ABSTRACT TEMPLATE

QUANTIFICATION OF URAPIDIL IN HUMAN PLASMA USING ULTRA PERFORMANCE LIQUID CHROMATOGRAPHY–ELECTROSPRAY IONIZATION MASS SPECTROMETRY (UPLC–MS/MS) FOR PHARMACOKINETIC STUDY IN HEALTHY INDIAN VOLUNTEERS

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ABSTRACT

A rapid and selective quantitative method was developed and validated in human plasma for urapidil pharmacokinetic study in healthy Indian volunteers. The ultra-performance liquid chromatography–tandem mass spectrometry (UPLC-MS/MS) method with solid-phase extraction technique utilized Strata X 33µ polymeric reversed phase (30 mg/mL), extraction cartridge. Simple gradient chromatographic conditions and selective reaction monitoring in mass spectrometric detection enabled accurate and precise measurement of urapidil at nanogram levels in 0.1 mL of human plasma. The method used a deuterium labeled internal standard. The method was validated for a linear range of 5–500 ng/mL for urapidil with a correlation coefficient ≥ 0.99 The intra-run and inter-run precision and accuracy were within 10%. The overall recoveries for urapidil and urapidil D4 were more than 90%. The urapidil was found to be stable in plasma matrix and aqueous media. The developed and validated method was specific, sensitive and reproducible in the analysis of clinical samples interspersed with quality control samples under freshly prepared calibration standards. The method was applied for the determination of the pharmacokinetic parameters of urapidil following a single oral administration of urapidil 60 mg capsules in nineteen healthy Indian male volunteers for fasting and fed study.

Keywords: Urapidil, UPLC–MS/MS, Human plasma, Pharmacokinetic study, Solid phase extraction