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Optimization of Mucoadhesive Polymer Micelle Nanoparticle Synthesis and Formulations for Commercialization

Topical administration is the most popular route of ocular drug delivery. However, only 5% of the administered dose is bioavailable for action at the target site, while the remaining 95% is removed via blinking, nasolacrimal drainage, or degradation. Frequent administrations of concentrated solutions are required to overcome these barriers to maintain therapeutic concentrations. Adhesion to the mucus layer of the ocular tear film (mucoadhesion) has been successfully demonstrated as a mechanism to bypass clearance by the tear film. We propose that the prolonged retention will result in less frequent administration, local targeting of the ocular tissue, a reduced administered dose, and therefore reduced adverse side effects. Nanobiotechnology is expected to be the next advent of the health care market, facilitating efficient, safe, and personalized therapies, but have had limited success penetrating the market. Despite numerous publications demonstrating the utility of nanoparticle platforms for drug delivery, analyses on commercial viability show there are several challenges to be addressed. This thesis work addresses some of these challenges, with a focus on mucoadhesive polymer micelle nanoparticles proposed in earlier works as a model system. This work investigates the mucoadhesive nanoparticle platform to optimize the synthesis methods and to develop a model facilitating modification for alternate delivery routes. The formulation challenges are addressed in accordance with the United States Pharmacopeia (USP), and investigations are made to address the challenges pertaining to the stability of colloidal nanosystems. The conclusions of this work aim to improve the commercial viability of the mucoadhesive polymer micelle nanoparticle platform. The recommendations can be applied to this and other novel platforms to address the common challenges to successful commercialization.