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Original Research Article

Design Development and Evaluation of Nanoparticles for the Treatment of Opthalmic Ailments

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Abstract: The objective of the study is to develop and evaluate nanoparticles of moxifloxacin and prednisolone for ophthalmic delivery. The nanoparticles were prepared by Double emulsion technique. Different formulations were prepared by varying the polymer and drug ration. The developed formulations were optimized and the characterisation of the nanoparticles was performed. Morphology, drug entrapment and release was examined. Mean particle size was found to be below 200 nm. The formulation possesses good antibacterial activity and no eye irritation was observed.

Keywords: Nanoparticle, Ocular, Moxifloxacin, Prednisolone, PLGA.

INTRODUCTION

Globally, at least 1 billion people have a near or distance vision impairment that could have been prevented or is yet to be addressed. In the absence of timely detection, reduced or absent eyesight can have long-term personal and economic effects. Vision impairment affects people of all ages, with the majority being over the age of 50. Young children with early onset of severe vision impairment can experience lower levels of educational achievement, and in adults, it often affects quality of life through lower productivity, decreased workforce participation and higher rates of depression. Vision impairment and blindness impact the lives of people everywhere. In low-and middle-income settings, the burden of vision impairment can be even greater due to fewer opportunities to access the most essential eye care services.

Cataracts and uncorrected refractive errors are estimated to be the leading cause of vision impairment; however, other causes for vision impairment cannot be ignored. Age-related macular degeneration. Glaucoma. long-standing systemic conditions like diabetes retinopathy, infectious diseases of the eye and trauma of the eye are all equally important causes for vision impairment that need to be addressed. (1) However, the efficiency of pharmacotherapy is highly limited by ocular physiological barriers. The conventional topical eye drops have a gain of over 5% bioavailability resulting from the precorneal loss, nasolacrimal drainage, blinking and corneal tight junctions. Nanoparticles surmount these by optimising size (<200nm),

mucoadhesion, and sustained release of the drug, which can be observed in the solid lipid nanoparticles (SLN) and chitosan-coated systems.

Notwithstanding advancements in either of the systems, critical limitations continue to exist, thereby disrupting the clinical transition for ophthalmic therapies. SLN shows an appreciable drug entrapment, of about 80% efficacy, but succumbs to a significant amount, being released in bursts under the physiological tear flow shear stress, while studies report close to 40% unprecedented drug expulsions within the first couple of hours of administration. The uncertainty undermines the sustained release claim that is essential for chronic conditions such as glaucoma, which requires constant intraocular pressure control.

Chitosan coatings widely improve mucoadhesion through positive zeta potential interactions with negatively charged corneal mucins, but their pH-dependent stability becomes problematic in the alkaline tear film environment. Alkaline conditions trigger the deprotonation of chitosan, thereby causing a reduction in the surface charge by 30-50% and foregoing long-term retention. To add further, posterior segment delivery remains virtually untouchable; even optimised nanoformulations achieve <10% retinal penetration due to the formidable blood-retinal barrier and its vitreous humour clearance mechanisms.

Lipid oxidation at the time of mandatory gamma sterilisation for clinical use degrades 25-30% of the encapsulated drug potency, while surfactant leaching from SLN matrices goes on to trigger corneal irritation in approximately 15% of the tested formulations. Scalability from laboratory bench to GMP manufacturing presents further obstacles, as high-shear homogenization methods fail to maintain the particle size distribution (<200 nm polydispersity index <0.2) at the time of large-batch productions taking place.

MATERIALS AND METHODS:

Materials:

Moxifloxacin hydrochloride and Prednisolone were used as the active pharmaceutical ingredients (APIs) for ocular delivery. Poly(lactic-co-glycolic acid) (PLGA) was selected as a biodegradable and biocompatible polymer suitable for ophthalmic applications. Dimethyl sulfoxide (DMSO) was used as the organic solvent for polymer dissolution. Polyvinyl alcohol (PVA) was employed as a stabilizing surfactant in the external aqueous phase. All reagents were of analytical grade and used without further purification. Double-distilled water was used throughout the study.

Preparation of Nanoparticle:

Drug-loaded PLGA nanoparticles intended for ophthalmic delivery were prepared by the double emulsion solvent evaporation ($W_1/O/W_2$) method, optimized to ensure sustained drug release and ocular compatibility.

An accurately weighed quantity of Moxifloxacin and Prednisolone was dissolved in the internal aqueous phase (W_1). Separately, PLGA was dissolved in DMSO to obtain the organic phase (O). The primary emulsion (W_1/O) was formed by slowly adding the aqueous drug solution into the organic polymer solution under continuous stirring, followed by probe sonication to achieve uniform dispersion of the drugs within the polymer matrix.

The primary emulsion was subsequently added dropwise into an external aqueous phase (W_2) containing PVA as a surfactant and stabilizer, under constant mechanical stirring. The mixture was further sonicated to form a stable double emulsion ($W_1/O/W_2$). The emulsion was maintained under stirring at room temperature to allow complete evaporation of the organic solvent, resulting in the formation of solid PLGA nanoparticles.

Formulation table for Nanoparticles

Formulation	Drug Polymer Ratio	Organic /Aqueous phase ratio
F1	01:02	01:02
F2	01:04	01:02
F3	01:06	01:02
F4	01:08	01:02
F5	01:10	01:02
F6	01:10	01:03
F7	01:10	01:04
F8	01:10	01:05

Characterization of PLGA Nanoparticles

Particle Size, Polydispersity Index, and Zeta Potential

The mean particle size, polydispersity index (PDI), and zeta potential of the prepared PLGA nanoparticles were determined using dynamic light scattering (DLS) and electrophoretic light scattering techniques (Zetasizer, Malvern Instruments, UK). Prior to analysis, the nanoparticle suspension was suitably diluted with filtered distilled water to avoid multiple scattering effects. Measurements were performed at 25 °C with a fixed scattering angle, and each sample was analyzed in triplicate. The average particle size and PDI were used to assess size distribution and formulation uniformity, while zeta potential values were recorded to evaluate surface charge and colloidal stability of the nanoparticles intended for ophthalmic administration.

Morphological Analysis

The surface morphology and shape of the nanoparticles were examined using Scanning electron microscopy (SEM). For SEM analysis, a small amount of lyophilised nanoparticle powder was mounted on aluminium stubs and coated with a thin layer of gold under vacuum conditions.

Drug Entrapment Efficiency and Drug Loading

The entrapment efficiency (EE%) and drug loading (DL%) of Moxifloxacin and Prednisolone in PLGA nanoparticles were determined by indirect analysis. An accurately measured volume of nanoparticle suspension was centrifuged at high speed to separate the nanoparticles from the aqueous medium. The supernatant containing the free (unentrapped) drug was collected and analyzed using UV–Visible spectrophotometry. The entrapment efficiency and drug loading were calculated using the following equations:

$$\text{Entrapment Efficiency (\%)} = \frac{\text{Total drug - Free drug}}{\text{Total drug}} \times 100$$

$$\text{Drug Loading (\%)} = \frac{\text{Amount of drug in nanoparticles}}{\text{Total weight of nanoparticles}} \times 100$$

Fourier Transform Infrared Spectroscopy (FTIR)

FTIR spectroscopy was carried out to evaluate possible drug–polymer interactions. Spectra of pure drugs (Moxifloxacin and Prednisolone), PLGA, physical mixtures, and drug-loaded nanoparticles were recorded using an FTIR spectrophotometer over the range of 4000–400 cm^{-1}. The samples were prepared using the potassium bromide (KBr) pellet method. The characteristic peaks were compared to confirm chemical compatibility and stability of the drugs within the polymer matrix.

Differential Scanning Calorimetry (DSC)

Thermal analysis of the pure drugs, PLGA, and drug-loaded nanoparticles was performed using differential scanning calorimetry (DSC). Samples were sealed in aluminium pans and heated at a controlled rate under a nitrogen atmosphere. Thermograms were analyzed to identify melting endotherms and to assess the physical state of the drugs (crystalline or amorphous) within the nanoparticles.

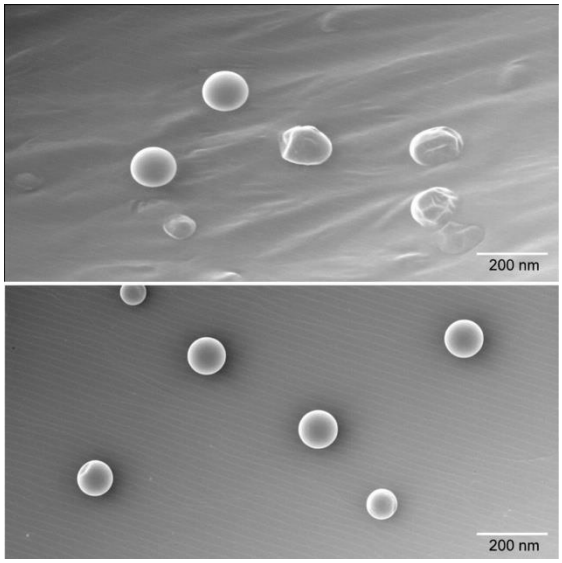
In Vitro Drug Release Study

The in vitro release profile of Moxifloxacin and Prednisolone from PLGA nanoparticles was evaluated using the dialysis bag diffusion method. An accurately measured amount of drug-loaded nanoparticles was placed in a pre-soaked dialysis membrane, which was then immersed in simulated tear fluid (pH 7.4) maintained at 37 ± 0.5 °C under constant stirring. At predetermined time intervals, aliquots were withdrawn and replaced with fresh release medium. The samples were analyzed using UV–Visible spectrophotometry to determine cumulative drug release.

RESULTS AND DISCUSSION:

Morphology:

SEM micrographs of nanoparticles showed smooth surfaced nanoparticles with spherical shape and uniformly distributed.



Size and Zeta Potential:
Formulations showed small mean size, which provides good patient comfort and is appropriate for ocular administration. The Size ranges from 153 to 194 nm. (Table 2)

The Zeta potential for Nanoparticles remained in positive values for all batches. Positive charge can facilitate the adhesion of the particle to the cornes, and tear film since they are negatively charged hence increasing the resident time in eye.

Formulation	Drug Polymer Ratio	Organic /Aqueous phase ratio	Particle Size	Poly Dipersity Index	Zeta Potential
F1	01:02	01:02	153±0.5	0.465±0.07	10.22±1.5
F2	01:04	01:02	168±1.5	0.412±0.05	12.65±1.8
F3	01:06	01:02	166±1.3	0.317±0.05	19.16±1.3
F4	01:08	01:02	172±1.8	0.325±0.02	21.25±1.4
F5	01:10	01:02	168±1.6	0.267±0.07	25.15±1.8
F6	01:10	01:03	175±0.9	0.432±0.05	31.23±1.5
F7	01:10	01:04	173±1.5	0.448±0.05	37.57±1.0
F8	01:10	01:05	194±1.6	0.567±0.02	40.12±1.5

Drug Entrapment Efficiency:
The entrapment efficiency was found to vary with drug and polymer ratio for both batches. It was observed that increase in polymer concentration in organic phase increases drug entrapment due to increase in organic phase viscosity.

In vitro Drug Release:
Therelease rate was found to be influenced by drug: polymer ratio. Increase of drug release wasobserved as a function of drug: polymer ratio. The Formulations showed prolonged release. No burst effect was observed.

Cumulative Drug Release								
Time (hrs)	F1	F2	F3	F4	F5	F6	F7	F8
1	13.35	14.67	15.17	16.05	18.21	18.26	18.78	20.03
2	24.22	26.74	27.54	28.13	31.22	26.98	28.88	30.17
4	33.76	36.35	41.23	43.35	47.45	48.35	32.08	42.98
6	46.81	49.4	53.46	51.44	57.69	55.35	54.56	55.54
8	50.75	55.23	57.65	58.23	63.12	62.25	62.35	60.89
12	55.98	56.12	59.47	61.67	68.12	66.56	66.56	64.54
16	61.35	63.24	65.7	68.25	74.34	73.24	71.53	70.57

18	63.38	66.35	69.05	71.02	78.71	77.65	74.31	73.46
24	66.97	70.22	70.76	72.94	81.56	80.04	74.98	75.12

CONCLUSION:

This study attempts were made to prepare sustained release nanoparticle of moxifloxacin and prednisolone for ocular release using PLGA as polymer. Rheological studies ,Drug entrapment, Drug Release were evaluated. Formulation containing variable such as, different drug: polymer ratios and different solvents ratios (organic phase: aqueous phase) were prepared. Optimised Nanoparticles posees Good Ocular retention, due to small particle size which is unique for ocular preparations. The in vivo drug release shows the release rate is related to drug polymer ratio.

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