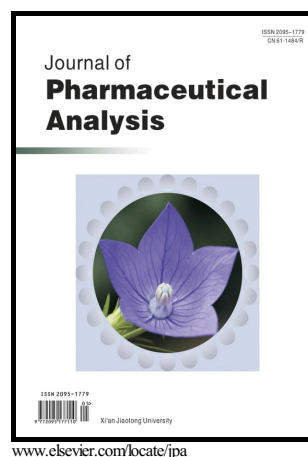


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ACCEPTED MANUSCRIPT

Application of an LC-MS/MS method for the analysis of amlodipine, valsartan and hydrochlorothiazide in polypill for a bioequivalence study

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Abstract

A sensitive and selective method has been proposed for the simultaneous determination of amlodipine (AML), valsartan (VAL) and hydrochlorothiazide (HCTZ) in human plasma by liquid chromatography-tandem mass spectrometry (LC-MS/MS). The analytes and their deuterated analogs were quantitatively extracted from 100 μ L human plasma by solid phase extraction on Oasis HLB cartridges. The chromatographic separation of the analytes was possible on a Chromolith RP_{18e} (100 mm $\times$ 4.6 mm) analytical column within 2.5 min. The resolution factor between AML & VAL, AML & HCTZ, and VAL & HCTZ was 2.9, 1.5 and 1.4, respectively under isocratic conditions. The method was validated over a dynamic concentration range of 0.02-20.0 ng/mL for AML, 5.00-10000 ng/mL for VAL and 0.20-200 ng/mL for HCTZ. Ion-suppression/enhancement effects were investigated by post-column infusion technique. The mean IS-normalized matrix factors for AML, VAL and HCTZ were 0.992, 0.994 and 0.998, respectively. The intra-batch and inter-batch precision (% CV) across quality control levels was $\leq$ 5.56 % and the recovery was in the range of 93.4 % – 99.6 % for all the analytes. The method was successfully applied to a bioequivalence study of 5 mg AML + 160 mg VAL + 12.5 mg

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