International Journal of ChemTech Research
CODEN (USA): IJCRGG, ISSN: 0974-4290, ISSN(Online):2455-9555
Vol.10 No.10, pp 752-761, 2017

Bioanalytical Method Validation for determination of Macitentan in K_2EDTA Human plasma by LC-MS/MS

M.Purushothaman*[1], R.Subramanian[2]

[1]Scient Institute of Pharmacy, Ibrahinpatnam, Hyderabad-501506, India

[2]Sun Rise University, Alwar, Rajasthan – 301030, India

Abstract: A simple reverse phase liquid chromatographic and mass spectroscopic analytical method has been developed and validated for estimation of Macitentan in plasma. The separation was carried out on Accucore AQ 100 X 2.1 mm, 2.6 µm as Stationary phase, Mobile Phase: 0.1% Formic acid: Acetonitrile Elution mode : Isocratic A: B= 20:80% v/v Flow rate: 350 µL/min. Losartan was used as internal standard. The Macitentan and Losartan showed retention factor of 1.01 min ± 0.5 minand 0.9 min ± 0.5 minrespectively. The injection volume was 5µL and the total run time was 3 min. The method shows selectivity and linearity. The described LC-MS/MS method was linear over a concentration range of 0.997 to 1020.793 ng/mL.The extraction recoveries for Macitentan and Losartan were found to be between 101.12 and 96.29%. The method shows to be stable for the studied parameters. The stability of the drug spiked human plasma samples during three freeze thaw cycles were stable in plasma for about one month when stored at frozen state. The results of the study showed that the proposed LC-MS/MS method is simple, rapid, precise and accurate, which is useful for the estimation of Macitentan in bulk fluids and biological plasma sample analyte with accuracy and reproducibility.
Keywords: Macitentan, LC MS method, Losartan and Freeze thaw cycles.

*****