AN OVERVIEW ON BIOANALYTICAL METHOD VALIDATION IN PHARMACY

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ABSTRACT

Validation of bioanalytical method is important to understand the pharmacokinetics of any drug or its metabolites.In pharmacokinetic studies, bio analytical method validation is crucial to minimizing random error and systematic bias, which ensures quality of analytical results.Bioanalytical method validation includes all the procedure that demonstrate that a particular method used for quantitative measurement of analytes in a given biological matrix is selective, sensitive, reliable and reproducible for the intended use. This article discusses the validation of bio analytical methods for small molecules with emphasis on chromatographic techniques. Bio analytical methods are used for the quantitation of drugs and their metabolites in biological matrices. In today's drug development environment, highly sensitive and selective methods are required to quantify drugs in matrices such as blood, plasma, serum, or urine. After developing a method with desired attributes, the method is validated to establish that it will continue to provide accurate, precise, and reproducible data during study-sample analysis. The validation is performed using a control matrix spiked with the compounds to be quantified. When validation begins, chances for its successful completion (and more important, successful sample analysis) are high. During method validation, values for validation parameters are obtained. While obtaining above validation parameters, other parameters are also determined during validation (e.g., extraction efficiency, calibration range and response function [linear or nonlinear], positional differences within an analytical run.

KEYWORDS: Validation parameters, Bio analytical method development, Documentation, Application

INTRODUCTION:

Analytical field deals with analysis of drugs, their metabolites and/or endogenous substances in the biological matrix. A properly validated bioanalytical