

Review Article

METHOD VALIDATION OF COMPENDIAL AND NON COMPENDIAL UV-VISIBLE SPECTROSCOPIC METHOD FOR DRUG SUBSTANCES AS PER USP AND ICH 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 which is called non-compendial method and method which is provided from pharmacopoeia is compendial Method. 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. The USP has published specific guidelines for method validation for compound evaluation. USP defines eight steps for validation which are Accuracy, Precision, Specificity, Limit of detection, Limit of Quantitation, Linearity and range, Ruggedness, Robustness. This review was written to assist chemists/analysts to perform for method validation on UV spectrophotometer. This review study may facilitate to academics and pharmaceutical industry personnel to know the analytical method validation of UV Spectrophotometer as per USP and ICH guidelines.

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

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