DEVELOPMENT AND VALIDATION OF STABILITY INDICATING ASSAY METHOD FOR ESTIMATION OF FOSAPREPITANT DIMEGLUMINE IN BULK AND ITS DOSAGE FORM

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ABSTRACT

A stability indicating assay method was developed and validated for estimation of Fosaprepitant Dimeglumine in bulk and its dosage form. The RP-HPLC method consisted isocratic separation mode with Agilent poroshell 120 EC-C18, (50 mm X 4.6 mm i.d., 2.7 µm particle size) column, at ambient temperature, optimum mobile phase consisted of Buffer and Acetonitrile (70:30 % v/v), apparent pH of buffer was adjusted to 3.5 with ortho phosphoric acid solution, flow rate monitored at 1.0 mL/min and UV detection has been done at wavelength of 210 nm. The drug product was exposed to acidic, alkaline, photolytic, reductive and oxidative stress conditions and the stressed samples were analysed. The method was successfully validated in accordance to ICH guidelines in terms of specificity, linearity, LOD & LOQ, precision, accuracy, and robustness. The retention time of Fosaprepitant Dimeglumine was 3.999 minutes. The developed method was linear over range of 76-299. The correlation coefficient was 0.9997. The accuracy of the developed method was found to be in the range 98-102 %. The limit of detection and limit of

quantitation was found to be 9 and 15 respectively. There was complete separation of degradation peak and Fosaprepitant Dimeglumine peak, which demonstrated the specificity of assay method for estimation of Fosaprepitant Dimeglumine in presence of its degradation products. The method can be applied for routine assay.

Keywords: Fosaprepitant Dimeglumine, Stability indicating RP-HPLC method, Forced degradation, Validation