REGULATORY ASPECTS OF
AYURVEDIC, SIDDHA & UNANI
MEDICINES

Government of India
Department of AYUSH
Ministry of Health & Family Welfare,
New Delhi
The Drugs and Cosmetics Act, 1940

ASU Medicines covered under the Act by inserting Chapter IV A.

• Came into force : 1\textsuperscript{st} February 1983.
• GMP enforced : 7\textsuperscript{th} March 2003.

Constitution of Central Drug Authority under consideration.
The First Schedule of Drugs & Cosmetics Act

Authoritative Books/Old Classical literature

Ayurvedic Books         54
(In addition - Ayurvedic Pharmacopoeia of India and Ayurvedic Formularies of India)

Siddha Books            30

Unani Books             14
Quality Standards For ASU Herbal Medicines

1. Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drugs that is Misbranded, Adulterated and Spurious Drugs.

2. Prohibition of sale, stock or exhibit the drugs manufactured in contravention of any of the provisions of the Act and the Rule made thereunder.
Manufacture of ASU Medicines

Governed by

2. Rule 156 – 160 – Conditions of Licensing.
3. Rule 160 A – 160 J – Approval of testing laboratory and regulate testing and quality control.
Limit of Heavy Metals for exports effective from 14\textsuperscript{th} October, 2006

- Lead: 10.0 ppm
- Arsenic: 3.0 ppm
- Cadmium: 0.3 ppm
- Mercury: 1.0 ppm
Standards of ASU Drugs made applicable from 26th June 1995

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Class of Drugs</th>
<th>Standards to be complied with</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>[***] drugs included in Ayurvedic Pharmacopoeia</td>
<td>The standards for identity, purity and strength as given in the editions of API for the time being in force.</td>
</tr>
<tr>
<td>2.</td>
<td>Asavas and Aristas</td>
<td>The upper limit of alcohol as self generated alcohol should not exceed 12% v/v excepting those that are otherwise notified by the Central Government from time to time.</td>
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</tbody>
</table>
Labeling & Packing of ASU Medicines
(Rule 161)

1. Name of the drug has given in API / UPI or mentioned in the authoritative books included in the First Schedule.
2. Quantity of the drugs in metric system.
3. Name and address of manufacturer.
4. Manufacturing License No. or “M.L.”.
5. Batch No. or Lot Number.
6. Date of Manufacture.  Contd.
Labeling & Packing of ASU Medicines
(Rule 161)

7. The word “Ayurvedic medicine or Siddha medicine or Unani medicine.

8. The words for external uses only if the medicine is for external application.

9. Physicians sample not to be sold if it is for distribution to the medical profession as a free sample.

Contd.
Labeling & Packing of export products of ASU Medicines

(Rule 161-A)

1) Labeling and packing to meet the requirement of the law of the country to which exported.

a) Name of the ASU drugs (Single or compound formulation).

b) Name and address of Manufacturer with Mfg. No.

c) Batch No. or Lot No.

d) Date of Mfg. along with date for “Best for uses before”.

e) Main ingredients with quantity, if required by the importing country.
Herbal ASU Drugs: Standards Published

1. API - Vol.-I 1986 -Drugs-80
2. API - Vol.-II 1999 -Drugs-78
3. API - Vol.-III 2001 -Drugs-100
4. API - Vol.-VI 2004 -Drugs-68
5. API - Vol.-V 2006 -Drugs-92
6. API Part II - Vol. -I 2007 -Drugs-50
7. API - Vol.-VI 2008 -Drugs-101 (under publication)

Total = 569
Compound Formulations : Standards Published

1. Ayurvedic Formulary of India - Part-I - 444 Formulations
   351 Single Drugs

2. Ayurvedic Formulary of India - Part-II - 191 Formulations
   271 Single Drugs

Total Formulations = 635 : Single Drugs = 622
GRAS List of Plants species in India

1. Plant species generally Regarded as Safe (GRAS) – 599

2. Plant species to be used after special purification and in a very small dose – 28.
Drugs & Magic Remedies (Objectionable Advertisements Act, 1954)

1. Prohibition of advertisement of certain drugs for treatment of certain diseases and disorders.

2. Prohibition of misleading advertisements relating to drugs.


4. Prohibition of import into, and export from, India of certain advertisements.
Categories under which ASU products can be considered

- Unlicensed OTC herbal medicines
- ASU Prescription medicines
- Herbal supplements
- Food supplements
- Nutraceuticals
- Botanicals

- Dietary supplements
- Novel foods
- Border line products
- Traditional Remedies
- Herbal extracts
- Raw herbs and
- Cosmetics
Issues to be flagged

• Quality, safety and efficacy need to be harmonised at international level for development of Trade of Traditional Medicines

• Working group to be constituted to harmonise the registration and market access permission for Traditional Medicinal Products

• Bibliographic references should suffice for therapeutic claims of Traditional Classical medicines

• Safety and efficacy data not required for the herbal formulation prepared from GRAS plants
Issues to be flagged

- Classical medicines to be excluded from the requirement of genotoxicity data
- WHO monographs on medicinal plants should be accepted on the basis of traditional use
- Quality and Safety should be based on limits of heavy metals, pesticide residue, aflatoxins and microbial load and not on the basis of chemical constituents.
- Emphasis to be given on synergy based efficacy and not on the basis of biomarkers
Issues to be flagged

• Traditional medicine practitioners should be allowed to practice across border and dispense and prescribe Traditional Medicines

• Traditional medicine cultural and scientific programmes need to be put in place for quicker and formal propagation of Traditional medicines

• Short term education programmes for creating awareness in medicinal practitioners and long term full course programmes as collaborative efforts between Universities to be encouraged

• GAP, GMP, GLP and such guidelines which are expected to be followed, should have a universal acceptance
Issues to be flagged

• A mechanism should be in place to report adverse events in using Traditional Medicines so that the regulatory authority can have a responsible dialogue before bans, alerts and notices are issued to licensed and imported formulations

• Best practices for manufacture and quality parameters of India and China may be adopted by all member countries.
Thank You