ANALYTICAL METHOD VALIDATION

Analytical method development and validation workflow

PRELIMINARY STUDY METHOD DEVELOPMENT

METHOD VALIDATION

ROUTINE ANALYSIS or TRANSFER METHOD

Acceptance criteria

Constant performance monitoring

Before introduction in routine use analytical methods are validated.

ANALYTICAL APPROACH CHOICE

Decision of use/not use instruments and kind of instruments on the basis of method fit for purpose

DEFINITION OF THE ANALYTICAL PROTOCOL AND FEASIBILITY TEST

Definition of all the analytical phases: sample preparation, extraction, purification, detection parameters. Feasibility tests to see if the method works properly

METHOD VALIDATION

Series of tests repetitions and results statistical treatment to evaluate the method performances



PERFORMANCE

VALIDATION PARAMETERS

Linearity · Selectivity · Limit of Quantification/ Detection · Precision · Accuracy · Uncertainty · System Suitability · Stability in Solution · Robustness

ACCEPTANCE CRITERIA