Development of a high-performance liquid chromatographic method for bioanalytical application with sulpride

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摘要

Abstract

An improved HPLC method using a silica gel column with fluorescence detection (excitation at 300 nm and emission at 365 nm) was developed for the determination of sulpiride concentrations in plasma. Analysis of sulpiride in plasma samples was simplified by a one-step liquid-liquid extraction after alkaline treatment of only 1 ml of plasma. The low limit of quantitation was 20 ng/ml with a coefficient of variation of less than 20%. A linear range was found from 20 to 1500 ng/ml. This HPLC method was validated with the precision for inter-day and intra-day runs being 0.36-8.01% and 0.29-5.25%, respectively, and the accuracy (standard deviation of mean, SD) for inter-day and intra-day runs being -1.58 to 5.02% and -2.14 to 5.21%, respectively. Bioequivalence of the two products was evaluated in 12 normal healthy male volunteers in a single-dose, two-period, two-sequence, two-treatment cross-over study. Sulpiride plasma concentrations were analyzed with this validated HPLC method. Results demonstrated that the two tablet formulations of sulpiride appear to be bioequivalent