Stability of Cefazolin Sodium Eye Drops

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ABSTRACT

In this study, the influence of storage temperature on the stability of cefazolin sodium in Tears Naturale II (33 mg/ml) was evaluated. Cefazolin sodium was reconstituted in Tears naturale II and the solutions stored at 4°C and 28°C for 28 days. The effects of different storage temperatures on the stability and microbial contamination were examined.

The fortified stock solutions of cefazolin sodium were prepared by reconstituting with water for injection and with Tears Naturale II. The stability was evaluated by measuring the absorbance spectrum and pH. During the study period, the levels of contamination of all of the solutions were examined by tryptic soy broth for 24-48 hours.

Throughout the 28-day period, no change was observed in the percentage of the labeled amount of cefazolin sodium stored at 4°C, but the percentage at 28°C decreased after 7 days (p<0.05). The pH of the eye drops was in the range of 3.5-10.5 which is usually tolerable by the eyes. No contamination was found in any of the solutions during the study period.

The main conclusions to be drawn from this study are that if topical fortified cefazolin sodium solutions are to be used for longer than 7 days, they should be stored at 4°C while those stored at 28°C should be discarded after 7 days.

Key words: Cefazolin sodium eye drops

INTRODUCTION

Depending on the seriousness of the condition, bacterial eye infections (e.g., corneal ulcers, keratitis) need "strengthened eye drops" containing a high concentration of antibiotics (Steinert, 1991). Cefazolin sodium eye drops (33 mg/ml) are administered topically to the eye to treat microbial keratitis (Tananuvat et al., 2004). As these are not commercially available, they are made up and prescribed for the treatment of eye infections due to sensitive bacterial combinations after isolation. The Division of Pharmacy, Chiang Mai University, routinely makes up eye drop preparations, containing 33 mg/ml cefazolin sodium. It has been reported that parenteral solutions of cefazolin sodium, following reconstitution with water for injection, should be discarded after 24 hours storage at 25°C or after 96 hours at