

## iii. Drugs and Cosmetics Act

### iii. Drugs and Cosmetics Act, 1940 in relation to ASU Drugs and Standardization of ASU drugs

The **Drugs and Cosmetics Act, 1940**, along with its **Rules (1945)** and subsequent amendments, forms the core legal framework governing **quality, safety, and efficacy** for **Ayurveda, Siddha, and Unani (ASU)** drugs in India. Over time, **Schedules** were added or updated to address unique challenges posed by traditional medicine systems, culminating in specialized provisions like **Schedule T** (GMP for ASU drugs) and **Schedule E(I)** (toxic substances). Below is a comprehensive overview of **(I) the Act, (II) key schedules, (III) standardization measures, (IV) a case study, and (V) future directions** for ensuring robust ASU drug regulation and acceptance.

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## Overview of the Drugs and Cosmetics Act, 1940

### Enactment and Objectives

#### 1. Year of Enactment

- **Drugs & Cosmetics Act** in 1940, **Rules** framed in 1945. Initially focused on allopathic drugs and cosmetics.

#### 2. Primary Objective

- Regulate **import, manufacture, distribution, and sale** of drugs and cosmetics in India. Protects consumers from substandard, adulterated, or mislabeled products.

#### 3. Key Amendments

- **1988**: Introduction of **Schedule M** for Good Manufacturing Practices (GMP) in allopathic pharmaceuticals.
- **2000**: Inclusion of **Schedule T** for GMP specific to Ayurveda, Siddha, Unani (ASU) medicines.

### Relevance to ASU Drugs

#### 1. Chapter IV-A

- Added via the 1964 Amendment, explicitly brought ASU drugs under the Act's purview.
- Mandates that ASU drugs meet certain standards of **quality, safety, and efficacy** in alignment with recognized Ayurvedic texts and schedules.

#### 2. Scope

- Governs licensing, labeling, and manufacturing compliance for classical and proprietary ASU formulations.
- Authorizes State Licensing Authorities to inspect ASU manufacturing units for adherence to **Schedule T**.

## Key Schedules Relevant to ASU Drugs

### Schedule T (GMP for ASU Medicines)

#### 1. Introduced: 2000.

#### 2. Scope:

- **Good Manufacturing Practices** for ASU drugs, ensuring standardized processes from raw material procurement to final packaging.
- Factories must comply to obtain a **Form 24D** manufacturing license for ASU.

#### 3. Requirements:

- **Infrastructure**: Separate areas for processing, storage, packaging, QC labs.
- **Raw Material Authentication**: E.g., morphological tests, DNA barcoding for herbs.
- **Quality Control**: Heavy metal testing (lead, arsenic), microbial limits, HPTLC for marker compounds.

## Schedule E(I) (Poisonous Substances)

- Purpose:**
  - Lists **toxic** or “poisonous” substances (metals, minerals, potent herbs) used in ASU formulations.
- Key Substances:**
  - Metals:** Lead ( $\leq 10$  ppm), Arsenic ( $\leq 3$  ppm), Cadmium ( $\leq 0.3$  ppm), Mercury in bhasma form, etc.
  - Toxic Herbs:** *Vatsanābha* (*Aconitum ferox*), *Kuchilā* (*Strychnos nux-vomica*).
- Compliance:**
  - Mandatory labeling of such ingredients, caution statements, and permissible limits.
  - Ensures post-processing (śodhana, marana) is properly executed to nullify toxicity.

## Schedule M (GMP for Pharmaceuticals)

- Amendment (1988)**
  - Introduced Good Manufacturing Practices for mainstream (allopathic) pharmaceuticals.
- Relevance to ASU**
  - Many ASU factories also handle near-allopathic segments or large-scale packaging, indirectly referencing Schedule M.
  - Merged with **Schedule T** considerations for a holistic GMP approach if producing both systems.

## Other Schedules

Schedule Purpose	Relevance to ASU
<b>G</b> Drugs requiring medical supervision	Rarely applies to classical ASU, but possible for advanced proprietary combos.
<b>H</b> Prescription drugs	If an ASU product contains substances requiring prescription.
<b>X</b> Psychotropic drugs	Excludes most ASU except in rare proprietary combos with narcotic elements.
<b>Y</b> Clinical trial guidelines (new drugs)	Governs trials for “new” ASU formulations or proprietary claims.

## Standardization of ASU Drugs

### Raw Material Standardization

- Botanical Authentication**
  - DNA barcoding or morphological checks are crucial for correct species identification (e.g., correct *Ashwagandha* vs. adulterant *Withania coagulans*).
- Heavy Metal Testing**
  - ICP-MS or AAS ensuring lead, arsenic, mercury within permissible limits per Schedule E(I).
  - Minimizes toxicity concerns, an ongoing critical point for global acceptance.

### Manufacturing Standardization

- GMP (Schedule T)**
  - Ensures hygienic production environment, in-process checks, validated SOPs for each classical or proprietary formula.
  - Integration with **API** (Ayurvedic Pharmacopoeia of India) monographs for raw drug authenticity.
- Formulation Protocols**
  - Classical references (Bhaiṣajya Ratnāvalī, Śārṅgadhara Saṃhitā) + modern QC tests (HPTLC for marker compounds, microbial checks).
  - E.g., *Chyawanprash* must maintain consistent vitamin C or phenolic content.

### Labeling and Packaging

- Mandatory Information**
  - Ingredient list, batch number, expiry date, dosage recommendations, anupāna, and any contraindications.
- Warning Statements**



- If containing toxic ingredients from Schedule E(I), labels must highlight caution (e.g., presence of *Vatsanābha* or heavy metals in bhasma form).

## Pharmacovigilance

### 1. National Pharmacovigilance Programme (since 2018)

- Tracks adverse drug reactions (ADRs) for AYUSH medicines across designated centers.
- Encourages real-time data capture to refine safety standards, reinforcing consumer trust.

## Intellectual Property and TKDL

### 1. TKDL (Traditional Knowledge Digital Library)

- Guards classical formulations from unauthorized patents (bio-piracy).
- Demonstrated success in turmeric (haldi) and neem cases.

## Case Study: Coronil Controversy (2020)

### 1. Context

- Patanjali's "Coronil" launched as a COVID-19 remedy, but lacked **Schedule Y**-compliant trials initially.

### 2. Outcome

- ICMR and the Ministry of AYUSH questioned the claims. Patanjali revised labeling as an "immunity booster" rather than "COVID cure."
- Highlighted the **imperative** for robust evidence, compliance with **Schedule T** (GMP) and **Schedule Y** (clinical trial norms) for new ASU products.

## Challenges and Future Directions

### Challenges

#### 1. Variability in Enforcement

- Some states have rigorous GMP inspections, others are less strict, leading to inconsistency.

#### 2. Global Acceptance

- Western regulatory bodies require advanced RCT data and uniform standardization of raw materials.

#### 3. Supply Chain Gaps

- Inconsistent herb quality if GACP guidelines are not followed, affecting final product efficacy.

### Future Directions

#### 1. Blockchain for Traceability

- Tracks raw materials from farm to pharmacy, ensuring no adulteration.

#### 2. AI-Driven QC

- Predictive analytics for contamination or supply chain disruptions, integrating real-time lab data.

#### 3. Global Harmonization

- Aligning with WHO and ISO guidelines fosters broader acceptance, bridging Indian pharmacopeial norms with EU/US regulations.

## Conclusion

The **Drugs and Cosmetics Act, 1940** and its **Rules (1945)**—especially **Schedules T** (GMP for ASU) and **Schedule E(I)** (toxic substances)—form the **regulatory bedrock** ensuring the **safety, quality, and efficacy** of **Ayurveda, Siddha, and Unani** medicines. By setting explicit standards (raw material authentication, heavy metal limits, advanced manufacturing protocols), they protect consumer welfare and fortify India's AYUSH sector for domestic and international markets. The integration of **modern QC tools**, **clinical trial guidelines** (Schedule Y), and **pharmacovigilance** fosters an **evidence-based** framework—sustaining classical authenticity while elevating **ASU** drug credibility in a globalized healthcare landscape.