PHARMACEUTICAL ANALYSIS

Reversed–Phase Liquid Chromatographic Determination of Zaleplon in Human Plasma and its Pharmacokinetic Application

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Abstract: A simple, rapid, specific, and reliable high performance liquid chromatographic assay of zaleplon in human plasma has been developed. Reversed-phase chromatography was conducted using a mobile phase of methanol:ammonium acetate buffer (50:50) v/v, pH 3.2 adjusted with orthophosphoric acid, UV detection at 232 nm. After extraction from plasma by precipitation the drug was chromatographed using a C18 reversed-phase analytical column. The average recoveries of zaleplon from spiked plasma in the concentration range from 0.005–0.2 μg/ml were 93.29%, and their respective CV% was 2.557%. Regression analysis for the calibration plot for plasma standards obtained on three different days for the drug concentrations between 0.005–0.2 μg/ml indicated excellent linearity (r > 0.999) and the coefficient of variation of the slopes of the three lines was less than 2%. The limit of detection was 5 ng/ml. Analysis of variance of the data showed no detectable difference in the slopes of the three standard plots (F = 3.1, P > 0.01). The high correlation coefficients and the similarities in the slopes are good indications of the excellent reproducibility and linearity of the proposed method. The proposed method was applied to study the bioequivalence of a commercial product of zaleplon, using as reference standard the

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