International Journal of ChemTech Research
CODEN(USA): IJCRGG, ISSN: 0974-4290, ISSN(Online):2455-9555
Vol.10, No.1,pp573-580, 2017

RP-HPLC Method Development and Validation for the Estimation of Sertaconazole Nitrate in Bulk and Tablet Dosage form

Satish K. Mandlik, Shridhar S. Siras*

Department of Pharmaceutics,Sinhgad College of Pharmacy,S.No.44/1, Vadgaon (Bk), off Sinhgad Road,Pune- 411041,Maharashtra,India.

Abstract:A reversed-phase high performance liquid chromatography (RP-HPLC) method was developed and validated for the estimation of sertaconazole nitrate (STZN) in bulk and tablet dosage forms. The separation was achieved on stainless steelPurospher® STAR Hibar® C_{18} analytical column (250 mm × 4.6 mm i.d., 5.0 µm) using 0.01 M monobasic sodium phosphate and acetonitrile in a ratio of20:80 % v/v as mobile phase and at a flow rate of 1.2 mL/min. Detection was carried out using a UV detector at 260 nm. The method was validated for accuracy, precision, linearity, LOD, LOQ and robustness. Validation studies demonstrated that this HPLC method is simple,specific, rapid, reliable and reproducible. The standard curve was linear over the concentration range of 100-600 µg/mL with R^2 close to one (0.997). The limit of detection (LOD) and limit of Quantitation (LOQ) obtained for STZN were 0.00192064 µg/mL and 0.00208267 µg/mL, respectively. The developed and validated method was successfully applied for the quantitative analysis of Onabet V1 tablets. This method can be used as more convenient and efficient option for the analysis of STZN to establish the quality of the drug substance during routine analysis with consistent and reproducible results.
Key Words:RP-HPLC method, Validation, Sertaconazole nitrate, Assay.

*****