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Simultaneous determination of Irbesartan and hydrochlorothiazide in human plasma using HPLC coupled with tandem mass spectrometry: Application to bioequivalence studies

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A sensitive, specific and selective liquid chromatography/tandem mass spectrometric method has been developed and validated for the simultaneous determination of Irbesartan and hydrochlorothiazide in human plasma. The chromatographic conditions were optimized to achieve high resolution, and peak symmetry with a short retention time for both analytes and the internal standard. Plasma samples were prepared using protein precipitation with acetonitrile, the two analytes and the internal standard losartan were separated on a reverse phase C.sub.18 column (50 mm x 4 mm, 3 [mu] m) using water with 2.5% formic acid, methanol and acetonitrile (40:45:15, v/v/v (%)) as a mobile phase (flow rate of 0.70 mL/min). Irbesartan and hydrochlorothiazide were ionized using ESI source in negative ion mode, prior to detection by multiple reaction monitoring (MRM) mode while monitoring at the following transitions: m/z 296→269 and m/z 296→] 205 for hydrochlorothiazide, 427→175 for Irbesartan. Linearity was demonstrated over the concentration range 0.06-6.00 µg/mL for Irbesartan and 1.00-112.00 ng/mL for hydrochlorothiazide. The method demonstrated high calibration sensitivity (0.2537 and 0.0129 for Irbesartan and HCTZ, respectively). The developed and validated method was successfully applied to a bioequivalence study of Irbesartan (300 mg) with hydrochlorothiazide (12.5 mg) tablet in healthy volunteers (N=36).

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