

Simultaneous determination of rabeprazole and its two active metabolites in human urine by liquid chromatography with tandem mass spectrometry and its application in a urinary excretion study

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Abstract

A simple and rapid liquid chromatography with tandem mass spectrometry method has been developed and validated for the determination of rabeprazole and its two active metabolites, rabeprazole thioether and desmethyl rabeprazole thioether, in human urine using donepezil as the internal standard. The sample preparation procedure involved a simple dilution of urine sample with methanol (1:3, v/v). The chromatographic separation was achieved on a Heder ODS-2 C₁₈ column using a mixture of methanol/10 mmol/L ammonium acetate solution (containing 0.05% formic acid; 55:45, v/v) as the mobile phase. The method was validated over the concentration ranges of 0.15–100 ng/mL for rabeprazole, 0.30–400 ng/mL for rabeprazole thioether, and 0.05–100 ng/mL for desmethyl rabeprazole thioether. The established method was highly sensitive with a lower limit of quantification of 0.15 ng/mL for rabeprazole, 0.30 ng/mL for rabeprazole thioether, and 0.05 ng/mL for desmethyl rabeprazole thioether. The intra- and interbatch precision was <4.5% for the low, medium, and high quality control samples of all the analytes. The recovery of the analytes was in the range 95.4–99.0%. The method was successfully applied to a urinary excretion profiles after intravenous infusion administration of 20 mg rabeprazole sodium in healthy volunteers.