



Pharmacognosy



Unit 3



Quality Control of Drugs of Natural Origin (WHO Guidelines)



Assured Quality
Reliable & Safe



Standardized
Evidence Based



Validated Methods
Accurate Results

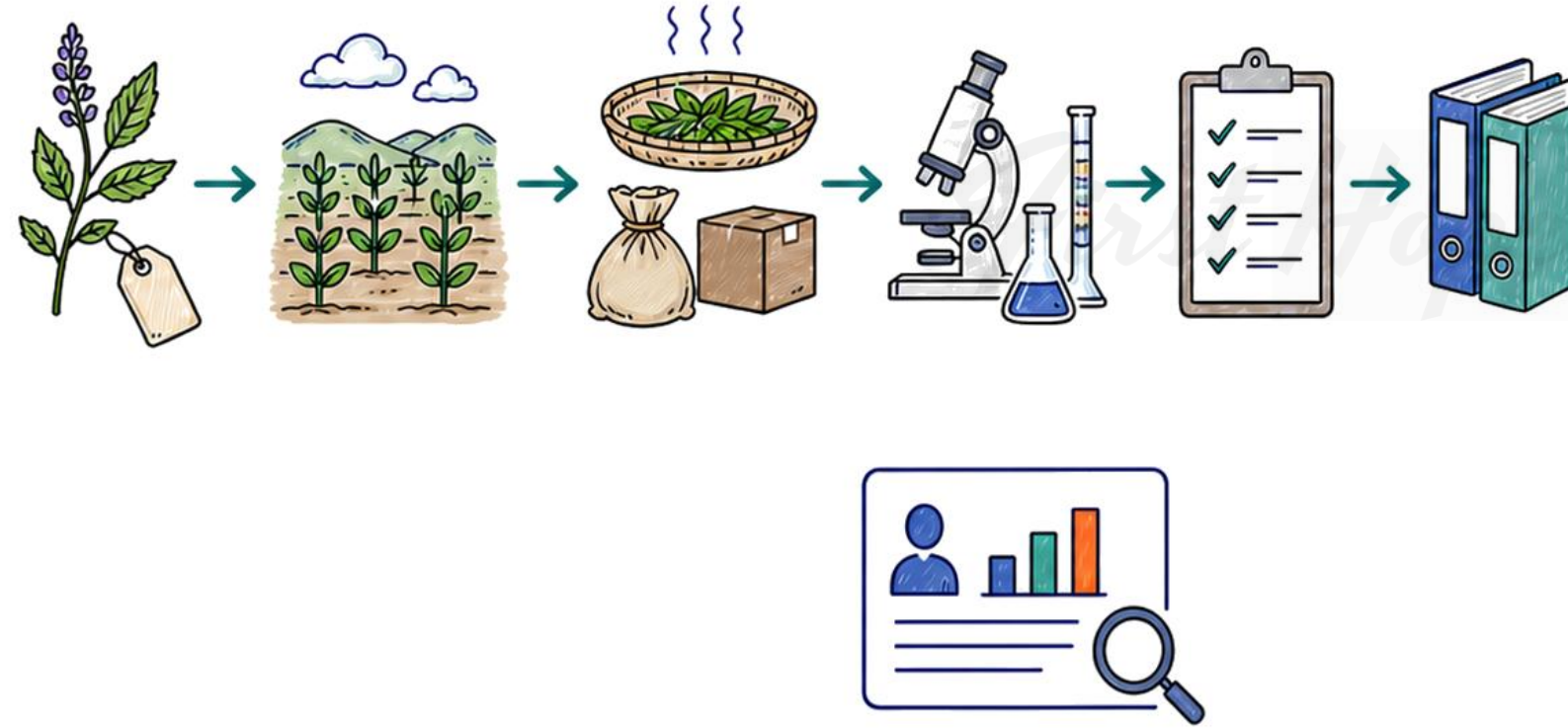


Global Standards
WHO Guidelines



WHO-ALIGNED QUALITY CONTROL OF NATURAL DRUGS

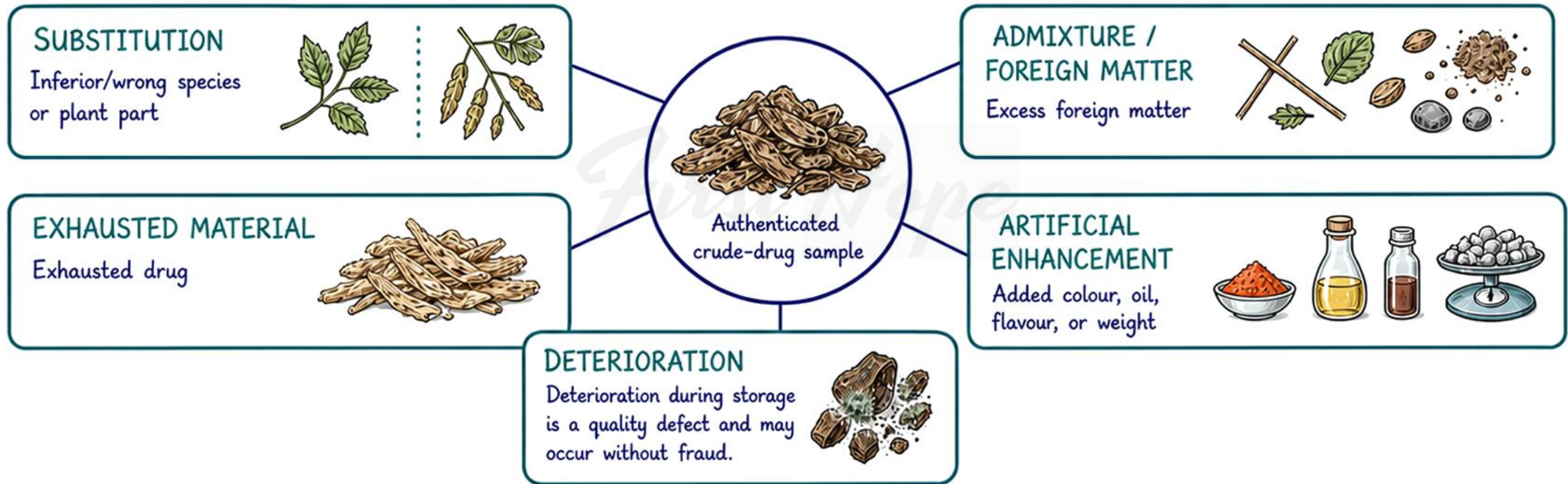
- Quality control establishes identity, purity, content/strength, consistency, and compliance with specifications.
- It supports safety and reproducible quality; it does not by itself prove clinical efficacy.



- Confirm accepted botanical name, author citation where required, family, plant part, geographical source, and voucher/reference specimen.
- GACP covers suitable cultivation or sustainable collection, correct harvest stage, trained personnel, contamination control, and traceability.
- Post-harvest controls include prompt cleaning, appropriate drying, grading, packaging, and protection from moisture, pests, light, and microbial growth.
- Test with complementary methods: organoleptic/macroscopic, microscopic, physicochemical, chromatographic/chemical, and biological where justified.
- Check relevant contaminants and residues against applicable limits.
- Maintain batch records from source to distribution; investigate deviations and retain representative samples.

ADULTERATION, SUBSTITUTION & DETERIORATION

- Adulteration is debasement of a drug by substitution, admixture, removal of valuable constituents, or artificial enhancement.
- It may be deliberate or accidental; deterioration during storage is a quality defect and may occur without fraud.
- Common patterns: inferior/wrong species or plant part; similar-looking material; exhausted drug; excess foreign matter; added colour, oil, flavour, or weight.
- Foreign matter includes unwanted plant parts, other organisms or their products, and mineral admixtures such as soil, sand, or stones.



DETECTION

- Detect by authenticated comparison plus macro-/organoleptic examination, microscopy, physicochemical constants, chromatographic fingerprint/assay, and DNA methods where suitable.

CONSEQUENCES

- Consequences include reduced potency, batch variability, contamination, toxicity, and treatment failure.

PREVENTION

- Prevent with qualified suppliers, botanical authentication, GACP/GMP, representative sampling, validated specifications, suitable storage, and traceable records.

ORGANOLEPTIC & MACROSCOPIC EVALUATION

- First-line examination uses sight, smell, touch, and safe macroscopic handling.
- Record external/internal colour, characteristic odour, size, shape, surface, texture, and fracture.
- These characters help compare a sample with an authenticated specimen and pharmacopoeial description.
- Unexpected darkening, mustiness, softening, insects, or mould may indicate poor drying or storage.



Sight
(Colour)



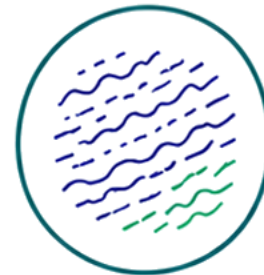
Smell
(Odour)



Touch
(Texture)



Size & Shape



Surface



Fracture

Advantages:

rapid, inexpensive, non-instrumental,
and useful before detailed testing.

Limitations:

observer-dependent; powdered or closely related
materials may be indistinguishable; chemical
content cannot be quantified.



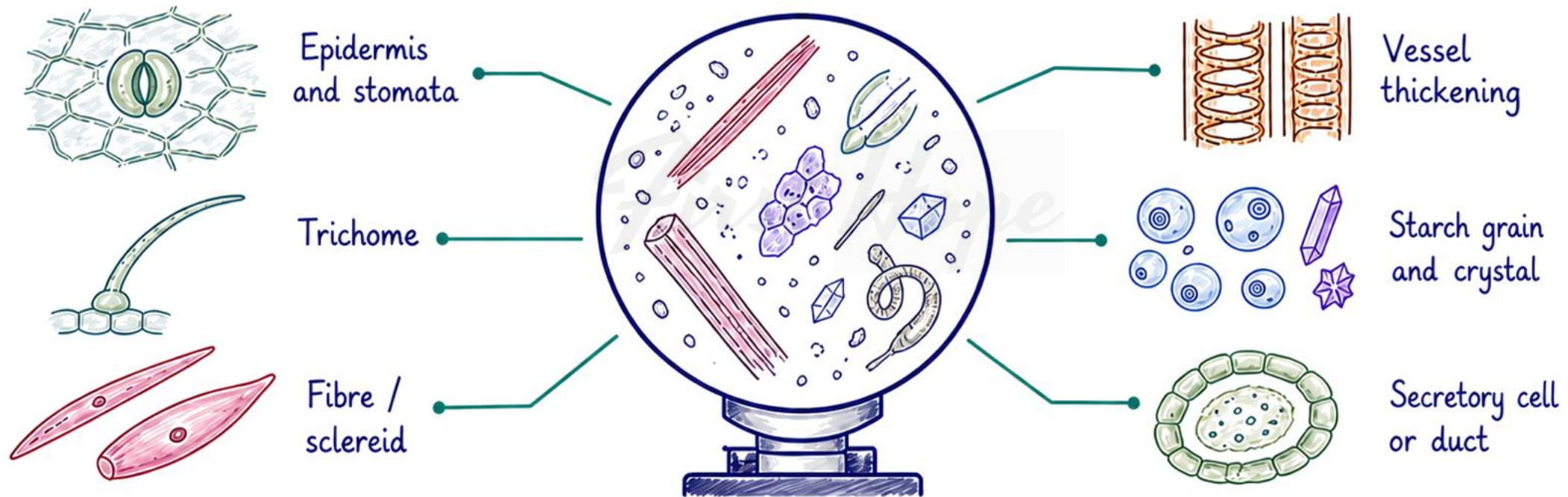
Safety rule: never taste an unidentified or potentially toxic drug. Pharmacopoeial bitterness testing is a separate controlled assay performed after identity is established.



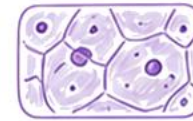
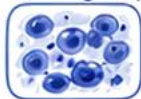
Taste is recorded only in a monograph-authorized procedure after identity is established; never taste unknown or toxic material.

QUALITATIVE & POWDER MICROSCOPY

- Microscopy confirms diagnostic tissues when external characters are absent or fragmented.
- Examine epidermis and stomatal type, trichomes, fibres, sclereids, vessel thickening, starch grains, crystals, and secretory cells/ducts.
- Powder microscopy is especially useful for detecting wrong plant parts, substitutes, and foreign tissue.
- Compare with an authenticated reference or monograph; one feature alone is rarely conclusive.



- Reagent clues: iodine → blue/blue-black starch; phloroglucinol + HCl → red/magenta lignified walls; Sudan dye → lipids; ruthenium red → mucilage/pectic material.



- Reagents indicate constituents or wall types; they do not independently prove species identity.

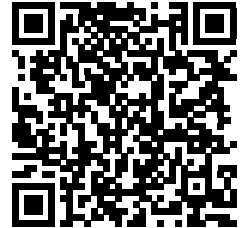


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