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HPLC Method Development and Validation Process of Drug Analysis and Applications

Mr. Kolekar Mahesh Dada, Prof. Jadhav S. V, Mr. Deshmukh S. V
Kishori College of Pharmacy, Beed

Abstract: *High-Performance Liquid Chromatography (HPLC) is a widely used analytical technique in pharmaceutical analysis due to its accuracy, sensitivity, and reproducibility. This project focuses on the development and validation of an HPLC method for the qualitative and quantitative analysis of a selected pharmaceutical drug compound. The objective is to establish a reliable, efficient, and robust method that can be applied in quality control and regulatory compliance.*

The method development phase involves the selection of optimal chromatographic conditions, including mobile phase composition, flow rate, detection wavelength, and stationary phase, to achieve precise separation and resolution of the drug from its impurities and degradation products. Method validation is carried out according to ICH g parameters such as es, assessing urity, accuracy,parameters such as linearity, accuracy, precision, specificity, limit of detection (LOD), limit of quantification (LOQ), robustness, and system suitability.

Keywords: HPLC

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