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Rapid Ultra flow liquid chromatography –tandem mass spectrometric method for quantification of Dexmethylphenidate in human plasma using Sold Phase Extraction

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A selective, sensitive and reliable method have been developed for quantification of Dexmethylphenidate in human plasma by using UFLC–MS/MS method. Venlafaxine was used as an internal standard(IS). The extraction of the Dexmethylphenidate from human plasma was performed using solid phase extraction. Reverse phase-Xterra RP 18 (4.6x150mm,5µm) column was employed for chromatographic separation of Dexmethylphenidate and Venlafaxine(IS) for MS/MS detection at 1 ml/min flow with mobile phase combination using 90:10 (v/v) Methanol: 5mM Ammonium Acetate (pH 4.00). Detection was performed at transitions of m/z 234.200→84.000 for Dexmethylphenidate and m/z 278.100→ 58.100 for Venlafaxine by positive electro-spray ionization (ESI+) in multiple reaction monitoring (MRM) mode using tandem mass spectrometry. Retention times were observed with in 3.2 min for both Dexmethylphenidate and Venlafaxine. The calibration curves were linear over a concentration range of 0.201 ng/mL to 80.434 ng/mL for quantification of Dexmethylphenidate with the correlation coefficients demonstrating good linearity (0.996-0.999). The lower limits of quantification were 0.201 ng/mL for Dexmethylphenidate. The developed method was compared in the terms of validation parameters including specificity,linearity, sensitivity, precision, accuracy and stability. Matrix based samples were stable at room temperature for >8 hrs, processed samples were stable at least for >20 hrs and also stable at six freeze-thaw cycles. No significant effect was observed due to the presence of potentially interfering drugs like Paracetamol, Ibuprofen, Caffeine and Aspirin in the plasma sample and also presence of hemolysed or lipemic in plasma sample. The method is validated in human plasma containing K2EDTA as the anticoagulant. This validated method was successfully applied for quantification of Dexmethylphenidate in human plasma for pharmacokinetic bioequivalence study.

Biography

S Raghunadha Reddy has completed his PhD at the age of 30 years from Jawaharlal Nehru Technological University Anantapur and currently doing postdoctoral studies from Department of Pharmaceutical Science, School of Pharmacy, University of Maryland. Previously he was worked as Head of Quality Assurance and Regulatory Affairs at Clinsync Clinical Research Pvt Ltd. He has published 17 papers in reputed journals and has been serving as an editorial board member of Journal of Comprehencive Pharmacy. He has extensive experience in Good Clinical Practice-ICH, Good Laboratory Practice, QMS (ISO9001-2008), Bioanalytical method Development and validation, Computer System Validations (21 CFR Part-11) and Regulatory Affairs.

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