DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF PARACETAMOL AND TAPENTADOL HYDROCHLORIDE IN TABLET DOSAGE FORM

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ABSTRACT

A RP-HPLC method was developed for simultaneous estimation of Paracetamol and Tapentadol Hydrochloride in tablet Dosage form. The calibration curve was linear in a concentration range of 32.5-97.25µg/ml for Paracetamol and 5-15µg/ml for and Tapentadol Hydrochloride. The RP-HPLC method has shown adequate separation of Paracetamol and Tapentadol Hydrochloride in Tablet Dosage Form. The separation was achieved on a BDS C_{18} (250mm x 4.6mm i.d., 5µm particle size) with an gradient system of Water: Methanol: Tri Ethyl Amine (TEA) in the ratio of (60:40:0.1) v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection used was 217nm. The retention time for Paracetamol and Tapentadol Hydrochloride was obtained as 3.920±0.1min and 5.307±0.1min, respectively. The linearity of the proposed method was investigated in the range of 32.5-97.5µl/ml and 5-15µl/ml for

Paracetamol and Tapentadol Hydrochloride, respectively. Correlation coefficient was 0.998 and 0.997 for Paracetamol and Tapentadol Hydrochloride, respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ and the Assay results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of Paracetamol and Tapentadol Hydrochloride. This analytical method is also applicable in ordinary laboratories. It can also be adopted for quality control tests for these drugs in tablet.

Key words: Paracetamol, Tapentadol Hydrochloride, RP-HPLC, Validation.