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Quantification of metformin in human plasma with sold 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 metformin in human plasma by using UFLC–MS/MS method. Phenformin was used as an internal standard(IS). The extraction of the metformin from human plasma was performed using solid phase extraction. Inertsil ODS-3 (250x4.6 mm,5µm) reverse phase column was employed for chromatographic separation of metformin and phenformin(IS) for MS/MS detection at 1 ml/min flow using 90:10 (v/v) methanol: 10 mM ammonium acetate. Detection was performed at transitions of m/z 130.000→71.000 for metformin and m/z 206.100→ 105.000 for phenformin by positive electro-spray ionization (ESI+) in multiple reaction monitoring (MRM) mode using tandem mass spectrometry. Analysis was carryout within 3.3 min. The calibration curves were linear over a concentration range of 25.0 ng/mL to 3500.0 ng/mL for quantification of Metformin with the correlation coefficients demonstrating good linearity (0.994-0.999). The lower limits of quantification were 25.0 ng/mL for metformin. The developed method was compared in the terms of validation parameters including specificity,linearity, sensitivity, precision, accuracy and stability. The method was shown rugged when new batch was performed with a different column, different analyst and with fresh solutions. 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 >16 hrs, processed samples were stable at least for >46 hrs and also stable at four freeze-thaw cycles. This validated method was successfully applied for quantification of metformin in human plasma for 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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Notes: