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SHAKTI'S CLASSES for AYURVEDA

A Complete Centre for MD/MS(AIAPGET.), MO (UPSC & PSC), Other Ayurvedic Entrance Examination and Foundation Courses for Proff. I, II & III

Ayush General Study

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AYUSH - GENERAL KNOWLEDGE

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(From Ayurveda Including Recent Current Affairs)

Drug and Cosmetic Act 1940 & Rule 1945

- In 1940 Drug act was passed and in 1945 rule was framed.
- 1962—cosmetic term is added.
- 1964—ASU drugs (Ayurvedic, Siddha and Unani) were brought into purview.

Objective – legislation gave the power to the government to make rules to regulate the import, manufacture, sales and distribution and sale **(IMS- D)** of drugs and cosmetics.

Drug and Cosmetic Act 1940

Chapter I	Introductory
Chapter II	The drugs technical advisory board (DTAB), the central drugs laboratory (CDL) and the drugs consultative committee. (DCC)
Chapter III	Import of drugs and cosmetics.
Chapter IV	Manufacture, sale and distribution of drugs and cosmetics
Chapter IVA	Provisions relating to Ayurvedic Siddha and Unani drugs
Chapter V	Miscellaneous

Chapter IV A

SECTIONS – 33B-33-O

33E	MISBRANDED
33EE	ADULTERATED
33EEA	SPURIOUS
33EEB	Regulation for manufacture for sale of ASU drugs.
33EEC	Prohibition for manufacture for sale of ASU drugs.
33EED	Power of central govt. prohibit and manufacture for sale of ASU drugs .

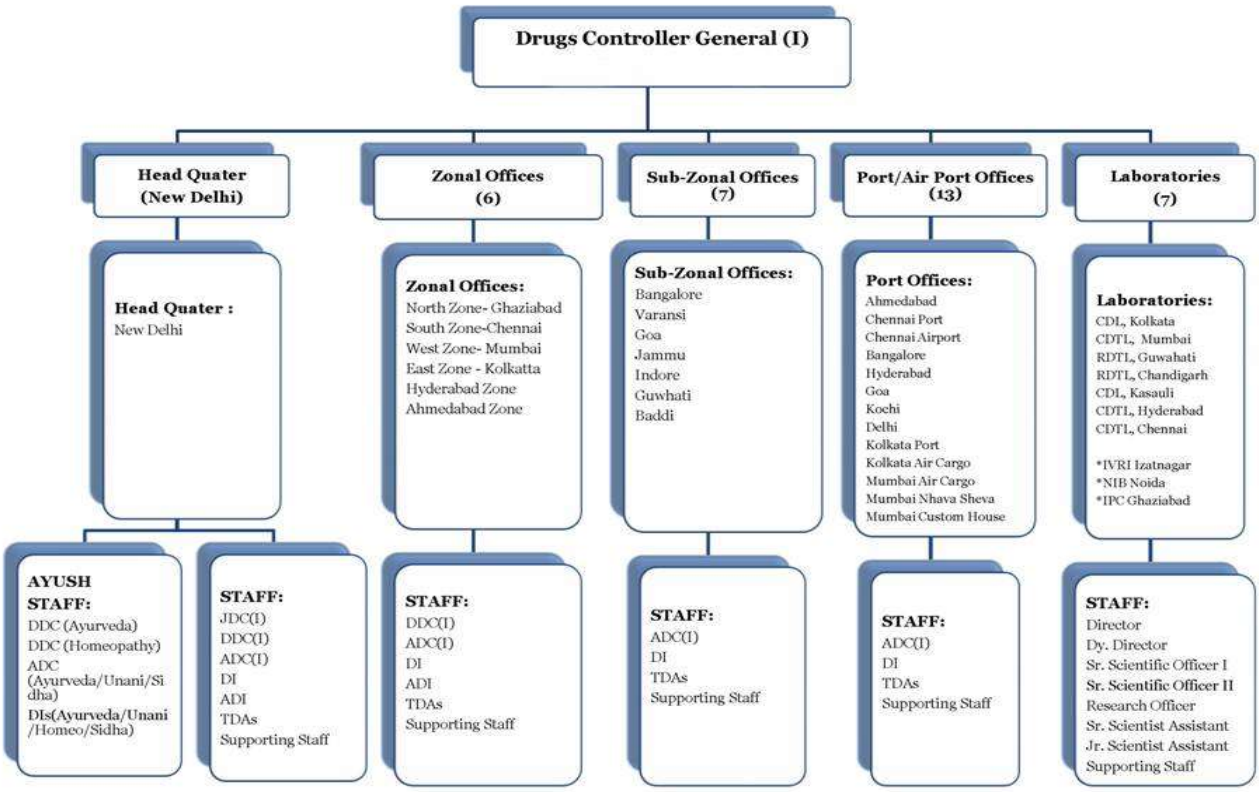
First Schedule Section 3(A):

54 – D -- Authortative Textbook of Ayurveda. (TOTAL-58).

Drug Control Setup at Central Level:

CDSCO (Central Drug Standard Control Organization)
CDL (Central Drug Laboratory)-- 7 (Kolkata, Mumbai, Chennai, Guwahati, Chandigarh, Kasauli, Hyderabad)

CIPL (Central Indian Pharmacopeial lab)



DRUG AND COSMETIC RULE 1945

Total Parts—XIX
XVI Part—manufacture for sale of Ayurvedic drugs.
Rule 151 to rule 160
XVII Part- Labelling , packing and limit of alcohol in ASU drugs.

- **Rule 161-** Labelling , packing and limit of alcohol.
- **Rule 161 A-** Exemption in Labeling & packing provisions for export of ASU drugs.

- **Rule 161 B-** Shelf life and expiry date of medicines.

S No	Dosage Form	Shelf Life and Date of Expiry
1.	Anjana	
	Anjana made from kastha aushadhi	1 year
	Anjana made from kastha aushadhi with rasa/uprasa / bhasma	2 years
	Anjana made with rasa/uprasa / bhasma	3 years
2.	Arka	1 years
3.	Asava, arista	10 years
4.	Avleha, khanada, paka , guda	3 years
5.	Churna, kwatha churna, danta churna, lepa churna	2 years
6.	Dhoopan	2 years
7.	Dravak, lavana, kshara	5 years
8.	Ghritra	2 years
9.	Taila	3 years
10.	Guggulu	5 years
11.	Vati / gutika	
	Vati / gutika containing kastha aushadhi with rasa/uprasa / bhasma/guggulu (imcluding lepa gutika, ghan vati)	5 years
	Vati / gutika containing only kastha aushadhi(including lepa gutika, ghan vati)	3 years
	Vati / gutika containing rasa/uprasa / bhasma except Naga, Vanga and Tamra Bhasma	10 years
12.	Karna/ nasa bindu	2 years
13.	Kupipakwa rasayan	10 years
14.	Lauha – mandura	10 years
15.	Parpati	10 years
16.	Shweta parpati	2 years
17	Pishti/ bhasma except Naga, Vanga and Tamra Bhasma	10 years
18.	Malhara	3 years
19.	Naga, Vanga and Tamra Bhasma	5 years
20.	Pravahi kwatha	3 years

21.	Sharkara , panaka, sharbat	5 years
22.	Varti	2 years
23	Sattva (derived from medicinal plants)	2 years
24	Netra bindu	1 years
25.	Rasayoga	
	Rasayoga containing only rasa/uprasa / bhasma except Naga, Vanga and Tamra Bhasma	10 years
	Rasayoga containing rasa/uprasa / bhasma along with kastha aushadhi and guggulu	5years

XIX Part – Standards of ASU drugs.

- **Rule 168-** Standards to be compiled with in manufacture for sale or for distribution of ASU drugs.
- **Rule 169-** permitted recipients.

Schedule A to Schedule Y

Schedule E (1)- list of poisonous substances under the Ayurveda, Siddha and Unani System of medicine.

Total 21 Drugs

1. Drugs of vegetable origin- 13

1. Ahiphena	2. Karveera
3. Arka	4. Langali
5. Bhallataka.	6. Parsika yavani
7. Bhanga.	8. Vatsnabha
9. Danti	10. Vishamushti
11. Dhatura	12. Gunja
13. Jaipala	

2. Drugs of animal origin- 1
3. Drugs of mineral origin- 07

Gauripashana
Hartala
Manashila
Parada.
Rasa karpura
Tuttha
Hingula

Schedule L-I – Good Laboratory Practices (GLP) and requirements of premises and equipments.
Schedule M -- GMP (Good Manufacturing Practices) for allopathic drugs.
Schedule T --- GMP (Good Manufacturing Practices) For ASU drugs.

- **Part 1-** Good Manufacturing Practices
- **Part 2- A.** List of machinery, equipments, and minimum manufacture of various categories of AS.drugs.
- **B-** List of machinery, equipments, and minimum manufacture of various categories of unani drugs.
- **C-** List of equipments recommended for in – house quality control section.
- **D-** Supplementary guidelines for manufacturing of Rasaushadhies or Rasamarunthukal and kushtajata (herbo-mineral- metallic compounds) of ASU medicines.
- All bio-medical waste shall be destroyed as per the provision of the Biomedical-waste (Management and Handling) Rules, 1996.

Minimum Premises:

S. No	Category of Medicine	Minimum Space (In Sq.Ft)
1.	Total Area	1200
2.	Anjana / Pishti	100
3.	Choorna/ Nasya/ Manjan/ Lepa/ Kwatha Choorna	200
4.	Pill / Vati / Gutika	100
5.	Tablets	100
6.	Kupipakwa/ Kshara/ Parpati/ Satva/ Sindoora	150
7.	Kajal	100
8.	Capsules	100
9.	Ointment/ Malham	100
10.	Pak, Avleha, Khanda, Modaka , Leham	100
11.	Panak, Syrup, Pravahi Kwatha	150
12.	Asava / Arishta	200
13.	Ark	100
14.	Taila/ Ghrita	100
15.	Achyotan, Netra Malham	100
16.	Quality Control Lab	150