

Quality Control of Drugs of Natural Origin (WHO Guidelines)

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Basic Idea

- Quality control is the process of ensuring that drugs of natural origin are safe, effective, pure, and of consistent quality.
- The World Health Organization (WHO) has developed guidelines to maintain the quality, safety, and efficacy of herbal medicines.
- These guidelines help prevent adulteration, contamination, and improper use of medicinal plants.

Objectives

- To ensure the identity and purity of herbal drugs.
- To maintain consistent quality from collection to the final product.
- To detect adulteration and contamination.
- To ensure the safety and effectiveness of herbal medicines.

WHO Guidelines Include

1. Proper Identification

- The correct botanical source of the medicinal plant should be confirmed.
- Scientific names should be used to avoid confusion.

2. Good Agricultural and Collection Practices (GACP)

- Medicinal plants should be cultivated and collected using recommended methods.
- Collection should be done at the proper stage of growth.

3. Proper Processing and Storage

- Drying, cleaning, grading, and packaging should be carried out correctly.
- Drugs should be protected from moisture, insects, microorganisms, and sunlight.

4. Quality Testing

- Herbal drugs should be evaluated using organoleptic, microscopic, physical, chemical, and biological methods.

5. Documentation

- Proper records should be maintained during cultivation, processing, storage, and distribution.
- Documentation helps ensure traceability and product quality.

Importance

- Herbal medicines become safer and more effective.
- Product quality remains consistent.
- Consumer confidence increases.
- National and international standards are maintained.

Adulteration of Drugs of Natural Origin

- Adulteration means reducing the quality of a natural drug by mixing it with inferior, harmful, exhausted, or unrelated materials.
- It may occur intentionally for profit or accidentally because of poor identification, collection, or storage.

Common Types of Adulteration

A. Substitution with Inferior Varieties

- A cheaper or lower-quality variety may be used instead of the genuine drug.
- The substitute may contain fewer active constituents.

B. Substitution with Similar-Looking Materials

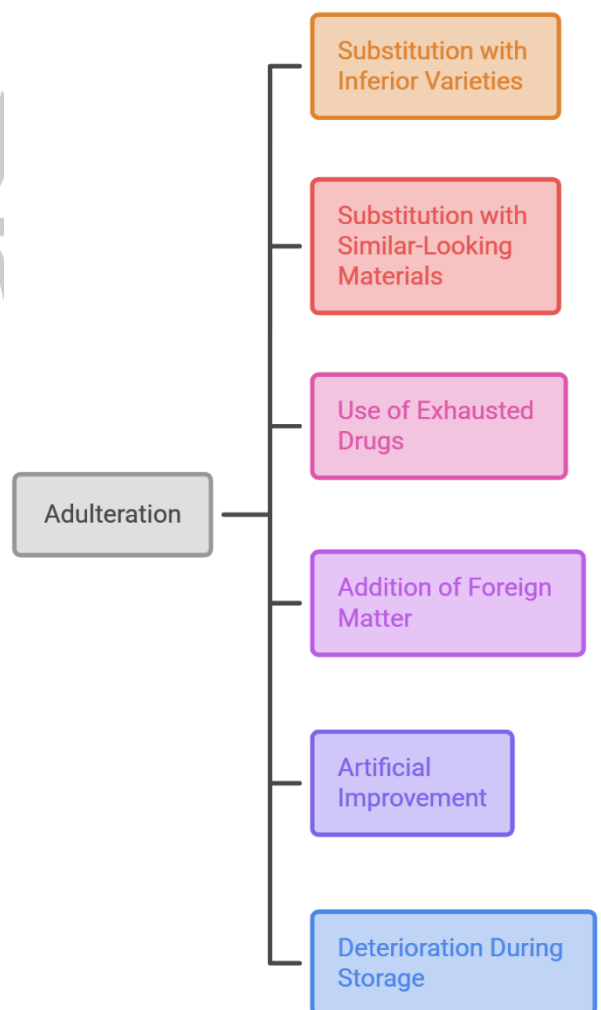
- A different plant material with a similar appearance may be sold as the genuine drug.
- This problem is common in powdered drugs.

C. Use of Exhausted Drugs

- Exhausted drugs are materials from which active constituents have already been removed.
- They may still look like the original drug but have little medicinal value.

D. Addition of Foreign Matter

- Soil, stones, weeds, unwanted plant parts, or other materials may be mixed with the drug.
- These substances may enter accidentally or may be added to increase weight.



E. Artificial Improvement

- Artificial colors, flavors, or oils may be added to improve the appearance or smell of a poor-quality drug.

F. Deterioration During Storage

- Moisture, heat, insects, fungi, and bacteria may damage natural drugs.
- Deterioration changes the color, odor, taste, and chemical quality of the material.

Detection

- Organoleptic examination detects changes in color, odor, taste, and texture.
- Microscopy identifies foreign tissues and characteristic cells.
- Physical and chemical tests detect impurities and confirm active constituents.
- Biological tests measure the actual activity of the drug.

Effects of Adulteration

- Drug quality decreases.
- Therapeutic effect becomes poor.
- Toxic effects may occur.
- Consumer safety is affected.
- The reputation of herbal medicines decreases.

Prevention

- Correct botanical identification should be carried out.
- Quality control tests should be performed regularly.
- Good storage and handling practices should be followed.
- Collection should be done by trained personnel.

Organoleptic Evaluation

Basic idea

- Organoleptic evaluation means examining a natural drug by using the sense organs.
- It is a simple and rapid method used for initial identification.

Main Parameters

1. Color

- The external and internal color of the drug is observed.
- Unusual color may indicate poor drying, aging, or fungal growth.

2. Odor

- The smell may be aromatic, spicy, unpleasant, characteristic, or absent.
- Drugs containing volatile oils usually have a strong odor.

3. Taste

- Taste may be sweet, bitter, pungent, sour, salty, or astringent.
- Chirata is bitter, liquorice is sweet, and ginger is pungent.
- Toxic drugs should not be tasted.

4. Size and Shape

- Length, width, thickness, and general form are examined.
- These features help distinguish genuine drugs from substitutes.

5. Surface and Texture

- The surface may be smooth, rough, hairy, wrinkled, or ridged.
- The texture may be hard, soft, fibrous, brittle, or spongy.

6. Fracture

- Fracture means the appearance of a drug after it is broken.
- It may be short, fibrous, splintery, smooth, or granular.

Advantages

- The method is simple and inexpensive.
- No complex instruments are required.
- It provides rapid preliminary identification.

Limitations

- Results depend on experience.
- Similar-looking drugs may be difficult to distinguish.
- The method cannot accurately determine chemical composition.

Qualitative Microscopy

Basic idea

- Qualitative microscopy is the study of the microscopic structures of a natural drug.
- It is especially useful for identifying powdered drugs.

Important Microscopic Features

1. Epidermal Cells and Stomata

- Epidermal cells form the outer layer of plant organs.
- The shape and arrangement of stomata help identify leaf drugs.

2. Trichomes

- Trichomes are hair-like structures on the plant surface.
- Their shape, size, and number of cells are useful for identification.

3. Vessels and Fibers

- Xylem vessels may show spiral, annular, pitted, or reticulate thickening.
- Fibers are long, thick-walled cells that provide support.

4. Stone Cells

- Stone cells are thick-walled cells commonly found in barks, fruits, and seeds.
- Their shape and distribution may be diagnostic.

5. Starch Grains and Crystals

- Starch grains may differ in size, shape, and structure.
- Calcium oxalate crystals may occur as prisms, rosettes, needles, or clusters.

6. Secretory Structures

- Oil cells, resin ducts, latex vessels, and mucilage cells may help confirm the drug's identity.

Common Reagents

- Iodine solution produces a blue or blue-black color with starch.
- Phloroglucinol with hydrochloric acid gives a red color with lignified tissues.
- Sudan dyes detect oils and fats.
- Ruthenium red detects mucilage.

Powder Microscopy

- Powder microscopy examines diagnostic structures in powdered drugs.
- It helps detect substitution and adulteration when external features are absent.

Quantitative Microscopy

Basic idea

- Quantitative microscopy measures specific microscopic features of a leaf or powdered drug.



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