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 |
| Descriptive - | (Qualitative analysis) Separation of components by | Precipitation, extraction, distillation | Chromatographic and electrophoretic techniques |
| Numerical < | (Quantitative analysis) Determination of the analyte amount by | Gravimetric or volumetric measurements | Electrode potential, conductivity, light absorption or emission, mass to charge ratio measurements |

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

Block diagram showing the overall process of instrumental measurements



- Specifications: Explicit set of <u>requirements</u> 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: A reference book for pharmaceutical drugs' specifications, test

 methods and other relevant data concerning drugs, excipients and analysis.

 * إذا عنك دواء و بدي المُحالِق المُوانِين .
- Monograph: Includes the name of the ingredient or preparation; the definition; packaging, storage, and labeling requirements; the specifications, test procedures and acceptance criteria.

International Pharmacopoeias and Their Contents

the Most Common.

- United States Pharmacopoeia (USP)
 - British Pharmacopoeia (BP)
- European Pharmacopoeia (Ph. Eur.)
- ♣ Japanese Pharmacopoeia (JP)

الجداول بتفرجينا كيف نقسيم الفارماكوبيا عشان لما نيجي نبحث فيهم بالريبورت ، ما عنا علم إذا حفظ أو لأ ، بكرا بنتأكد من د. لبنى وبنبعت مسج عالقناة بالجواب

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

| ВР | | | |
|-------------------------------------|--|--|--|
| 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 | General notices | As described above | |
| volume 1 & volume 2 | 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 | 222 | |
| | Appendices | Reagents General test methods; equivalent to general chapters in USP | |
| | Supplementary chapters | Explanatory and other ancillary texts | |
| | Index | 2776 | |



Artery Academy

Done by Saja DW