Preparation and Evaluation of Niosome based ophthalmic gel of Prednisolone Acetate

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Abstract

Conjunctivitis refers to inflammation of the conjunctiva (the outermost layer of the eye and the inner surface of the eyelids). It is a typically self-limited process; however, depending on the immune status of the patient and the etiology, conjunctivitis can progress to more severe and sight-threatening infections. Prednisolone corticosteroid drug with predominant glucocorticoid and low mineralocorticoid activity, making it useful for the treatment of a wide range of inflammatory and auto-immune conditions. The aim of present investigation was to prepare and evaluate niosomes based ophthalmic gel of prednisolone. Drug excipients compatibility was determined using Fourier Transform Infrared Spectroscopic (FTIR). Niosomes were prepared by thin film hydration technique using span 60 (non ionic surfactant) and cholesterol combination. Various molar ratios of span 60 and cholesterol were optimized for better characteristics. A 3^2 full factorial design was used for optimization of various formulation parameters. Developed niosomes were evaluated for vesicle size, zeta potential and percentage drug entrapment. Niosomes were converted to niosomal gel using structured vehicle Hydroxy propyl methyl cellulose K 100M. Niosomal gel was evaluated for viscosity, pH and drug content. *In vitro* drug release was performed on Franz diffusion cell using dialysis bag. Histopathological examination was performed using goat eye by evaluating epithelial

cell necrosis. Sterility testing was performed using fluid thioglycolate media and soya bean casein digest media. Stability study was performed at room temperature and accelerated conditions. Absence of incompatibility between drug and excipients was confirmed by FTIR. Optimized niosomes formulation is containing drug to total lipid (surfactant and cholesterol) ratio (1:15) and surfactant to cholesterol ratio (8:2) showed optimum particle size (113.4±0.068 nm), zeta potential (-41.5±0.42mV) and percent drug entrapment (76.43±0.17%). Viscosity, pH and drug content of optimized batch of niosomal gel of prednisolone were found to be 28000±0.045 cps, 7.2±0.025 and 92.55±0.23% respectively. *In vitro* drug release of prepared niosomal gel and marketed formulation was found to be 64.57±0.021% and 82.68±0.043% up to 270 minutes respectively. Histopathological study indicates no pathological changes in conjunctiva of goat. Sterility testing showed no microbial growth in both the mediums which indicates that the formulation of niosomal gel is sterile. The stability study indicated that niosomal gel stored at room temperature remains stable with almost no change in niosomal gel characteristic. The present investigation shows a practical approach used to sustain the release of drug in affected eye by enhancing corneal residence time. Small vesicles size of niosomes in the nanometre range would increase the penetration through ocular mucosa which will ultimately improve the drug bioavailability. Drug entrapped in niosomes vesicles might have reduce the direct contact of ocular mucosa with drug that might have decreased the irritation.

Keywords: Prednisolone, Niosomes, Conjunctivitis, HPMC K 100M