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Bioanalytical Method Validation: A Review Article

Darshan R. Telange

SVKM's, NMIMS University, Babulde, Shirpur, India

Method validation is a process that demonstrates that a method will successfully meet or exceed the minimum standards recommended in the Food and Drug Administration (FDA) guidance for accuracy, precision, selectivity, sensitivity, reproducibility, and stability. This article discusses the validation of bioanalytical methods for small molecules with emphasis on chromatographic techniques. Bioanalytical 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. Chromatographic methods (high-performance liquid chromatography [HPLC] or gas chromatography [GC] have been widely used for the bioanalysis of small molecules, with liquid chromatography coupled to triple quadrupole mass spectrometry (LC/MS/MS) being the single most commonly used technology. 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 (eg, extraction efficiency, calibration range and response function [linear or nonlinear], positional differences within an analytical run.