



Chemical Stability of Ketoconazole Ear Drops in Srinagarind Hospital

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Background and Objectives : According to the Thai National Formulary 2013, clotrimazole ear drops was the single topical antifungal agent indicated for the treatment of otomycosis. Ketoconazole ear drops was developed as alternative drugs for patients who did not response to clotrimazole. To assure the quality of the developed product, the chemical stability of ketoconazole ear drops was studied for 180 days.

Methods : Ketoconazole solution was prepared by dissolving ketoconazole powder 20 g in PEG-400 1,000 ml. The solution was filled into 10-mL sterile polyethylene bottles, then stored at room temperature. The samples were analyzed for the initial and the remaining concentrations of ketoconazole on days 0, 30, 60, 90, 120, 150 and 180.

Results : This was experimental research at Faculty of Medicine, Khon Kaen University. On days 0, 30, 60, 90, 120, 150 and 180, the percentages of labeled amount were 102.43, 102.70, 100.70, 97.50, 90.10, 85.80 and 84.30, respectively and the percentages of the concentration remaining were 100.00, 100.26, 98.31, 95.18, 88.00, 83.80 and 82.26, respectively. The percentages of the concentration remaining were less than 90 on days 120, 150 and 180 throughout 180-day study period.

Conclusions : The result of the study showed that the ketoconazole ear drops, developed in Srinagarind Hospital was stable for 90 days when stored at room temperature.

Keywords : Chemical stability, Ketoconazole ear drops, Otomycosis

