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Development and characterization of a novel topical polymeric nanomicellar formulation (size 25-30 nm) for intermediate and posterior uveitis

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Purpose: To develop Dexamethasone (DEX) loaded polymeric nanomicelles in size range of 25-30nm using experimental design.

Methods: A low molecular weight diblock co-polymers (PCL2500-mPEG2000) was synthesized by ring opening polymerization using mPEG as initiator and stannous octoate as catalyst. Polymerwas characterized by H1 NMR, IR spectroscopy, gel permeation chromatography, critical micelle concentration (CMC) and cytotoxicity studies in corneal, conjunctival and retinal cell-lines. DEX-loaded nanomicelles were prepared by film hydration method. In order to understand the drug-polymer interactions influencing drug solubilization in micelle core, a 2factors-3 level response surface methodology was generated using SAS9.02 (exploratory model).The independent factors were polymer amount (X1) and DEX amount(X2). Solubility of DEX in micelle solution was taken as response variable (Y). Micelle preparation method was modified based on the results obtained from exploratory model. The formulation was optimized by another response surface design (optimization model to achieve DEX solubility of 1mg/mL). The optimized formulation was characterized for solubility of DEX, micelle size and PDI & TEM analysis. The formulation was also subjected to *in vitro* transport across conjunctival cellline and *ex vivo* transport across excised rabbit's clera.

Results: The Mw, Mn and PDI for newly synthesized polymer were 4586 Da, 3155 Da and 1.45, respectively. The CMC was determined by pyrene method and was found to be 12.3µg/mL. The information on DEX-polymer interactions obtained from exploratory model was utilized to modify the micelle preparation method to obtain optimized nanomicellar formulation of DEX (1 mg/mL). The optimized nanomicelle formulation exhibited mean size in range of 25-30 nm with unimodel size distribution and low polydispersity. The nanomicelles increased DEX permeability by 2 fold across conjunctival cell line and by ~2.5 fold across the excised rabbit's clear as compared to DEX suspension.

Conclusion: The design of experiment was successfully utilized for understanding the effects of drug-polymer interaction on DEX solubility. The exploratory model further helped to improve DEX solubility in micelle core. Higher permeability of DEX was observed across both conjunctival cell line and excised rabbits clera with nanomicellar formulation.

Biography

Ravi Vaishya is currently an interdisciplinary Ph.D. candidate at University of Missouri-Kansas City, Missouri. He has worked extensively on development and characterization of nanomicelle solution formulation for small molecules using statistical design of experiments. He is also experienced in developing polymeric sustained drug delivery systems based on nanoparticle and thermosensitive gel for protein delivery. He currently has several research manuscripts, patents, and review articles published in various reputed journals.

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