DEVELOPMENT AND VALIDATION OF ANALYTICAL METHODS FOR SIMULTANEOUS ESTIMATION OF CEFTAZIDIME AND CLAVULANIC ACID IN THEIR PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

The present work involves the development and validation of a simple, accurate and precise Simultaneous equation UV- Spectrophotometric method and RP-HPLC method for the assay of Ceftazidime and Clavulanic acid.

Simple, specific, accurate, precise and reproducible method have been developed and validated for the simultaneous estimation of both drugs in their tablet dosage form.

UV- Spectrophotometric Method was determined by using the simultaneous equation spectrophotometric method at 256nm (ZCP of Ceftazidime) and 278nm (ZCP of Clavulanic acid) over the concentration range 4-20µg/ml and 50-250µg/ml for Ceftazidime and Clavulanic acid in methanol respectively. The % recoveries of the both the drugs (in sample preparation) were found to be 99.64-100.873% and 99.72-100.83% respectively.

The RP-HPLC Method has shown adequate separation of Ceftazidime and Clavulanic acid in their tablet dosage Form. The separation was achieved on a Enable C_{18} (250mm X 4.6 mm i.d., 5 µm particle size) with a isocratic system of (Na_2HPO_4: water) in the ratio of (85:15 v/v), pH adjusted 4.4 with Ortho-phosphoric acid. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection used was 264nm. The retention time for Ceftazidime and Clavulanic acid was obtained as 2.707±0.1min and 4.427±0.1min, respectively. The linearity of the proposed method was investigated in the range of 10-50µg/ml and 2.5-12.5µg/ml for Ceftazidime and Clavulanic acid respectively. Correlation coefficient was 0.9988 and 0.9979 for Ceftazidime and Clavulanic acid, respectively. The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ, Robustness and the results were found to be satisfactory, thus the method is specific, rapid and simple with good sensitivity for estimation of Ceftazidime and Clavulanic acid. These analytical methods are also applicable in ordinary laboratories. It can also be adopted for quality control tests for these drugs in tablets. The % recoveries of the both the drugs (in sample preparation) were found to be 98.00-100.65% and 99.98-100.93% respectively.

Key words: Ceftazidime, Clavulanic acid, Simultaneous equation spectrophotometric method, RP-HPLC method, Analytical method validation.