# Industrial Pharmacognosy

Unit II

Commercial Production and Standardization of Botanicals

## Pills & Python Notes

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

Syllabus coverage: Unit II (10 hours).

CHAPTER 3

# Quality Facilities & Commercial Production of Extracts and Oils

## 3.1 Learning Objectives

1. Explain the significance of AYUSH/WHO-GMP, GLP and USFDA-compliant facilities.
2. Describe commercial production of standardized extracts of Coleus, Amla, Turmeric, Ashwagandha, Senna.
3. Describe commercial production and standardization of volatile oils (eucalyptus, lavender, peppermint, rosemary).

**DEFINITIONS**

- **GMP (Good Manufacturing Practices):** Rules that ensure medicines are made cleanly, consistently and with correct identity, purity and strength — "say what you do, do what you say, and write it down."
- **WHO-GMP:** GMP standards recognized by the World Health Organization; needed for export credibility.
- **AYUSH GMP (Schedule T):** GMP rules under India's Drugs and Cosmetics Rules specifically for Ayurveda, Siddha and Unani drugs.
- **GLP (Good Laboratory Practices):** Rules for laboratories so that test results are reliable and traceable.
- **USFDA-compliant facility:** A factory that meets the United States Food and Drug Administration's standards — the toughest quality bar, opening the US market.
- **Standardized extract:** A plant extract adjusted so that every batch contains a fixed amount of marker active compound(s) (e.g., "turmeric extract standardized to 95% curcuminoids").

## 3.3 Terminology

| Term | Simple meaning |
|---|---|
| Marker compound | A known chemical used to check extract quality (e.g., curcumin for turmeric) |
| Batch | One production lot made at one time |
| SOP | Standard Operating Procedure — written step-by-step method |
| Volatile oil | Essential oil; evaporates easily, carries plant fragrance |
| Steam distillation | Passing steam through plant material to carry out the volatile oil |

## 3.4 Explanation — Why compliant facilities matter

Technical concept: Herbal products vary naturally (soil, season, region). Only a GMP/GLP system — validated processes, trained staff, calibrated equipment, documented batches — can make every bottle the same quality.

Simple explanation: Without GMP, one bottle of ashwagandha capsules may be strong and the next may be just coloured powder. GMP is the promise system that every batch is tested and identical. WHO-GMP opens export markets; USFDA compliance opens the USA.

Key takeaway: Quality is not tested into a product at the end — it is built in at every step, which is what GMP/GLP facilities do.

## 3.5 Flowchart — Commercial production of a standardized extract

1. **Sourcing:** authenticated raw herb (GACP farms; identity checked)
2. **Cleaning, drying, grinding** to uniform particle size
3. **Extraction:** solvent (water/ethanol) in extractor — maceration, percolation or Soxhlet at industrial scale
4. **Filtration & concentration:** under vacuum (to protect heat-sensitive actives)
5. **Drying:** spray drying / vacuum drying to powder
6. **Standardization:** assay marker compound; blend batches to hit the target % (e.g., 2.5% withanolides)
7. **QC testing:** identity, purity, heavy metals, microbial limits, aflatoxins (GLP lab)
8. **Packing, labelling, batch records** → market

## 3.6 Commercial extracts with clinical relevance (table)

| Extract | Marker standardized to (typical industry targets — confirm current specs) | Clinical relevance (simple) |
|---|---|---|
| **Coleus** (Coleus forskohlii) | Forskolin | Weight management, traditional heart/respiratory support; widely exported extract |
| **Amla** | Vitamin C / tannins / gallic acid | Antioxidant, Chyawanprash base, immunomodulator |
| **Turmeric** | Curcuminoids (commonly ~95% in high-strength extracts) | Anti-inflammatory, antioxidant; huge global supplement market |
| **Ashwagandha** | Withanolides | Antistress/adaptogen; one of the top-selling botanicals worldwide |
| **Senna** | Sennosides | Stimulant laxative; official in IP/BP/USP |

## 3.7 Commercial production & standardization of volatile oils

Technical concept: Volatile oils are obtained mainly by steam distillation (or hydro-distillation, expression for citrus). Standardization checks odour, specific gravity, refractive index, optical rotation and GC fingerprint.

| Oil | Plant part | Key constituents | Simple production note |
|---|---|---|---|
| **Eucalyptus oil** | Leaves of Eucalyptus globulus | 1,8-cineole (eucalyptol) | Steam distillation of leaves; cineole % is the quality marker |
| **Lavender oil** | Flowers of Lavandula spp. | Linalool, linalyl acetate | Steam distillation of flowering tops; prized in aromatherapy |
| **Peppermint oil** | Leaves of Mentha piperita | Menthol, menthone | Steam distillation; menthol content decides price |
| **Rosemary oil** | Leaves of Rosmarinus officinalis | 1,8-cineole, camphor, α-pinene | Steam distillation; used in food, cosmetics, pharma |

**Standardization tests for volatile oils (simple):** appearance/odour, specific gravity, refractive index, optical rotation, solubility in alcohol, and GC profile matching a reference — "the oil's fingerprint must match the standard fingerprint".

## 3.8 Diagrams (describe for drawing)

- **Diagram 1 — Steam distillation unit:** boiler → steam pipe → still (plant material) → condenser (cold water in/out) → separator (oil floats on water) → collection.
- **Diagram 2 — Standardization loop:** extract → assay marker → too low? blend with stronger batch → re-assay → release.

**INFOGRAPHIC CONCEPT**

**From Leaf to Label — the Quality Chain** GACP farm → authenticated herb → GMP extraction → vacuum concentration → spray-dried powder → marker assay (GLP lab) → batch blending to target % → heavy-metal & micro testing → packed with batch number. **Slogan: "Quality is built in, not tested in."** WHO-GMP = export passport; USFDA compliance = USA market key.

**EXAMPLES**

1. A turmeric extract labelled "95% curcuminoids" means 950 mg of curcuminoids per gram — blended from stronger and weaker batches.
2. Peppermint oil from a Kannauj-style distillery is graded by menthol %; higher menthol = higher price.
3. An ashwagandha capsule brand prints "standardized to 2.5% withanolides" — that is the marker promise.

**ANALOGIES**

- **Standardized extract = "fixed-recipe chai":** every cup tastes the same because the recipe (marker %) is fixed, even if the tea leaves differ slightly.
- **GMP = traffic rules:** everyone may drive differently, but rules keep every journey safe.

**PHARMACY RELEVANCE**

Industrial pharmacists run extraction, QC and documentation; a pharmacist must read a Certificate of Analysis (CoA) and know what marker %, heavy-metal limits and microbial limits mean.

**INDIA CONTEXT**

India's Schedule T (AYUSH GMP) is mandatory for licensed Ayurvedic manufacturers; many Indian herbal companies are WHO-GMP and some are USFDA-audited, which is why Indian extracts reach US/EU shelves.

**KEY POINTS**

- GMP/GLP/USFDA compliance = consistent quality + market access.
- Standardized extract = fixed marker % in every batch.
- 5 commercial extracts: Coleus (forskolin), Amla (vitamin C/tannins), Turmeric (curcuminoids), Ashwagandha (withanolides), Senna (sennosides).
- 4 volatile oils: eucalyptus, lavender, peppermint, rosemary — made by steam distillation, standardized by physical constants + GC fingerprint.

**COMMON CONFUSIONS**

- **GMP vs GLP:** GMP = factory rules; GLP = laboratory rules.
- **Standardized vs whole herb powder:** standardized extract guarantees marker %; plain powder does not.
- **Volatile oil vs fixed oil:** volatile oils evaporate (fragrance); fixed oils do not (e.g., coconut oil).

**COMMON MISTAKES**

- Saying "steam distillation" for all oils — citrus oils are usually expressed (cold-pressed).
- Confusing marker compound with "the only active" — it is a quality indicator, others may also act.
- Writing exact % figures as universal — always add "typical industry target; confirm current specification".

**MNEMONIC**

- 5 extracts: **"CATAS"** — **C**oleus, **A**mla, **T**urmeric, **A**shwagandha, **S**enna ("CAT ASk for quality").
- 4 oils: **"ELPR"** — **E**ucalyptus, **L**avender, **P**eppermint, **R**osemary.

**EXAM SUMMARY**

AYUSH/WHO-GMP, GLP and USFDA-compliant facilities ensure herbal products are consistent, pure and export-worthy. Commercial standardized extracts (Coleus, Amla, Turmeric, Ashwagandha, Senna) are made by extraction → concentration → drying → marker-based blending. Volatile oils (eucalyptus, lavender, peppermint, rosemary) are produced mainly by steam distillation and standardized by physical constants and GC fingerprint.

**ONE-MINUTE REVISION**

- GMP = factory quality rules; GLP = lab quality rules.
- Standardized extract = fixed marker % every batch.
- CATAS: Coleus, Amla, Turmeric, Ashwagandha, Senna.
- ELPR oils: Eucalyptus, Lavender, Peppermint, Rosemary.
- Steam distillation → separator → GC fingerprint.

## 3.20 Exam questions

**Short answer:**

1. Define standardized extract with an example.
2. Differentiate GMP and GLP.

3. Name the marker compounds of turmeric and senna extracts.
4. How is peppermint oil produced commercially?

**Long answer:**

5. Explain the significance of AYUSH/WHO-GMP, GLP and USFDA-compliant facilities in herbal product manufacture.
6. Describe the commercial production and standardization of volatile oils with examples.

**MCQs:**

7. Senna extract is standardized for: (a) Curcumin (b) Sennosides (c) Forskolin (d) Menthol — **Answer: (b)**
8. Coleus extract marker is: (a) Withanolides (b) Forskolin (c) Cineole (d) Gallic acid — **Answer: (b)**
9. Schedule T of the Drugs and Cosmetics Rules is GMP for: (a) Allopathy (b) ASU drugs (c) Cosmetics (d) Devices — **Answer: (b)**
10. Eucalyptus oil quality is judged mainly by: (a) Menthol % (b) 1,8-cineole % (c) Linalool % (d) Camphor % — **Answer: (b)**

**Viva:**

11. Why do we blend batches during standardization?
12. What is a Certificate of Analysis?

**Application-based:**

13. A buyer rejects your eucalyptus oil lot. List four tests you would run before disputing the rejection.

CHAPTER 4

# Preparation & Standardization of AYUSH Formulations

## 4.1 Learning Objectives

1. Name the classical AYUSH dosage forms in the syllabus.
2. Describe the preparation method of each: Arista/Asava, Gutika/Habb, Churna/Shafoof, Arq, Sharbat, Tincture, Bhasma.
3. Explain how each is standardized.

**DEFINITIONS**

- **Arista / Asava:** Fermented herbal liquids (like herbal wines without distillation) — Arista is made by fermenting a decoction (boiled extract); Asava by fermenting fresh juice/infusion. Both contain self-generated alcohol (~5–10%) which acts as preservative.
- **Gutika (Vati) / Habb (Unani):** Herbal tablets/pills — powdered herbs rolled into pills with a binder.
- **Churna / Shafoof (Unani):** Fine herbal powders for internal use.
- **Arq:** A distillate — aromatic water obtained by distilling herbs with water (e.g., Arq Gulab = rose water).
- **Sharbat:** Herbal syrup — sugar-based sweet liquid with herbal extract.
- **Tincture:** Alcoholic extract of a herb (e.g., 1 part herb in 5–10 parts alcohol).
- **Bhasma:** Calcined metal/mineral preparation — metals purified, triturated with herbs and heated repeatedly until a fine ash; a specialized Ayurvedic dosage form.

## 4.3 Terminology

| Term | Simple meaning |
|---|---|
| Sandhana (fermentation) | The process that makes Arista/Asava |
| Dravya | The herbal ingredient |
| Shodhana | Purification process (especially before Bhasma making) |
| Marana | The calcination/heating step in Bhasma preparation |
| Decoction (Kwatha) | Herbs boiled in water and reduced |

## 4.4 Explanation — Preparation methods (simple step sequences)

**Arista (e.g., Ashokarista) / Asava (e.g., Kumariasava):**

1. Prepare decoction (Arista) or juice/infusion (Asava) of the herbs.
2. Add sweetening/fermenting agents (jaggery, honey) and prakshepa dravyas (spices).
3. Transfer to a clean vessel, close, keep for fermentation (Sandhana) for the prescribed days.
4. Filter the clear liquid; the self-generated alcohol preserves it.

**Gutika/Habb (e.g., herbal digestive pills):**

1. Powder the herbs finely (Churna).

2. Mix with binder (gum, honey, jaggery).
3. Roll into pills of uniform size; dry in shade.

**Churna/Shafoof (e.g., Triphala churna):**

1. Clean, dry and powder each herb separately.
2. Sieve through fine mesh; mix uniformly.
3. Pack airtight (powders absorb moisture fast).

**Arq (e.g., Arq Gulab, Arq Ajwain):**

1. Soak the herb in water.
2. Distil; collect the aromatic distillate.
3. Store in cool, airtight containers (aroma escapes easily).

**Sharbat (e.g., Sharbat-e-Anar):**

1. Prepare herbal decoction/juice.
2. Add sugar to make syrup consistency; boil briefly.
3. Cool, add permitted preservatives/flavours; bottle.

**Tincture:**

1. Coarse powder of herb + alcohol (ethanol–water) in fixed ratio.
2. Macerate/percolate for the prescribed time.
3. Filter; adjust to volume.

**Bhasma (e.g., Swarna bhasma — gold; Abhrak bhasma — mica):**

1. **Shodhana:** purify the metal/mineral.
2. **Bhavana:** triturate with herbal juices.
3. **Marana/Puta:** heat in sealed earthen crucibles, repeatedly, till fine ash passes classical tests (e.g., rekhapurnata — fills finger lines; varitara — floats on water).

## 4.5 Standardization of AYUSH formulations (table)

| Formulation | Key quality tests (simple) |
|---|---|
| Arista/Asava | Alcohol content, total solids, pH, TLC fingerprint, microbial limits |
| Gutika/Habb | Weight uniformity, hardness, disintegration, assay of marker |
| Churna/Shafoof | Particle size/sieve test, loss on drying, total ash, extractive values, TLC |
| Arq | Clarity, odour, pH, specific gravity, TLC/GC of volatile components |
| Sharbat | Total solids/sugar %, pH, viscosity, microbial limits |
| Tincture | Alcohol content, extractive value, TLC fingerprint |
| Bhasma | Classical tests (rekhapurnata, varitara) + modern: particle size, XRD, heavy-metal safety within limits |

**INFOGRAPHIC CONCEPT**

Note: exact limits are given in the Ayurvedic/Unani Pharmacopoeias — always "as per the pharmacopoeial monograph".

## 4.6 Diagrams (describe for drawing)

- **Diagram 1 — Arista fermentation vessel:** labelled pot with decoction + jaggery + herbs, lid, "ferment 30 days" note, filter, bottle.
- **Diagram 2 — Bhasma puta:** crucible with pellets inside, sealed, heap of cow-dung cakes around, flame; arrow "repeat puta cycles".

**INFOGRAPHIC CONCEPT**

**Seven Classical Forms, One Quality Goal** Arista/Asava = fermented liquids (self-made alcohol preserves) Gutika/Habb = herbal pills | Churna/Shafoof = fine powders Arq = distilled aromatic water | Sharbat = herbal syrup Tincture = alcohol extract | Bhasma = calcined mineral ash **Every form has pharmacopoeial tests — tradition + testing = trust.**

**EXAMPLES**

1. Ashokarista — Arista used traditionally for women's health.
2. Triphala churna — the most famous Churna (amla + baheda + haritaki).
3. Arq Gulab — rose distillate used as eye/skin tonic.

**ANALOGIES**

- **Arista fermentation = making idli batter:** natural fermentation by microbes, time and warmth do the work.
- **Bhasma = "metal to micro-powder":** like grinding a stone to talcum fineness by repeated heating and grinding.

**PHARMACY RELEVANCE**

Pharmacists in AYUSH industry prepare, test and dispense these forms; in retail, you must store them right (Arq away from heat, Churna airtight) and counsel on dose and duration.

**INDIA CONTEXT**

These dosage forms are made by thousands of licensed AYUSH pharmacies across India under Schedule T GMP; the Ayurvedic Pharmacopoeia of India (API) and Unani Pharmacopoeia of India (UPI) give official monographs.

**KEY POINTS**

- 7 forms: Arista/Asava, Gutika/Habb, Churna/Shafoof, Arq, Sharbat, Tincture, Bhasma.
- Arista = from decoction; Asava = from juice/infusion.
- Bhasma = purified + triturated + repeatedly calcined metal/mineral.
- Each form has specific pharmacopoeial standardization tests.

**COMMON CONFUSIONS**

- **Arista vs Asava:** Arista starts from a decoction; Asava from fresh juice/infusion.
- **Gutika vs Churna:** Gutika is a pill (with binder); Churna is loose powder.
- **Bhasma vs Churna:** Bhasma is calcined mineral/metal ash, not just herb powder.

**COMMON MISTAKES**

- Calling Bhasma a "herbal powder" — it is a processed mineral/metal preparation.
- Saying Arq is "just flavoured water" — it is a distillate with volatile actives.
- Forgetting that Arista/Asava contain self-generated alcohol (relevant for counselling).

**MNEMONIC**

- 7 forms: **"A G C A S T B"** — **A**rista/Asava, **G**utika, **C**hurna, **A**rq, **S**harbat, **T**incture, **B**hasma ("Ayurveda Gives Complete And Safe Traditional Blessings").

**EXAM SUMMARY**

Classical AYUSH formulations: Arista/Asava (fermented liquids), Gutika/Habb (pills), Churna/Shafoof (powders), Arq (distillates), Sharbat (syrups), Tincture (alcoholic extracts), Bhasma (calcined mineral preparations). Each is prepared by a defined classical method and standardized by pharmacopoeial tests (alcohol content, ash values, TLC fingerprints, classical bhasma tests).

**ONE-MINUTE REVISION**

- A G C A S T B: 7 classical forms.
- Arista = decoction fermented; Asava = juice fermented.
- Bhasma: shodhana → bhavana → marana (puta).
- Tests: alcohol %, ash, TLC, classical bhasma tests.

## 4.18 Exam questions

**Short answer:**

1. Differentiate Arista and Asava.
2. What is Bhasma? Name the three main steps of its preparation.
3. How is Arq prepared?
4. List the standardization tests for Churna.

**Long answer:**

5. Describe the preparation and standardization of Arista/Asava and Gutika.
6. Write a note on Bhasma: preparation, classical tests and modern standardization.

**MCQs:**

7. Self-generated alcohol is characteristic of: (a) Churna (b) Arista (c) Arq (d) Bhasma — **Answer: (b)**
8. Rekhapurnata test is for: (a) Tincture (b) Sharbat (c) Bhasma (d) Gutika — **Answer: (c)**
9. Triphala is a: (a) Gutika (b) Churna (c) Arista (d) Arq — **Answer: (b)**
10. Rose water (Arq Gulab) is a: (a) Fermented liquid (b) Distillate (c) Syrup (d) Calcined ash — **Answer: (b)**

**Viva:**

11. Why must Churna be packed airtight?

12. What is the preservative principle in Arista?

**Application-based:**

13. A customer complains that an Arq smells weak. What two handling/storage faults would you suspect?

## UNIT II — REFERENCES

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