissolved, dispersed, or surfacebonded i n nanoparticles comprised of biodegradable and biocompatible polymers.

Precorneal contact duration and transcornea l permeability are two factors that are being studied to improve intraocular bioavailabili ty.

Colloidal nanoparticulate lipid systems, inc

luding liposomes, nanoemulsions, solid lipi d nanoparticles, and nanostructure lipid carr iers, have received a lot of attention as viab le drug delivery techniques for both anterio r and posterior ocular disorders.Lipid nanop articles have numerous advantages, includi ng increased absorption, modified release, minimal degradation, high stability, in vivo compatibility, and flexibility to various deli very modalities**[11]**. The lipids employed to create this nano system are biocompatible and biodegradable, and they have the poten tial to significantly reduce the deleterious ef fects of the ophthalmic preparation.

Lipid nanoparticles have numerous advanta ges over polymeric nanoparticles, such as modified release, improved stability, less li pid breakdown, invitro tolerability, and flex ibility to various delivery systems. This ma kes lipid nanoparticles a suitable and efficie nt drug delivery medium for use in a variet y of delivery systems **[12]**.

BULK MATERIALS USED FOR PREPARATION OF LNS

The ultimate physicochemical and biologic al qualities of every formulation are greatly influenced by the appropriate selection of bulk components.

Lipids:

The impact of constituent mix on LNs' ulti mate quality. Crucial elements for the prod uction of nanoparticles include lipid type an d characteristics, including hydrophobicity, crystallisation behaviour, and lipid crystal s tructure.Lipid and its physical condition are further factors influencing the characteristi cs of LNs **[13]**.

Solid lipids:

Solid lipids used to manufacture LNs inclu de steroids, waxes, fatty acids, triglycerides , and partial glycerides. Tricarpin, trilaurin (Dynasan® 112), trimyristin (Dynasan® 11 4), tripalmitin (Dynasan® 116), tristearin (Dynasan® 118), and other triglycerides hav e all been used in the production of LN. Longer hydrocarbon chains are generally li nked to higher melting points and more sta ble nanoparticles. To enhance drug loading and avoid aberrant lipid crystallisation, exp erts advice utilising a blend of lipids with v arying chain lengths. It is significant to rem ember that the behaviour of lipid bulk mate rial and colloidal nanosystems might vary s ignificantly.

As a result, the qualities required for the fin ished product should be taken into consider ation while choosing the type of lipid. Mixt ures of mono, di, and triglycerides called pa rtial glycerides are frequently utilised to cre ate SLNs with poorly soluble medications. (e.g.Compritol®, Gelucire®, Precirol®). Several glyceride combinations promote SL N drug loading while inhibiting lipid recrys tallization**[19]**.One common fatty acid utilis ed to prepare SLNs for ODD is stearic acid. It is preferable to use a lipid mixture of stea ric acid and Compritol® rather than just the

fatty acid alone. They noticed that the com bination of the two lipids produced SLN wi th low crystallinity, which led to higher dru g loading and improved stability.

One steroid that is frequently employed in l iposome construction is cholesterol, which has also been used to elaborate LNs.

Following interaction with ocular structures the proposed formulation exhibited appropr iate physicochemical parameters and no tiss ue injury. Compared to SLNs made with gl ycerides, those formulated with waxes sho wed reduced drug entrapment but improved physical stability.

They attributed these findings to waxes' hig h degree of crystallinity after particle solidi fication, as opposed to the SLN's disorganis ed lattices that were polished with glyceride s **[14]**.

Liquid lipids

Oils having mediumtoshort hydrocarbon ch ains and a melting point lower than body te mperature are referred to as liquid lipids.

Liquid and solid lipids are combined in rati os ranging from 70:30 to 99.9:0.1 to genera te NLCs.Liquid lipids like oleic acid, castor oil, squalene, Mygliol®, and their combina tions are used to make NLCs for ODD. A 7 0:30 combination of castor oil and Mygliol ® is used to make NLCs for topical ocular t reatment.

These liquid lipids were chosen for their dr ug solubility potential as well as safety con cerns for ocular delivery.

Furthermore, even when the overall lipid co ntent exceeded 10%, this lipid mixture facil itated the formation of NLCs with small par ticle sizes **[15]**.

Cationic lipids

A positively charged head group and one or more hydrocarbon chains or steroid structu res make up cationic lipids.

Topical ODD medicines such as DOTAP (1 ,2-dioleoyl-

3TrimethylAmmoniumPropane) or DDAB are commonly utilised.

The nanosystem's surface contains cationic moieties, which endow the LNs with a posit ive charge, allowing them to interact with t he negatively charged corneal epithelium th rough electrostatic forces. Leonardi *etal*. di scovered that mixing melatoninloaded SLN s with the cationic lipid DDAB improved b oth mucoadhesion and preocular retention i n rabbit eyes.

In fact, the medication's hypotensive effect lasted up to 24 hours following just one top ical application.Cationic lipids are also use d in some types of ocular gene therapy.

In these situations, the lipid serves two purp oses.To shield the negatively charged genet ic material from enzymatic destruction, it fi rst promotes its adsorption on the nanoparti cle's surface.Second, the LNgenetic comple x's positive charge facilitates contact with t he corneal epithelium, lengthening its resid ence period and boosting transfection effici ency.Other cationic lipids authorised for us

e in ophthalmology are cetyl trimethyl amm onium bromide (CTAB), benzalkonium chl oride, cetylpyridinium chloride, and benzet honium chloride **[16]**.

Surfactants

Surface tension between phases is typically decreased by surfactants, which are amphip hilic molecules with a polar head and a non polar tail, to stabilise compositions. When d eveloping lipophilic substances (LNs) for o cular distribution, it is critical to choose app ropriate surfactants and cosurfactants.

The kind of surfactant influences both the b iocompatibility and physicochemical aspect s of the nanosystem **[17]**.

Crucially, the type of surfactant utilised in LNs influences their cytotoxicity more than the type of lipids used to make them.

As a result, choosing the best surfactant typ e and concentration requires striking a bala nce between toxicity and stability. Surfacta nts are classed as either ionic or non. The c harge indicates ionic whether it is ionicor a mphoteric.

Nonionic surfactants, like polysorbates (Tw een® 80) and sorbitan esters (Span 80), are less irritating and harmful than ionic surfact ants. Pensado *et.al*. used Span 80 and oleyl amine to create A new type of solid nanopa rticle for gene therapy in the eyes.

Here, Span 80rather than a surfactantwas th e primary component of the nanoparticle.

The nanosystem showed excellent biocomp atibility and high transfection efficiency.

Tyloxapol, poloxamers, cremophors, and vi tamin E TPGS (Dtocopherol polyethylene g lycol 1000 succinate) are other surfactants t hat are frequently employed in ODD **[18]**.

Surface modifiers

Researchers have proposed a variety of met hods for increasing nanoparticle residency t ime in the precorneal region, including the use of surface modifiers for nanoparticles a nd viscosity enhancers for in situ gelling po lymers.

Enhancing the interaction between LNs and OS structures and/or facilitating nanopartic le penetration are the main objectives of sur face modifiers. These two surface modificat ions that are most frequently used are chito san and hyaluronic acid **[19]**.

Surfactants and Lipid Functions in Form ulation Design

The surfaceactive chemicals' properties and concentrations have a significant impact on the efficacy and efficiency of nano lipid pa rticles and carriers.

Because of their amphiphilic nature, these s urfactants are more typically found near int erfaces, reducing interfacial tension betwee n the lipid and aqueous phases.

Nonionic emulsifiers, particularly Poloxam er 188, provide an extrasteric stabilising act ion to prevent microscopic particles in the c olloidal system from aggregating **[20]**.

Table 1: Example of lipid base drug delivery system

Sr. No.	Model Drug	Summary	Excipients Used	Method of Preparation	Reference
1.	Bimatoprost (2023)	Sandeep Divate Satyanarayana *et al* Ocular Delivery of Bimatoprost-Loaded Solid Lipid Nanoparticles for Effective Management of Glaucoma	Lipid : Glyceryl monostearate Surfactant : poloxamer 407	Solvent evaporation method	(21)
2.	Dexamethasone (2023)	Junfeng Ban *et al* Corneal permeation properties of a charged lipid nanoparticle carrier containing dexamethasone	Lipid : Soy and egg yolk lecithins Surfactant : Soybean oil and Pluronic F68	Film-dispersion high-pressure homogenization method	(22)
3.	Brinzolamide- and latanoprost (2022)	Liping Chen *et a l* Brinzolamide- and latanoprost-loaded nano lipid carrier prevents synergistic retinal damage in glaucoma	Lipid : Soya lecithin Surfactant : Polysorbate 80	Hot microemulsion method	(23)
4.	Tetrandrine (2022)	Radwan S. *et al* Chitosan-coated bovine serum albumin nanoparticles for topical tetrandrine delivery in glaucoma: in vitro and in vivo assessment	Lipid : Chitosan Surfactant: Bovine albumin	Desolvation method	(24)
5.	Dorzolamide (2022)	Mohammed Shadab *et al* Formulation, optimization and evaluation of vitamin E TPGS emulsified dorzolamide solid lipid nanoparticles	Lipid :Glyceryl monostearate Surfactant : Vitamin E TPGS	Ultrasonic emulsification method	(25)
6.	Latanoprost (2022)	Hui Dang *et al* Sustained latanoprost release from PEGylated solid lipid nanoparticle-laden soft contact lens to treat glaucoma	Lipid :Glyceryl monostearate Surfactant : PEG	High shear homogenization followed by ultrasonication method	(26)
7.	Methazolamide (2021)	John Youshia *et al* Gamma sterilization and in vivo evaluation of cationic nanostructured lipid carriers as potential ocular delivery systems for antiglaucoma drugs	Lipid :Compritol ATO 888 Surfactant : Polysorbate 80	High shear homogenization followed by ultrasonication method	(27)
8.	Brimonidine Tartrate (2021)	Pankaj Kumar Sharma *et al* Optimization and Characterization of Brimonidine Tartrate Nanoparticles-loaded In Situ Gel for the Treatment of Glaucoma	Lipid : PLGA Surfactant : TPGS, , Poloxamer 407	Nanoprecipitation method	(28)
9.	Brimonidine (2021)	Sven Schnichels *et al* Improved Treatment Options for Glaucoma with BrimonidineLoaded Lipid DNA Nanoparticles	Lipid :oligonucleotides	Hydrophobic interactions with double stranded micelles method	(29)

ADVANCED OCULAR DRUG DELIVERY SYSTEM [31-34]

Table 2: Advanced Ocular Drug Delivery System

Sr no.	Drug delivery system	Principle	Application
1.	Liposomes and nanoparticles	Drugs can be better dissolved, stabilised, and released under regulated conditions by being encapsulated in nanoparticles and liposomes. Benefits include improved drug penetration, prolonged drug release, and defence against drug deterioration	Management of glaucoma and macular degeneration, among other eye conditions

2.	**Gels in-situ**	**The goal of in situ gel is to increase the length of medicine retention on the ocular surface by giving liquid formulation that convert to the gel state. Benefit includes simple administration, longer contact length and increase absorption.**	**Use of Contact Lenses for Drug delivery**
3.	**Contact lenses**	**Contact lenses provide a continuous and non-invasive drug delivery system by medications gradually into the tear film.[6] Benefits include less systemic adverse effects, increased patient compliance, and prolonged medication releas**	**include increased patient compliance, prolonged medication release, and less systemic adverse effectMedicine delivery for ailments including dry eye and glaucoma**
4.	**Inserts & Implants**	**Drugs are released gradually by tiny devices called implants and inserts that are inserted into the eye. Benefits include localised medication distribution, sustained release, and a decrease in dosage frequency**	**Management of long-term diseases such uveitis and diabetic retinopathy.**
5.	**Nanomicelles**	**Self-assembling nanoparticles called nanomicelles increase the stability and solubility of drugs. Benefits include tailored medication administration, less adverse effects, and increased bioavailability**	**Management of different ocular conditions, particularly those that need exact medication targeting.**
6.	**Inserts for the eyes**	**Ocular inserts are solid dosage form that are place in the conjunctiva and gradually release drug .controlled pharmaceutical release, ease of administration and improve patient adherence.**	**The treatment of disease like inflammation and bacterial infection.**
7.	**emulsions**	**Theoretically stable formulations known as microemulsions enhance medication solubility and promote quick absorption. Better ocular penetration and increased medication absorption**	**Inflammation and infection management.**
8.	**Nanofibers Electrospun**	**The idea behind electrospun nanofibers is that they are high-surface-area polymeric fibres that help with regulated medication release. Benefits include increased bioavailability, prolonged release, and improved medication stability.**	**Management of infections and diseases of the ocular surface**

CONCLUSION:

Nanotechnologybased ophthalmic medicati on delivery devices show great promise in t he field of ocular therapies.

Using allnano drug carriers provides variou s benefits, including greater drug solubility, extended release periods, and higher bioava ilability.

Traditional ocular pharmaceutical delivery systems may be ineffective and have poor d rug retention, however new nanoscale deliv ery devices may address this.

In order to decrease dosage intervals, admi nistered doses, and side effects while increa sing ocular retention time, drug penetration efficacy, and ocular bioavailability, a variet y of techniques and technologies have been used in a controlled and sustained drug deli very system.

CONFLICT OF INTEREST:

The authors have no conflicts of interest regarding this investigation**.**

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