CHROMATOGRAPHIC AND MICROBIOLOGICAL DETERMINATION OF FLUCONAZOLE IN INJECTABLE PREPARATIONS

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Fluconazole is a synthetic triazole antifungal agent used in the treatment of candidiasis and other fungal infections. A high performance liquid chromatographic method and a microbiological assay have been developed for the determination of fluconazole in injectable solutions. A Phenomenex® Synergi Fusion RP-80 C_{18} (150 x 4,60 mm, 4 µm) column was used for fluconazole separation, using isocratic elution with water : methanol (55:45, v/v) and UV detection at 260 nm. Microbiological assay was performed using the agar diffusion method, using *Saccharomyces cerevisiae* ATCC 1600 as the test microorganism and antibiotic medium 19 for agar layer. The two methods were validated and applied for quantitative determination of fluconazole and have been demonstrated good linearity, precision and accuracy. The assays were linear in the concentration range of 25-200 µg/mL, for HPLC, and 25-400 µg/mL for microbiological method. The precision of the methods was determinated by repeatability (RSD 0.33%, for HPLC, and 4.60% for bioassay) and intermediate precision (RSD 0.53%, for HPLC, and 5.35% for bioassay). The accuracy was determined and the mean recovery was found to be 99.05%, for HPLC, and 100.83% for bioassay. The two proposed methods have been successfully validated and may be considered for routine analysis of fluconazole in pharmaceutical injectable preparations.

Keywords: Fluconazole; injectable solutions; HPLC; microbiological assay