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PCP009

QUANTITATIVE ANALYSIS OF TOPIRAMATE IN HUMAN PLASMA USING LC-MS/MS AND ITS APPLICATION TO PHARMACOKINETIC STUDY

AP0003
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Abstract

A simple, sensitive and reliable liquid chromatography-tandem mass spectrometry (LC-MS/MS) method was developed for the quantification of topiramate in human plasma. The liquid-liquid extraction was used to extract topiramate from human plasma. Chromatographic separation was achieved on Gemini C_{18} (150 mm x 4.6 mm, 5µm) column with the mobile phase composed of acetonitrile: 2 mM ammonium acetate (85:15, *v/v*) at a flow-rate of 0.5 mL/min. The method was validated over the linearity range 15 – 3000 ng/mL with 0.2 mL of human plasma using niclosamide as an internal standard (IS). The precursor to product ion transition was monitored at m/z 338.20 → 78.20 and m/z 325.20 → 171.20 for topiramate and IS in negative mode, respectively. This method confirmed precision, accuracy and extraction recoveries obtained for topiramate were consistent and reproducible. Topiramate was found to be stable throughout the freeze-thaw cycles, bench-top and post-operative stability studies. The method was successfully applied to epileptic patients to monitor the plasma drug concentration versus time profile. The inter variability in pharmacokinetic parameters shows the need for individual monitoring of topiramate plasma profile by the accurate, specific and sensitive bioanalytical method.

Keywords: Bioanalytical method; Human plasma; LC-MS/MS; Pharmacokinetic study; Topiramate