High-Performance Liquid Chromatographic Determination of Fluconazole in Plasma and its Application to a Bioequivalence Study

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SUMMARY. A sensitive and accurate HPLC-UV method for the quantification of fluconazole (FNZ) in human plasma has been developed. The sample was prepared by liquid–liquid extraction (LLE) of FNZ from plasma using ethyl acetate. Nevirapine (NVP) was used as internal standard. The chromatographic retention times of FNZ and NVP were 3.4 and 5.7 min, respectively. The lower limit of quantitation (LLOQ) was 0.5 μ g/mL, and no interferences were detected in the chromatograms. The HPLC-UV method was validated by evaluating its intra-day and inter-day precisions and accuracies in a linear concentration range between 0.5 and 8.0 μ g/mL. The method was developed, validated and successfully applied to bioequivalence studies involving the oral administration of a single 150 mg FNZ capsules in healthy Brazilian male volunteers.

KEY WORDS: Bioequivalence, Fluconazole, High performance liquid chromatography (HPLC), Validation.

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