RECENT TREND IN BIOANALYTICAL METHOD VALIDATION AND ITS APPLICATION :A REVIEW

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Abstract:

In the development of medicinal products, bioanalytical methods are used in clinical and non-clinical pharmacokinetic studies to evaluate the efficacy and safety of drugs and their metabolites. Drug concentrations determinedin biological samples are used for the assessment of characteristics such as in vivo pharmacokinetics (adsorption, distribution, metabolism, and excretion), bioavailability, bioequivalence, and drug-drug interaction. Bioanalytical methods, based on a variety of physico-chemical and biological techniques such as chromatography, immunoassay and mass spectrometry, must be validated prior to and during use to give confidence in the results generated. It is the process used to establish that a quantitative analytical method is suitable for biomedical applications. Any method developed for the analysis of analytes in biological fluids must yield consistent results despite the variations in conditions during the course of a project. An ideal bioanalytical method should include all of the probable effects that are going to occur during the routine analysis of study samples.

The present manuscript focuses on the consistent evaluation of the key bioanalytical validation parameters is discussed accuracy, precision, sensitivity, selectivity, limits ofquantification, range, linearity, ruggedness, robustness, and stability. Some of the proposals were made to the validation procedure to encounter the possible situations in the routine study sample analysis. An attempt has been made to understand and explain the bioanalytical method validation for chromatographic assays from the quality assurance auditor viewpoint.

KEY-WORDS: Bioanalytical method,Biomedical applications, Validation parameters, Quality assurance auditor.

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