BP401T · B.PHARM THEORY

BP401T Herbal Drug Technology

Unit III — Quality Control & Standardisation

Pills & Python Notes

From-zero teaching standard: every technical term is defined before use.

B.Pharm Semester IV · Unit III · 7 Hours

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CHAPTER 7 — Standardisation Approaches, Testing Methods and DNA Fingerprinting

7.1 Learning Objectives

1. Explain approaches for standardisation and quality control of botanicals and formulations.
2. Describe testing methods and regulatory considerations.
3. Explain the role of DNA fingerprinting and molecular markers (rbcL, matK, SCAR) in quality control.

7.2 Definitions

- **Standardisation:** The process of adjusting and confirming that every batch of a herbal product meets fixed quality standards (identity, purity, strength).
- **Quality control (QC):** All the tests done to make sure a product is what it claims to be, is pure, and works as expected.
- **DNA fingerprinting:** Identifying a plant by its unique DNA pattern — like identifying a person by fingerprint, but using genes.
- **Molecular marker:** A small, known piece of DNA used as an identity tag for a species.

7.3 Key Terminology

Term	Simple meaning
Botanical	The plant raw material
Adulteration	Mixing a cheap/fake material into the genuine drug
Substitution	Replacing the genuine drug fully with another (cheaper) plant
rbcL / matK	Two standard DNA "barcode" regions used to identify plant species
SCAR	A DNA test designed to detect one specific species (Sequence Characterized Amplified Region)

7.4 Explanation

> **Technical concept:** Standardisation of botanicals and formulations combines classical pharmacognostic evaluation (morphology, microscopy, chemical tests, TLC/HPLC fingerprints, marker assays, limits for contaminants) with DNA-based authentication (barcoding with rbcL/matK, species-specific SCAR markers) to guarantee identity, purity, and consistent strength.

> **Simple explanation:** Checking a herbal drug is like checking a student's identity card at an exam: first you look at the photo (morphology — does it look right?), then check details (microscopy, chemical tests), and for a final foolproof check you match the DNA — because two plants may look alike when powdered, but their DNA never lies.

Approaches for standardisation and QC (stepwise):

1. **Authentication of raw material:** Correct species, plant part (WHO GACP guidelines for collection).
2. **Morphological & microscopical evaluation:** Shape, size, colour; powder microscopy (hairs, stomata, crystals) — detects substitution.
3. **Physical constants:** Ash values (total ash, acid-insoluble ash — detects sand/soil), extractive values (how much dissolves — indicates strength), moisture content, foreign matter.
4. **Chemical evaluation:** Qualitative tests for alkaloids/glycosides/tannins; TLC/HPLC fingerprint; quantitative assay of marker compounds.
5. **Contaminant testing:** Heavy metals (lead, arsenic, mercury, cadmium), pesticide residues, microbial load, aflatoxins — must be within limits.
6. **Finished product QC:** Identity, marker content, uniformity, disintegration/dissolution, stability.

Testing methods and regulatory considerations: Tests must follow pharmacopoeial or WHO/AYUSH methods; methods must be validated (shown to be accurate and repeatable); records must allow traceability from farm to shelf; regulators (AYUSH in India) can inspect and demand these records.

7.5 DNA fingerprint and molecular markers in QC

- **Why DNA?** Dried/powdered herbs of different species can look identical under the microscope. DNA survives drying and gives a definite answer.
- **rbcL and matK:** Two regions of the chloroplast DNA officially adopted as the "barcode of life" for plants. Sequencing these regions and comparing with a database tells you exactly which species the sample is — like scanning a product barcode at a shop.
- **SCAR markers:** Once scientists find a DNA difference unique to one species, they design a simple PCR test (SCAR) that gives a "yes/no" band only for that species — a quick identity test usable in QC labs.
- **Role in QC:** (1) Detect adulteration/substitution even in powders; (2) distinguish closely related species (e.g., different *Berberis* or *Asparagus* species); (3) support legal/regulatory action with objective evidence.

> **Flowchart — DNA-based authentication:** Powdered sample → DNA extracted → PCR amplifies rbcL/matK (or SCAR test) → DNA sequence/band pattern obtained → compared with reference database → match = genuine; mismatch = adulterated/substituted.

7.6 Infographic concept box — Chapter 7

> A "3-layer security check" shield: Layer 1 — Eyes (morphology/microscopy); Layer 2 — Chemistry (TLC fingerprint, marker assay, contaminant limits); Layer 3 — DNA (barcode rbcL/matK + SCAR tick). Caption: "Look → Test → DNA-verify."

7.7 Pharmacy relevance

- QC pharmacists run these exact tests; DNA barcoding is increasingly demanded for export consignments.
- Understanding limits (heavy metals, pesticides) helps pharmacists explain product safety to consumers.

7.8 India context

India's AYUSH pharmacopoeias (Ayurvedic, Siddha, Unani Pharmacopoeias of India) lay down these standards; Indian exporters use DNA barcoding to satisfy EU/US buyers who demand proof against adulteration.

7.9 Key points

1. Standardisation = fixed identity, purity, strength in every batch.
2. Classical tests: morphology, microscopy, ash/extractive values, TLC/HPLC, marker assay, contaminant limits.
3. DNA barcodes rbcL + matK identify species; SCAR gives a species-specific yes/no test.
4. Methods must be validated; records must be traceable.

7.10 Common confusions

- **Standardisation vs quality control:** Standardisation is SETTING and ACHIEVING the standard; QC is TESTING whether it was achieved.
- **rbcL/matK vs SCAR:** rbcL/matK are universal barcodes for identifying ANY plant; SCAR is a custom test for ONE specific species.
- **Adulteration vs substitution:** Adulteration = mixing fake with genuine; substitution = fully replacing genuine with another plant.

7.11 Common mistakes

- Writing only chemical tests and forgetting DNA markers — the syllabus explicitly asks for rbcL, matK, SCAR.
- Confusing extractive values (strength indicator) with ash values (purity/contamination indicator).

7.12 Mnemonics

- QC layers: "**M**y **C**hemistry **D**etects **F**akes" — Morphology, Chemistry, DNA Fingerprint.
- Barcodes: "**R**eal **M**edicines **B**ar-coded" — rbcL, matK, Barcode.

7.13 Exam summary

Standardisation of botanicals/formulations uses authentication, morphological/microscopical evaluation, physical constants (ash, extractive values, moisture), chemical evaluation (TLC/HPLC fingerprints, marker assays), and contaminant testing (heavy metals, pesticides, microbes, aflatoxins), with validated methods and traceable records. DNA fingerprinting with rbcL/matK barcodes and species-specific SCAR markers gives foolproof identity confirmation, detecting adulteration even in powders.

7.14 One-minute revision

Look (morphology) → test (chemistry + contaminants) → DNA-verify (rbcL/matK/SCAR) → every batch same standard.

7.15 Exam questions

Short answers:

1. Define standardisation and adulteration.
2. What are rbcL and matK?
3. What is a SCAR marker?
4. Name four contaminant tests for herbal drugs.

Long answers:

1. Describe the approaches for standardisation and quality control of botanicals and formulations.
2. Explain the role of DNA fingerprinting and molecular markers (rbcL, matK, SCAR) in herbal quality control.

MCQs:

1. rbcL and matK are: (a) chemical reagents (b) DNA barcode regions (c) TLC solvents (d) microscopes — **Answer: (b)**
2. Acid-insoluble ash mainly detects: (a) active content (b) silica/sand contamination (c) moisture (d) colour — **Answer: (b)**
3. A SCAR marker is: (a) universal for all plants (b) species-specific DNA test (c) a microscope stain (d) a heavy metal — **Answer: (b)**

Viva:

1. Why is DNA barcoding needed when microscopy exists?
2. What does a high extractive value indicate?

Application-based:

1. A powder labelled "Shatavari" is suspected to be mixed with a cheaper root. Outline a three-layer testing plan.

7.16 References

1. Waldesch, F. G. Herbal Medicinal Products. CRC Press.
2. Indian Herbal Pharmacopoeia. Indian Drug Manufacturers' Association.
3. World Health Organization. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants.

CHAPTER 8 — WHO, AYUSH and EU Guidelines; Stability, Shelf Life and Forensic Pharmacognosy

8.1 Learning Objectives

1. Summarize WHO, AYUSH, and EU guidelines on quality control of herbal medicines.
2. Explain stability and shelf-life studies of herbal medicines.
3. Explain forensic pharmacognosy and its role in identifying illicit herbal drugs (Cannabis, Opium).

8.2 Definitions

- **Guideline:** An official document telling manufacturers HOW to ensure quality (not optional in practice — regulators enforce it).
- **Stability study:** Testing how a product's quality changes over time under different temperatures/humidity, to fix its expiry date.
- **Shelf life:** The period during which the product stays safe and effective when stored properly.
- **Forensic pharmacognosy:** Using plant-identification science to help law/police — e.g., proving a seized sample is Cannabis or Opium.

8.3 Key Terminology

Term	Simple meaning
AYUSH	India's Ministry for Ayurveda, Yoga, Naturopathy, Unani, Siddha, Homoeopathy
Accelerated stability	Testing at high heat/humidity to predict long-term shelf life quickly
Real-time stability	Testing at normal storage conditions for the full shelf life
Illicit drug	A drug banned or strictly controlled by law

8.4 Explanation

> **Technical concept:** WHO, AYUSH, and EU guidelines require herbal medicines to meet standards for identity, purity, and content, supported by stability studies (real-time and accelerated) that establish shelf life; forensic pharmacognosy applies the same identification tools (morphology, microscopy, chemical tests, DNA) to detect illicit herbal drugs such as Cannabis and Opium for legal purposes.

> **Simple explanation:** Guidelines are the "rule books" — WHO writes the global rule book, AYUSH writes India's rule book for Ayurvedic/Siddha/Unani drugs, and the EU has its own strict rule book for herbal medicines sold in Europe. Stability studies answer "till when is this medicine good?" Forensic pharmacognosy is the detective branch: when police seize suspicious plant material, pharmacognosists prove in court whether it is Cannabis or Opium.

Guidelines overview (table):

Body	Focus (simple)
WHO	Global guidelines: GACP for medicinal plants (how to grow/collect properly), QC methods for herbal materials, contaminant limits
AYUSH (India)	Ayurvedic/Siddha/Unani Pharmacopoeias of India (quality standards), GMP rules (Schedule T), labelling and licensing requirements
EU	Strict quality, safety, and efficacy documentation for herbal medicinal products; traditional-use registration pathway for long-used herbs

Stability and shelf-life studies:

- **What is tested:** Marker/actives content, appearance, odour, moisture, microbial load, TLC fingerprint — at intervals (e.g., 0, 3, 6, 9, 12, 24 months).
- **Real-time:** Product stored at normal recommended conditions for the whole claimed shelf life — the most reliable proof.
- **Accelerated:** Product stored at higher temperature/humidity (e.g., 40°C/75% RH) for 6 months — if it stays good under stress, normal shelf life is predicted (commonly used to support 2-year claims; exact conditions follow ICH/AYUSH guidance).
- **Why it matters for herbals:** Plant extracts can lose actives, absorb moisture, or grow mould — shelf life must be PROVEN, not guessed.

Forensic pharmacognosy — Cannabis and Opium (table):

Drug	Source plant	Identification features (textbook)
Cannabis (Ganja/Charas/Bhang)	*Cannabis sativa*	Microscopy: cystolithic hairs (bear-claw hairs with calcium carbonate), glandular trichomes; chemical: Duquenois–Levine colour test (purple colour); TLC for cannabinoids
Opium (Afeem)	*Papaver somniferum* (poppy capsules/latex)	Dried latex lumps; microscopy of capsule fragments; chemical: test for meconic acid (characteristic of opium); TLC for morphine/codeine

Role in law: A forensic pharmacognosist examines the seized material, runs these tests, and gives an expert report/court testimony confirming whether the material is a controlled narcotic — this decides the legal case.

8.5 Infographic concept box — Chapter 8

Three rule books (WHO globe, AYUSH lamp, EU stars) on a shelf → arrow to a calendar marked "stability tested → expiry date fixed" → arrow to a magnifier over a leaf labelled "forensic: Cannabis or Opium? — science answers for the court."

8.6 Pharmacy relevance

- Pharmacists must respect expiry dates — especially for herbals, where actives fade.
- Forensic awareness helps pharmacists recognize and report suspicious trafficking of controlled plant drugs.

8.7 India context

Cannabis (ganja/charas) and opium are controlled under India's NDPS Act, 1985; only licensed cultivation (e.g., government opium farms for medicinal use) is legal. AYUSH pharmacopoeias and Schedule E1 list which AYUSH drugs are poisonous/controlled.

8.8 Key points

1. WHO = global QC/GACP guidance; AYUSH = Indian pharmacopoeias + GMP; EU = strict documentation + traditional-use pathway.
2. Stability: real-time (normal conditions, full period) + accelerated (stress conditions, predictive).
3. Forensic pharmacognosy identifies Cannabis (cystolithic hairs, Duquenois–Levine test) and Opium (meconic acid test) for legal cases.

8.9 Common confusions

- **GACP vs GMP:** GACP = Good Agricultural and Collection Practices (FARM stage, WHO); GMP = Good Manufacturing Practices (FACTORY stage, e.g., Schedule T).
- **Bhang vs ganja/charas (legal):** In India, bhang (leaves) has a different traditional/legal status from ganja/charas under the NDPS framework — details are legal, so state cautiously.

8.10 Common mistakes

- Writing "stability = just checking expiry date" — stability studies GENERATE the data that justifies the expiry date.
- Forgetting that forensic identification needs BOTH microscopy and chemical confirmation.

8.11 Mnemonics

- Guideline trio: "**W**e **A**ll **E**xpect quality" — WHO, AYUSH, EU.
- Cannabis microscopy: "**C**ystolithic **C**law **C**annabis" — cystolithic (bear-claw) hairs = Cannabis.

8.12 Exam summary

WHO, AYUSH, and EU guidelines govern QC of herbal medicines (identity, purity, content, contaminants). Stability studies (real-time at normal conditions; accelerated at stress conditions) establish shelf life, which must be proven for herbals. Forensic pharmacognosy applies pharmacognostic identification to legal cases — Cannabis identified by cystolithic hairs and Duquenois–Levine test; Opium by meconic acid test — supporting narcotics law enforcement.

8.13 One-minute revision

WHO/AYUSH/EU = rule books → stability proves shelf life → forensic botany catches Cannabis (hairs + purple test) and Opium (meconic acid) for the courts.

8.14 Exam questions

Short answers:

1. Expand AYUSH and GACP.
2. Differentiate real-time and accelerated stability studies.
3. Name the microscopic feature characteristic of Cannabis.
4. Which chemical test indicates Opium?

Long answers:

1. Summarize the WHO, AYUSH, and EU guidelines on quality control of herbal medicines.
2. Explain stability and shelf-life studies of herbal medicines.
3. Write a note on forensic pharmacognosy with reference to Cannabis and Opium.

MCQs:

1. GACP guidelines are issued by: (a) EU (b) WHO (c) AYUSH (d) IPC — **Answer: (b)**
2. Cystolithic hairs are characteristic of: (a) Opium (b) Cannabis (c) Vasaka (d) Neem — **Answer: (b)**
3. Meconic acid test is used to identify: (a) Cannabis (b) Opium (c) Turmeric (d) Amla — **Answer: (b)**
4. Accelerated stability studies are done at: (a) normal storage (b) stress (high temp/humidity) (c) freezing (d) vacuum — **Answer: (b)**

Viva:

1. Why do herbal medicines especially need stability studies?
2. What is the difference between GACP and GMP?

Application-based:

1. Police seize dried plant material suspected to be ganja. As a forensic pharmacognosist, list the examinations you would perform and the conclusion each supports.

8.15 References

1. Waldesch, F. G. Herbal Medicinal Products. CRC Press.
2. Indian Herbal Pharmacopoeia. Indian Drug Manufacturers' Association.
3. World Health Organization. Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants.
4. Drugs and Cosmetics Act and Rules (India). Government of India.

COMBINED REFERENCES

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