FP-01
DOI: 10.14232/syrptbrs.2026.59

Combined ophthalmic nanoformulation of Dexamethasone for improved bioavailability

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Eye drops are the most commonly used topical preparations for eye diseases. In general, they have a low bioavailability due to the natural elimination mechanisms of the eye. There are two main lines of action to increase bioavailability: increasing retention time and increasing penetration. Dexamethasone (DXM) has poor water solubility, so it is difficult to formulate in eye drops. Moreover, it is mainly used in suspension form, which does not help its penetration and retention. Nanostructured lipid carriers (NLCs) allow dissolution of lipophilic active substances, while increasing corneal penetration of the active ingredients as a nanodispersion.

Our aim was to formulate an eye drop, which is able to increase the residence time of the active substance on the cornea and to improve its penetration. NLCs were prepared and combined with temperature sensitive polymer to form an *in situ* gelling eye drop.

The physical and chemical properties of the starting materials and their mixtures, and the particle size, zeta potential, entrapment efficiency of the nanolipids were investigated. Rheological measurements were used to analyse the flow properties and gelling temperature of the smart gels. *In vitro* mucoadhesion measurements were performed on artificial mucosa. Drug release from the smart systems was evaluated using dialysis membranes. Penetration was investigated with *ex vivo* porcine eyes examination, supplemented with Raman mapping.

The size of the nanocarrier was between 100-200 nm, and zeta potential suggested a sterically stabilization. The gelling temperature of the systems was shifted by the NLCs. The polymer-NLC combination resulted in a good adhesion property and had a strong effect on drug release. On the basis of the Raman mapping, NLCs accumulated in the stroma section of the cornea.

As conclusion, the combination of NLC and polymer resulted unexpected structural changes, but based on the tests and results obtained, it can be optimized for the desired purpose.

Acknowledgement:

Project no TKP2021-EGA-32 has been implemented with the support provided by the Ministry of Culture and Innovation of Hungary from the National Research, Development and Innovation Fund, financed under the TKP2021- EGA funding scheme.