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Int J Pharm. 2016 Dec 30;515(1-2):575-582. doi: 10.1016/j.jipharm.2016.10.044. Epub 2016 Oct 19.

Preformulation of cysteamine gels for treatment of the ophthalmic complications in cystinosis.

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Abstract

Nephropathic cystinosis is a rare autosomal recessive disease characterised by raised lysosomal levels of cystine in the cells of all organs. It is treated by regular administration of the aminothioli, cysteamine. Corneal crystal deposition is one of the most troublesome complications affecting patients and requires the hourly administration of cysteamine eye drops. In an attempt to reduce this frequency and improve the treatment, the preformulation and evaluation of cysteamine containing gels is reported. Suitability for ophthalmic delivery was determined by analysis of rheology, bioadhesion, dissolution and stability. The results demonstrated that three polymers were suitable for ophthalmic delivery of cysteamine; namely sodium hyaluronate, hydroxyethyl cellulose and carbomer 934. Sodium hyaluronate displayed optimum performance in the preformulation tests, being pseudoplastic (reduction in apparent viscosity under increasing shear rate), bioadhesive, releasing cysteamine over 40min and displaying stability over time. In conclusion these results offer the possibility to formulate cysteamine in an ocular applicable gel formulation.

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KEYWORDS: Cysteamine; Cystinosis; Gel; Ophthalmic delivery; Preformulation

PMID: 27771488 DOI: [10.1016/j.jipharm.2016.10.044](https://doi.org/10.1016/j.jipharm.2016.10.044)

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