DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF RABEPRAZOLE SODIUM AND LAFUTIDINE IN CAPSULE DOSAGE FORM

Submitted By

Talaviya Piyushkumar M

Supervised By

Ms. Jignasa Modi,

M.pharm, Assistant professor,

Department of Quality Assurance.

Abstract

A Q-Absoption ratio and RP-HPLC methods were developed and validated for simultaneous estimation of Rabeprazole sodium and Lafutidine in Capsule dosage form. Accurate and precised UV spectrophotometric method with good sensitivity has been developed for simultaneous estimation of Rabeprazole sodium and Lafutidine. The employed Q-Absoption ratio method based on the measurement of absorbance at 278.27 nm and 283.8 nm, Isobestic Point and ʎmax of Rabepraprasole sodium, respectively. The calibration curve was linear in a concentration range of 10-60 µg/ml for Rabeprazole sodium and 5-30 µg/ml for Lafutidine. The RP-HPLC method has shown adequate seperation of Rabeprazole sodium and Lafutidine in Capsule dosage form. The separation was achieved on an Phenomenex luna, ODS C_{18} (250 mmX4.6 mm i.d., 5 µm particle size) with an isocratic system of Buffer:Methanol in the ratio of 28:72 v/v. The mobile phase at a flow rate of 1.2 ml/min, Injection volume 20µl and wavelength of detection used was 278nm. The retention time for Lafutidine and Rabeprazole sodium was obtained as 1.76min and 2.83min respectively. The linearity of the proposed method was

investigated in the range of 20-120 µg/ml and 10-60 µg/ml for Rabeprazole sodium and Lafutidine respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ and the results were found to be satisfactory, thus the method is simple with good sensitivity for estimation of Rabeprazole sodium and Lafutidine in Marketed dosage Form.

Key words: Rabeprazole sodium, Lafutidine, Q-Absorption ratio method, RP-HPLC, Validation.