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PHARMACOGNOSY AND PHYTOCHEMISTRY – I

UNIT 1

TOPIC :

- **Quality control of Drugs of Natural Origin :**

  Adulteration of drugs of natural origin. Evaluation by organoleptic, microscopic, physical, chemical and biological methods and properties.

  Quantitative microscopy of crude drugs including lycopodium spore method, leaf constants, camera lucida and diagrams of microscopic objects to scale with camera lucida

Quality Control of Drugs of Natural Origin

Quality control refers to the processes and procedures employed to ensure that medicinal products derived from plants, animals, marine sources, or minerals are:

- Safe
- Effective
- Consistent
- Authentic

It involves identification, evaluation, and standardization of crude drugs to avoid adulteration and ensure therapeutic efficacy.

Adulteration of Drugs

- Adulteration is the process of mixing, substituting, or contaminating crude drugs with inferior, harmful, or non-therapeutic substances.
- It is usually done to increase profit, but it makes the drug less effective, unsafe, or even toxic.

Example:

- Mixing genuine herbal powders with chalk powder or starch.
- Substituting high-quality herbs with cheaper, less effective varieties.

Types of Adulteration

1. **Addition of Foreign Substances**
    - Mixing drugs with unwanted, low-cost materials like starch, sugar, sand, or synthetic chemicals.
    - Reduces purity and potency.
    - *Example*: Herbal powders mixed with talc or starch.
2. **Substitution with Inferior Ingredients**
    - Replacing a genuine drug with a similar-looking but inferior plant or part.

- Done to save cost.
- *Example*: Using a common plant instead of a rare, medicinal plant.

3. **Contamination**
   - Drugs become contaminated during processing, handling, or storage.
   - Contaminants include pesticides, heavy metals, microbes, or toxic chemicals.
   - *Example*: Herbs contaminated with polluted water or stored in unhygienic conditions.
4. **Degradation or Spoiling**
   - Poor storage conditions (light, air, heat, moisture) cause loss of potency.
   - Leads to growth of mold, bacteria, or chemical breakdown.
   - *Example*: Essential oils losing aroma or herbs developing fungal growth.

Consequences of Adulteration

1. **Health Risks**
   - Adulterated products may cause toxicity, allergic reactions, or side effects.
   - Example: Synthetic chemicals added to herbal medicines causing harmful reactions.
2. **Loss of Effectiveness**
   - Therapeutic action is reduced or completely lost.
   - May lead to treatment failure.
3. **Legal Issues**
   - Adulteration is illegal and punishable under Drug & Cosmetic Act and other regulations.
4. **Trust Issues**
   - Adulteration reduces public confidence in herbal and natural medicines.

Examples of Adulteration

- Ayurvedic herbs like Ashwagandha and Brahmi → adulterated with synthetic chemicals or cheaper plants.
- Essential oils like Lavender, Eucalyptus → adulterated with synthetic fragrances or diluted oils.

Prevention of Adulteration

- Purchase drugs from reputed suppliers who follow Good Manufacturing Practices (GMP).
- Look for certification and standardization marks.
- Regular testing of raw materials for purity and authenticity.
- Maintain proper storage and handling conditions.
- Educate consumers about quality parameters of crude drugs.

Evaluation of Crude Drugs

- Evaluation of crude drugs refers to the systematic process of determining the identity, purity, quality, and potency of crude drugs obtained from natural sources. It ensures that drugs are genuine, free from adulterants, and therapeutically effective.
- Evaluation is carried out using organoleptic, microscopic, physical, chemical, and biological methods.

1. Organoleptic Evaluation

Organoleptic evaluation is the examination of crude drugs using the sense organs such as sight, smell, taste, and touch to study their macroscopic characters.

Parameters:

- Color – e.g., saffron has a characteristic orange-red color.
- Odor – e.g., clove has a strong aromatic odor.
- Taste – e.g., quinine is bitter, ginger is pungent.
- Size & Shape – e.g., leaves of senna are lanceolate, cloves are nail-shaped.
- Texture – rough, smooth, brittle, or hard.

Example:

- *Clove* → aromatic smell, pungent taste.
- *Cinnamon* → sweet taste and characteristic fragrance.

Use: First step in drug evaluation, useful for quick identification.

2. Microscopic Evaluation

Microscopic evaluation involves the detailed study of cellular structures and tissues of crude drugs under the microscope (whole, powdered, or sectioned drugs).

Parameters:

- Stomatal index – ratio of stomata to epidermal cells in leaves.
- Vein-islet number – number of vein-islets per unit area of leaf.
- Trichomes – unicellular/multicellular hairs.
- Starch grains – size, shape, hilum position.
- Calcium oxalate crystals – prism, rosette, or raphide type.

Examples:

- *Digitalis leaves* → vein-islet number and palisade ratio.
- *Rhubarb* → rosette crystals of calcium oxalate.
- *Clove* → oil glands visible under microscope.

Use: Helps in identifying drugs when morphological features are lost (e.g., in powders).

3. Physical Evaluation

Physical evaluation is the determination of physical constants of crude drugs and their constituents. These constants give a quantitative measure of purity and quality.

Parameters:

- Ash values
  - *Total ash* – total inorganic content.
  - *Acid-insoluble ash* – indicates siliceous matter.
  - *Water-soluble ash* – soluble inorganic salts.
- Extractive values
  - *Alcohol-soluble extractive* – amount of constituents soluble in alcohol.
  - *Water-soluble extractive* – amount soluble in water.
- Other physical constants
  - Melting point.
  - Refractive index.
  - Specific rotation.
  - Viscosity.
  - Moisture content.

Examples:

- Ash value of *ginger* helps detect earthy matter adulteration.
- Refractive index used in identification of volatile oils.

Use: Detects adulteration and substitution.

4. Chemical Evaluation

Chemical evaluation involves the use of specific chemical tests to detect the presence of active chemical constituents in crude drugs.

Examples of Tests:

- Alkaloids → Dragendorff's test, Mayer's test.
- Glycosides → Keller-Killiani test (for cardiac glycosides).
- Tannins → Ferric chloride test (blue-black/green color).
- Flavonoids → Shinoda test (red coloration).
- Saponins → Froth formation test.

Use: Helps confirm the presence of active principles.

5. Biological Evaluation (Bioassay)

Biological evaluation (bioassay) refers to the process of determining the potency and concentration of a crude drug by testing its effect on living organisms, tissues, or cells.

Examples:

- *Digitalis* → bioassayed on frog heart.
- *Insulin* → tested on rabbit blood sugar level.
- *Oxytocin* → assayed on rat uterus.

Use:

- Provides information on the therapeutic efficacy of crude drugs.
- Useful when chemical methods are not sufficient (e.g., hormones, vitamins, antibiotics).

Quantitative Microscopy of Crude Drugs

- Quantitative microscopy refers to the measurement of various microscopic features of crude drugs using the microscope and specific tools.
- It provides numerical data that helps in standardization, identification, and detection of adulteration in powdered drugs and plant materials.

1. Importance of Quantitative Microscopy

- Useful when morphological characters are lost (e.g., in powdered drugs).
- Provides definite constants (leaf constants, spore counts, etc.) for drug identification.
- Helps in quality control of crude drugs.
- Detects substitution and adulteration.

2. Leaf Constants (Microscopic Constants)

Leaf constants are fixed numerical values obtained from leaf microscopy. They are characteristic for each plant species.

Types of Leaf Constants:

1. **Stomatal Number**
   - Definition: Average number of stomata per square mm of epidermis.
   - Use: Species identification.
2. **Stomatal Index**
   - Definition: Percentage of the number of stomata to the total number of epidermal cells including stomata.
   - Formula:

$$Stomatal\ Index = \frac{S}{E+S} \times 100$$

Where:
S = number of stomata
E = number of epidermal cells.

3. **Vein-Islet Number**
    - Definition: Number of vein-islets per square mm of leaf surface.
    - A vein-islet = small area of green tissue surrounded by veinlets.
4. **Vein-Termination Number**
    - Definition: Average number of vein terminations (endings of a veinlet) per square mm of leaf surface.
5. **Palisade Ratio**
    - Definition: Average number of palisade cells lying beneath one epidermal cell.
    - Constant for a species, useful in powdered drug identification.

3. Lycopodium Spore Method

A standard quantitative microscopy method used to determine the starch content, crude drug content, or number of particles in powdered drugs by comparison with lycopodium spores (which have a known and constant spore count).

Principle:

- Lycopodium powder has a fixed spore number per mg (around 94,000 spores/mg).
- By mixing drug powder with lycopodium spores and counting under microscope, the quantity of the drug can be estimated.

Applications:

- Determination of starch content in starch-containing drugs (e.g., rhizomes).
- Estimation of number of foreign particles in powdered drugs.
- Standardization of seeds, starch, and powdered crude drugs.

Procedure (simplified):

1. Weigh accurately a known quantity of drug powder and lycopodium powder.
2. Mix properly.
3. Mount a small portion under microscope.
4. Count the number of lycopodium spores and drug particles.
5. Apply formula to calculate drug constituent.

Formula:

$$\frac{N}{n} = \frac{W \times X}{w \times Y}$$

Where:

- N = number of characteristic structures of drug observed
- n = number of lycopodium spores observed
- W = weight of lycopodium taken
- w = weight of drug taken
- X = 94,000 (no. of spores per mg of lycopodium)
- Y = number of drug structures per mg of drug

4. Camera Lucida

A drawing device used in microscopy that projects the image of the microscopic object onto paper, enabling accurate drawing to scale.

Working:

- A prism or mirror arrangement allows the microscopist to see both the specimen and the paper at the same time.
- The outline of the object is traced on the paper.

Uses:

- To prepare accurate diagrams of microscopic objects.
- To draw leaf constants (stomata, vein-islets, trichomes, crystals, fibers, etc.) to scale.

5. Diagrams of Microscopic Objects to Scale with Camera Lucida

- Objects like stomata, trichomes, starch grains, calcium oxalate crystals, fibers, vessels can be drawn.
- The drawing should be labeled with magnification (e.g., 10X, 40X).
- Helps in record keeping and standardization of crude drugs.