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Evaluation of Ophthalmic Lyophilisate Carrier System

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Abstract: *A major problem associated with ocular therapeutics is the achieving optimal drug concentration at the site of action, which is compromised mainly due to precorneal loss resulted in ocular absorptionof small fraction of the drug. The objective of the present study was to develop Ophthalmic Lyophilisate Carrier System (OLCS) of selected drugs including Ciprofoxacin Hydrochloride, Ketorolac, Tromethamine, Acyclovir and Azithromycin to overcome the drawbacks associated with available market formulations. Different hydrophilic polymers were screened to select best polymer for imparting satisfactory strength to the system for carrier platform. METHOCEL ES was optimized as best polymer for preparing drug-best carrier. polymer solution having optimal strength. Poly propylene was optimized as Exhaustive preformulation study and drug excipients compatibility study was performed. The supportive media was sterilized by steam sterilizer. OLCS was finally lyophilized by conventional laboratory freeze dryer by optimized process. The developed formulation was characterized for various physicochemical parameters. Further to achieve modified release, nanoparticles based OLCs system of Acyclovir and Azithromycin were developed. Moreover, OLCs nanoparticles based OLCs were compared with in situ gel forming system and market products. Ocular irritation study of OLCS was performed using a modified het-cam test and assessed by irritation score. The OLCs were charged for the accelerated stability studies as per ICH guidelines for 6 months. The IS score of the each optimized OLCs was within limit (>0.9) indicating that non irritancy. In a nutshell, OLCs can be a promising approach for ophthalmic delivery of drug with better bioavailability and minimal loss and nanoparticles based OLCs can be a suitable approach for controlled release. The developed formulations were optimized and characterized for physicochemical properties, in vitro Drug release, in vitro penetration and ex vivo Ocular irritation. The OLCs was compared and proved superior to in situ gelling system of same drugs. Further, nanoparticulate formulations of (ACV and AZT) were developed and optimized with OLCs. The NP size of ACV (nanosuspension) and AZT (nanosphere) were 1070.63 mm and 187.36 nm respectively. The comparative study of all developed formulations with commercially available productswas performed, where the drug loaded OLCs showed better retention time, higher concentration in tear fluid for longer time period as compared to eye drops along with overcoming the lag time.*

Keywords: Correlation coefficient, species diversity, medicinal plants, medicinal trees

I. INTRODUCTION

Drug Delivery System for the Eye Mechanism of Topical Drug absorption through ocular route[19]

The most common method of drug treatment in ocular disease is to instill an aqueous eye drop into the lower conjuctival fornix. The site of drug action may be on the surface tissues (e.g. in conjunctivitis), but most ophthalmic drugs must permeate through the ocular barriers (cornea, conjunctiva and sclera) to exert their therapeutic activity (e.g. in glaucoma, intraocular inflammation and infection). After instillation of an eye drop, less than 5% of applied dose is absorbed into the intraocular tissue. This is due to the tightness of the corneal epithelium, rapid drainage; tear turnover, blinking and non-productive absorption to the conjunctiva as described in fig 2. The goal of ophthalmic drug delivery system has traditionally been to maximize ocular drug absorption rather than to minimize the systemic absorption.

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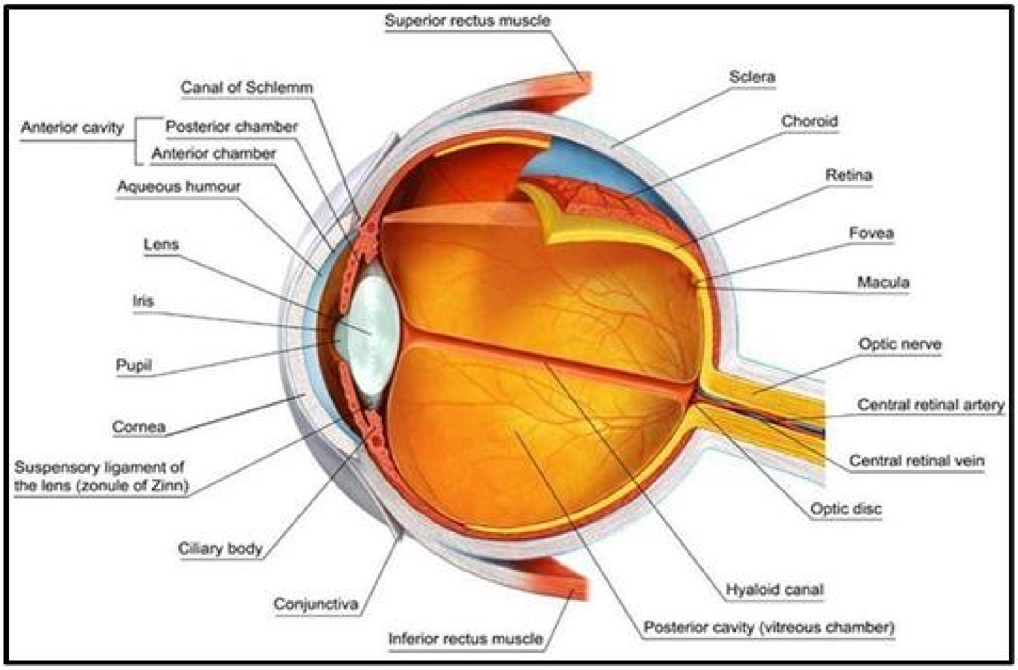

Figure 1: Anatomy and Physiology of Eye

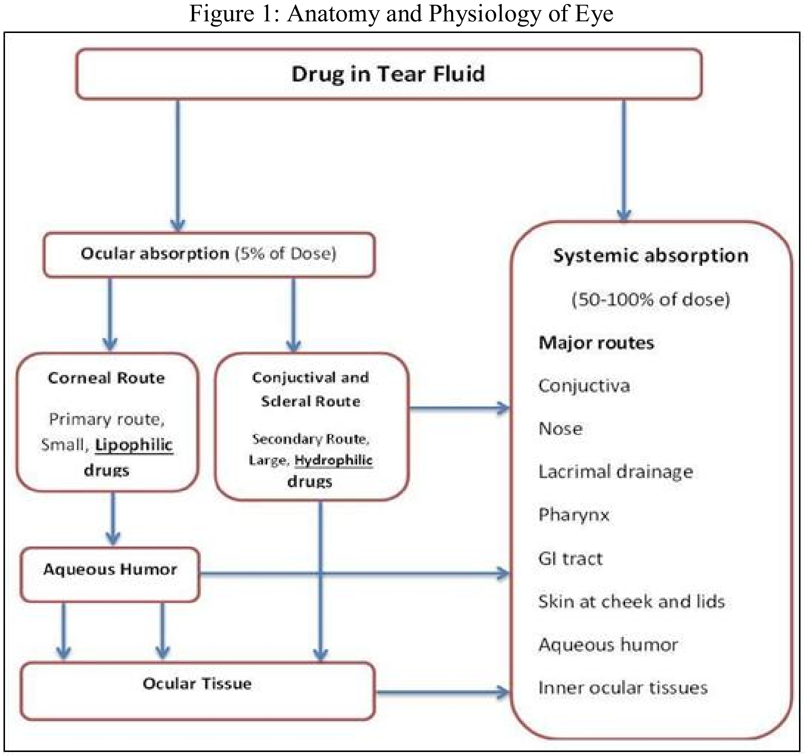

Figure 2:Drug absorption in eye

1.1.1 General consideration for design of ocular drug delivery formulations [20]

The brief about general composition for Ocular DDS is narrated in following Table.1.

Components Properties

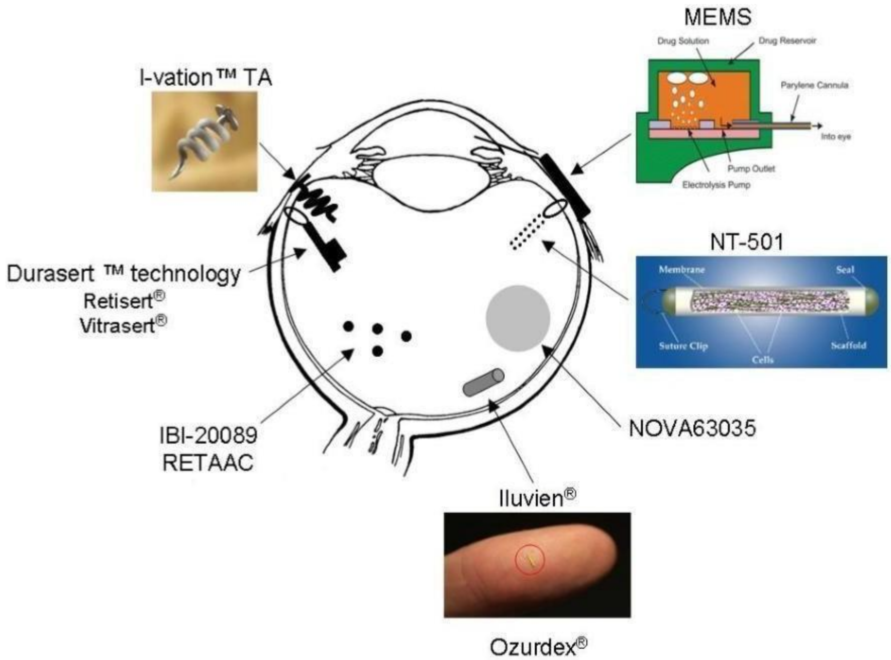

Figure 3: Example of intravitreal drug delivery systems for vitreoretinal diseases

Various approaches attempted in the early stages can be divided into two main categories:

(1) By improving ocular bioavailabilityand (2)Controlled release drug delivery. The various approaches that have been attempted to increase the bioavailability and the duration of the therapeutic action of ocular drugs can be divided into two categories. The first one is based on maximizing corneal drug absorption and minimizing precorneal drug loss through viscosity and penetration enhancers, prodrug, gel, and liposomes. The second one is based on the use of sustained drug delivery systems which provide the controlled and continuous delivery of ophthalmic drugs, such as implants, inserts, nanoparticles, micro particulates, and colloid.

Table 2: Approaches in ophthalmic drug delivery system[26-30]

Dosage forms	Description	Advantages	Disadvantages
Approaches to improve ocular bioavailability			
Ointments	Eye ointments are semisolid preparations usually intended for application to the conjunctiva, cornea, or eyelid. A suitable ophthalmic ointment base (Soft paraffin and liquid paraffin is more preferred) is nonirritating to the eye and permits diffusion of the drug substance throughout the secretions bathing the eye.	Reduce drug drainage increasing corneal residence time Improved stability Improved bioavailability Can be used for drug having poor aqueous solubility	Blurring of vision Poor patient compliance
Gels	Semisolid gel type preparations are an alternative to traditional ointments and are based on the effect of increasing the	Reduce systemic exposure of drug Increase Precorneal	Blurred vision Matted eyelids Poor

	viscosity to prolong the retention of the drug in the eye. Several types of gelling agents can be used, such as polyacrylic acid derivatives, carbomer, and hypromellose. Ocular drug delivery system has been observed to be, in part, due to their surface charge. Positively charged liposomes seem to be preferentially captured at the negatively charged corneal surface as compared with neutral or negatively charged liposomes.	residence time Improvement in bioavailability Decreasing dosing frequency low partition co-efficient Sustained and site specific delivery Reduced dosing frequency Improved bioavailability	patient complance manufacturing sterile preparation
Niosomes	Niosomes are bilayered structural vesicles made up of nonionic surfactant which are capable of encapsulating both lipophilic and hydrophilic compounds. They are nonbiodegradable and nonbiocompatible in nature	Reduce systemic drainage Improve residence time Increase ocular bioavailabilty	Less bioavailability when uptake by conjunctival cells
Nanoparticles	These are polymeric colloidal particles, ranging from 10 nm to 1 mm, in which the drug is dissolved, entrapped, encapsulated, or adsorbed. Encapsulation of the drug leads to stabilization of the drug. They represent promising drug carriers for ophthalmic application.	Small size Long shelf life, Highly stable Improved bioavailability Reduced dosing frequency	Particle contamination
Nano suspension	This can be defined as submicron colloidal system which consists of poorly watersoluble drug, suspended in an appropriate dispersion medium	Improve ocular bioavailability Prolonged contact time Improve stability	Use for poorly soluble drugs

RECENT APPROACHES IN OCULAR DDS:

Ophthalmic inserts [31-33]

Ophthalmic inserts are defined as sterile preparations, with thin, multilayered, drugimpregnated, solid or semisolid consistency devices whose size and shape are especially designed for ophthalmic application. The ocular insert can be inserted under either the upper lid or the lower dose preservative free delivery system for the Ophthalmology, which consists of freeze-dried droplets of a hydrophobic support membrane.

Figure 4: Ophthalmic Lyophilisate Carrier System (OLCs)

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The lyophilized drop contains a polymer (gelling agent), if necessary, an Low molecular structure-, and one or more active substances that dissolved but also dispersed or suspended may be present. Following contact with the Tears the polymer forms a gel and thus extends the Drug release. For the development of the OLCs a single dose of active ingredient is dissolved or dispersed in a drop of aqueous solution of a hydrophilic polymer, which is freeze dried on a soft hydrophobic carrier membrane attached to a paper handle. Upon administration, the lyophilisate is stripped off its carrier by a wiping motion over the lower eyelid, adheres to the conjunctiva and dissolves in the tear fluid.

Advantages of OLCs

The application system has a number of advantages over traditional eye drops.

1. Possess low water content which increase stability.
2. Better chemical stability, especially for substances sensitive to hydrolysis.
3. Better compatibility topical, as the pH and osmolality not must be set.
4. Precise dosing. By introducing the single dose, the exact overdose by repeated instillation, the expiry of the active ingredient by excess fluid volume, as well as the influence of Viscosity, surface tension and the properties of the drop on the volume of the applied drop of excluded.

II. REVIEW OF LITERATURE

This section of literature review covers significant work done on:

1. Work done on ophthalmic DDS: Ophthalmic Insert, In Situ Ophthalmic Gel, Liposomes, Microemulsion, Nanoparticles, Miscellaneous
2. Work done on selected APIS: CPF, ACV, AZT and KET (For ophthalmic route)
3. Work done on OLCs
4. Patent Review on Ophthalmic Drug Delivery Systems

Table 4: Work Done on Ophthalmic DDS

Name of Drugs	Key Components	Experimental work	Inference	Ref.
OPHTHALMIC INSERT				
Bimatoprost	Chitosan	Formulate ocular inserts for sustained release of Bimatoprost (BIM) for effective treatment of glaucoma.	BIM-loaded inserts provided sustained release of BIM and seem to be a promising system for glaucoma management.	[36]
Gatifloxacin	Thiolated sodium alginate	Preparation of bilayered ocular inserts of gatifloxacin from thiolated sodium alginate.	The bilayered films were found to be flexible, with good folding endurance, uniform thickness, and appropriate drug content, and showed a release of about 80% of loaded gatifloxacin in 12 hr.	[37]
Lidocaine HCl	HPMC, PVA, β cyclodextrin	Develop ocular inserts as a new form of lidocaine HCl to give a sufficient level of topical ocular anesthetic	In vivo study showed that the additions of β-cyclodextrins in formulation significantly increase the drug content in the aqueous humor.	[38]
Gatifloxacin Sesqui-hydrate	Na.alginate, PVA, Glycerine, Eudragit RL100, Eudragit RS100.	Fabricate ocular inserts for improve ocular bioavailability &retention of drug which shown advantages of reduce dosing frequency and	The cross-linked and Eudragit RL-100 coated ocular insert of gatifloxacin provides better in vitro drug release and sustained upto 11 hr.	[39]

		increased corneal residence time.		
Brimonidinet artarate	PVP K90, HPMC, Na.alginate, Carbopol, Chitosan, EC, Eudragit RSPO	Preparation of biodegradable ocular inserts for sustained delivery of brimonidine tartrate.	Due to both the mucoadhesive property and the drug sustainment effect, coated ocular insert showed more IOP lowering effect	[40]
Piroxicam	HPMC, CMC, and carbopol	Formulate ocular inserts from bioadhesive& film forming polymers of piroxicam for inflammation.	It sustained the drug release and enhanced the bioavailability of piroxicam as compared to piroxicam eye drops	[41]
Dorzolamide HCl	Olive oils Brij	Thirty-six systems consisting of different oils, surfactants, and cosurfactants were prepared and their pseudoternaryphase diagrams were constructed by water titration method.	Biological evaluation of dorzolamide hydrochloride nanoemulsions on normotensive albino rabbits indicated that these products had higher therapeutic efficacy, faster onset of action, and prolonged effect relative to either drug solution or the market product.	[58]
Mangiferin	Glyceryl monostearate, Polysorbate 80, Gelucire44/ 14, Labrasol	The physicochemical properties of MGN-loaded NLC (MGN-NLC) formulation were characterized by particle size, polydispersity index, zeta potential, entrapment efficiency, drug loading, morphological property, and crystalline state.	The optimized formulation showed an appropriate particle size, a sustained release property with good stability during storage, an improved corneal permeability, a high ophthalmic tolerability, and prolonged retention capacity	[59]
Placebo	Dynasan® 114 Cremophor® A 25 Lipoid® S100	This study was planned to assess the technological properties of some surfactants, commonly used for the production of lipid nanoparticles, as well as their ocular safety profile.	The SLN produced using Cremophor® A25 and Lipoid® S100 were tolerated up to a surfactant concentration of 0.2% by weight, while for Tween® 80 and Kolliphor® HS 15 a maximum concentration of 0.05% can be considered totally not-irritant.	[60]

Type of DDS	Methodology	Inference	Ref.
Niosomes Entrapped *In Situ* Hydrogel	The preparation of acyclovir niosomes was done by reverse phase evaporation method. Methylcellulose (1.5% w/w) gels were prepared by dispersing the required amount of methylcellulose in distill water.	The niosomes entrapped hydrogel is the formulation i.e., able to release sufficient quantity of drug in order to provide immediate relief directly to the affected area.	[73]
In-Situ Gel	Gelrite and sodium alginate was used as gelling	All studies shown favourable	[74]

	agents in combination with hydroxyl propyl methyl cellulose (HPMC-E50 LV) as a viscosity enhancer. Benzalkonium chloride in suitable concentration used as a preservative.	results thus acyclovir in situ gelling system is a valuable alternative for the treatment of herpes simplex keratitis with the delivery of the drug in a controlled manner.	
Nanosuspension	A quassi-emulsion solvent evaporation method was used to prepare ACV loaded Eudragit RS 100 ONS with the aim of improved ocular bioavailability and distribution.	The release profile revealed from best formulation followed Non-Fickian diffusion mechanism. In vivo studies showed that ACV concentration in aqueous humor at 8 h was 82.83, 77.49 and 34.15 mg/ml.	[75]
AZT			
Ocular inserts	Ocular inserts of AZT are prepared using alginate, carbopol, and hydroxypropyl methylcellulose (HPMC) to solve the said formulation problem of drug and to facilitate ocular bioavailability. Ocular inserts were prepared by film casting method.	The physicochemical, bioadhesive, and swelling properties of films were found to vary significantly depending on the type of polymers used and their combinations. The alginate films exhibited greater bioadhesion and showed higher tensile strength and elasticity than the carbopol films.	[76]
Mucoadhesive eye drops	Formulations of 0.5% and 1.0% azithromycin were created in polycarbophil, a lightly cross-linked polyacrylic acid polymer that was adjusted to a viscosity, pH, and osmolality that are suitable for dispensing in the eye.	The polycarbophilbased ophthalmic delivery system, , helps solubilize azithromycin and retard its degradation in aqueous solution.	[77]
In situ gel	Pectin was used in different concentrations (1-5% w/v) and different proportions of the hydrocolloids hydroxypropyl methylcellulose and sodium carboxymethyl cellulose of different grades of viscosity were used. The primary criteria for formulation optimization were gelling capacity and rheological behavior	The results indicate that pectin based in situ gels can be successfully used to prolong the duration of action of azithromycin	[78]

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Type of DDS	Methodology	Inference	Ref.
Niosomal in situ gel	Azithromycin-β-CD complex was prepared and niosomes containing this complex were developed based on 32 full factorial design using ether injection method and characterized.	Delivery via complexvesicle based system exhibited potential to carry hydrophobic drug to scleral segment of the eye and capable of treating	[79]

		bacterial conjunctivitis	
Nanoparticles	AZTNPs were prepared by Modified Quasi-Emulsion Solvent Diffusion method. The antibacterial activities of prepared NPs in comparison with AZT solution.	These results indicated an improved potency of AZTNPs which could be attributed to the modified surface characteristics as well as increased drug adsorption and uptake.	[80]
KET			
In situ gel	Polyacrylic acid (Carbopol® 934) was used as the gelling agent in combination with hydroxypropylmethylcellulose (Methocel K4M) which acted as a viscosity enhancing agent. Compatibility studies of the drug excipients were carried out using differential scanning calorimetry (DSC).	The developed formulation is a viable alternative to conventional eye drops by virtue of its ability to enhance bioavailability through its longer precorneal residence time and ability to produce sustained drug release.	[81]
Polymeric solution	Polymers including HPMC, NaCMC, Eudragit type E/RL/RS, Carbopol ETD 2020 and Carbopol 934 were used to formulate polymeric eye drops.	Observations made in this study indicate the potentiality of the ophthalmic formulations containing mucoadhesive/viscosity imparting agents	[82]
Ocuserts	Ketorolac tromethamine ocuserts were prepared using different polymers such as HPMC, PVP, MC and EC at various concentrations. The in vitro release of the drug from the formulations was studied using commercial semi permeable membrane.	The expected zero order release for one day was observed in formulation (Drug reservoir with 4% HPMC and 3% EC as rate controlling membrane).	[83]
Bioadhesive insert	Bioadhesive in-situ gelling ocular inserts were prepared using sodium alginate and chitosan with glycerin as a plasticizer by solvent casting method and evaluated for various parameters.	The formulation F4 was shown 98.62 % drug release at the end of 12 h There was no evidence of microbial growth and hence the ocular insert passed the sterility test and there was no significant change in the physicochemical properties from 0th to 30th day.	[84]

Table 6: Work Done on OLCs

Drug	Method	Inference	Ref.
Fluorescein	A new lyophilization technique where only one unit is frozen and dried in a small chamber at any time under closely controlled conditions (3,4) solves this problem. Lyophilization is converted	The development of the fast precision freeze drying technique is a prerequisite for the reproducible manufacturing of ophthalmic lyophilisate carriers on an	[85]

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	to a quasi–continuous operation by simultaneous, time–staggered operation of several drying chambers and the cycle time for each drop is reduced to less than 20 min (about 1/50 of the batch process) by reducing the residual gas pressure to less than 10–2 mbar, minimizing the distance between the condenser surface and the samples and supplying the heat of sublimation directly to the frozen drops by radiation.	industrial scale. Since the volume of production is controlled by the addition or removal of more chambers of the same dimensions to or from an automated loading system and by the length of production runs, there is no need for a process scale–up. A modification of the FPFD process is particularly suited for sensitive proteins and other biotechnology products in containers.	
Clinical trial	In a randomised, open label study 22 healthy volunteers applied a single lyophilisate to one eye (+1 minute) and three conventional eye drops (+1, 16, 31 minutes) of fluorescein ophthalmic solutionto the fellow eye. The fluorescein dose of the lyophilisate was 204 mg corresponding to three conventional,preservative-free eye drops of 40 ml fluorescein SE Thilo 0.17% (68 µg each)	A triple dose was delivered to the human eye with a single lyophilisate application for the first time. A significantly better bioavailability was achieved in the cornea and anterior chamber for up to 7 hours by means of drug application with lyophilisates. The application of medications by means of the lyophilisate will improve the treatment of, for	[14]
	(Alcon).Fluorophotometry was performed (Fluorotron Master II Ocumetrics, USA) before and +15, 30, 45, 60, 120, 180, 240, 300, 360, 420 minutes after application.	example, glaucoma, bacterial, viral and fungal infections, as well as dry eye syndrome.	

Table 7: Patent Review on Ophthalmic Drug Delivery Systems

ASSIGNEE	Drug	Description	Ref
SANOFIAVENTIS DEUTSCHLAND GMBH	Medical device	The present application relates to medical devices and methods of delivering at least two drug agents from separate reservoirs using ophthalmic drug delivery devices having only a single activation mechanism, button or trigger and a single dispense interface.	[86]
COLLINS, JAM F.	Device	The present invention relates to drug delivery devices for dispensing liquid as an aerosol or atomized mist and, more particularly, for dispensing medicaments to the eye.	[87]
GNT, LLC	Dexmedetomid ine	An ophthalmic drug delivery composition comprising from 2% to 12% w/v nonionic surfactant, one or more non-Newtonian high blend viscosity enhancing, nongelling agents and from 0.10% to 0.90% NaCl.	[88]
HANNA, CALVIN	Phenylephrine HCl	A nonaqueous oil delivery system for suspending ophthalmic drugs for use in ophthalmic preparations.	[89]
TAIWAN CO., LIPOSOME LTD.	Avastin	He present invention is based on an unexpected discovery that a drug delivery system containing phospholipid and cholesterol significantly prolongs the lifetime of Avastin.	[90]
STEELE FRASER	ketotifen	The present invention relates to ophthalmic compositions and in particular to a topical ophthalmic composition	[91]

		comprising a polyaphron dispersion.	
NANOCARRIER KABUSHIKI KAISHA	Porphyrin	The present invention relates to an ophthalmic drug delivery system formed by polymeric micelles delivering a drug to posterior tissues	[92]
OCULIS EHF	Antibacterials	The invention provides an ophthalmic composition which is an aqueous suspension comprising drug, cyclodextrin and water, the composition having an aqueous phase of from about 0.1% (w/v) to about 90% (w/v) of the drug in solution,	[93]
ALCON LABORATORIES , INC.	Tocophersolan	This application is directed to stable and comfortable preserved ophthalmic formulations containing an acidic drug.	[94]
GNT, LLC	Cyclosporin-A	Ophthalmic Lipophilic and Hydrophilic Drug Delivery Vehicle Formulations	[95]

III. RATIONALE AND HYPOTHESIS

RATIONALE

Considering few clear advantages of OLCs, an attempt is made to develop novel ocular drug delivery system platform technology which could be easily adopted for different drugs used in ophthalmology. An optimized OLC platform system is developed and compared with in situ gelling and eye drop. Both conventional and modified delivery system is developed for different category of drugs:

• Ciprofloxacin Hydrochloride (Anti-infective, BCS class III drug)
• Azithromycin (Macrolide antibiotic, BCS class II drug)
• Acyclovir (Anti-viral, BCS class IV drug)
• Ketorolac Tromethamine (Anti-inflammatory, BSC class I drug)

These drugs require precise dosing and continuous dose administration in anterior chamber with sufficient contact time with ocular surface. These drugs are indicated for various chronic diseases like conjunctivitis, bacterial or viral infection, inflammation, corneal ulcers, ocular herpes. The high and steady concentration of drug is required in cornea and anterior chamber over a sufficient long time period such that frequency of administration is reduced. Moreover, the proposed medication therapy can be easily applied to eye in standing position without causing injury which is suitable to elderly patients, children and patients with impaired manual skill.

HYPOTHESIS

Picturesque hypothetical diagram of MR dosage form

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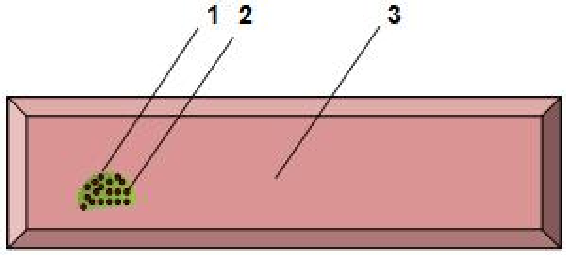
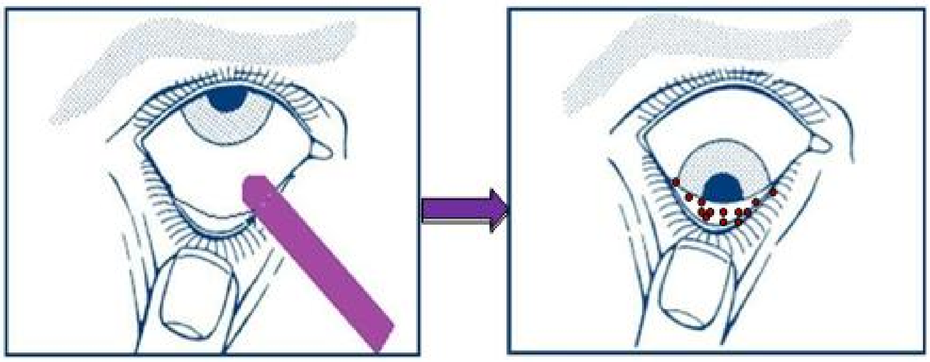


Figure of Nanoparticles loaded on Ophthalmic Lyophilizate Carrier System

1 - Freeze dried droplets, 2-Nanoparticles, 3-Supporting membrane



IV. OBJECTIVES

Aim of present work is to develop and optimize lyophilizate carrier based drug delivery system. The final dosage form is a polymeric sterile unit dosage form loaded with single dose of drug dissolved in hydrophilic polymer and freeze dried at the tip of soft hydrophobic carrier for CPF (0.14 mg/unit), ACV (0.39 mg/unit), AZT (0.6 mg/unit) and KET (0.2 mg/unit). The therapeutic superiority of the system is evaluated comparatively with eye drop and in situ gelling system with the aim of

- Microbiological quality: Sterility and non-preservative system
- Versatile system for different drug molecules
- Safety and tolerability
- Constant dose delivery with steady drug concentration level in tear fluid for long time interval.
- No loss of dose administered

The specific research objectives are:

1. Analytical method (UV spectrophotometric and HPLC method) for selected APIs
2. Preformulation study
3. Development and optimization of OLCs
a. Development and optimization of placebo OLCs
b. Development and optimization of Drug loaded OLCs
4. Development and optimization of In situ gel forming system
5. Development and optimization of Nano particulate loaded OLCs
6. Physicochemical, in vitrodissolutionand In vitro permeation characterization of developed drug delivery systems.

V. SUMMARY

In the present work, drugs were selected based on wide spectrum different indication related to occurrence of different diseases related to eye. Moreover, the drugs possess wide spectrum of solubility and permeability. So the success of developed delivery system may work for ample of drugs and can be proved as a platform technology.

All selected drugs are official in Pharmacopoeia. UV spectroscopy and HPLC methods were used for determination of drug in screening, Preformulation, dissolution studies and stability studies.

Preformulation study of drug and excipients revealed stable characteristics of drug and also suitability of selected excipients for development of ocular drug delivery system. Various physicochemical parameters of selected drugs showed suitability of drugs for ocular drug delivery system. Drug excipients compatibility study exhibited stable characteristics of drug with selected excipients. Moreover, not a single sign of interaction was observed in the FTIR and DSC spectra of drugs and selected excipients.

The method adopted for formulation of OLCs was critical in terms of steps as far as lyophilization is concerned. Sterility played an important role in selection of various components of OLCs. The material of carrier film of OLCS was Non PVC (poly propylene). Role of mannitol as a bulking agent was found mandatory in the development of OLCs. Judicious selection of polymers was required for finalizing core polymer as a building block of OLCs. Stem sterilization method yielded optimal sterilization without compromising the quality of supporting media and drug product. Various characterization studies of OLCsrevealed that developed systems for selected all four drugs passed the limit of acceptance. In vitro drug release study of OLCs indicated immediate release pattern of drug and this is attributed to the lyophilized nature of the product. Within 1 HrOLCS of CPF, ACV, AZT and KET showed 92.14, 78.51, 81.34 and 91.04% drug release.

In situ gel forming system (ISGFS) was developed with an aim to get appropriate drug release and also to establish the application of OLCS over ISGFS. In the preliminary trials, various polymers were screen based on gelling capacity and clarity.Out of selected polymers,

VI. CONCLUSION AND FUTURE SCOPE

Ophthalmic disease, either anterior eye or posterior eye diseases, require complete and constant delivery of dose administered with long residence time. The successful ophthalmic delivery system should exclude loss of drug by either of the routes or reasons along with complete sterility of each applied dosage unit: eye drop, eye ointment, eye gel, ocular inserts etc. Moreover, application in ocular cavity should be easy by any group patient, i.e. elderly patients, children, patients with impaired manual skills.

OLCs successfully fulfils above criteria as a device or applicator system. The results of present work further substantiate the superiority of OLCs over in situ gel system and eye drop. It is also successfully concluded that the system is versatile to carry all types of drug, hydrophilic, hydrophobic, soluble or insoluble. The effect is better in any case with no ocular irritancy. Therefore, OLCs should be further taken for scalability and clinical study. It is a promising futuristic approach for ophthalmic drug delivery systems either conventional or modified.

REFERENCES

[1] H.F. Edelhauser, C.L. Rowe-Rendleman, M.R. Robinson, D.G. Dawson, G.J. Chader, H.E. Grossniklaus, K.D. Rittenhouse, C.G. Wilson, D.A. Weber, B.D. Kuppermann, Ophthalmic drug delivery systems for the treatment of retinal diseases: basic research to clinical applications, Investigative ophthalmology & visual science, 51 (2010) 5403-5420.

[2] C.D. Hepler, L.M. Strand, Opportunities and responsibilities in pharmaceutical care, Am J hosp pharm, 47 (1990) 533-543.

[3] J.L. Greaves, C.G. Wilson, Treatment of diseases of the eye with mucoadhesive delivery systems, Advanced drug delivery reviews, 11 (1993) 349-383.

[4] A. Urtti, Challenges and obstacles of ocular pharmacokinetics and drug delivery, Advanced drug delivery reviews, 58 (2006) 1131-1135.
[5] Z. Liu, J. Li, S. Nie, H. Liu, P. Ding, W. Pan, Study of an alginate/HPMC-based in situ gelling ophthalmic delivery system for gatifloxacin, International journal of pharmaceutics, 315 (2006) 12-17.
[6] R.M. Mainardes, M.C. Urban, P.O. Cinto, N.M. Khalil, M.V. Chaud, R.C. Evangelista,
M.P. Daflon Gremiao, Colloidal carriers for ophthalmic drug delivery, Current Drug Targets, 6 (2005) 363-371.
[7] Z. Liu, X. Zhang, H. Wu, J. Li, L. Shu, R. Liu, L. Li, N. Li, Preparation and evaluation of solid lipid nanoparticles of baicalin for ocular drug delivery system in vitro and in vivo, Drug development and industrial pharmacy, 37 (2011) 475-481.
[8] M.F. Saettone, Progress and problems in ophthalmic drug delivery, Business Briefing: Pharmatech, 1 (2002) 167-171.
[9] S. KUMAR, B.O. HAGLUND, K.J. HIMMELSTEIN, In situ-forming gels for ophthalmic drug delivery, Journal of ocular pharmacology and therapeutics, 10 (1994) 47-56.
[10] H. Almeida, M.H. Amaral, P. Lobão, J.M.S. Lobo, In situ gelling systems: a strategy to improve the bioavailability of ophthalmic pharmaceutical formulations, Drug discovery today, 19 (2014) 400-412.
[11] V. Wagh, B. Inamdar, M. Samanta, Polymers used in ocular dosage form and drug delivery systems, Asian journal of Pharmaceutics, 2 (2008) 12.