Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/03th6x68

RULES AND REGULATIONS CONCERNED WITH AYURVEDIC PHARMACY IN INDIA

Dr. Ranjit Kumar [1]*, Dr. Prabhat Kumar Dwivedi [2]

[1*]MD Scholar, Department of Rasashastra & Bhaishajya Kalpana, Government Ayurvedic College and Hospital Patna, Bihar, India ranjitawake@gmail.com,Mob.No-8292474297
[2]Professor, Department of Rasashastra & Bhaishajya Kalpana, Government Ayurvedic College and Hospital Patna, Bihar, India drprabhatkd@gmail.com,Mob.No-9431172175

***Corresponding author:** Dr. Ranjit Kumar
*MD Scholar, Department of Rasashastra & Bhaishajya Kalpana, Government Ayurvedic College and Hospital Patna, Bihar, India ranjitawake@gmail.com,Mob.No-8292474297

INTRODUCTION

Ayurveda, one of the oldest systems of medicine, has gained renewed attention in recent years due to its holistic approach and minimal side effects. With this resurgence, Ayurvedic pharmaceuticals have emerged as a prominent industry. However, to ensure safety, efficacy, and quality, the Government of India has laid down comprehensive rules and regulations governing the manufacturing, marketing, and sale of Ayurvedic medicines. This article explores the major legal frameworks, regulatory bodies, and compliance procedures that govern Ayurvedic pharmacy in India.

The **Drugs and Cosmetics Act, 1940** is an important legislation enacted in India to regulate the **import, manufacture, distribution, and sale** of drugs and cosmetics. Its primary purpose is to ensure that **drugs and cosmetics sold in India are safe, effective, and conform to quality standards**.

- **Chapters**: 5 Main + 1 Special (ASU drugs)
- **Sections**: 33 main sections + 15 ASU-related = ~48 total
- **Rules**: Drugs and Cosmetics Rules, 1945 (170+ rules)
- **Schedules**: Over 20 Schedules (A to Y, M, H1, X, etc.)

TABLE-1 Detailed structure of drug and cosmetic act

Chapter I – Preliminary	
Section 1	Short title, extent, and commencement
Section 2	Application of other laws not barred
Section 3	Definitions (drug, cosmetic, manufacture, misbranded, etc.)
Section 3A	Construction of references to any law not in force or any functionary not in existence
Chapter II – DTAB and DCC	
Section 5	Drugs Technical Advisory Board (DTAB)
Section 6	Drugs Consultative Committee (DCC)
Section 7	Functions and procedures of DTAB
Chapter III – Import of Drugs and Cosmetics	
Section 10	Prohibition of import of certain drugs or cosmetics
Section 10A	Power to prohibit import of drugs and cosmetics in public interest

Section 11	Application of law relating to customs
Section 12	Power of Central Government to make rules
Section 13	Offences
Chapter IV – Manufacture, Sale, and Distribution	
Section 16	Standards of quality
Section 17	Misbranded drugs
Section 17A	Adulterated drugs
Section 17B	Spurious drugs
Section 18	Prohibition of manufacture and sale of certain drugs and cosmetics
Section 19	Pleas
Section 20 Section 21	Government analysts Inspectors
Section 22	Powers of inspectors
Section 23	Procedure for samples
Section 24	Reports from analysts
Section 25	Evidence
Section 26	Prosecution
Section 27	Penalty for manufacture/sale of drugs in violation
Section 27A	Penalty for cosmetics
Section 28	Penalty for not keeping documents
Section 28A	Penalty for not disclosing the name of the manufacturer
Section 29	Penalty for false warranty
Section 30	Penalty for subsequent offences
Section 31	Confiscation
Section 32	Cognizance of offences
Section 32A	Compounding of certain offences
Section 33	Power of Central Government to make rules
Chapter IVA – ASU Drugs	
Section 33A	Application of Chapter IV-A
Section 33B to 33O	Similar provisions as Chapter IV but specific to Ayurvedic, Siddha, and Unani drugs
Section 33C	Misbranded ASU drugs
Section 33D	Adulterated ASU drugs
Section 33E	Prohibition of manufacture/sale of ASU drugs not in accordance with the standards
Section 33G	Licensing for ASU drugs
Section 33H	Government Analysts (ASU)
Section 33I	Inspectors (ASU)
Section 33L	Penalties

TABLE-2 Detailed schedule of drug and cosmetic act

Schedule	Purpose
Schedule A	Forms for applications
Schedule B	Fees for testing
Schedule C & C(1)	Biological and special products
Schedule D	Exemptions
Schedule E	Poisonous substances (Ayurveda)
Schedule F	Blood banks, surgical dressings
Schedule G	Prescription drugs

Schedule H/H1/X	Controlled drugs
Schedule M	GMP Guidelines
Schedule Y	Clinical Trials

1. LEGAL FRAMEWORK GOVERNING AYURVEDIC PHARMACY

The Drug and Cosmetic Act (D&C Act) is structured into 6 Chapters and contains 38 Sections. Chapters IV and IVA are most relevant to Ayurvedic, Siddha, and Unani (ASU) medicines. The structure also includes critical schedules, such as Schedule 1A and 1B, which list authoritative texts, and Schedule 2, which outlines standards to be complied with.

Table: 3 - Chapter Overview

Chapter	Sections	Description
I	1–4	Introduction
II	5–7A	DTAB (Drugs Technical Advisory Board), CDL, DLC
III	8–15	Import of Drugs and Cosmetics
IV	16–33A	Manufacture and Sale
IVA	33B–33O	Provisions Relating to ASU Drugs
V	33P–38	Miscellaneous

SCHEDULES RELEVANT TO AYURVEDIC PHARMACY:

- Schedule 1A: Lists authoritative books for Ayurveda and Siddha.
- Schedule 1B: Lists authoritative books for Unani.
- Schedule 2: Defines the minimum standards for identity, purity, and strength of drugs.

1.1. Drugs and Cosmetics Act, 1940 (Chapter IV-A and IV-B)

- The Drugs and Cosmetics Act, 1940 is the principal legislation regulating Ayurvedic, Siddha, and Unani (ASU) drugs in India.
- Chapter IVA (Sections 33B to 33O) specifically deals with provisions relating to Ayurvedic, Siddha, and Unani drugs.
- It defines what constitutes a **'misbranded,' 'adulterated,'** or **'spurious'** Ayurvedic medicine.
- Provides legal backing for the quality control and licensing of Ayurvedic drug manufacturing units.

Definitions Under the Act

1. Misbranded Drugs (Section 17 / 33C for ASU)

A drug is deemed to be misbranded if:

- It is colored, coated, powdered, or polished to conceal damage or make it appear of better or greater therapeutic value than it actually is.
- It is not labelled properly as per the provisions of the Act and Rules.
- Its label or container bears false or misleading statements.

Example: A medicine claiming to “cure cancer” without evidence or approval is misbranded.

2. Adulterated Drugs (Section 17A / 33D for ASU)

A drug is considered adulterated if:

- It contains filthy, putrid, decomposed substances.
- It is prepared, packed, or stored under unsanitary conditions which may contaminate it.
- It contains any harmful or toxic substance that may render it injurious to health.
- Its container is made with poisonous or deleterious substances.
- It has been mixed or substituted with any substance to lower its quality or strength.

Example: A cough syrup stored in dirty containers or containing insect fragments is adulterated.

3. Spurious Drugs (Section 17B)

A drug is considered spurious if:

- It is manufactured under a name which belongs to another drug.
- It is an imitation or substitute of another drug or resembles another drug in a manner likely to deceive.
- It falsely claims to be the product of a manufacturer.
- Its label or packaging is copied to mislead consumers.

Example: A tablet labeled "Paracetamol" manufactured by a fake company using another brand's identity.

Also Applies to Cosmetics

Similar definitions apply to cosmetics under the same sections:

- Misbranded Cosmetics – Improper labelling or misleading claims.
- Adulterated Cosmetics – Contain harmful or contaminated substances.
- Spurious Cosmetics – Fake or counterfeited branded cosmetics.

Legal Implications:

Selling or manufacturing misbranded, adulterated, or spurious drugs/cosmetics is a criminal offense under the Act and may result in:

- Fines
- Imprisonment
- License cancellation
- Product seizure

TABLE-4 Detailed sections of drug and cosmetic act concerning ASU drugs

33B	Application of Chapter IVA
33C	ASU Drugs Technical Advisory Board (ASUDTAB)
33D	ASU Drugs Consultative Committee (ASUDCC)
33E-33EEA	Definitions and classification of Misbranded, Adulterated, and Spurious ASU drugs
33EEB	Regulations for manufacture and sale
33EEC	Prohibition of manufacture or sale
33EED	Power of Central Government to restrict manufacture/sale
33F-33O	Covering inspection, penalties, confiscation, government analysis, rule-making powers, and amendment authority

1.2. Drugs and Cosmetics Rules, 1945

- Rules 151 to 170 govern licensing, labeling, and Good Manufacturing Practices (GMP) for ASU drugs.
- Schedule T outlines GMP standards mandatory for Ayurvedic manufacturing.

2. LICENSING AND APPROVAL PROCESS

2.1. Manufacturing License

- A license must be obtained from the State Licensing Authority (SLA).
- Application is made using Form 24-D.
- Premises must fulfill GMP requirements under Schedule T.
- A qualified Ayurveda expert (BAMS/MD Ayu) is mandatory.

2.2. Product Approval
- Formulations must be registered and approved based on classical texts or proprietary evidence.

3. QUALITY CONTROL STANDARDS
3.1. Pharmacopeial Standards
- Based on the Ayurvedic Pharmacopoeia of India (API) and Ayurvedic Formulary of India (AFI).
- Tests include identity, purity, ash value, microbial load, heavy metals, pesticides, and aflatoxins.

3.2. In-House Quality Testing
- Manufacturers must have in-house or NABL-accredited lab tie-ups.

4. GOOD MANUFACTURING PRACTICES (GMP)
- Schedule T outlines GMP for Ayurvedic manufacturing.
- Includes factory layout, hygiene, equipment standards, batch records, and SOPs.
- GMP certificate is mandatory for license renewal.

5. LABELING AND PACKAGING RULES
- Labeling must comply with Rule 161 of the Drugs and Cosmetics Rules:
- Product name, ingredients, license number, batch number, manufacturing/expiry date, dosage, and warnings are required.

6. MARKETING AND ADVERTISEMENT CONTROL
6.1. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
- Prohibits misleading ads related to diseases like cancer, diabetes, AIDS, etc.

6.2. Guidelines from Ministry of AYUSH
- Only approved claims based on textual references are allowed in advertisements.

7. ROLE OF REGULATORY BODIES
- Ministry of AYUSH: Policy, standards, and promotion.
- State Licensing Authorities: License issuance and monitoring.
- PCIM&H: Develops official pharmacopoeia and formulary standards.

8. EXPORT REGULATIONS
- Comply with phytosanitary certification, international labeling norms.
- Follow importing country's regulations.
- Supported by AYUSH Export Promotion Scheme.

9. PENALTIES AND OFFENSES
- Manufacturing without a license: Up to 3 years' imprisonment and fines.
- Misbranded/adulterated drugs attract higher penalties.
- Repeated violations lead to license cancellation.

10. CHALLENGES AND RECOMMENDATIONS
Challenges:
- Uneven enforcement across states.
- Proliferation of unlicensed units.
- Low awareness of GMP/pharmacopoeia.
- Risk of adulteration.

Recommendations:
- Digital tracking of licenses and manufacturing records.
- Mandatory pharmacist training.
- Strengthen post-marketing surveillance.
- Public education on authentic Ayurveda.

CONCLUSION

With Ayurveda's growing popularity, ensuring the authenticity and safety of Ayurvedic formulations is vital. The robust regulatory framework laid down by the Government of India, including the Drugs and Cosmetics Act, GMP norms, and labeling standards, ensures a balance between traditional wisdom and modern safety norms. A compliant Ayurvedic pharmacy not only gains consumer trust but also contributes to the global reputation of Indian traditional medicine.

REFERENCES

1. The Drugs and Cosmetics Act, 1940 and Rules, 1945. Ministry of Health and Family Welfare, Government of India. Available at: https://cdsco.gov.in
2. Schedule T: Good Manufacturing Practices for Ayurvedic, Siddha, and Unani Drugs. Included in the Drugs and Cosmetics Rules, 1945.
3. Ayurvedic Pharmacopoeia of India (API). Published by Pharmacopeial Commission for Indian Medicine & Homoeopathy (PCIM&H).
4. Ayurvedic Formulary of India (AFI). Published by Ministry of AYUSH, Government of India.
5. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. Available at: https://legislative.gov.in
6. Guidelines for Licensing of ASU Drugs. Ministry of AYUSH, Government of India. Available at: https://ayush.gov.in
7. Ministry of AYUSH Notification on Proprietary Ayurvedic Medicines. Government of India.
8. Pharmacopeial Commission for Indian Medicine & Homoeopathy (PCIM&H). Website: https://pcimh.gov.in
9. National Accreditation Board for Testing and Calibration Laboratories (NABL). Website: https://nabl-india.org
10. Guidelines for Good Clinical Practices and Research in AYUSH. Issued by CCRAS and Ministry of AYUSH.