Review Article

METHOD VALIDATION OF COMPENDIAL ICP-OES METHOD FOR DRUG SUBSTANCES AS PER USP AND EU PHARMACOPOEIAS

Prajapat Harish * and Maheshwari Monika

Geetanjali Institute of Pharmacy, Udaipur, Rajasthan. 313002

Method Validation is the main regulatory requirement in pharmaceutical analysis with compliance as per the guidelines or chapter any pharmacopoeia of the same scope. Method Validation is a critical quality attribute for the evaluation of any drug substance through an established method in the quality control laboratory. 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 ICP-OES. This review study may facilitate to academics and pharmaceutical industry personnel to know the analytical method validation of ICP-OES as per USP and EU guidelines.

Keywords: ICP-OES, QC Lab, Method Validation, USP, EU

www.pharmaerudition.org May. 2022, 12(1), 11-16