



An Overview of Bioanalytical Methods

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EDITORIAL NOTE

Bioanalytical Method Validation (BMV) is the process used to establish that a quantitative analytical method is suitable for biochemical applications. Bioanalysis covers the quantitative measurement of xenobiotics of drugs such as their metabolites, and biological molecules in unnatural locations or concentrations and Biotics like macromolecules, proteins, DNA, large molecule drugs, metabolites in biological systems. Bioanalysis is a progressive discipline for which the future holds many exciting opportunities to further improve sensitivity, specificity, accuracy, efficiency, assay throughput, data quality, data handling and processing, analysis cost and environmental impact. The field of bioanalysis has matured significantly from early studies in drug metabolism using many simple and advanced techniques, and in today's bioanalyst is well equipped to deal with the modern challenges. A bioanalytical method is a set of procedures involved in the collection, processing, storage, and analysis of a biological matrix for a chemical compound. The main impact of bioanalysis in the pharmaceutical industry is to obtain a quantitative measure of the drug or its metabolites for the study of pharmacokinetics, toxicokinetics, bioequivalence and exposure-response like pharmacokinetic or pharmacodynamic studies. The focus of bioanalysis in the pharmaceutical industry is to provide a quantitative measure of the active drug and/or its metabolite for the purpose of pharmacokinetics, toxicokinetics, bioequivalence and exposure-response (pharmacokinetics). The reliability of analytical findings is a matter of great importance in forensic and clinical toxicology, as it is of course a prerequisite for correct interpretation of toxicological findings. Unreliable results might not only be contested in court, but could also lead to unjustified legal consequences for the defendant or to wrong treatment of the patient. In the last decade, similar discussions have been going on in the closely related field of pharmacokinetic studies for registration of pharmaceuticals.

As per Bioanalytical Method Validation (BMV) guidelines for industry, these guidelines are applied to bioanalytical methods that are used for the quantitative determination of drugs and their metabolites in biological matrices such as plasma, urine and preclinical studies. Bioanalytical method validation includes

all of the procedures that demonstrate that a particular method developed and used for quantitative measurement of analytes in a given biological matrix is reliable and reproducible. Validation of a bioanalytical method is the process by which it is established that the performance characteristics of the method meet the requirements for the intended bioanalytical application. These performance characteristics are expressed in terms of bioanalytical method validation parameters. The fundamental bioanalytical method validation parameters include precision and accuracy, sensitivity.

Bioanalytical techniques

Some techniques commonly used in bioanalytical studies include:

Hyphenated techniques

- LC-MS (Liquid Chromatography-Mass Spectrometry)
- GC-MS (Gas Chromatography-Mass Spectrometry)
- CE-MS (Capillary Electrophoresis-Mass Spectrometry)

Chromatographic methods

- HPLC (High Performance Liquid Chromatography)
- Gas chromatography

High Performance Liquid Chromatography (HPLC)

High performance liquid chromatography is a form of column chromatography used frequently in bio chemistry and analytical chromatographic packing material (stationary phase), a pump that moves the mobile phase through the column, and a detector that shows the retention time of the molecules, retention time varies depending on the interactions between the stationary phase, the molecules being analyzed and the solvent used. Bioanalytical method development is the process of creating a procedure to enable a compound of interest to be identified and quantified in a matrix. By using biological products can be measured by several methods and the choice of bioanalytical method involves several considerations of quantitative or qualitative measurement, and precision are required with necessary equipment.

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