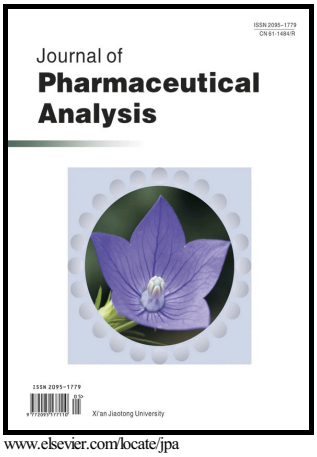

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Application of an LC-MS/MS method for the analysis of amlodipine, valsartan and hydrochlorothiazide in polypill for a bioequivalence study

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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 µL 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 × 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 ≤ 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