Development of ready-to-use cefuroxime syringes for use in ophtalmology

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Objectives: To improve the safety of the preparation and its availability in ophthalmology, a ready-to-use cefuroxime syringe prepared under aseptic conditions according to good manufacturing practice was developed by the hospital pharmacy.

Methods: The chemical stability of cefuroxime solution at 10 mg/mL in 0.9% sodium chloride in syringes (0.5 mL) was achieved at −18°C by a capillary electrophoresis method. Syringes of the last acceptable time were then stored at 4°C and the study was continued for one additional month. The pH was measured throughout the study and the presence of particle matter was controlled. Sterility testing was performed to test the integrity of the syringes.

Results: An optimal period of 4 months at −18°C was defined for storage of syringes of cefuroxime without significant loss in potency and an acceptable rate (4%) of degradation products. After thawing and storage at 4°C, degradation products progressively increased. As these derivatives can represent up to 10% of cefuroxime in terms of peak area after 1 month, it is recommended that the syringes are used within 1 h after thawing. The pH did not change appreciably during the study and the sterility testing results were negative. Moreover, in all cases the syringes fulfilled all the European Pharmacopoeia criteria with regard to non-visible particles.

Conclusions: The availability of cefuroxime for use in ophthalmology is improved as ready-to-use syringes can be stored in the ward freezer and administered immediately after thawing.

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