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Quantification of quetiapine in human plasma with solid phase extraction using sensitive ultra flow liquid chromatography –tandem mass spectrometric detection

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A selective and sensitive method have been developed for quantification of Quetiapine in human plasma by using UFLC–MS/MS method. Clozapine was used as an internal standard (IS). The extraction of the Quetiapine from human plasma was performed using solid phase extraction. Inertsil ODS-3 (50x4.6mm, 3µm) reverse phase column was employed for chromatographic separation of Quetiapine and Clozapine (ISTD) for MS/MS detection at 0.8 ml/min flow using 10 mM Ammonium Acetate: ACN: MeOH (10:25:65). Detection was performed at transitions of m/z 384.20→253.10 for Quetiapine and m/z 327.20→270.10 for Clozapine by positive electro-spray ionization (ESI+) in multiple reaction monitoring (MRM) mode using tandem mass spectrometry. Analysis was carryout within 1.5 min. The calibration curves were linear over a concentration range of 5.0 ng/mL to 1000.0 ng/mL for quantification of Quetiapine with the correlation coefficients demonstrating good linearity (0.996-0.999). The lower limits of quantification were 5.0 ng/mL for Quetiapine. The developed method was compared in the terms of validation parameters including specificity, linearity, sensitivity, precision, accuracy and stability. No effect was observed in presence of hemolysed or lipemic content in plasma sample and in presence of potentially interfering drugs. Matrix based samples were stable at room temperature for >8 hrs, processed samples were stable at least for >24 hrs and also stable at six freeze-thaw cycles. This validated method was successfully applied for quantification of Quetiapine in human plasma for bioequivalence study.

Biography

Raghunadh Reddy Seelam has completed his PhD from Jawaharlal Nehru Technological University Anantapur and is currently doing Post-doctoral studies from Department of Pharmaceutical Science, School of Pharmacy, University of Maryland. Previously he 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 Comprehensive 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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