



Unit 1

Introduction to Pharmaceutical Analysis, Errors & Impurities



ANALYSIS



ACCURACY



QUALITY



RELIABILITY



PHARMACEUTICAL ANALYSIS

DEFINITION

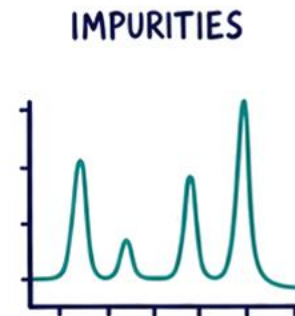
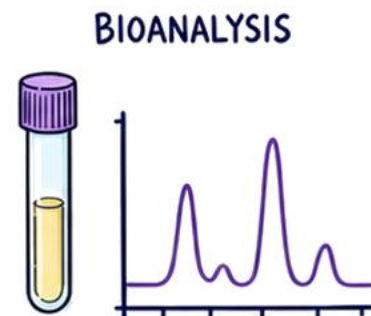
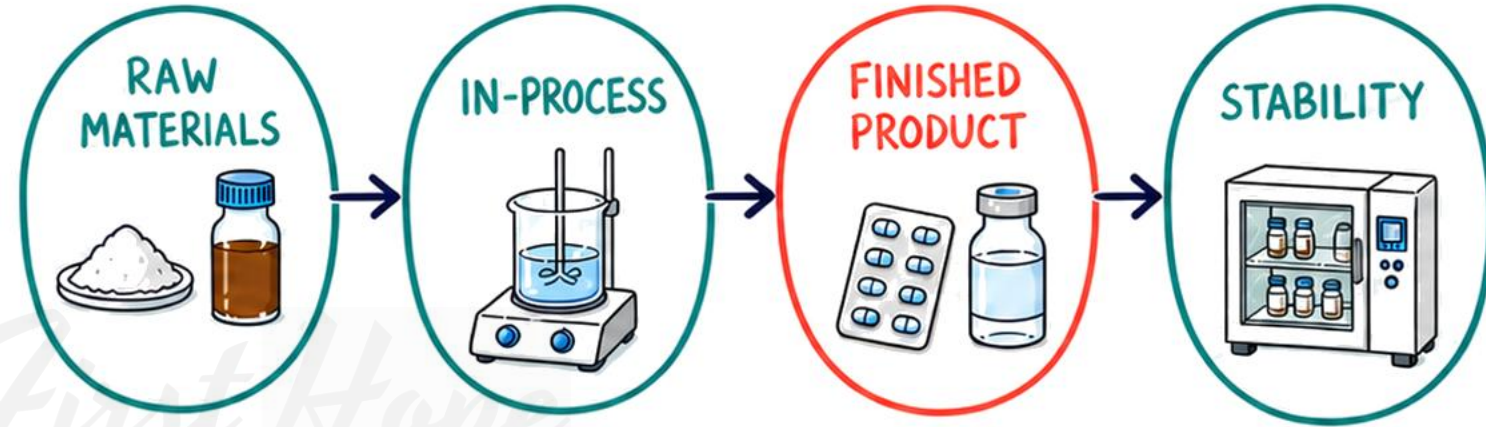
Pharmaceutical analysis applies chemical, physical, biological, and instrumental methods to establish the identity, content, purity, quality attributes, and stability of pharmaceutical materials and products.

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.

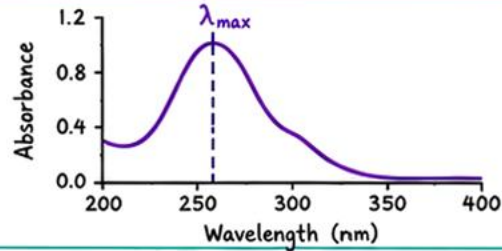


ANALYTICAL TECHNIQUES

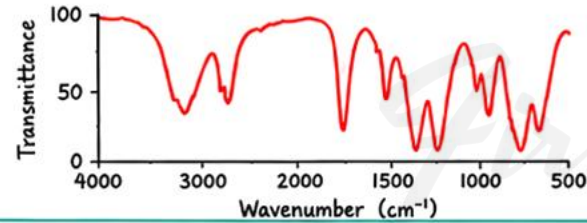
SPECTROSCOPY & CHROMATOGRAPHY

SPECTROSCOPY + MASS SPECTROMETRY

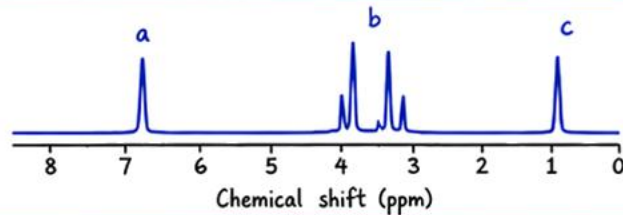
UV-Vis — electronic absorption;
commonly used for
quantitative analysis



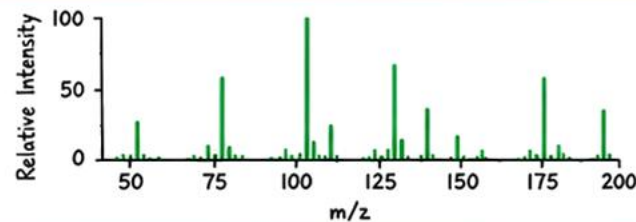
IR — vibrational bands;
functional groups and
fingerprint identification



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

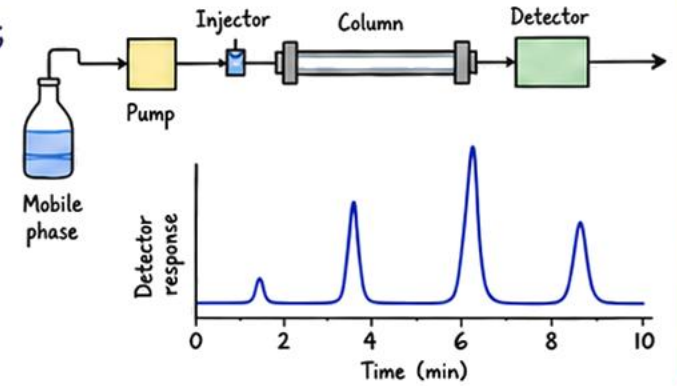


MS — mass-to-charge ratio
(m/z) of ions;
identification and
calibrated quantitation

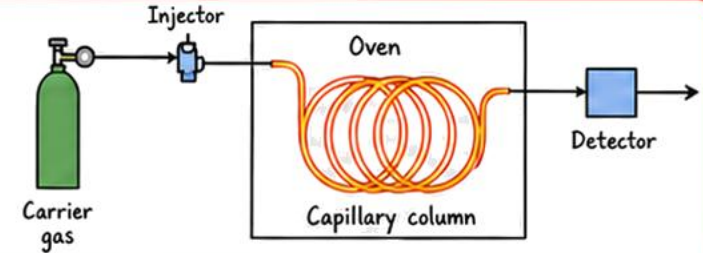


CHROMATOGRAPHY

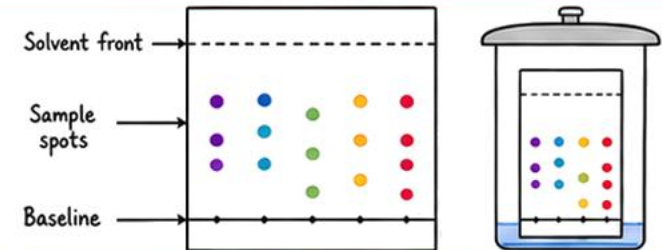
HPLC — liquid mobile phase;
separates and
measures mixture
components



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



TLC — planar separation
for screening,
identity, and
comparison

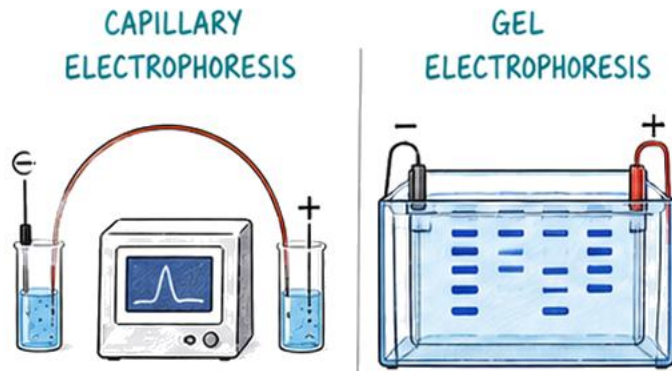


KEY RULE Separation alone does not equal quantitation.

OTHER ANALYTICAL TECHNIQUES

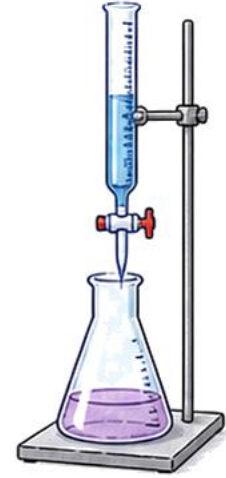
ELECTROPHORESIS

- 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



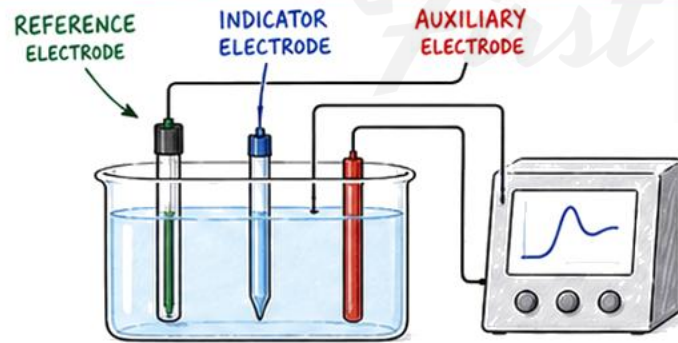
TITRIMETRY

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



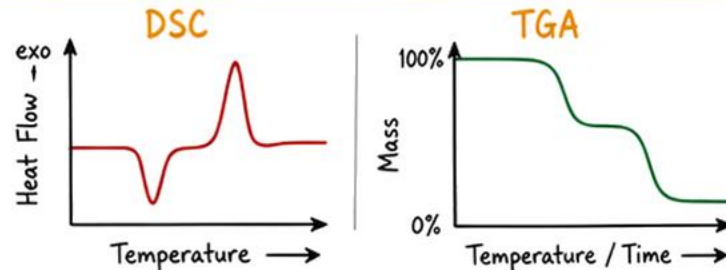
ELECTROANALYSIS

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



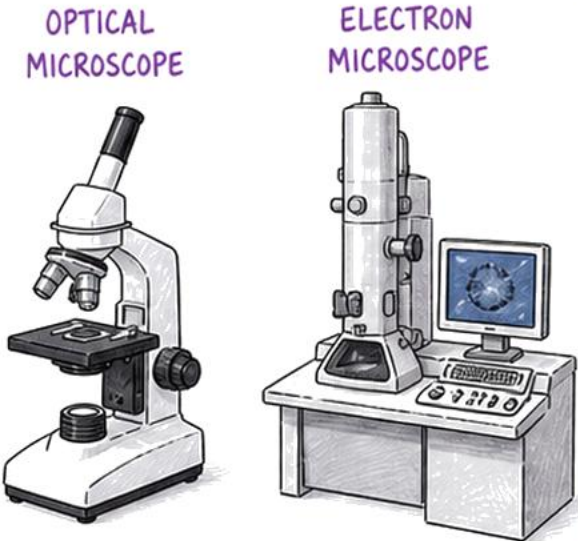
THERMAL ANALYSIS

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



MICROSCOPY

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



CONCENTRATION & SOLUTION STRENGTH

PERCENT EXPRESSIONS

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

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

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

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.

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, $x_i = n_i \div \sum n_j$
dimensionless; $\sum x_i = 1$

Normality, $N = \text{equivalents of reacting species} \div \text{litres of solution}$
unit: eq L^{-1} ; reaction-dependent





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