

Innovation in method development; Drugs solubility and stability during bioanalysis process

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The stability of a drug, metabolite, or any chemical agent during the development of the bioanalytical procedure, is essential for method validation. Some drugs are critically unstable and other groups of important drug agents are either insoluble or less soluble in the aqueous matrix. Innovative research in this area is needed to assure drug stability and solubility during the entire analysis process. This work not only eases the validation process, but also assures the accuracy and precision of the final data. The stock solution of the analyte should be confirmed for complete solubility, storage condition and stability, similarly, working standard solutions which are lower in concentration. Stock solution stability is demonstrated by preparing a fresh solution from the reference material and comparing the absolute response of the fresh solution with that of the stored solution. In that study sample results are directly influenced by analyte stock solutions. It is recommended that the acceptable difference between the absolute responses of fresh stock solutions and the aged stock solutions be tighter (within 2%-5%) than that normally applied to the bioanalytical results (ie, within 15%-20%). The stability of the drug in the spiked matrix during the sample preparation or extraction is key to the successful analytical method used for the less stable analyte and related metabolites. Methods for drugs such as Omeprazole and UC-781 will be presented. Chromatographic-based assays mostly use internal standards. Compounds used as internal standards should be stable and soluble. The analyte of interest and the method internal standard must be reliable and behave similarly during sample prep, extraction, and analysis.

Biography

Dr. Rezk is the founder of the clinical pharmacology and analytical chemistry core laboratory at University of North Carolina-Chapel Hill. Honors include; the UNC Chancellor's award for innovation, and the State of North Carolina Governor's award for innovation in science. He acts as the PI for many HIV-research projects. Dr. Rezk published 36 papers in reputed journals and 32 scientific abstracts. Currently, Dr. Rezk is in charge of developing BE/BA unit and clinical pharmacology research center in KSA. His research interests include innovation in analytical chemistry and, clinical pharmacology. Recently, he added a focus on better laboratory science practice for improving generic drugs.

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