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A Detailed Examination and Evaluation of the Applicability of Bioanalytical Methods

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Abstract: *For the analytical and bio-analytical procedures to be reliable and high-quality method development processes, validation is a must. Developing bio-analytical methods is crucial to getting marketing approval for medications at all phases of the development process. The processes required in validating the best pharmacokinetic, toxic kinetic, bioavailability, and bioequivalence investigations will be reviewed in this study. Additionally, it will provide a practical approach to determine the different metrics, including range, accuracy, precision, ruggedness, robustness, recovery, and linearity. The goal of bioanalysis research is to quantitatively identify drugs and their metabolites in bodily fluids. The effectiveness of drugs and their metabolites in preclinical, biopharmaceutical, and clinical pharmacology is dependent on accurate and reliable methods for quantitative evaluation.*

Keywords: Robustness, Sensitivity, Linearity, Method development

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