

A Review on Method Development and Validation of Metformin Hydrochloride by RP-HPLC Method

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Abstract: The RP-HPLC (reversed phase high-performance liquid chromatography) method has developed to estimate and validate the metformin hydrochloride in tablet dosage form using C18 analytical reverse-phase column. The maximum absorption of metformin hydrochloride was found to be 236.40nm, in methanol, Acetonitrile, water (1:3:6), pumped at a flow rate 0.8ml/min at ambient temperature and the run time was 10 min, the symmetry of the column is $4.6 \times 150 \mu\text{m}$, with the particle size of 5mm. The analysis complied with Beer's law in the concentration range at 233nm for metformin hydrochloride by RP-HPLC & UV method methanol, acetonitrile, the proposed method was validated as per ICH guidelines parameters like linearity, specificity, precision, accuracy, robustness, degradation studies, absorption maximum, LOD & LOQ. Good recovery results were obtained. The results obtained showed a good agreement with the declared contents in case pharmaceutical formulations. The same is also applied for degradation studies. The proposed method was rapid, accurate, economical selective.

Keywords: validation, metformin hydrochloride, degradation studies, RP-HPLC, UV spectrophotometry

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