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.

Table Of Contents

Add a header to begin generating the table of contents

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)

1. **Purpose**:
   - Lists **toxic** or "poisonous" substances (metals, minerals, potent herbs) used in ASU formulations.
2. **Key Substances**:
   - **Metals**: Lead (≤10 ppm), Arsenic (≤3 ppm), Cadmium (≤0.3 ppm), Mercury in bhasma form, etc.
   - **Toxic Herbs**: *Vatsanābha* (Aconitum ferox), *Kuchilā* (Strychnos nux-vomica).
3. **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)

1. **Amendment (1988)**
   - Introduced Good Manufacturing Practices for mainstream (allopathic) pharmaceuticals.
2. **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
G	Drugs requiring medical supervision	Rarely applies to classical ASU, but possible for advanced proprietary combos.
H	Prescription drugs	If an ASU product contains substances requiring prescription.
X	Psychotropic drugs	Excludes most ASU except in rare proprietary combos with narcotic elements.
Y	Clinical trial guidelines (new drugs)	Governs trials for "new" ASU formulations or proprietary claims.

Standardization of ASU Drugs

Raw Material Standardization

1. **Botanical Authentication**
   - DNA barcoding or morphological checks are crucial for correct species identification (e.g., correct *Ashwagandha* vs. adulterant *Withania coagulans*).
2. **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

1. **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.
2. **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

1. **Mandatory Information**
   - Ingredient list, batch number, expiry date, dosage recommendations, anupāna, and any contraindications.
2. **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.