B.PHARM THEORY

BP401T HERBAL DRUG TECHNOLOGY

Unit V — Regulatory Requirements of Herbal Drugs

Pills & Python Notes

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

Syllabus coverage: Unit V (8 hours).

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UNIT V — REGULATORY REQUIREMENTS OF HERBAL DRUGS AND BOTANICALS

CHAPTER 11 — REGULATORY FRAMEWORK IN INDIA FOR HERBAL AND ASU MEDICINES

11.1 Learning Objectives

1. Describe the regulatory framework in India for herbal and ASU medicines.
2. Explain the role of regulatory bodies, ASU DTAB, and ASU DCC.
3. Explain Schedule T (GMP for ASU drugs) and Schedule E1 (poisonous AYUSH drugs).
4. Summarize the Drugs and Cosmetics Act provisions for herbal/ASU medicines: registration, trade, export.
5. Explain the concepts of phytopharmaceuticals and Ayush Aahara.

11.2 Definitions

- **ASU drugs:** Ayurveda, Siddha, and Unani medicines — India's traditional systems, regulated separately from modern (allopathic) drugs.
- **Regulatory framework:** The complete set of laws, rules, bodies, and procedures that control how medicines are made and sold.
- **GMP (Good Manufacturing Practices):** The legally required quality rules for factories (clean premises, trained staff, records, testing).
- **Phytopharmaceutical:** A relatively new Indian regulatory category — a purified, standardized fraction of a medicinal plant (with defined markers) regulated with modern scientific data, bridging traditional knowledge and modern drug standards.
- **Ayush Aahara:** Ayurveda-based food products regulated as a distinct category, bridging traditional diet wisdom with modern food safety law.

11.3 Key Terminology

Term	Simple meaning
DTAB	Drugs Technical Advisory Board — top technical advisory body under the Act
DCC	Drugs Consultative Committee — coordination body between Centre and States
Schedule T	The rule book of GMP specifically for ASU drug factories
Schedule E1	The official list of poisonous substances used in AYUSH
AYUSH Ministry	Government of India ministry for traditional medicine systems

11.4 Explanation

Technical concept: Herbal and ASU medicines in India are regulated under the Drugs and Cosmetics Act, 1940 and Rules, 1945, through AYUSH regulatory bodies (ASU DTAB for technical advice, ASU DCC for Centre–State coordination), GMP requirements (Schedule T), a poisonous-drugs list (Schedule E1), and licensing procedures for manufacture, sale, and export; newer concepts like phytopharmaceuticals and Ayush Aahara bridge traditional knowledge with modern science.

Simple explanation: Just like allopathic medicines need a licence, Ayurvedic/Siddha/Unani medicines also need licences — but from a separate AYUSH track. The factory must follow GMP (Schedule T), poisonous ingredients are listed and specially controlled (Schedule E1), and experts advise the government through two committees (DTAB and DCC).

a) Role of regulatory bodies:

Body	Role (simple)
Ministry of AYUSH	Policy-making for traditional medicine; promotes and regulates the sector
State AYUSH Licensing Authorities	Grant manufacturing licences for ASU drugs in each state
Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H)	Publishes quality standards (Ayurvedic/Siddha/Unani Pharmacopoeias)
Central/State drug inspectors	Inspect factories and shops; draw samples for testing

b) ASU DTAB (Ayurveda, Siddha and Unani Drugs Technical Advisory Board): The top technical advisory committee for ASU drugs — advises the government on technical/scientific matters like standards, testing methods, and safety of ASU medicines. (Think: the "professor panel" for traditional drugs.)

c) ASU DCC (Drugs Consultative Committee for ASU drugs): The coordination committee that brings Centre and States together so that ASU drug regulation is uniform across India. (Think: the "coordination meeting" between Delhi and the states.)

d) Schedule T — GMP requirements for ASU drugs: A dedicated schedule in the Drugs and Cosmetics Rules laying down Good Manufacturing Practices for Ayurvedic, Siddha, and Unani medicines — covering factory premises, hygiene, equipment, raw-material control, manufacturing records, and quality control. A licence requires compliance with Schedule T.

e) Schedule E1 — Poisonous drugs listed under AYUSH: The official list of poisonous substances of plant/mineral origin recognized in AYUSH practice (examples from the traditional lists include aconite/*Vatsanabha*, datura, nux-vomica/*Kuchla*, opium, cannabis preparations used in classical formulations). Products containing them face stricter controls — labelling warnings, qualified supervision, and record-keeping. (Cautious note: always refer to the current official Schedule E1 text for the exact listed entries.)

f) Drugs and Cosmetics Act — provisions for herbal/ASU medicines:

- **Registration/licensing:** No ASU medicine may be manufactured for sale without a licence from the State Licensing Authority; the application must show GMP (Schedule T) compliance, qualified technical staff, and proper premises.
- **Trade (sale/distribution):** Sale licences, proper labelling (name, composition, licence number, expiry), and storage conditions are legally required; inspectors can sample and test.
- **Export:** Export-oriented units must meet the importing country's standards (e.g., EU/US requirements) plus Indian law; AYUSH issues export-related certifications (such as Certificates of Pharmaceutical Product) as applicable.
- Classical ASU formulations (described in authoritative texts) and patent/proprietary ASU medicines follow defined approval pathways, with safety/efficacy data requirements increasing for new proprietary products.

g) Phytopharmaceuticals and Ayush Aahara — bridging tradition with modern science:

- **Phytopharmaceuticals:** A regulatory category introduced to cover purified, standardized plant fractions evaluated with modern scientific data (quality, safety, and efficacy studies) — it lets a traditional plant ingredient meet pharmaceutical-grade standards, creating a bridge between Indian traditional knowledge and modern drug development.
- **Ayush Aahara:** Ayurveda-inspired food products brought under food regulation with AYUSH-defined parameters — bridging traditional dietary wisdom (like classical *pathya*/diet concepts) with modern food safety law.
- **The bridge idea:** Both concepts take something from India's traditional knowledge systems and give it a modern, science-backed, legally recognized form — so traditional wisdom can reach global markets with credibility.

11.5 Infographic concept box — Chapter 11

A building labelled "Drugs & Cosmetics Act" with floors: Ground floor — State Licensing Authority (licences); First floor — Schedule T (GMP factory); Second floor — Schedule E1 (poison list, locked cabinet); Roof — DTAB (advisors) + DCC (coordinators). A bridge from the building to a modern laboratory labelled "Phytopharmaceuticals & Ayush Aahara — tradition meets science."

11.6 Pharmacy relevance

- Every pharmacist working with AYUSH products must know licensing, Schedule T, and labelling law — inspections are real and penalties exist.
- Understanding phytopharmaceuticals helps pharmacists explain why some herbal products carry stronger scientific dossiers than classical churnas.

11.7 India context

India is the global home of Ayurveda; the AYUSH Ministry (created 2014) and the separate ASU regulatory track reflect the scale of this industry — from village vaidya pharmacies to large exporters.

11.8 Key points

1. ASU drugs are regulated under the Drugs and Cosmetics Act via a dedicated AYUSH track.
2. ASU DTAB = technical advice; ASU DCC = Centre–State coordination.
3. Schedule T = GMP for ASU factories; Schedule E1 = poisonous AYUSH substances list.
4. Manufacture needs a state licence; sale needs proper labelling; export needs importing-country compliance.
5. Phytopharmaceuticals and Ayush Aahara bridge traditional knowledge with modern science.

11.9 Common confusions

- **DTAB vs DCC:** DTAB ADVISES on technical matters; DCC COORDINATES between Centre and States.
- **Schedule T vs Schedule E1:** T = HOW to manufacture (GMP); E1 = WHICH substances are poisonous (list).
- **Phytopharmaceutical vs classical Ayurvedic drug:** Phytopharmaceutical = purified standardized fraction with modern data dossier; classical drug = traditional formulation as per texts.

11.10 Common mistakes

- Saying ASU drugs need no licence — they DO, from the State Licensing Authority.
- Mixing up AYUSH Ministry (policy) with PCIM&H (pharmacopoeia standards).

11.11 Mnemonics

- "**T** for **T**idy factory (GMP); **E1** for **E**xtremely poisonous list."
- "**D**TAB **D**ecides technical; **D**CC **C**oordinates."

11.12 Exam summary

India regulates herbal/ASU medicines under the Drugs and Cosmetics Act through AYUSH bodies: the Ministry of AYUSH (policy), State Licensing Authorities (licences), PCIM&H (pharmacopoeial standards), ASU DTAB (technical advice), and ASU DCC (Centre–State coordination). Schedule T lays down GMP for ASU drug manufacture; Schedule E1 lists poisonous AYUSH substances under special control. Manufacture, sale, and export all need licences and legal compliance. Phytopharmaceuticals (standardized plant fractions with modern scientific dossiers) and Ayush Aahara (Ayurveda-based foods) bridge Indian traditional knowledge with modern science.

11.13 One-minute revision

Act → AYUSH track → DTAB advises, DCC coordinates → Schedule T (GMP factory) → Schedule E1 (poison list) → licence to make/sell/export → phytopharmaceuticals & Ayush Aahara = tradition + science.

11.14 Exam questions

Short answers:

1. Expand ASU, DTAB, DCC.
2. What is Schedule T?
3. What is Schedule E1?
4. Define phytopharmaceutical and Ayush Aahara.

Long answers:

1. Describe the regulatory framework in India for herbal and ASU medicines, covering regulatory bodies, ASU DTAB, and ASU DCC.
2. Explain Schedule T and Schedule E1 with their significance.
3. Summarize the Drugs and Cosmetics Act provisions for herbal/ASU medicines regarding registration, trade, and export.
4. Write a note on phytopharmaceuticals and Ayush Aahara as bridges between traditional knowledge and modern science.

MCQs:

1. GMP requirements for ASU drugs are given in: (a) Schedule T (b) Schedule E1 (c) Schedule X (d) Schedule H — **Answer: (a)**
2. ASU DTAB is: (a) a licensing office (b) a technical advisory board (c) a factory (d) a court — **Answer: (b)**
3. Schedule E1 lists: (a) GMP rules (b) poisonous AYUSH substances (c) sweeteners (d) cosmetic colours — **Answer: (b)**
4. Ayush Aahara relates to: (a) surgical tools (b) Ayurveda-based food products (c) antibiotics (d) vaccines — **Answer: (b)**

Viva:

1. Who grants a manufacturing licence for an Ayurvedic medicine?
2. How does a phytopharmaceutical differ from a classical churna legally and scientifically?

Application-based:

1. A startup wants to manufacture and export a standardized Bacopa capsule. List the regulatory steps and bodies involved.

11.15 References

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