

HPLC Method Development and Validation: A Review

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Abstract: Analytical methods development and validation play important roles in new discovery, development, manufacture of pharmaceutical drugs and various other studies related to humans and animals. Chromatography is the backbone of separation science and is being used in all research laboratories and pharmaceutical industries universally. High-performance liquid chromatography (HPLC) is dominant separation technique where analytes are separated by passage through a column packed with micro meter-sized particles. Now a day reversed-phase chromatography is the most commonly used separation technique in HPLC. This review covers the principle, types, instrumentation, validation, application of HPLC. Validation of HPLC method gives information about various stages and parameters like accuracy, precision, linearity, Limit of detection, Limit of quantification, specificity and robustness. Validation should be done as per regulatory guidelines such as ICH guidelines.

Keywords: Analytical, Chromatography HPLC, Method, Validation

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