DEVELOPMENT AND VALIDATION OF STABILITY INDICATING RP-HPLC METHOD FOR ESTIMATION OF RELATED SUBSTANCES OF ESOMEPRAZOLE IN CAPSULE DOSAGE FORM

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ABSTRACT

A sensitive, accurate and precise method has been developed for the estimation of related substances of Esomeprazole in capsule dosage form. The RP-HPLC method has shown adequate separation for Esomeprazole and its Impurities from its degradation products. The separation was achieved on Sustain Inertsil C18, (250mm x 4.6mm), 5 µm column using a gradient mixture of phosphate buffer pH 7.6 ± 0.05 and acetonitrile at a flow rate of 1.5 ml/min, Injection volume 40µl with detection wavelength of 302 nm. Retention times for Esomeprazole, Impurity A, Impurity D and Impurity C were 27.06, 9.40, 25.50 and 39.36 min respectively. The described method was linear over a range of 0.04-0.6 µg/ml for Esomeprazole and 0.15-1.5 µg/ml for Impurities. The correlation coefficient for Esomeprazole, Impurity A, Impurity D and Impurity C were 0.9997, 0.9995, 0.9995 and 0.9995 respectively. The limit of detection for Esomeprazole, Impurity A, Impurity D and Impurity C were 0.015 µg/ml, 0.05µg/ml, 0.05µg/ml and 0.05µg/ml respectively. The limit of

quantification for Esomeprazole, Impurity A, Impurity D and Impurity C were 0.04 µg/ml, 0.15µg/ml, 0.15µg/ml and 0.15µg/ml respectively. Force degradation study was carried out on dosage form as per ICH guideline and it was subjected to acid and base hydrolysis, oxidative, thermal and photolytic degradation. Proposed method was validated as per ICH guidelines for linearity, accuracy, precision, specificity and LOD and LOQ for estimation of Esomeprazole in capsule dosage form and results were found to be satisfactory. Thus the developed and validated stability indicating method can be used successfully for marketed formulations.

Key words: Esomeprazole, Stability indicating RP-HPLC method, Related substances, Validation.