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Development and Validation of Stability Indicating Assay Method of Ofloxacin in Bulk and Pharmaceutical Dosage Form by RP-HPLC

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Abstract : A simple, precise, sensitive and reproducible stability indicating Reverse Phase High Performance Liquid Chromatographic (RP-HPLC) method for determination of Ofloxacin in bulk and pharmaceutical dosage form was developed. The present study describes the development of stability indicating RP-HPLC method for determination of Ofloxacin in presence of its degradation products, generated from forced degradation studies. Ofloxacin drug product were exposed to acid, base, neutral hydrolysis, oxidation, dry heat, photolytic stress conditions and the stressed sample were analyzed by proposed method. The method was carried out on a Qualisil BDS C_{18} (250mm × 4.6mm, 5µm) column with a mobile phase consisting of buffer (0.02 M potassium dihydrogenphosphate): methanol:acetonitrile in ratio 75:15:10 v/v at pH maintained at 3.2 with OPA was used and flow rate of 1 ml/min. The retention time of OFLX was found to be 4.3 min and quantification was achieved with UV detection at 294 nm. The analytical method was validated as per ICH guideline for linearity, accuracy, precision, and specificity, LOD, LOQ, stability in analytical solution etc. The method was found to be accurate with percent recoveries between 97.6 and 92.9 and % RSD was < 2. The above method was a rapid and cost-effective quality-control tool for routine analysis of ofloxacin in bulk and in pharmaceutical dosage form.

Keywords: Ofloxacin, RP-HPLC, stability indicating method, forced degradation studies, validation.

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