Development and Validation of Analytical Method for Simultaneous Estimation of Levosulpiride and Pantoprazole sodium in capsule dosage form

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Abstract

A Q-absorption ratio spectroscopy and RP-HPLC methods were developed and validated for simultaneous estimation of Levosulpiride and Pantoprazole Sodium in capsule dosage form. A simple and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous estimation of Levosulpiride and Pantoprazole Sodium. The method employed Q-absorption ratio method based on the measurement of absorbance at two wavelengths, 288 nm and 251 nm, λ-max of Levosulpiride and Iso-absorptive point, respectively. The calibration curve was linear in a concentration range of 10-60 µg/ml for Levosulpiride and 5-30 µg/ml for Pantoprazole Sodium. The RP-HPLC method has shown adequate separation of Levosulpiride and Pantoprazole Sodium. The separation was achieved on an Enable C18 (250mm X 4.6 mm i.d, 5 µm particle size) with an gradient system of Methanol: Water (pH 4.2 is adjusted with ortho phosphoric acid) in the ratio of 70:30 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20 µl and wavelength of detection used was 251 nm. The retention time for Levosulpiride and Pantoprazole Sodium was obtained as 2.635±0.1min and 5.262±0.1min, respectively. The linearity of the proposed method was investigated in the range of 10-60 µg/ml and 5-30 µg/ml for Levosulpiride and Pantoprazole Sodium, respectively. Correlation coefficient was

0.9982 and 0.9973 for Levosulpiride and Pantoprazole Sodium, respectively. The developed method was validated as per ICH guideline, for its accuracy, precision and robustness, the results were found to be satisfactory, thus the method is rapid and simple with good for estimation of Levosulpiride and Pantoprazole Sodium. These analytical methods are also applicable in ordinary laboratories. It can also be adopted for quality control tests for these drugs in dosage form.

Key words: Levosulpiride, Pantoprazole Sodium, Q-absorption ratio method, RP-HPLC