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Simultaneous quantification of Naproxen and Esomeprazole in human plasma with Sold Phase Extraction by using fully validated High-throughput liquid chromatography –tandem mass spectrometric method

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A sensitive and reliable method have been developed for simultaneous quantification of Naproxen and Esomeprazole in human plasma by using HTLC–MS/MS method. Pantoprazole was used as an internal standard(IS). The extraction of the Naproxen and Esomeprazole from human plasma was performed using solid phase extraction. Xterra RP 18 (4.6x150mm,5µm) reverse phase column was employed for chromatographic separation of analyte and internal standard for MS/MS detection at 1 ml/min flow(Split Ratio-70:30). Detection was performed at transitions of m/z 230.10→180.10 for Naproxen, m/z 345.40→198.20 for Esomeprazole and m/z 382.16→ 230.99 for Pantoprazole by positive electro-spray ionization (ESI+) in multiple reaction monitoring (MRM) mode using tandem mass spectrometry and analysis was carried out in 3.0 min. The developed method was compared in the terms of validation parameters including specificity,linearity, sensitivity, precision, accuracy and stability. The calibration curves were linear over a concentration range of 1.00 µg/mL to 120.0 µg/mL of Naproxen and 1.00 ng/mL to 500.0 ng/mL of Esomeprazole for quantification with the correlation coefficients demonstrating good linearity (0.995-0.999). The lower limits of quantification were 1.00 µg/mL for Naproxen and 1.00 ng/mL for Esomeprazole, respectively. Matrix based samples were stable at room temperature for 10 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 determination of Naproxen and Esomeprazole in human plasma for pharmacokinetic 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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