Regulatory & Quality Control Provisions for Ayurvedic, Siddha, Unani and Homoeopathy (ASU&H) Drugs

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AYUSH

- **A**: Ayurveda
- **Y**: Yoga and Naturopathy (Drugless systems)
- **U**: Unani Tibb
- **S**: Siddha and Sowa Rigpa
- H: Homoeopathy

Stand-alone AYUSH Network

Registered Practitioners	7,71,468*
Total Teaching Institutions (ASU&H): (A-281, U-44, S-9, H- 197)	550
Postgraduate Institutions (ASU&H): (A-112, U-9, S-3, H-43)	170
Annual Intake in Degree courses: (A-15117, U-2131, S- 410, H-13658)	33,601
Annual Intake in PG courses: (A-3089, U-147, S-140, H-918)	4,876
Hospitals in Government Sector	3,639
Dispensaries in Government Sector	26, 405
Drug Manufacturing units (A-7439, U- 585, S-235, H-408)	8,667

**Coverage: About 6 AYUSH practitioners per 10,000 population (as on 1/4/2016)*

Integrated or Co-located AYUSH Functionaries

- **AYUSH services available in-**

  506 out of 697 District Hospitals,

  374 out of 2725 Sub-district Hospitals,

  2871 out of 11225 Community Health Centres,

  8995 out of 31849 Primary Health Centres

  5716 other healthcare centres.

- 15649 AYUSH practitioners appointed for National Child Health Program and 12263 for imparting general health services.

What are regulations ?

Legal norms for-

- ✓ What is required to be done for an intended purpose
- ✓ How and in what manner it can be done
- ✓ What can not be done for achieving the intended purpose
- ✓ Penalizing the persons for committing any omission from prescribed standards or for commission of prohibited actions.
- ✓ Who can make, amend and enforce the provisions.

Needs for Drugs Regulation

- To prescribe and enforce standards for manufacturing, distribution, sale, marketing and information of drugs.
- To ensure availability of quality drugs to the people.
- To promote public protection from hazards/harmful effects of drugs.

Types of Legal Provisions

- Enabling provisions
- Prohibitive provisions
- Penal provisions
- Empowering provisions for authorities/specific actions
- Exemption provisions

Legal Provisions /Regulations for ASU &H drugs

- **Drugs and Cosmetics Act, 1940**
  - Section 3(a) & (h), Chapter IVA from Section 33B to 33O and First Schedule pertain to ASU drugs.
  - Second Schedule (4A) provides for quality standards of Homoeopathic drugs.
- **Drugs and Cosmetics Rules, 1945**
  - Rules 151 to 169, Schedules E(I), T, TA pertain to ASU drugs.
  - Rules 30AA, 67, 85 (A to I), 106-A, Schedule K, Schedule M-I pertain to Homoeopathic drugs.
- **Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules**

ASU drugs related provisions of Chapter IVA

- ASUDTAB and ADUDCC- Advisory bodies to Central and State Governments.
- Misbranded, Spurious and Adulterated drugs
- Standards of ASU drugs
- Prohibition of manufacturing and sale of ASU drugs by State Government.
- Prohibition of manufacturing, sale etc of ASU drugs by Central Government.
- Appointment of Government Analysts, Inspectors
- Penalties
- Confiscation of the stock of ASU drugs
- Disclosure of ASU drug information to the Inspector
- Maintenance of records and furnishing of information by license holder
- Cognizance of offences
- Rules making power of the Central Government
- Powers of Central Government to amend First Schedule

Powers of Central Government to give directions to State Governments

Other Related Acts applicable to ASU&H Products

- **Food Standards & Safety Act**
- **Bio-diversity Act**
- **Wild Life Protection Act**
- **Indian Forests Act**
- **Narcotic Drugs and Psychotropic Substances Act**
- **The Standards of Weights and Measures Act**

➢ *Legal provisions are made and amended by the Central Government and enforcement is done by the State Governments.*

National Committees for Drugs

- Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB): for policy advice to Central Government on regulation of ASU drugs.
- Ayurveda, Siddha, Unani Drugs Consultative Committee (ASUDCC): for advice to Central and State Governments on enforcement issues of ASU drugs.
- Sub-committee on Homoeopathy under Drugs Technical Advisory Board (DTAB)
- Pharmacopoeia Commission of Indian Medicine and Homeopathy.
- Pharmacopeia Committees for development of standards of ASU&H drugs.

Institutional arrangement for development of Quality Standards

- Pharmacopeial Commission of Indian Medicine (PCIM&H) to coordinate and promote pharmacopoieal work.
- Pharmacopoeia Committees of Ayurveda, Siddha, Unani and Homoeopathy to steer pharmacopoieal work in standard template.
- Scientific Institutions / R&D Institutes / laboratories undertake basic work of standardization.
- Experts of ASU&H systems, phytochemistry, pharmaceutical sciences, pharmacognosy, inorganic chemistry, geochemistry and medicinal plants are associated for evaluation and approval of Pharmacopoeial monographs.

Nature of ASU Drugs

- Made from wholesome natural substances of plant, animal, mineral or marine origin.
- Formulation may be of single ingredient or multiple ingredients or combination of different formulations.
- Formulation could be herbal, herbo-mineral or any kind of mixture of two or more natural substances.
- Wholesome extract of medicinal plant (aqueous extract or hydro-alcoholic extract or any other extract) can be the ingredient of ASU formulations.

Categories of Medicinal Products

- Classical or generic formulae
- Proprietary:

i) Textual rationale, Experiential and R&D based medicinal formulations

ii) Nutritive medicinal formulations

iii) Cosmaceutical medicinal formulations

iv) Extract-based formulations (Aqueous, hydro-alcoholic and other extracts)

❑ Phyto-pharmaceuticals (are not ASU&H drugs)

Broad Types of ASU Drugs

- **<u>Classical/Shastriye/Traditional:</u>** Ayurvedic, Siddha or Unani drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the Schedule I of the Act.

i.e such *formulations as are described in 103 authoritative books including pharmacopoeias and formularies.*

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- **Patent or Proprietary**: ASU formulations containing only such ingredients, which are mentioned in the formulae described in the authoritative books and do not include a medicine for parenteral administration and the formulation mentioned in any of the authoritative books.

i.e. only ingredients/natural substances mentioned in the authoritative books can be used for manufacturing of patent/proprietary ASU medicines.

Requirements for Licensing of ASU Medicines

- Reference of the formulation/ingredients from the authoritative books of Ayurvedic, Siddha or Unani Tibb systems listed in First Schedule of the Drugs & Cosmetics Act, 1940.

- Manufacturing unit compliant with the GMP requirements as prescribed in Schedule ‘T’ of the Drugs & Cosmetics Rules, 1945 and Schedule M1 for Homoeopathic medicines.

- Proof of safety and effectiveness as prescribed in Rule 158-B for various categories of ASU medicines.

Safety, Efficacy, Quality:
Standards of ASU medicines

- Standards of identity, purity and strength as given in the respective Pharmacopeias.
- Standardized classical formulations prescribed in National Formularies
- Standard of self generated alcohol (not more than 12% v/v) for Asavas & Arishtas prescribed in Rule 158.
- In-house standards and testing protocols for proprietary medicines.

Phytopharmaceuticals are not ASU Drugs

Phytocpharmaceutical drug means and includes purified and standardized fraction with defined minimum four bio-active or phytochemical compounds (qualitatively and quantitatively assessed) of an extract of a medicinal plant or its part, for internal or external use of human beings or animals for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include administration by parenteral route.

Sub-Types of Proprietary ASU Formulations

Medicinal Formulation

Nutritive Formulation *(Balya, Poshak)*

Cosmaceutical Formulation (*Saundaryaprasadak*)

Aqueous or Hydro alcoholic Extract based Formulation

Other Extract-based Formulation

Conditions for Commercial Manufacturing of ASU drugs

1. License of the manufacturing unit and intended formulations

2. GMP Compliance

3. Adequate infrastructural facility, staff, equipment, reference books , record keeping etc.

4. Compliance to Standards given in the pharmacopoeia

License requirements for Classical/Shastriye/Traditional Formulations

1.	**Traditional ASU formulation with dosage form and indications as per authoritative text**	• **Safety study not required** • **Evidence of effectiveness from authoritative source required.**
2.	Traditional ASU formulation with change in dosage form	• Safety study not required • Evidence of effectiveness from published literature required.
3.	Traditional ASU formulation for new indication	• Safety study not required • Evidence from published literature and/or proof of effectiveness required.

License Requirements for Proprietary Formulations

1. Proprietary formulation with ingredients not from Schedule E(I) and based on textual rationale from authoritative books.	• **Safety study not required** • **Evidence of effectiveness of ingredients from published literature required.** • **Proof of effectiveness from a pilot study required.**
2. Proprietary formulation with any of the ingredients from Schedule E(I) and based on textual rationale from authoritative books.	• Safety study required • Evidence of effectiveness from published literature and proof from pilot study required.

License Requirements for Extract-based Formulations

1.	**Aqueous extract as per text**	• **References from the authoritative texts required**
2.	Aqueous extract as per text but with new indication	• Safety study not required • Proof of effectiveness required
3.	Hydro-alcoholic extract as per text	• Evidence of effectiveness may be required on case to case basis.
4.	Specific Hydro-alcoholic extract with New Indication	• Safety study required • Evidence and proof of effectiveness required
5.	Other extracts made from various solvents.	• Acute and Chronic Toxicity, Mutagenicity and Teratogenicity data required. • Evidence of effectiveness from published literature and proof from clinical study required.

Requirements for making License Application

- Reference of the formulation/ingredients from the authoritative books listed in the Drugs & Cosmetics Act, 1940.

- Manufacturing unit should be compliant with the GMP guidelines as prescribed in Schedule ‘T’ of the Drugs & Cosmetics Rules, 1945.

- Proof of safety and effectiveness as prescribed in Rule 158-B for various categories of ASU medicines.

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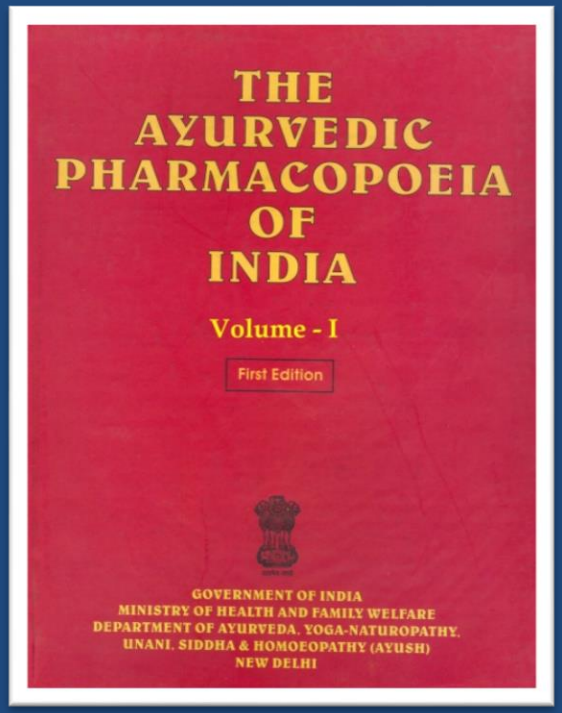
- Standards of identity, purity and strength and permissible limits of heavy metals, aflatoxins, microbial load and pesticide residue of medicinal plant materials prescribed in the respective Pharmacopeias.
- Standardized classical formulations prescribed in National Formularies.
- Label containing true list of ingredients (with plant part and form), manufacturing and expiry dates and caution in case of presence of any of Schedule E(I) ingredients in the formulation.
- Test report/Certificate of Analysis of not more than 12% v/v self generated alcohol in *Asavas & Arishtas.*
- In-house standards and testing protocols for proprietary medicines.

Standards of Identity – Purity-Strength of ASU Drugs

Ayurvedic Pharmacopoeia of India	Unani Pharmacopoeia of India	Siddha Pharmacopoeia of India
645 (9) monographs of Single Drugs	298 monographs of Single Drugs	139 monographs of Single Drugs
202 (4) monographs of compound formulations	150 monographs of compound formulations	–

Standard ASU Formulations

Ayurvedic Formulary of India	National Formulary of Unani Medicine	Siddha Formulary of India
985 (3 volumes) including 280 mineral-based formulations	1229 (6 volumes)	399 (2 volumes)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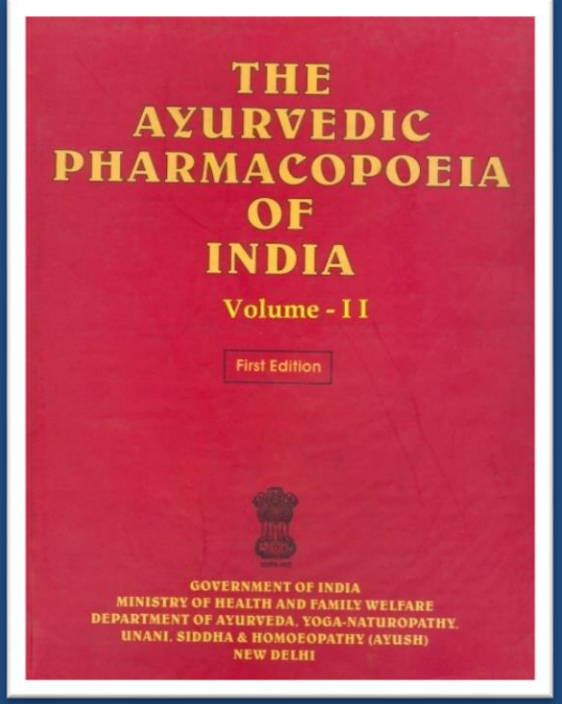
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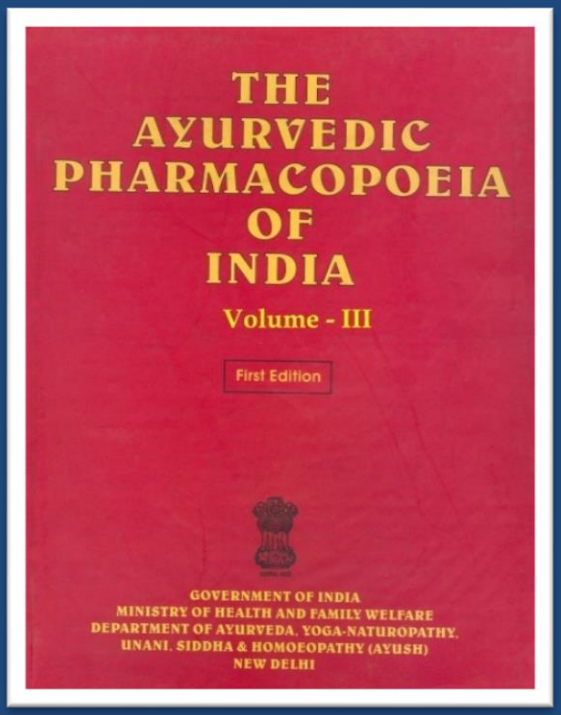
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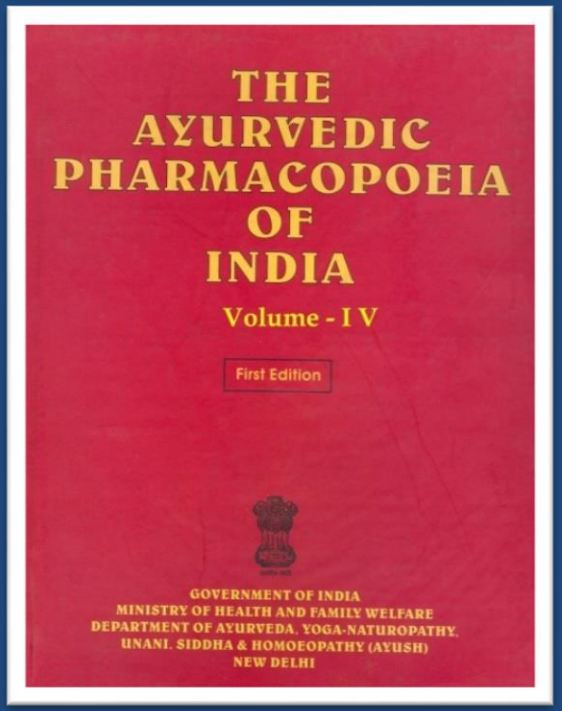
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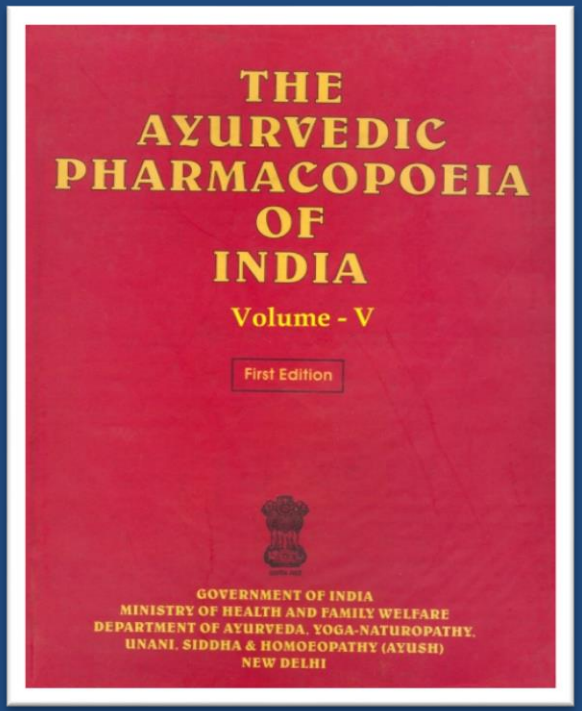
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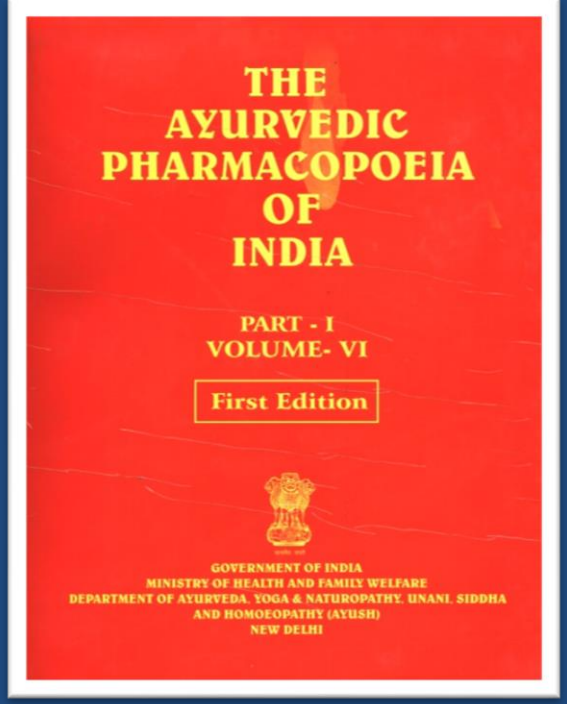
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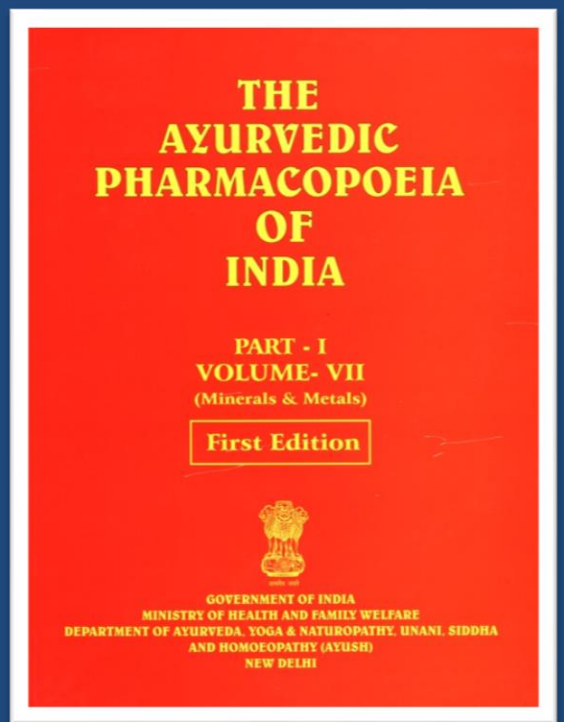
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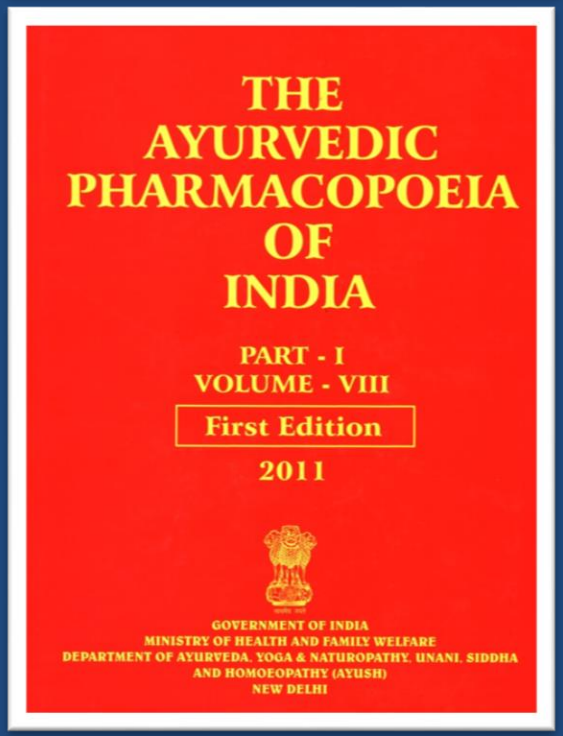
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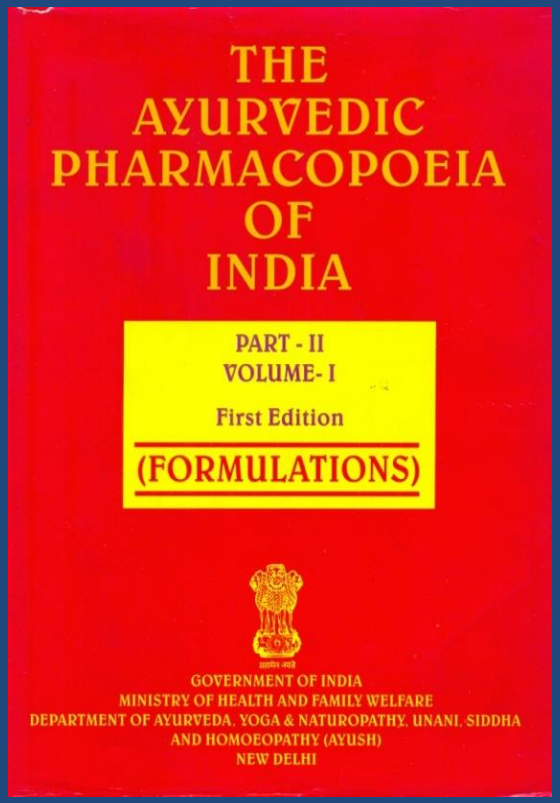

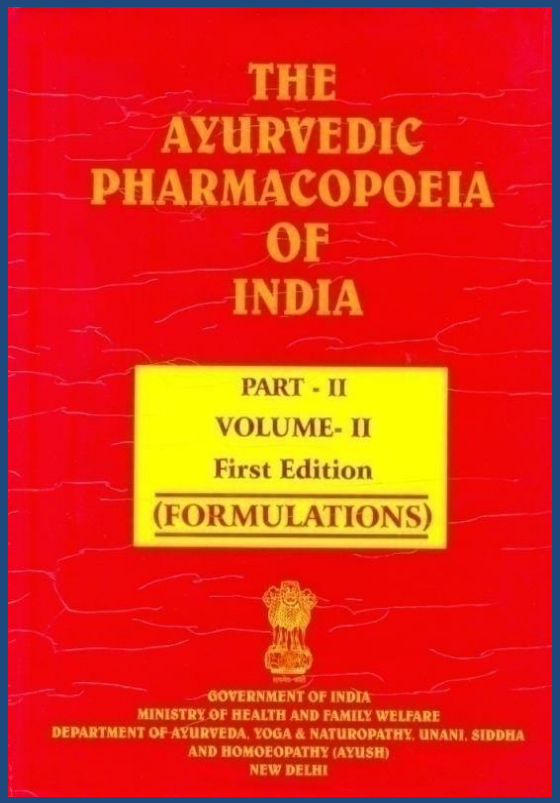

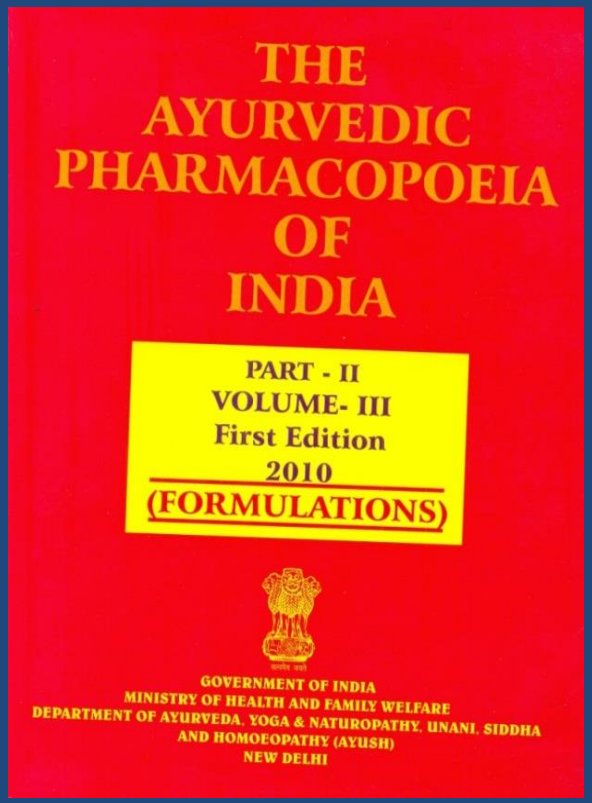

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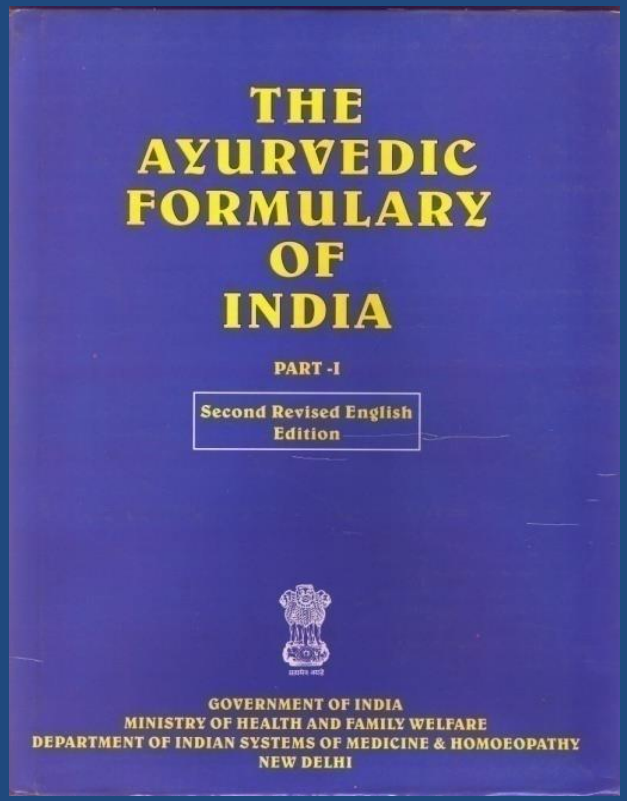

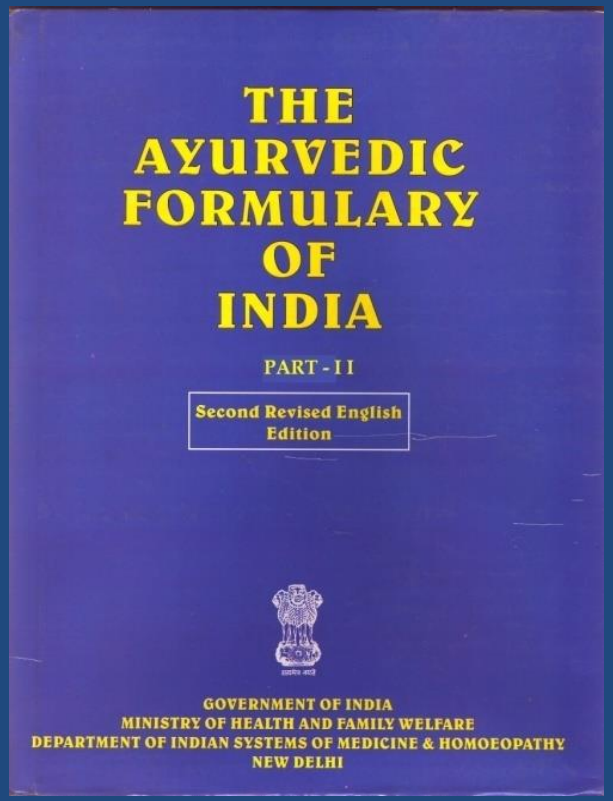

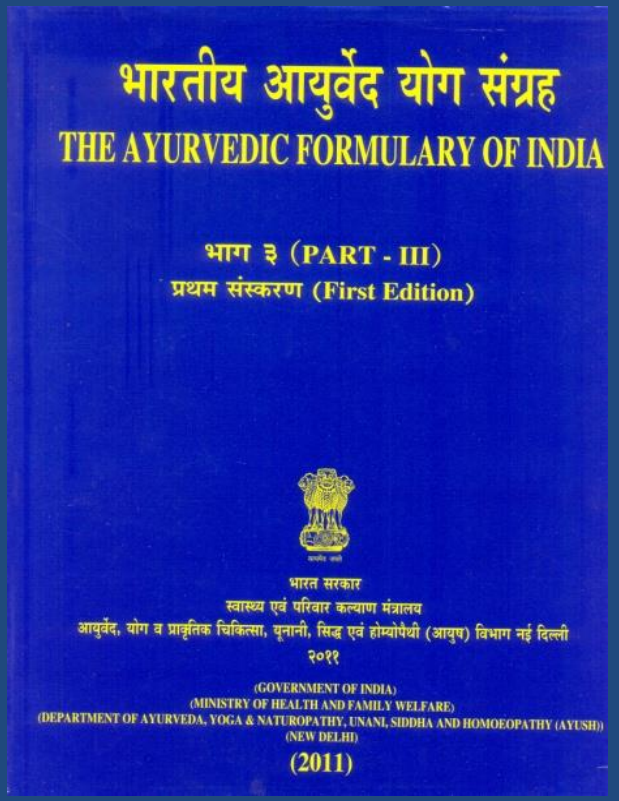

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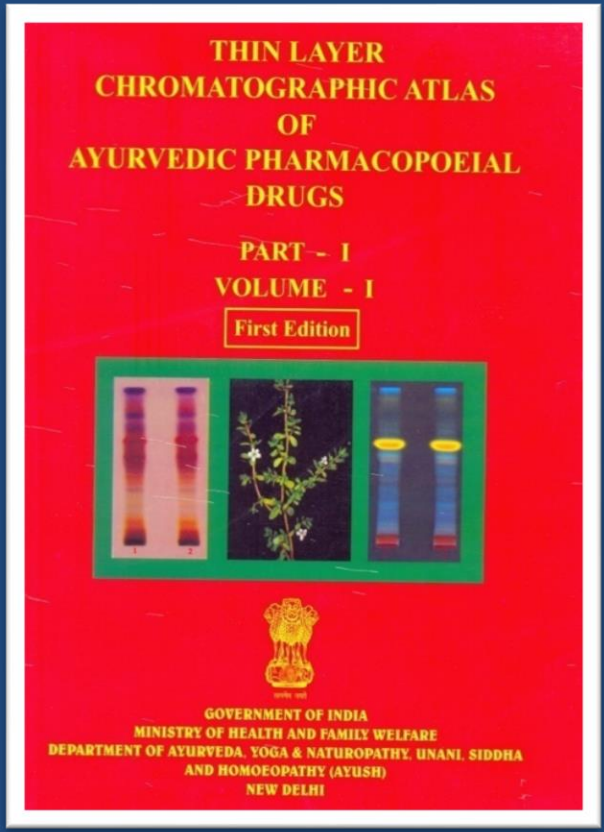

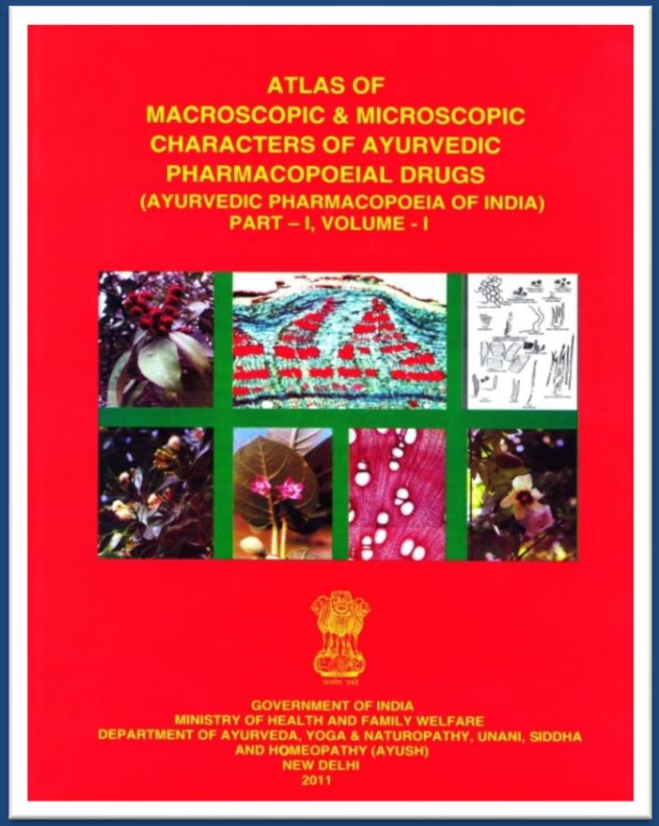

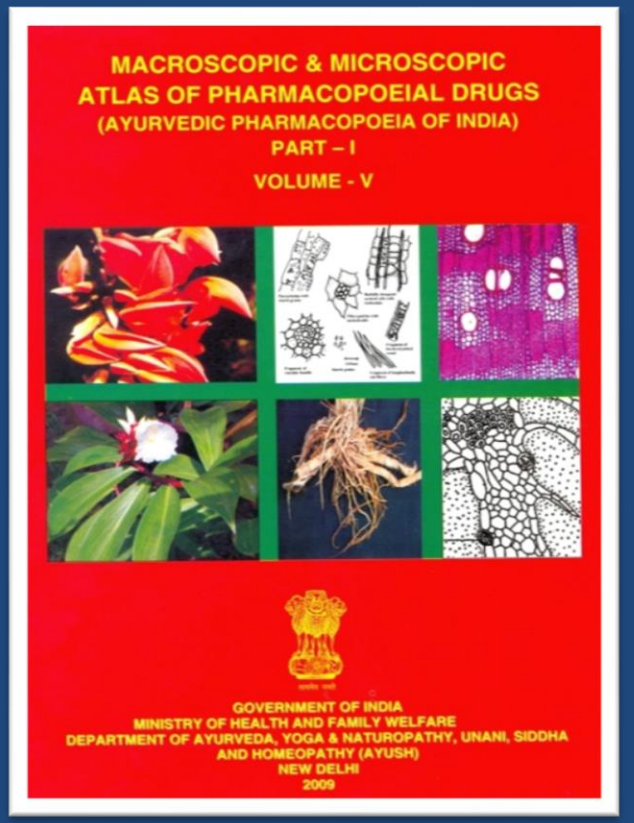

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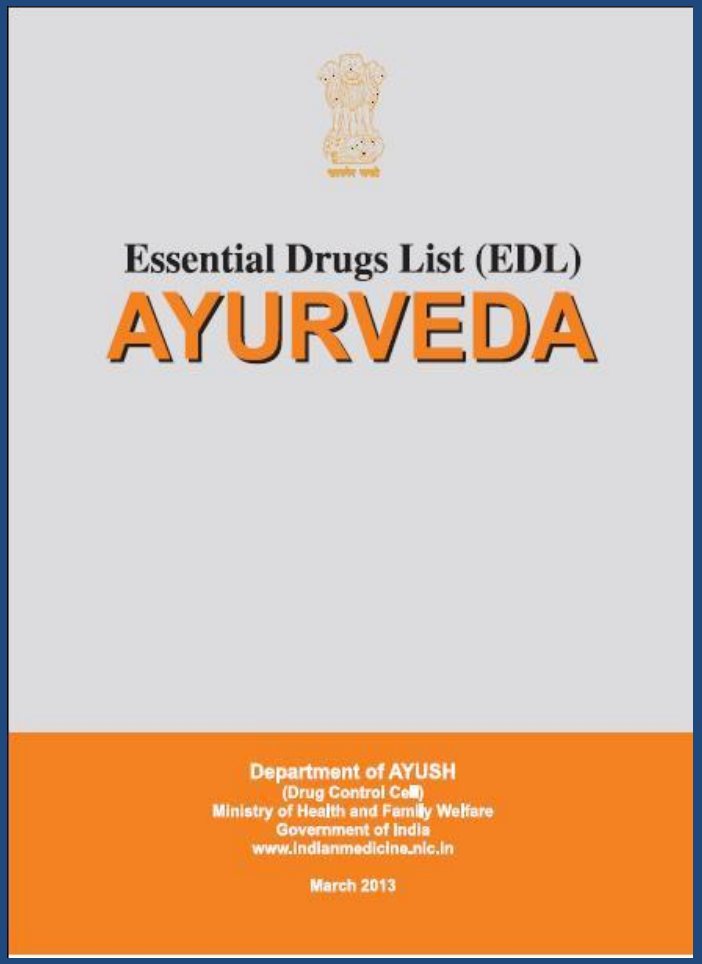

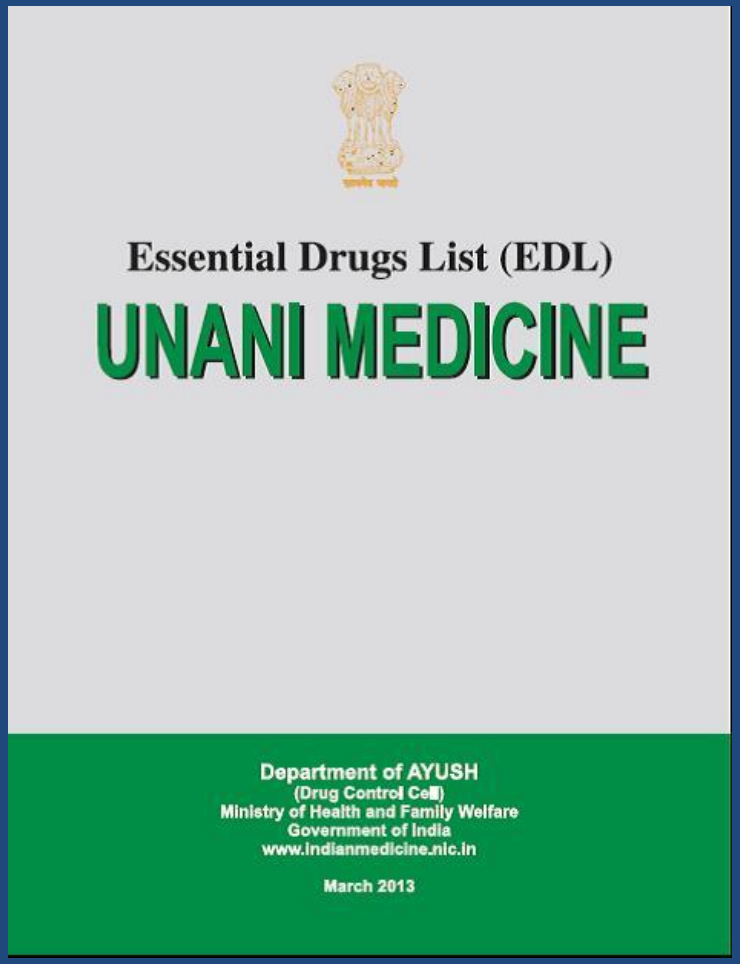

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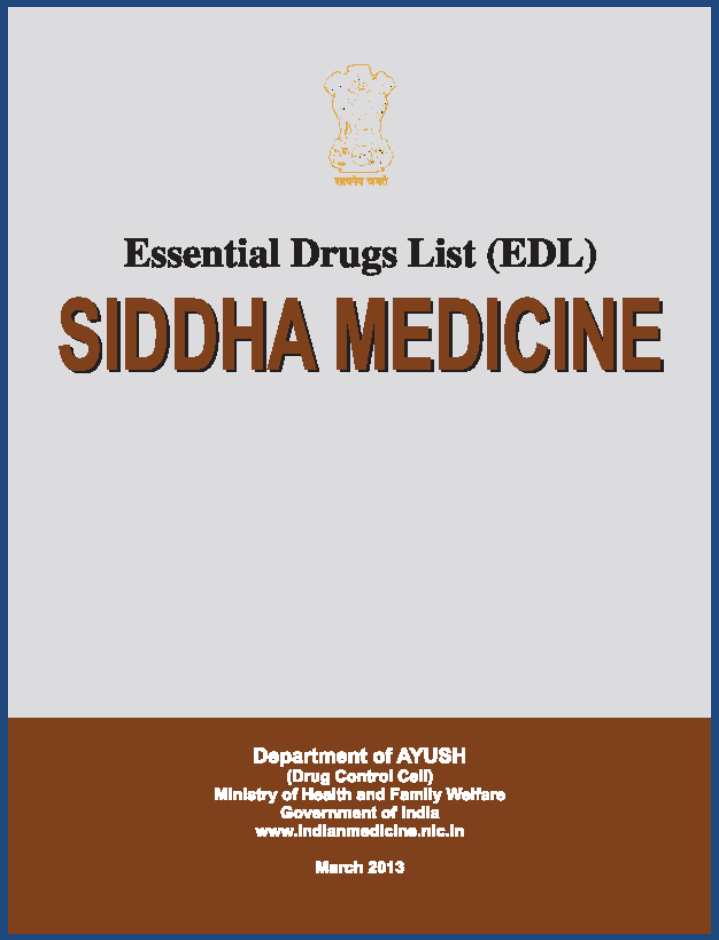
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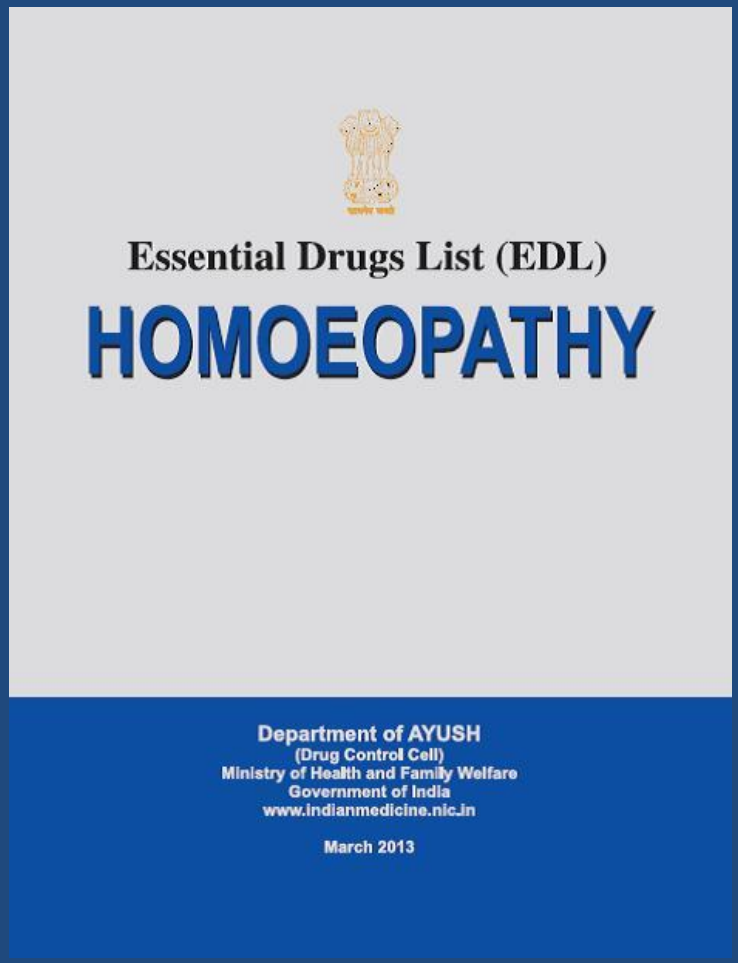
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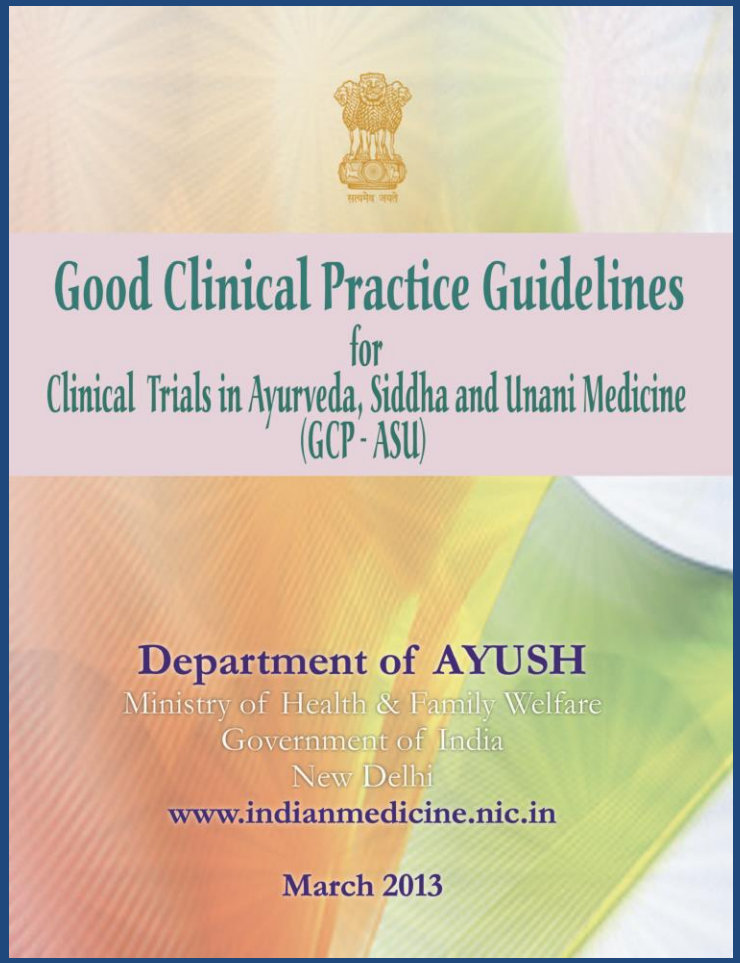
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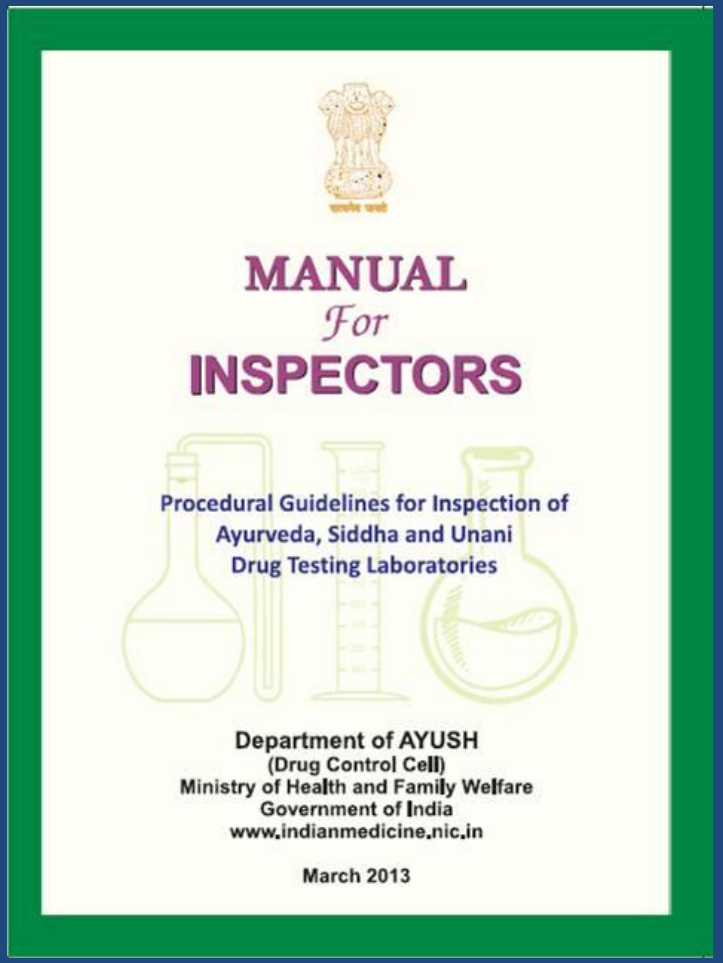
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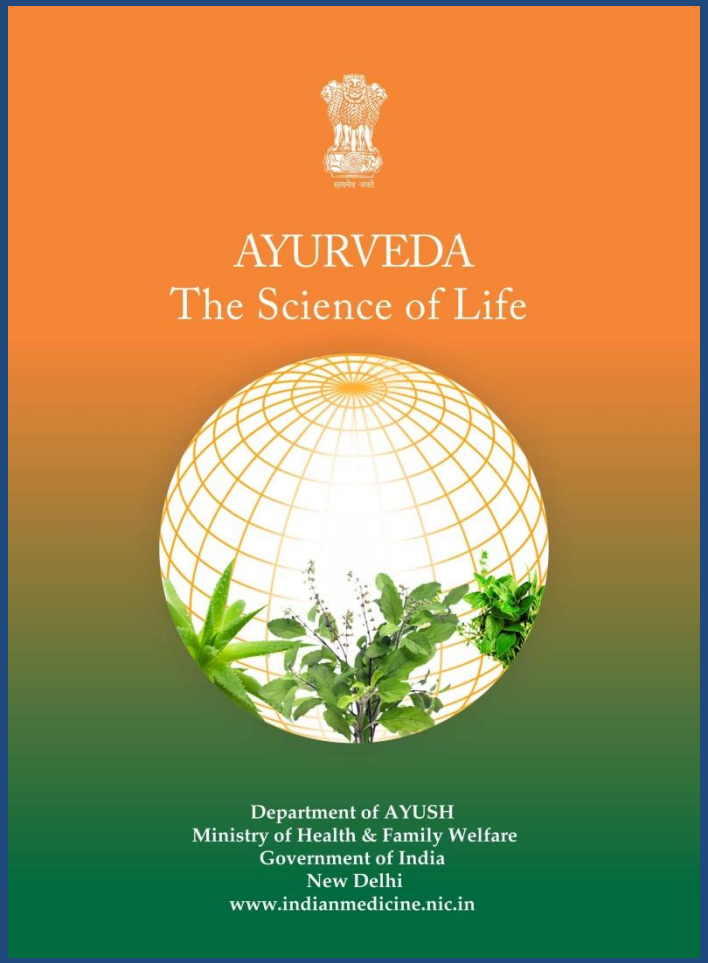
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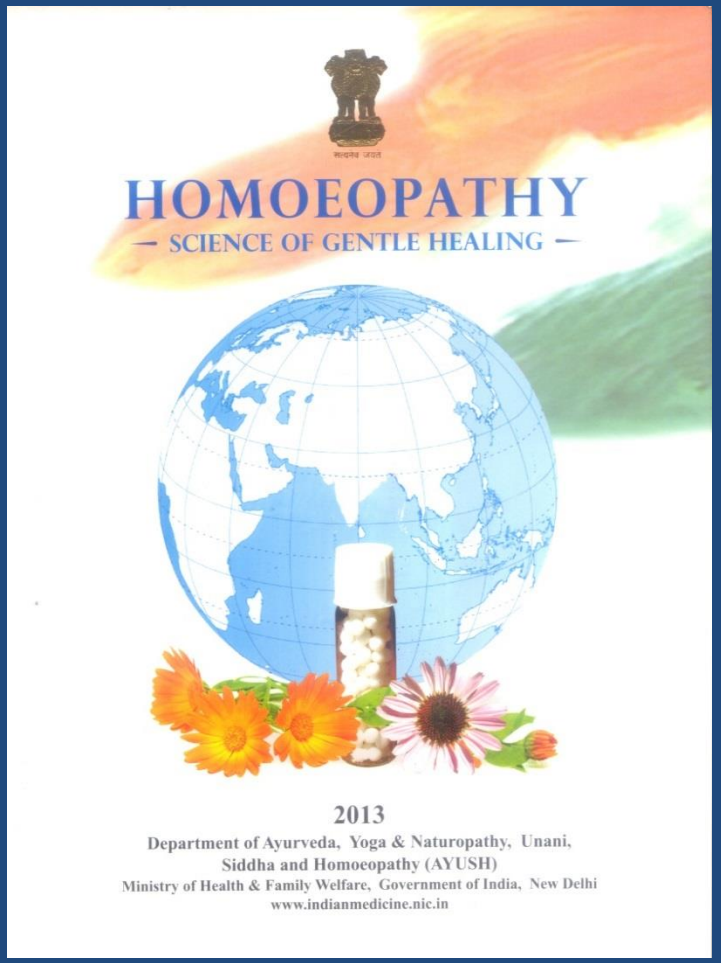
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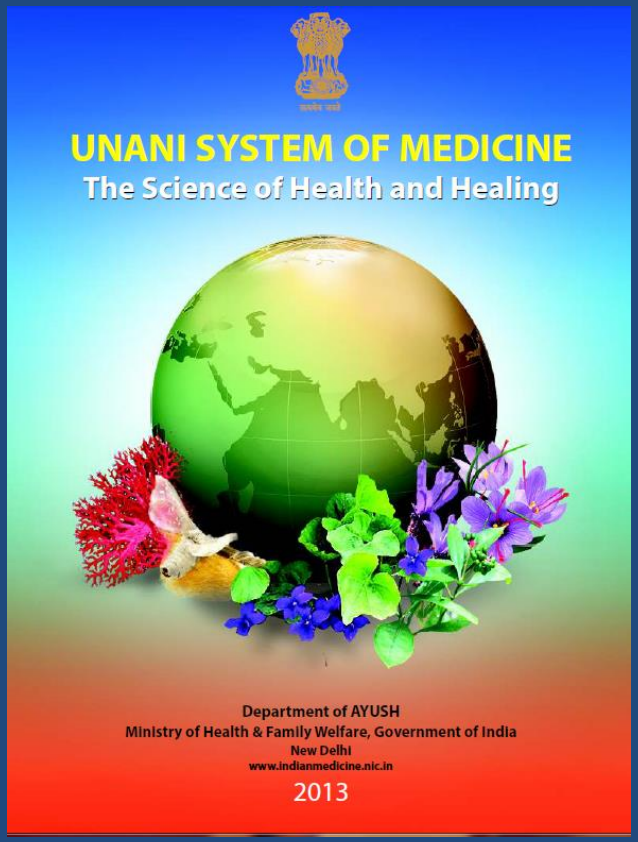
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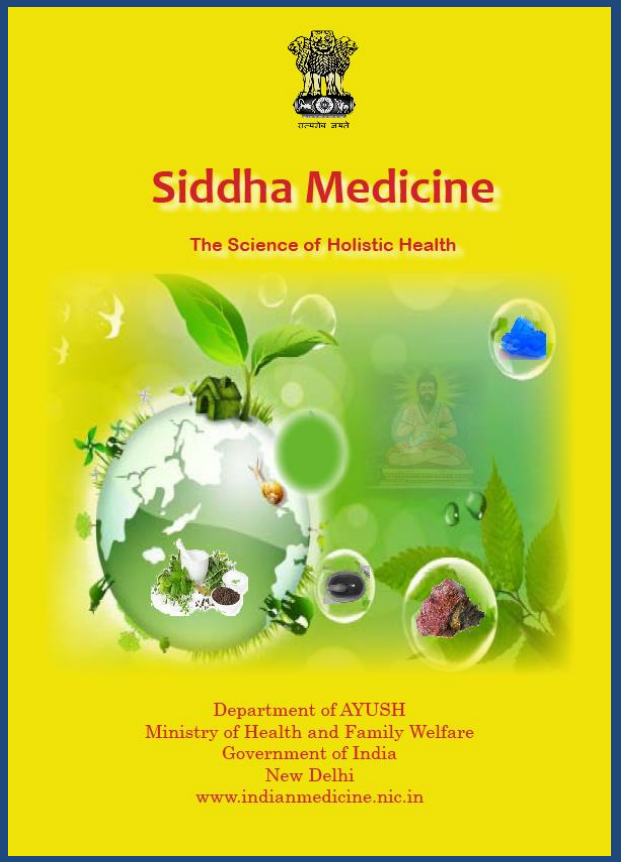
Siddha Medicine
The Science of Holistic Health
Department of AYUSH
Ministry of Health and Family Welfare
Government of India
New Delhi
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Quality Certification Systems

- **GMP certification must.**
- **Free Sale Certificate and Non-conviction Certificate on demand.**
- **WHO-GMP/COPP certification for export-oriented ASU herbal drugs.**
- **Voluntary certification of quality of AYUSH products through Quality Council of India (QCI) scheme.**
  - **Ayush Standard Mark:** based on compliance to the standards more than the domestic regulatory requirements.
  - **Ayush Premium Mark:** broadly based on compliance to WHO-GMP/USFDA criteria or GMP prescribed by importing country or fulfillment of quality requirements as per international norms.

Overall Regulatory Framework for ASU & H Drugs

Central Govt.

- Drug Control Cell and AYUSH Vertical in CDSCO.
- Makes and amends regulatory provisions.
- Has the powers to give direction to the State Governments for implementation of the regulatory provisions.
- Pharmacopoeia Commission of Indian Medicine & Homoeopathy and Pharmacopoeia Committees.
- Central Laboratories – PLIM and HPL with Govt. Analysts.

State Govt.

- Responsible to enforce the legal provisions.
- Appointment of Licensing Authority/Drug Controller and Drug Inspectors .
- Drug Testing Laboratory
- Notification of Govt. Analysts.

Statutory bodies

- ASUDCC
- ASUDTAB
- Sub-committee of Homoeopathy and Drugs Technical Advisory Board (DTAB).

Responsibilities of Licensing Authority

- To ensure that manufacturing site has all required clearances and approvals and adequate manufacturing facilities.
- To ensure whether the manufacturing premises are complying with the GMP norms.
- To consider whether the documents submitted with license application are complete and the conditions laid down in Rule 158-B are fulfilled to grant or renew the license.
- To consider correctness of the contents on the label of medicines in accordance with labeling provisions.
- To undertake quality check of adequate number of ASU & H drug samples taken from manufacturing sites and market.
- To monitor advertisements of ASU&H drugs appearing in print and electronic media for misleading claims.
- To make the lists of licensed manufacturers and products and upload in the website.
- To take regulatory action against defaulters acting in contravention of the provisions of Drugs & Cosmetics Act and Drugs & Magic Remedies Act and rules thereunder.

Thanks

* *For any regulatory/enforcement query, clarification or guidance, write to-*

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