A pharmacokinetic assay is a laboratory procedure used to measure the concentration of a drug or its metabolites in biological samples (typically blood, plasma, serum, or urine) over time. This data helps determine how the body absorbs, distributes, metabolizes, and excretes the drug — collectively known as pharmacokinetics (PK).

Key Components of a Pharmacokinetic Assay: Sample Collection:

Timed biological samples are collected after drug administration to assess drug levels at multiple points (e.g., 0, 0.5, 1, 2, 4, 8, 24 hours post-dose).

Analytical Method:

Common techniques include:

LC-MS/MS (Liquid Chromatography–Tandem Mass Spectrometry) – gold standard for sensitivity and specificity.

HPLC (High-Performance Liquid Chromatography) – often used for drugs with chromophores.

ELISA (Enzyme-Linked Immunosorbent Assay) – for biologics or macromolecules like monoclonal antibodies.

Validation Parameters (as per FDA or EMA guidelines):

Specificity

Accuracy

Precision

Linearity

Sensitivity (Lower Limit of Quantification, LLOQ)

Stability

Pharmacokinetic Parameters Calculated:

C_max (maximum concentration)

T_max (time to reach C_max)

AUC (Area Under the Curve)

t_½ (elimination half-life)

CL (clearance)

V_d (volume of distribution)

Applications:

Drug development (preclinical and clinical trials)

Bioequivalence studies

Therapeutic drug monitoring (TDM)

Toxicokinetics