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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 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.