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# A Review of the Development and Validation of Bioanalytical Methods

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**Abstract:** *This review article often uses bioanalytical techniques to assess pharmaceuticals and their metabolites in plasma matrices; these approaches must be used in clinical research including both humans and nonhuman subjects. An essential stage in the estimate and interpretation of bioequivalence, pharmacokinetic, and toxicokinetic studies is the use of the bioanalytical technique for the quantitative evaluation of medicines and their metabolites in biological medium. The three main bioanalytic tasks are method development, method validation, and sample analysis. To determine how much the environment, the matrix, or procedural factors might affect the estimate of analyte in the matrix from the time of set up to the time of analysis, each step of the process must be examined. Techniques for bioanalyzing pharmaceuticals in the body include high pressure liquid chromatography (HPLC) and liquid chromatography combined with double mass spectrometry (LCMS-MS). Each instrument has certain advantages and disadvantages. For the bioanalysis of both small and large compounds, gas chromatography and LC/MS/MS have been the most used chromatographic techniques. A few often used metrics include linearity, accuracy, precision, selectivity, sensitivity, repeatability, and stability. It is suggested that we include some information on the creation and verification of bioanalytical procedures in this review research. These details will help with quality control since they allow us to identify the medicine, its concentration, and its metabolite.*

**Keywords:** Clinical and nonclinical study, Method development, Validation parameter.

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