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Development and validation of liquid chromatography-tandem mass spectrometric method for the quantification of ciprofibrate from human plasma

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The aim of the work was to develop and validate liquid chromatography-tandem mass spectrometric method for the quantification of ciprofibrate from human plasma. Ciprofibrate and furosemide (IS) were extracted from human plasma using Oasis HLB 1cc 30 mg solid phase extraction cartridge. The chromatographic separation was performed on ACE C18, 50×4.6 mm, 5 µ column. The mobile phase consisted of 0.001% ammonia in methanol-acetonitrile-water (70:20:10, v/v/v) was delivered at rate of 1 mL/min. Detection and quantitation were performed by a triple quadrupole equipped with electrospray ionization and multiple reaction monitoring in negative ionization mode (API 3200). The most intense [M-H]- transition for ciprofibrate at m/z 287.0→85.0 and for IS at m/z 328.9.0→204.9 were used for quantification. The developed method was successfully applied for bioequivalence study of ciprofibrate. The method was found to linear over the range of 25-30000 ng/mL (r>0.998). The lower limit of quantitation (LLOQ) was 25 ng/mL. The extraction recovery was above 90%. The accuracy was found to 101.26%-106.44%. The intra and inter-day precision expressed as % CV were 1.15% and 5.25%, respectively. The stability testing was also investigated and it was found that both drug and IS were quite stable. A simple, rapid, sensitive, accurate and precise LC-ESI/MS/MS method has been developed for the quantification of ciprofibrate from human plasma using SPE method. The method exhibited good linear response over the selected concentration range 25-30000 ng/mL. Selectivity and sensitivity were sufficient for detecting and quantifying ciprofibrate in human plasma. These features coupled with a short run time at 1.8 min compared to reported methods, facilitated a high analysis throughput, with the ability to quantify a larger number of clinical samples in a shorter time frame.

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