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Formulation and physicochemical evaluation of sustained release diclofenac sodium ocular film

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Background and Aims: Ophthalmic diclofenac is used to treat eye pain, redness and swelling in patient who are recovering from cataract surgery. In this study, an attempt was made to prepare diclofenac sodium ocular film, with the aim of increasing the contact time, reducing the frequency of administration, obtaining greater therapeutic efficiency and improving patient compliance.
Methods: In the present study, diclofenac ocular films were prepared by solvent casting technique, using film forming polymers like: HPMC4000, carbomer 940, PVP k30 and Eudragit® L100, S100. Glycerin was used as plasticizer. The different ratio of water and alcohol were used as solvent. Due to the rapid release of diclofenac from the film matrix. They were coated with different solutions such containing Eudragit®&HPMC either alone or in combination. Finally, all formulations were evaluated for their physicochemical parameters like thickness, assay, weight, swelling capacity and invitro drug release in artificial tear fluid (pH:7.4, under 25 ℃ within 8 hours).
Results: In vitro studies showed that, 85% of diclofenac was released in less than 3hr, from non-coated film matrix that contained HPMC and Eudragit®. After coating there matrixes with a solution containing Eudragit® and HPMC in a 50:50 ratio a controlled 8hr release obtained. Physicochemical evaluation revealed that coating film matrix with either Eudragit® or HPMC:Eudragit® in a 1:3 ratio will result in fragile films. Flexible film were them prepared using a coating solution contains HPMC:Eudragit® in a 50:50 ratio.
Conclusions: Because of the fast and uncontrolled drug release from non-coated films which were prepared using solvent casting method, coating of the films seems necessary. As a result diclofenac ocular films were successfully prepared.

Keywords: Ocular film; Novel drug delivery system; Diclofenac sodium; Solvent casting