Review Article

A REVIEW ON HPLC METHOD DEVELOPMENT AND VALIDATION

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Analytical technique development, validation, and transfer are critical components of any pharmaceutical development effort. Effective method development optimizes laboratory resources and ensures techniques meet drug development objectives at all stages. High performance liquid chromatography is a reliable technology for analyzing medicinal products, both qualitatively and quantitatively. Developing and validating analytical methods is crucial for drug discovery, development, and manufacturing. It comprises determining the purity and toxicity of a pharmacological substance. Method development for the interested component in finished product or in process tests and the sample preparation of drug product and to provide practical approaches for determining selectivity, specificity, limit of detection, limit of quantitation, linearity, range accuracy, precision, recovery solution stability, ruggedness, and robustness of liquid chromatographic methods to support the Routine, in process and stability analysis.

Keywords: Analytical Method Development, Method Validation, HPLC, specificity, stability analysis.

www.pharmaerudition.org Nov. 2025, 15(3), 18-24