Review Article

ANALYTICAL METHOD VALIDATION OF COMPENDIAL HPLC METHOD FOR PHARMACEUTICALS AS PER RECENT USP AND ICH GUIDELINES

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Analytical methods validation is a main regulatory requirement in pharmaceutical analysis in quality control laboratory. High-Performance Liquid chromatography (HPLC) is usually used as an analytical technique to evaluate the assay and organic impurities of drug product and drug substances. Method validation provides documented proof, and a high degree of assurance that an analytical method for a particular test is appropriate for its intended use. As per USP 43 NF 38 and ICH Q2 (R1) guideline of Analytical method Validation provides the elaborate guidance of method validation of any compendial or non-compendial method. This review focuses on approach to the validation of HPLC method with the compliance of restrictive needs and accepted pharmaceutical practices. The information during this review provides the explanations for performing analytical method validation. The validation parameters needed to be performed in validation for assay and organic impurities strategies. Individual validation parameters are mentioned in reference to the kind of method such assay and organic impurities method to be valid. This review was written to assist chemists/analysts to perform for method validation. This review study might facilitate to academics and pharmaceutical industry personnel to know the analytical method validation of HPLC as per USP and ICH guidelines.

Key Words: Validation, HPLC, USP, ICH, Compendial, Regulatory, QC Lab

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