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Clear aqueous mixed nanomicellarcyclosporine-A topical drops for anterior and posterior ocular delivery

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Purpose: The objectives of this study are to preparecyclosporine-A (Cys-A) loaded mixed nanomicellar (MNF) aqueous drop, evaluate *in vitro* and *in vivo* ocular biocompatibility and ocular tissue Cys-A levels with single and multiple topical drops.

Materials and methods: Cys-A loaded MNF was prepared following solvent casting/rehydration method. MNF Size, polydispersity index (PDI), shape, qualitative proton nuclear magnetic resonance (1H NMR), critical micellar concentration (CMC), entrapment and loading were studied. *In vitro* cytotoxicity studies were conducted on rPCEC and D407 cells. Ocular tolerability, toxicity and tissue distribution of Cys-A were studied in rabbits with single and multiple drop instillation.

Results: Cys-Awas loaded into MNF to generate a loading of 1 mg/mL and hasa low CMC of 7.07 x 10-3wt%. Optimized MNF demonstrated high drug loading with an average spherical diameter of ~20 nm and narrow PDI (0.147).TEM revealed MNF to be spherical with smooth surface morphology. Absence of unentrapped Cys-A in MNF was confirmed with1H NMR spectroscopy. Cytotoxicity, *in vivo* ocular tolerability and toxicity studies revealed MNF to be safe and well tolerated.Cys-A ocular tissue distribution with single and multiple topical drops showed higher Cys-A concentrations. Single dose Cmaxin anterior and posterior tissue was ~3 times higher with MNF than Restasis® i.e., MNF delivered 828 ng/g tissue in cornea and 26.93 ng/g in retina/choroid.

Conclusions: Anaqueous, clear, safe and well-tolerated Cys-A loaded MNF that delivers high Cys-A levels in anterior and back of the eye tissues with topical drop is prepared and evaluated.

Biography

Kishore Cholkar obtained his B.Pharmacy from Kakatiya University, India and Master's in Chemistry from Western Illinois University, IL, USA. In 2008, he joined Dr. Ashim K Mitra's research group as a graduate student and has been working for development and preclinical evaluation of aqueous topical eye drops. As a Doctoral Candidate, he has extensively published (14 publications) which is evident from his peer reviewed publications. He has been honored with several travel awards to present his work at conferences such as AAPS, ARVO, ACS, PGSRM and student research summit. Also, he published six book chapters in formulations and ocular drug delivery.

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