Simultaneous determination of triprolidine and pseudoephedrine in human plasma by liquid chromatography-ion trap mass spectrometry.

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Abstract

A highly efficient, selective and specific method for simultaneous quantitation of triprolidine and pseudoephedrine in human plasma by liquid chromatography-ion trap-tandem mass spectrometry coupled with electro spray ionization (LC-ESI-ion trap-tandem MS) has been validated and successfully applied to a clinical pharmacokinetic study. Both targeted compounds together with the internal standard (gabapentin) were extracted from the plasma by direct protein precipitation. Chromatographic separation was achieved on a C(18) ACE(R) column (50.0mmx2.1mm, 5mum, Advance Chromatography Technologies, Aberdeen, UK), using an isocratic mobile phase, consisting of water, methanol and formic acid (55:45:0.5, v/v/v), at a flow-rate of 0.3mL/min. The transition monitored (positive mode) was m/z 279.1-->m/z 208.1 for triprolidine, m/z 165.9-->m/z 148.0 for pseudoephedrine and m/z 172.0-->m/z 154.0 for gabapentin (IS). This method had a chromatographic run time of 5.0min and a linear calibration curves ranged from 0.2 to 20.0ng/mL for triprolidine and 5.0-500.0ng/mL for pseudoephedrine. The within- and between-batch accuracy and precision (expressed as coefficient of variation, %C.V.) evaluated at four quality control levels were within 94.3-106.3% and 1.0-9.6% respectively. The mean recoveries of triprolidine, pseudoephedrine and gabapentin were 93.6, 76.3 and 82.0% respectively. Stability of triprolidine and pseudoephedrine was assessed under different storage conditions. The validated method was successfully employed for the bioequivalence study of triprolidine and pseudoephedrine formulation in twenty six volunteers under fasting conditions.