BIOANALYTICAL METHOD VALIDATION AND STUDY SAMPLE ANALYSIS

M10

Frequently Asked Questions (FAQs)

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To support the implementation of ICH M10, the Expert Working Group has developed a series of FAQs.

Guideline Section	Questions	Answers
1	The guideline states that it is applicable to "nonclinical pharmacokinetic (PK) studies conducted as surrogates for clinical studies…" Please provide an example for such studies.	One example which includes nonclinical PK data to support human dosing is rescue agents for acute radiation syndromes or anthrax etc., under the Animal Rule (FDA, United States).
3	What does the guideline mean with respect to "concentrations" in the following sentence: "The dilution factor(s) and concentrations applied during study sample analysis should be within the range of the dilution factors and concentrations evaluated during validation"?	The diluted concentrations should fall within the validated calibration curve range.
3	What is the purpose of measuring the concentration of the QC at time zero?	To confirm the QCs were correctly prepared. Stability in the matrix (e.g., bench-top, long-term, freeze-thaw) should be evaluated by comparing with the nominal value.