Review Article

VALIDATION OF HPLC METHOD AND UV-VISIBLE METHOD FOR PHARMACEUTICALS AS PER OFFICIAL GUIDELINES

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Methods Validation is a critical quality attribute for the evaluation of any drug substance through an established method in the quality control laboratory. Method Validation is also the main regulatory requirement in pharmaceutical analysis with compliance as per the guidelines or chapter any pharmacopeia of the same scope. Method on UV spectrophotometer can be developed. Validation is establishing documented evidences, which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality characteristics. Validation is considered a good manufacturing practice (GMP) activity; validation experiments must be properly documented and performed on qualified and calibrated instrumentation and equipment. At this stage, there should be documented evidence that the method is robust. USP defines eight steps for validation which are Accuracy, Precision, Specificity, Limit of detection, Limit of Quantitation, Linearity and range, Ruggedness, Robustness. 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 validated. This review was written to assist chemists/analysts to perform for method validation on UV spectrophotometer and HPLC. This review study may facilitate to academics and pharmaceutical industry personnel to know the analytical method validation as per Official guidelines.

Keywords: Validation, UV Spectroscopy, HLC, ICH, Regulatory, QC Lab

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