Pharmaceutical Inorganic and Analytical Chemistry

Unit 1

Introduction to Pharmaceutical Analysis, Errors & Impurities

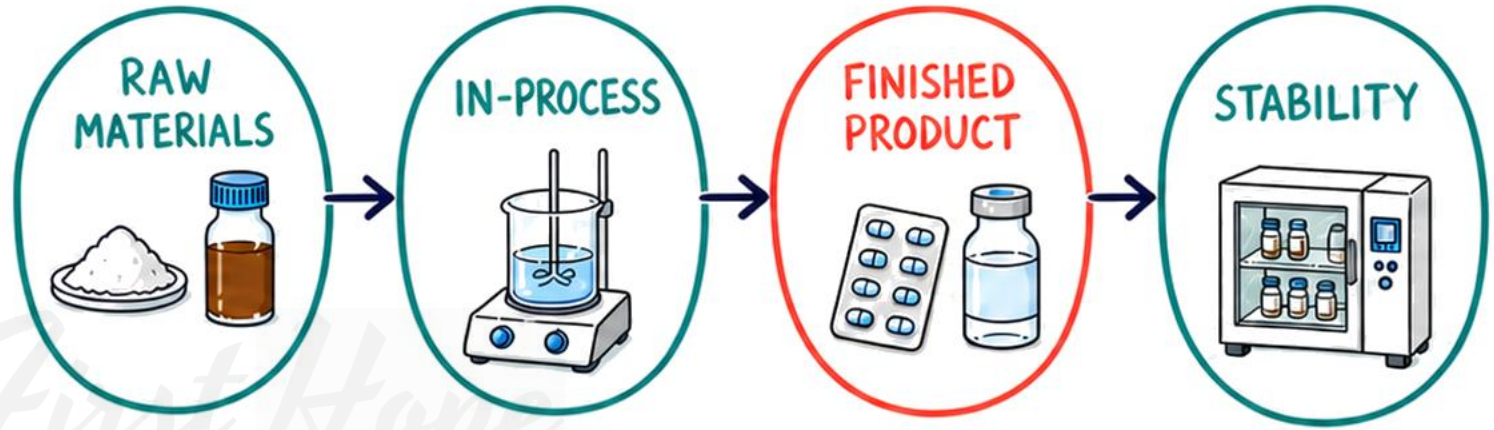


ANALYSIS | ACCURACY | QUALITY | RELIABILITY

PHARMACEUTICAL ANALYSIS

DEFINITION

Pharmaceutical analysis applies chemical, physical, biological, and instrumental methods to establish the identity, content, purity, quality attributes, and stability of pharmaceutical materials and products.

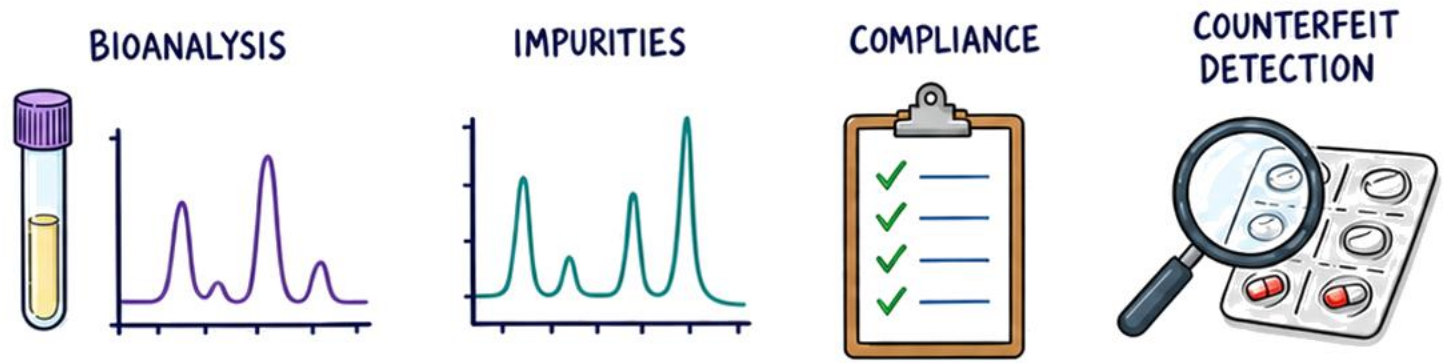


SCOPE

- Quality control: raw materials, in-process controls, finished products, and packaging
- Drug development: API and excipient characterization
- Method development and validation
- Bioanalysis and pharmacokinetic studies
- Stability and packaging compatibility
- Impurity profiling and regulatory compliance
- Counterfeit and adulteration detection

IMPORTANT

Analysis supports quality, safety, and efficacy decisions; it does not by itself establish clinical safety or efficacy.

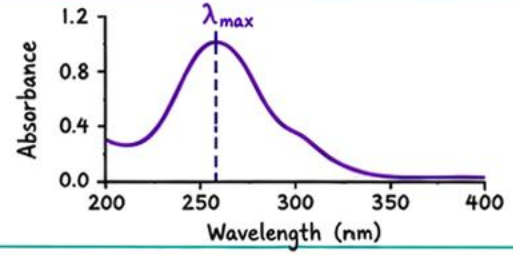


ANALYTICAL TECHNIQUES

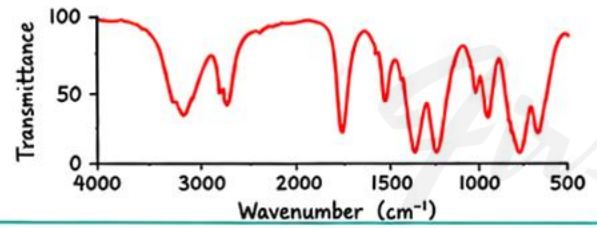
SPECTROSCOPY & CHROMATOGRAPHY

SPECTROSCOPY + MASS SPECTROMETRY

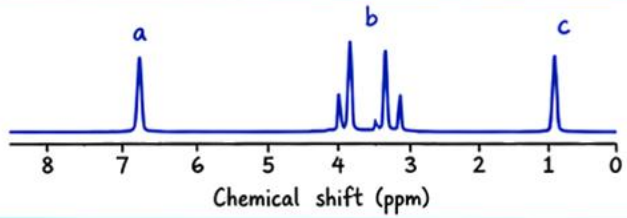
UV-Vis — electronic absorption; commonly used for quantitative analysis



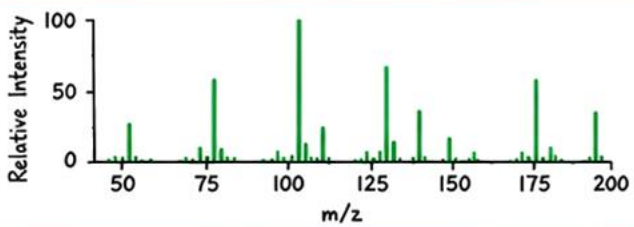
IR — vibrational bands; functional groups and fingerprint identification



NMR — chemical environment and molecular structure; quantitative NMR when validated

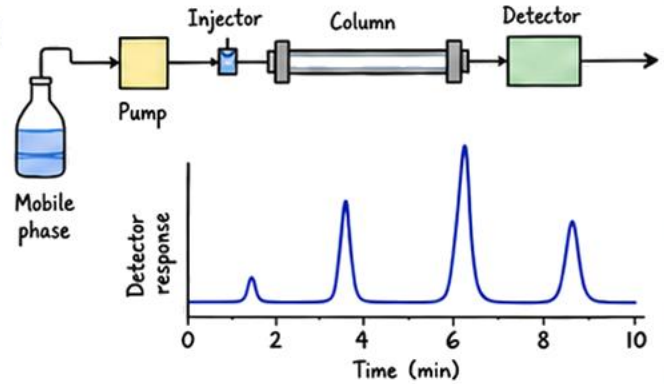


MS — mass-to-charge ratio (m/z) of ions; identification and calibrated quantitation

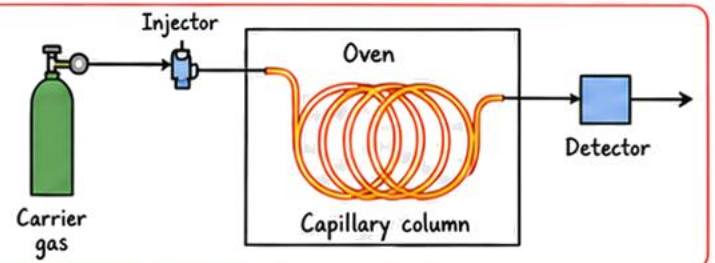


CHROMATOGRAPHY

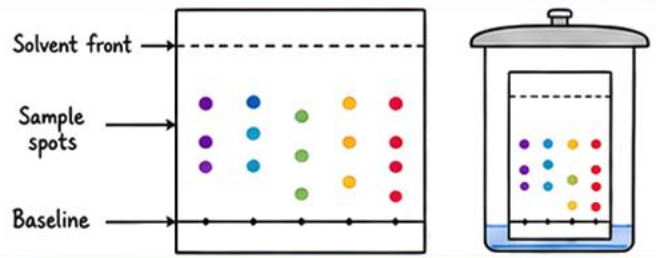
HPLC — liquid mobile phase; separates and measures mixture components



GC — gas mobile phase; for volatile, thermally suitable analytes



TLC — planar separation for screening, identity, and comparison

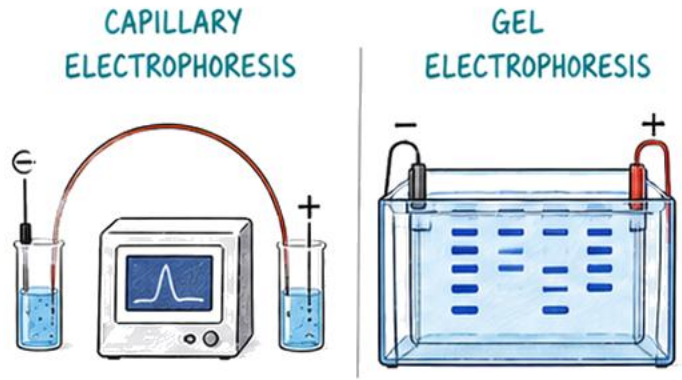


KEY RULE Separation alone does not equal quantitation.

OTHER ANALYTICAL TECHNIQUES

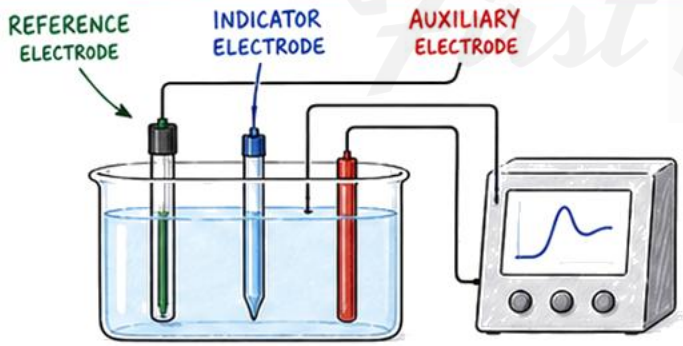
ELECTROPHORESIS

- Capillary electrophoresis — separation by electrophoretic mobility, influenced by charge-to-size ratio and electroosmotic flow
- Gel electrophoresis — separates proteins or nucleic acids by size and charge



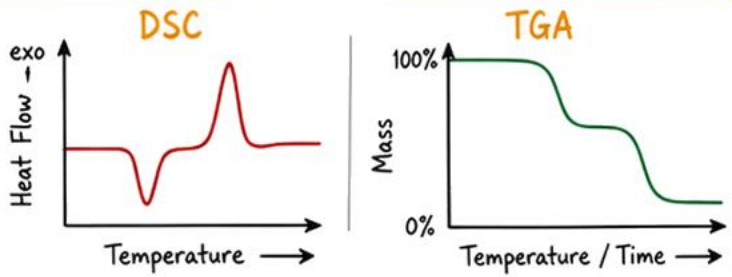
ELECTROANALYSIS

- Potentiometry — electrode potential measured relative to a reference electrode at negligible current
- Voltammetry — current recorded as a function of applied potential



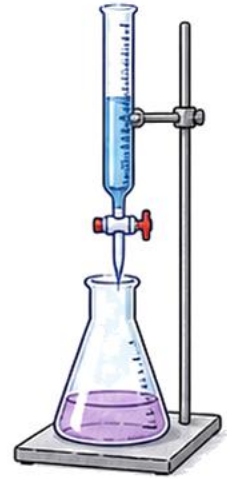
THERMAL ANALYSIS

- DSC — differential heat flow during thermal events
- TGA — change in mass with temperature or time



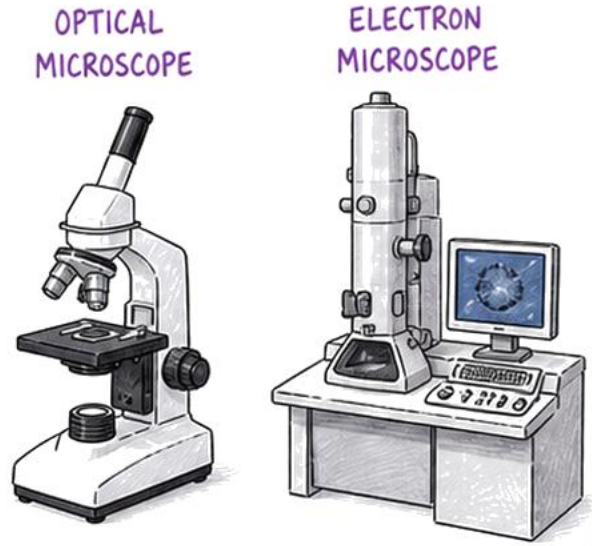
TITRIMETRY

- Acid–base — concentration from a stoichiometric neutralization
- Redox — concentration from a stoichiometric electron-transfer reaction



MICROSCOPY

- Optical — visible-light imaging
- Electron — high-resolution structure and composition



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Concentration & Solution Strength

Percent Expressions

$\%\ w/w = (\text{mass of solute} \div \text{mass of final solution}) \times 100$

grams per 100 g of final solution

$\%\ v/v = (\text{volume of solute} \div \text{volume of final solution}) \times 100$

millilitres per 100 mL of final solution

$\%\ w/v = [\text{mass of solute (g)} \div \text{final solution volume (mL)}] \times 100$

grams per 100 mL of final solution

Amount-Concentration Expressions

Molarity, $M = \text{moles of solute} \div \text{litres of final solution}$

unit: mol L^{-1}

Molality, $m = \text{moles of solute} \div \text{kilograms of solvent}$

unit: mol kg^{-1}

Mole fraction, $x_i = n_i \div \Sigma n_j$

dimensionless; $\Sigma x_i = 1$

Normality, $N = \text{equivalents of reacting species} \div \text{litres of solution}$

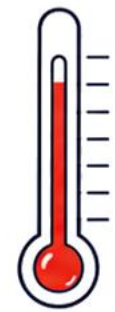
unit: eq L^{-1}; reaction-dependent

Key Rules

- State the basis: final solution, except molality uses solvent mass.
- Molarity and volume percentages can change with temperature.
- Prefer molarity plus a balanced equation when possible.







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