

Stability of 10 mg/mL cefuroxime solution for intracameral injection in commonly used polypropylene syringes and new ready-to-use cyclic olefin copolymer sterile vials using the LC-UV stability-indicating method

F. Feutry^{1,3}, N. Simon^{1,2}, D. Lannoy^{1,2}, P. Labalette^{1,2}, S. Genay^{1,2}, F. Potié¹, C. Barthélémy¹, B. Décaudin^{1,2}, P. Odou^{1,2}

¹ Univ. Lille, EA 7365 - GRITA - Groupe de Recherche sur les formes Injectables et les Technologies Associées, F-59000 Lille, France

² Pharmacy institute, University Hospital, Lille, France

³ Oscar Lambret Centre, Lille, France

Context

Injecting intracameral cefuroxime has been found beneficial in reducing the risk of postoperative endophthalmitis but its use has been limited through a lack of approved marketing and of ready-to-use single-units as well as the problem of aseptic compounding.

Objective

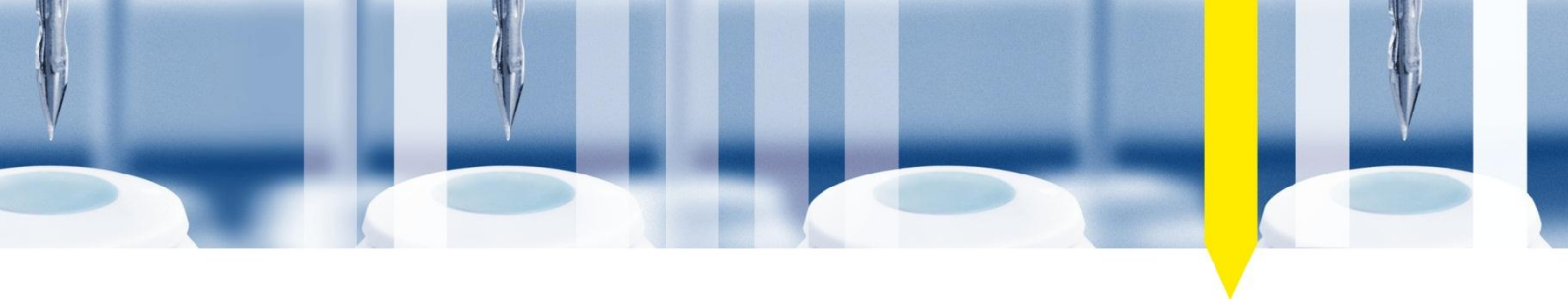
Our aim was to assess a new automated primary packaging system which should ensure a higher level of sterility, thanks to its closed, sterile, ready-to-use polymer vial called "Crystal[®] vial". The chemical stability of a 10 mg/mL cefuroxime solution was compared in 1 mL Crystal[®] vials and 1 mL Luer-lock polypropylene syringes (actual reference) to eliminate any potential and specific interactions with its cyclic olefin copolymer (COC) body and elastomer stopper.

Methods

Cefuroxime solution was introduced into vials and syringes and stored at -20°C , $+5^{\circ}\text{C}$ and $+25^{\circ}\text{C}/60\%$ Relative Humidity. Cefuroxime concentration and the relative amount of the main degradation product (descarbamoyl-cefuroxime) were both determined by an HPLC/UV method indicating stability. Solutions were considered steady if the concentration remained at over 90% of the initial value. In the adapted storage conditions, the evolution of osmolality, pH and sterility was assessed.

Results

Stability profiles were identical between vials and syringes in all storage and temperature conditions. The solution was stable (cefuroxime concentration, pH and osmolality) and still sterile for 365 days at -20°C . The concentration fell below 90% after 21 days at $+5^{\circ}\text{C}$ and after 16 h at $+25^{\circ}\text{C}/60\%$ s relative humidity.



Conclusions

The COC and thermoplastic elastomer of the vials had no impact on the degradation process confirming its possible use for a ready-to-use cefuroxime solution single-unit dose.

Source: <http://www.tandfonline.com/doi/pdf/10.3109/03639045.2015.1038273>