Application of HPLC method using normal phase column in a comparative pharmacokietic study of two sulpiride tablet formulations

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Abstract

An HPLC method using normal phase column eluted with an aqueous solvent and detected by fluorescence was applied to analyze sulpiride concentrations in plasma samples obtained from a comparative pharmacokinetic study. This comparative study was conducted to determine the bioequivalence of two tablet products (Dogmatyl and Sulpin) containing sulpiride on 12 normal healthy Chinese male volunteers in a single-dose, two-period, two-sequence, two-treatment crossover design. The pharmacokinetic parameters, AUC0-last, AUC0-inf, and Cmax, were calculated from plasma data and compared using the SAS General Linear Model computer program. A two onesided t distribution test was also performed, as well as the 90% confidence interval method, to determine the mean difference of these three pharmacokinetic parameters. The results suggest that these two sulpiride tablet products are bioequivalent when orally administered in a 400 mg single dose of two tablets.

Key words: sulpiride, normal phase column, bioequivalence, HPLC