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Analytical Method Development and Validation of Metformin by using RP-HPLC System

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Abstract: *A precise and reliable high-performance liquid chromatography (HPLC) method was developed and validated for the quantitative determination of metformin in pharmaceutical formulations. The method employed a reverse-phase chromatographic separation using a C18 column, with a mixture of mobile phase. Detection was performed at a wavelength of 236 nm. This study presents a comprehensive theoretical and practical framework for the development and validation of a high-performance liquid chromatography (HPLC) method for the quantitative analysis of metformin in pharmaceutical formulations. The theoretical aspects of HPLC, including chromatographic theory, column chemistry, and detector principles, are discussed in relation to the development of a robust and reliable analytical method. The validated method can be readily applied for the routine analysis of metformin in pharmaceutical products, ensuring the quality and purity of the active pharmaceutical ingredient.*

Keywords: Reverse phase-HPLC (RP-HPLC), Limit of detection, Limit of quantification, Method validation, System suitability, Relative standard deviation, Specificity, Linearity, Range, Precision, Intermediate precision, Accuracy, Solution stability and system suitability

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