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Effect of Storage Conditions on Stability of Ophthalmological Compounded Cysteamine Eye Drops.

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Abstract

Cystinosis is a hereditary genetic disease that results in the accumulation of cystine crystals in the lysosomes, leading to many clinical manifestations. One of these manifestations is the formation of corneal cystine crystals, which can cause serious ocular complications. The only available drug to treat cystinosis is cysteamine, which breaks cystine and depletes its accumulation in the lysosomes. However, the oral form of cysteamine is not effective in treating corneal manifestations. Thus, ophthalmic solutions of cysteamine are applied. Because the commercial cysteamine eye drops are not available in most countries, hospital pharmacies are responsible for preparing "homemade" drops usually without a control of stability of cysteamine in different storage conditions. Hence, we aimed in this study to investigate the effect of different storage conditions on the stability of a cysteamine ophthalmic compounded solution. Cysteamine ophthalmic solution was prepared in the hospital pharmacy and sterilized using a candle filter. The preparations are then stored either in the freezer at -20°C or in the refrigerator at +4°C for up to 52 weeks. The amount of cysteamine hydrochloride in the preparation at different time points was determined using capillary electrophoresis (CE). Storage of the cysteamine ophthalmic preparations at +4° resulted in significant loss of free cysteamine at all time points, from 1 to 52 weeks of storage, when compared with storage in the freezer (-20°C). We demonstrate that cysteamine 0.5% compounded eye drops are easily oxidized within the first week after storage at +4°C, rendering the preparation less effective. Storage at -20°C is recommended to prevent this process.

KEYWORDS: Cysteamine; Cystinosis; Ophthalmic preparation

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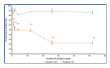

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