Development and Validation of RP-HPLC method for the determination of impurity profile of Desvenlafaxine Extended Release Tablet

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ABSTRACT

A accurate, rapid, precise and specific RP-HPLC method was developed for the determination of impurity profile of Desvenlafaxine in Desvenlafaxine ER tablet. Both known impurities i.e., venlafaxine Base and ODV Dimer were kindly gifted by Aarti Industries Ltd. and Intas Pharmaceuticals Ltd. Respectively. The method was developed using a High performance liquid chromatograph, Agilent 1200 series, using Zorbax SB CN (250 x 4.6 mm) 5µ Particle., with mobile phase composition of Buffer pH3.0:Acetonitrile (80:20). The flow rate was 1.0 ml min-1 and effluent was detected at 225 nm. The retention time of Desvenlafaxine was about 7.0 min. All validation parameters like specificity, limit of detection, limit of quantification, linearity, precision, accuracy, robustness were performed as per ICH Guidelines. Linearity was observed over concentration range of 0.076-2.403µg/ml, which is 0.008% to 0.240% of nominal test concentration for Desvenlafaxine, 0.138-6.003µg/mL, which is

0.014% to 0.600% of nominal test concentration for Venlafaxine Base and 0.500-2.402µg/mL, which is 0.050% to 0.240% of nominal test concentration for ODV Dimer. The limit of detection was 0.003% (0.026µg/mL), 0.005% (0.045µg/mL), 0.020% (0.200µg/mL) of nominal test concentration for Desvenlafaxine, Venlafaxine Base, ODV Dimer respectively and the limit of quantification was 0.008% (0.079µg/mL), 0.014% (0.138µg/mL), 0.050% (0.500µg/mL) of nominal test concentration for Desvenlafaxine, Venlafaxine Base, ODV Dimer respectively. Marketed formulations were successfully analyzed using the developed method.

Key words: RP-HPLC method, Impurity profile, Desvenlafaxine, Venlafaxine Base, ODV Dimer