Development and Validation of Analytical Methods for Simultaneous Estimation of Paracetamol and Flupirtine Maleate as API and Its Formulation

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ABSTRACT

A Q-absorption ratio spectroscopy and stability indicating RP-HPLC methods were developed and validated for simultaneous estimation of Paracetamol and Flupirtine Maleate as API and its dosage form. A simple and easy UV spectrophotometric method with good sensitivity has been developed for simultaneous estimation of Paracetamol and Flupirtine Maleate. The method employed Q-absorption ratio method based on the measurement of absorbance at two wavelengths, 245.2 and 294.2 nm, ƛ-max of Flupirtine Maleate and Iso-absorptive point, respectively. The calibration curve was linear in a concentration range of 1-7 µg/ml for Flupirtine Maleate and 3.25-22.75 µg/ml for Paracetamol. The RP-HPLC method has shown adequate separation of Paracetamol and

Flupirtine Maleate as API and its dosage form. The separation was achieved on a Enable C18 (250mm X 4.6 mm i.d, 5 µm particle size) with an gradient system of Methanol: Acetonitrile: Water (pH 9 is adjusted with triethyl amine) in the ratio of 50:40: 10 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20 µl and wavelength of detection used was 249 nm. The retention time for Paracetamol and Flupirtine Maleate was obtained as 2.84±0.1min and 3.67±0.1min, respectively. The linearity of the proposed method was investigated in the range of 5-25 µg/ml and 16.25-81.25 µg/ml for Flupirtine Maleate and Paracetamol and Correlation coefficient was 0.9972 and 0.9932 for Flupirtine Maleate and Paracetamol, respectively. Force degradation study was carried out on combined dosage form as per ICH guideline and it was exposed to hydrolysis (acid and base hydrolysis), oxidative and thermal conditions to apply stress The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ and the results were found to be satisfactory.

Key words: Paracetamol, Flupirtine Maleate, Q-absorption ratio method, RP-HPLC, Validation.