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PHARMACEUTICAL ANALYSIS I

UNIT 1

TOPIC :

- **Pharmacopoeia, Sources of impurities in medicinal agents, limit tests.**



Pharmacopoeia

➤ A pharmacopoeia is a book of standards applicable to drug substances and their dosage forms. used in a country or region, which accepts it as such. It is prepared by a recognized authority appointed by & Government of the concerned country. A knowledge of the history of pharmacy would help us better to understand the development of pharmacopoeias

Impurity

→ Impurity - Impurity is undesirable foreign material which may be toxic or may not be toxic, present in the pharmaceutical substances. Impurity is the substance or the matter pharmaceutical substances or drugs.

Sources of Impurities

- Raw materials used in the manufacture
- Reagents used in the manufacturing process.
- Method used in manufacture.
- Action of Solvents and Reagents on Reaction Vessels
- Atmospheric contamination during the manufacturing process.
- Storage Condition
- Adulteration

Effect of Impurities

- ❖ Impurities having a toxic effect, can be injurious when present above certain limits.
- ❖ Impurities may sometimes harmless. However, if these are present in large such proportions that active strength of the substance gets lowered, its therapeutic effect gets decreased.
- ❖ Impurities may cause an incompatibility with other substances,
- ❖ Impurities may decrease the shelf life of the substance.

Limit Test

→ Limit test are the quantitative or semi- quantitative test designed to identify & control small quality of impurity, which are likely to be present in the substance.

Examples

- Limit test of sulphates
- Limit test for iron
- Limit test Arsenic etc.

→ Limit test are generally carried out in Apparatus known as Nessler cylinder which is made up of colourless glass.

Importance of limit test

- They are used for quantitative determination of impurity
- They provide visible appearance to test the appearance.
- To test moisture volatile matter and residual solvents.
- for the specificity of test and to control the sensitivity of test.
- To test and detect various in soluble and soluble matter.