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Development and Validation of HPLC and Spectrophotometric Methods for the Estimation of Metformin HCl

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Abstract: *The objective of this research was to develop and validate precise, accurate, and robust analytical methods for the quantification of Metformin HCl in tablet dosage forms using UV spectroscopy and Reverse Phase High-Performance Liquid Chromatography (RP-HPLC). UV spectroscopic analysis identified the maximum absorption wavelengths (λmax) for Metformin HCl at 234 nm. The RP-HPLC method was optimized with a mobile phase consisting of Acetonitrile, Phosphate Buffer pH 7.4 and water (65:15:20 v/v), a flow rate of 1.0 mL/min, and UV detection at 234 nm. The retention times were approximately 4.8 minutes for Metformin HCl.*

The methods were validated according to ICH guidelines for linearity, accuracy, precision, specificity, sensitivity, and robustness. Linearity was observed in the concentration ranges of 25-125 µg/mL for Metformin HCl, with correlation coefficients (r^2) greater than 0.9992. Accuracy was confirmed with recovery rates near 100%, and precision was demonstrated with low relative standard deviation (RSD) values. The methods were specific, showing clear separation from degradation products and excipients, and sensitive, with low limits of detection (LOD) and quantification (LOQ). The developed UV and RP-HPLC methods are reliable, efficient, and suitable for routine quality control analysis of Metformin HCl in tablet dosage forms. These methods meet regulatory requirements, offering a cost-effective solution for ensuring the quality, safety, and efficacy of these pharmaceutical products. Overall, the study provides validated analytical tools that enhance the quality assurance processes for combination drug products used in the management of type 2 diabetes, ensuring their therapeutic effectiveness and safety.

Keywords: RP-HPLC, Method Development, Method Validation, Simultaneous Estimation, Metformin, Fixed-Dose Combination, Pharmaceutical Analysis

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