EXPERIMENT 1: Introduction to Instrumental Analysis, Pharmacopoeias and Monographs

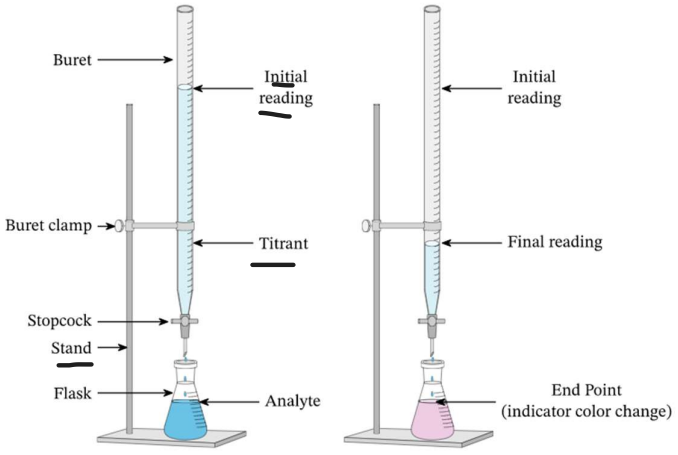
Analytical methods are classified as being either classical (wet-chemical methods) or instrumental.

Comparison	Analytical Methods	
	Classical	Instrumental
(Qualitative analysis) Separation of components by	Precipitation, extraction, distillation	Chromatographic and electrophoretic techniques
(Quantitative analysis) Determination of the analyte amount by	Gravimetric (s-wt) or volumetric measurements (tit)	Electrode potential, conductivity, light absorption or emission, mass to charge ratio measurements

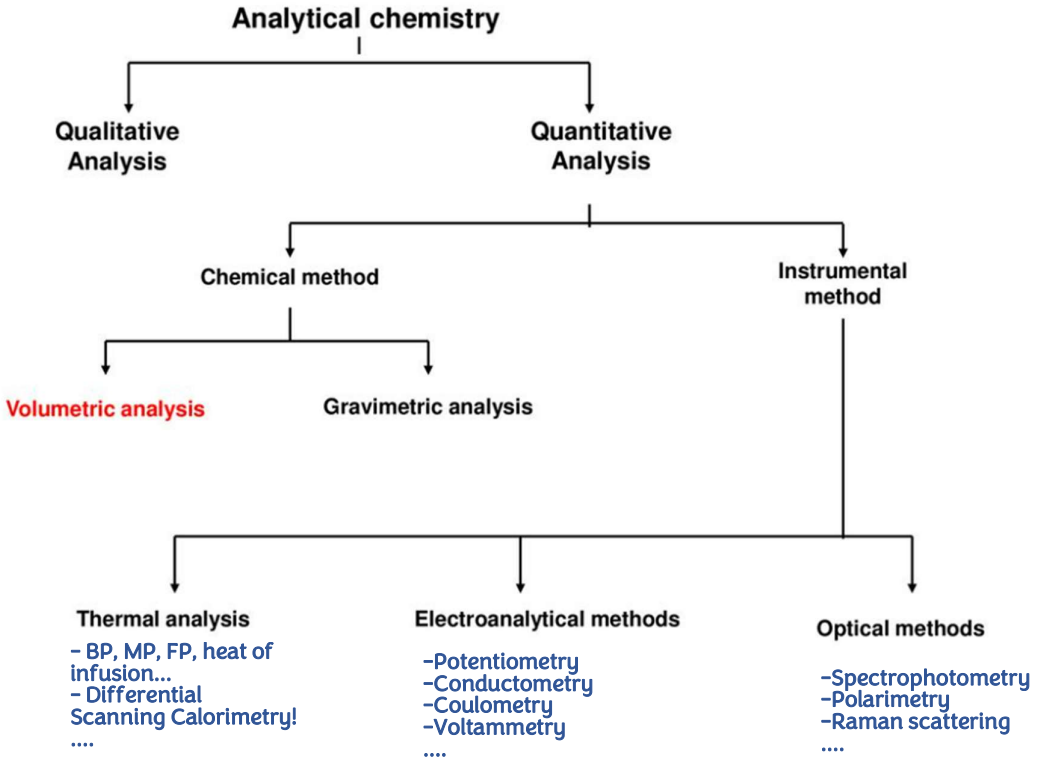
Gravimetric Analysis ex:

(a) Weighing the sample to be analysed (b) Dissolving this sample in water (c) Adding a suitable chemical to form a precipitate (d) Filtering to collect the precipitate (e) Repeated drying and weighing until a constant mass of precipitate is obtained

Volumetric Analysis ex:



Instrumental Analysis: Applying the newer methods for separating and determining the chemical species and their amounts.



The following block diagram shows the overall process of instrumental measurements:

Energy source System under study (Sample) Analytical information

Specifications: Explicit set of *requirements* to be satisfied by a material or product. Should a material or product fail to meet one or more of the applicable specifications, it may be referred to as being out of specification; the abbreviation OOS may also be used.

Test Method: Technical analysis (analytical procedure) applied on a material or product, to determine the material/ product compliance with the relevant specifications.

Pharmacopoeia: the official book of standards for drugs prepared by any country or regulatory body to specify the standards of identity, purity and strength for the drugs imported, manufactured, or distributed throughout the country or a specific region.

- ❖ A reference book for pharmaceutical drugs' specifications, test methods and other relevant data concerning drugs, excipients, and analysis.
- ❖ The term Pharmacopoeia comes from the Greek word "Pharmakon" meaning drug and "Poieo" meaning make, and the combination means any formula or standards required to make a drug.
- ❖ It is a book containing collection of monographs and published by an authorized body like government or pharmaceutical society.

Monograph: Written, Scientific, factual document that reflects the quality attributes of a drug product approved by an official organization (ex: US FDA). Includes the name of the ingredient or preparation; the definition; packaging, storage, and labeling requirements; the specifications, test procedures and acceptance criteria.

- ➢ **A monograph usually contains:**
  1. Chemical name 2. Formula 3. Solubility 4. Identification 5. pH 6. dose 7. Assay 8. Loss on Drying 9. Sulphated ash 10. Specific optical rotation

Formularies: are the list of drugs or collections of formulas for the compounding of medicinal preparations. Formulary contains more comprehensive details on therapeutics. ·

Collectively these books are known as drug compendia. Pharmacopoeias + Formularies = Drug Compendia

Importance of pharmacopoeia

1. To maintain the uniformity and control the standards of the drugs available in market.
2. Avoid adulterated drugs.
3. Complete information on drugs and their dosage forms.
4. Reference for laboratory, industry, and academic institutions.

- **International Pharmacopoeias and Their Contents**
    - United States Pharmacopoeia (USP)
    - British Pharmacopoeia (BP)
    - European Pharmacopoeia (Ph. Eur.)
    - Japanese Pharmacopoeia (JP)
    - Indian Pharmacopoeia
    - Chinese Pharmacopoeia

British Pharmacopoeia (BP) is the source of official standards of drugs in UK and other parts of the world. It was first published by the General Medicine Council and was later done by the Pharmaceutical Commission. Since then, Pharmacopoeia commission is reconstituted from time to time and new editions of British Pharmacopoeia are published.

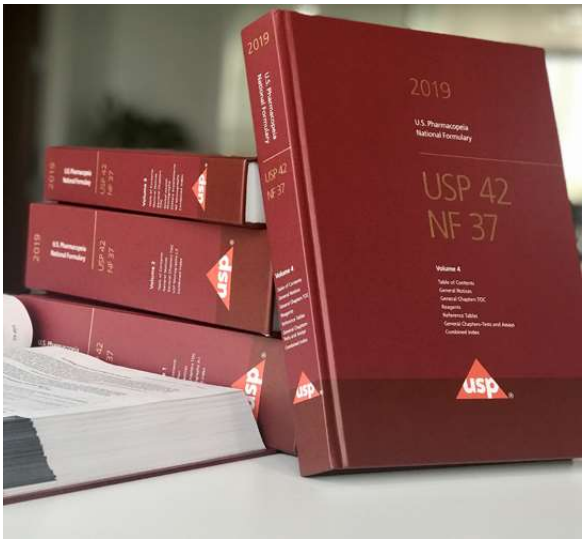
- **British National Formulary** is a source of essential information on drugs and medicines published by pharmaceutical society of Great Britain and British Medical Association.

BP		
# of volumes	**Veterinary Volume + 5 Volumes for human medicinal substances and products**	Brief Description
Contents of veterinary volume	**General notices**	Include remarks such as: - Meaning of general terms - Solubility descriptive terms
	Monographs	❖ Introduced alphabetically
	IR spectra	---
	Appendices	---
	Index	---
Contents of volume 1 & volume 2	**General notices**	As described above
	Monographs	Monographs of drug substances only and organized alphabetically
Contents of volume 3	**General notices**	As described above
	General monographs	Monographs describing tests of a dosage form. (ex. Oral liquid tests)
	Monographs	Monographs of drug products only and organized alphabetically
Contents of volume 4	**Herbal drugs**	General notices General monographs (ex. Tincture tests) Monographs of herbals
	Homoeopathic preparations	General and specific monographs
	Blood related products	General and specific monographs
	Immunological products	General and specific monographs
	Radiopharmaceutical preparations	General and specific monographs
	Surgical materials	Specific monographs
Contents of volume 5	**General notices**	As described above
	IR spectra	---
	Appendices	Reagents General test methods; equivalent to general chapters in USP
	Supplementary chapters	Explanatory and other ancillary texts
	Index	---

International Pharmacopoeia is published by the **WHO** and is practically used in developing countries. It was prepared to meet the international uniformity and standardization of drugs.

International Pharmacopoeia was first published in 1951 in Multi-languages (English, French, German, Japanese, etc.).

United States Pharmacopoeia (USP) and the **National Formulary (USP-NF)** are recognized as the official compendia and are used as reference books for determining the strength, quality, purity, packaging and labeling of drugs and other related articles. USP contains monographs and general chapters that describe specific procedures to support monograph tests and other information as well.



- **USP contains monographs for:**
  - Drug substances and products·
  - Dietary and nutritional supplements.
- **NF covers monographs for:**
  - Excipients
  - Botanicals.

USP		Brief Description
# of volumes	3	
Contents of volume 1	**General notices**	Include remarks such as: - The rounding rules - Meanings of certain terms used within the Pharmacopoeia (ex. Tight container, cold, freezer, ...)

	General chapters Each chapter is assigned a number between brackets < > such as <11>	**Include description of:** ❖ General tests such as: ❖ Microbiological tests ❖ Apparatus for tests and assays ❖ Chemical tests and assays ❖ Physical tests and determinations ❖ **General information such as:** ❖ Quality assurance in pharmaceutical compounding ❖ Good storage and shipping practices ❖ Analytical instrument qualification ❖ Dietary supplements (imp)
	Reagents	Include description of: ❖ Reagents ❖ Indicators ❖ Solutions
	Reference tables	Include tables concerning solubilities, atomic weights, … etc
	Dietary supplements	Include monographs for the dietary supplements
	National Formulary (NF)	Include monographs for the excipients
	Index	---
Contents of volume 2	**General notices**	As in volume 1
	Official Monographs	Monographs for the drug substances and products organized alphabetically
	Index	---
Contents of volume 3	**General notices**	As in volume 1
	Official Monographs	Monographs for the drug substances and products organized alphabetically and they are continuation of those included in volume 2
	Index	---