

Basic tests for drugs

Basic Tests for Drugs – Pharmaceutical Substances, Medicinal Plant Materials, and Dosage Forms

- Quality control begins with testing the identity, purity, strength, and quality of drugs.
- These tests are essential to make sure the drug is safe, effective, and consistent.

Pharmaceutical Substances

- These are the active chemical ingredients (APIs – Active Pharmaceutical Ingredients) used to make medicines.

Basic Tests Include:

- **Identity Test:** Confirms the substance is what it claims to be. Techniques like Thin Layer Chromatography (TLC), UV spectroscopy, or IR spectroscopy are used.
- **Purity Test:** Checks whether any unwanted substances (impurities) are present. Tests include:
 - Limit tests for heavy metals (like arsenic, lead).
 - Residual solvent tests.
 - Microbial contamination test.
- **Moisture Content:** Some substances can absorb moisture, so we measure the water content to avoid spoilage. This is done using Karl Fischer titration or loss on drying method.
- **Melting Point / Boiling Point:** These help verify purity – a pure substance has a sharp melting/boiling point.
- **Solubility:** Helps in identifying the substance and understanding how it will behave in the body.

Medicinal Plant Materials (Raw herbs)

- Medicinal plant materials are crude herbs, dried or fresh, collected for medicinal use.

Basic Tests Include:

- **Macroscopic and Microscopic Examination:**
 - Macroscopy: Observing with naked eye (color, texture, size, etc.)
 - Microscopy: Looking under a microscope to see cell structures like trichomes, stomata, etc.
- **Foreign Matter:** Checking if the sample contains unwanted material like stones, insects, or other plant parts.
- **Ash Values:** These indicate the amount of mineral (inorganic) content:

- Total ash.
- Acid-insoluble ash (shows presence of sand or dirt).
- Water-soluble ash.
- **Extractive Values:** How much active constituents can be extracted using water or alcohol.
- **Moisture Content:** Excess water can cause mold growth.
- **Chromatographic Fingerprinting:** Used for identifying and confirming the presence of active components.

Dosage Forms (like tablets, capsules, syrups made from herbs)

- These are final medicinal products made from pharmaceutical substances or herbs.

Basic Tests Include:

- **Uniformity of Weight/Content:** Ensures each unit (e.g., each tablet) has the correct amount of drug.
- **Disintegration and Dissolution Tests:**
 - Disintegration: Checks how fast a tablet breaks down in the body.
 - Dissolution: Measures how fast the drug is released into the bloodstream.
- **Microbial Limits:** Confirms that the product is free from harmful bacteria and fungi.
- **Stability Testing:** Tests how long the product stays effective under different storage conditions.
- **Container-Closure Integrity:** Ensures that the packaging protects the product from air, moisture, and microbes.

WHO Guidelines for Quality Control of Herbal Drugs

- The **World Health Organization (WHO)** has given detailed guidance to help countries and industries ensure the quality, safety, and effectiveness of herbal medicines.

Objectives of WHO Guidelines:

- To establish consistent procedures for evaluating herbal medicines.
- To ensure herbal products are free from harmful contaminants.
- To promote safety and international trade of herbal medicines.

Key Points from WHO Guidelines:

A. Raw Material Quality Control

- **Botanical Identity Confirmation:** Ensure correct plant is used by checking scientific name, part used, and identification tests.



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