STABILITY OF CEFUROXIME 80 MG/ML SOLUTION IN READY-TO-ADMINISTER POLYPROPYLENE SYRINGES

M. Helin-Tanninen[1], J. Mustonen[2], M. Lehtonen[2], O. Korhonen[2].

[1]Hospital District of Northern Savo - Kuopio University Hospital, Pharmacy, Kuopio, Finland.
[2]University of Eastern Finland, The School of Pharmacy / Faculty of Health Sciences, Kuopio, Finland.

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Background

Cefuroxime is antibiotic agent which is widely used in hospitals. Thus, robotic preparation of prefilled ready-to-administer (RTA) cefuroxime 80 mg/ml injections was validated in our pharmacy. The physicochemical stability of these RTA products is a challenge in Centralised IntraVenous Additive Services (CIVAS). Published stability data for concentrated cefuroxime solutions is limited. Cefuroxime solutions of 10 mg/ml and 50 mg/ml, remained stable for 21 days at +5ºC and only 16-48h at 25ºC, respectively (Feutry et al. 2015, Gupta 2003).

Objectives

To determine the physicochemical stability of cefuroxime 80mg/ml solution in polypropylene syringes to establish the shelf-life of the product.

Figures 1 and 2. IV Icon Basic® (Newicon Oy) reconstituted cefuroxime injections. Filled syringes were closed manually. Over 40 000 RTA-syringes were reconstituted in Kuopio University Hospital on 2017.

Methods

Cefuroxime powders 1.5g (n=42) were reconstituted with 18ml of water for injection. Robot added water into vials, solved powder and filled polypropylene syringes. The samples were stored at two different temperatures (4°C and 23°C) protected from light. Drug concentration, appearance, pH of the solution and amount of degradation products were studied on days 0, 1, 3, 7, 15, 30 and 45. A stability indicating HPLC method for quantitative analysis of cefuroxime was developed and validated. Test for uniformity of dosage units was carried out according to European Pharmacopoeia.

Results

The concentration of cefuroxime remained over 90% of the initial concentration (Cl 95%) 11 days at 4°C and 2 days at 23°C. No color change was detected in samples that were stored at 4°C, but slight change in color appeared after 24 hours at 23°C. The pH increased from 7,4 to 7,6 during the storage, while the amount of degradation products increased but still stayed under the limit of 3%. Acceptance value for the test for uniformity of dosage units was calculated to be within acceptance limit.
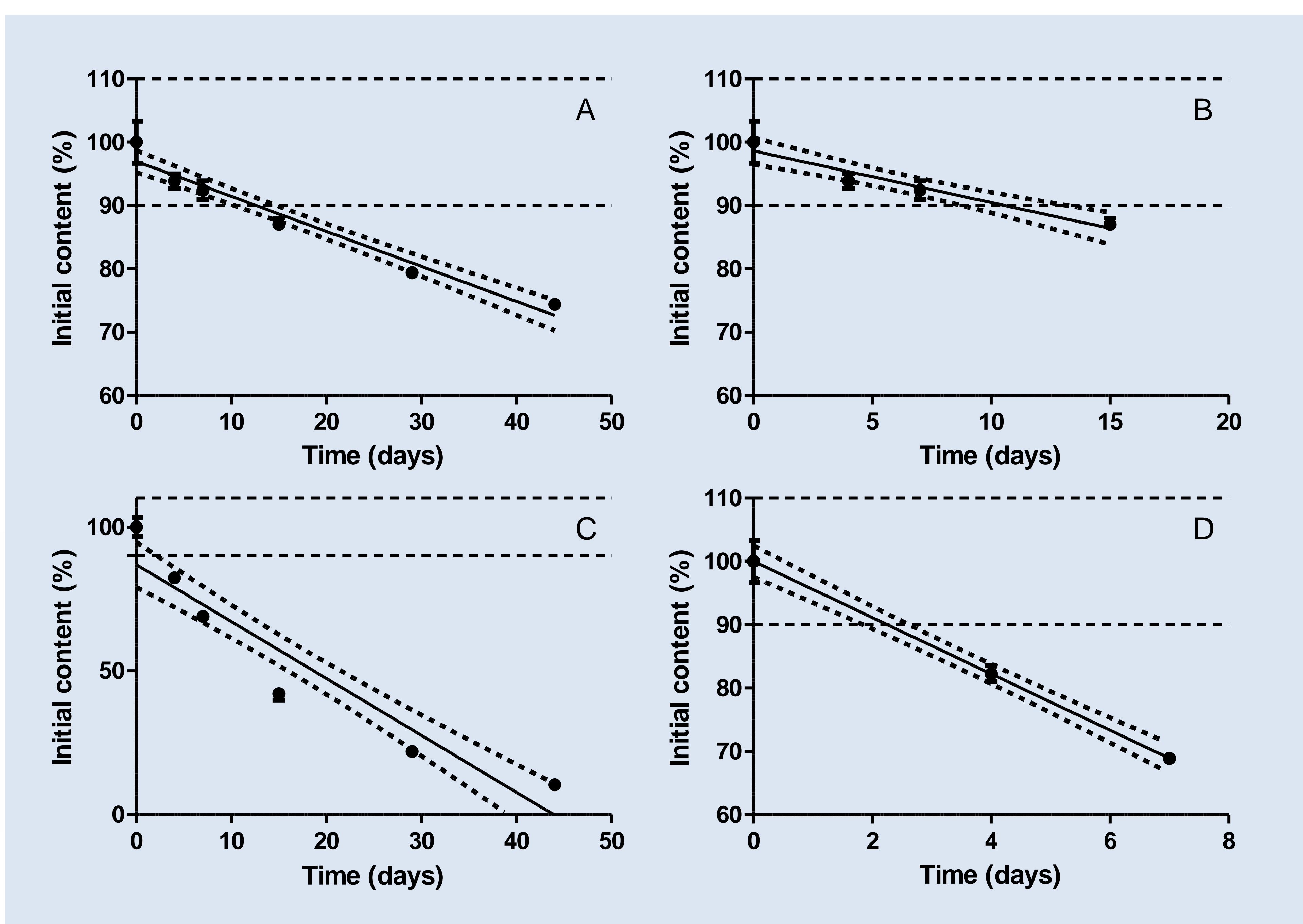

Figure 3. Cefuroxime solutions stored at 4°C for 45 days (A), defined for 15 days (B), and at 23°C for 45 days (C), defined for 7 days (D).

Conclusions

- Compared to literature data, the physicochemical stability of cefuroxime 80 mg/ml solution stored in refrigerator was reduced.
- The determined shelf-life of 11 days in refrigerator enables CIVAS and storage of cefuroxime injections.
- Storage at room temperature needs to be minimized according to these results.

References

Feutry F et al. Drug Dev Ind Pharm, 2016;42(1):166-174
Gupta VD. Int J Pharm Compound, 2003;7(4):310-312