DEVELOPMENT AND VALIDATION OF ANALYTICAL METHOD FOR SIMULTANEOUS ESTIMATION OF CEFUROXIME AND CLAVULANIC ACID IN BULK AND ITS FORMULATION

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ABSTRACT

The RP-HPLC method was developed and validated for simultaneous estimation of Cefuroxime and Clavulanic acid bulk and its Tablet dosage form. The RP-HPLC method has shown adequate separation of Cefuroxime and Clavulanic acid in bulk and its formulation. The separation was achieved on a BDS hypersil C_{18}, (250mm X 4.6mm i.d., 5µm particle size) using ACN: Potassium dihydrogen phosphate buffer (75:25 v/v) as mobile phase. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection used was 217 nm. The retention time for Cefuroxime and Clavulanic acid was obtained as 3.060 min and 7.683 min, respectively. The linearity of the proposed method was investigated in the range of 12.5-37.5 µg/ml and 6.25-18.75 µg/ml for Cefuroxime and Clavulanic acid, respectively. Regression coefficient for Cefuroxime and Clavulanic acid was obtained as 0.9991 and 0.998, respectively.The developed method was validated as per ICH guideline, for its accuracy, precision, LOD & LOQ, Robustness,specificity and the results were

found to be satisfactory, thus the method is accurate, precise , rapid and simple for estimation of Cefuroxime and Clavulanic acid. **Key words:**Cefuroxime, Clavulanic acid, RP-HPLC, Validation.