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Development and validation of UPLC–MS/MS assay for the determination of phenelzine in plasma using solid phase extraction

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A fast and highly sensitive ultra-high performance liquid chromatography (UPLC) method for the determination of phenelzine in human plasma have been developed using tandem mass spectrometry (MS/MS) detection. Hydroxyzine was used as an internal standard(IS). The extraction of the phenelzine from human plasma was performed using solid phase extraction. ACE-C18 (5µm, 100x4.6 mm) reverse phase column was employed for chromatographic separation of analyte and internal standard for MS/MS detection at 0.9 ml/min flow. Detection was performed at transitions of m/z 137.258→106.906 for phenelzine and m/z 376.300→202.100 for hydroxyzine by positive electro-spray ionization (ESI+) in multiple reaction monitoring (MRM) mode using tandem mass spectrometry. The developed method was compared in the terms of validation parameters including linearity, sensitivity, precision and accuracy. The analysis was carried out in 3.5 min and the matrix matched calibration curves in the range of 0.508 ng/mL to 25.144 ng/mL were used for quantification with the correlation coefficients demonstrating good linearity (0.996-0.999). The mean extraction recoveries for phenelzine and IS from plasma were 96.5% and 88.3%, respectively. Matrix based samples were stable at room temperature for 12 hrs, processed samples were stable at least for 28 hrs and also stable at six freeze-thaw cycles. This method was successfully applied for determination of phenelzine in human plasma for pharmacokinetic study.

Biography

S Raghunadha Reddy has completed his PhD 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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