

# THE DRUG AND COSMETIC ACT AND RULES

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ACT AND RULES

# Schedules to the Act & Rules

## ❖ First Schedule: List of Ayurvedic, Siddha & Unani books

### ➤ Ayurvedic books

- Charak Samhita
- Sushrut Samhita,
- Vaidya Chintamani
- Ayurveda Chintamani

### ➤ Siddha Books

- Siddha vaidya Thiratu,
- Nagmuni
- Bhogar (700)

### ➤ Unani books

- Karabadin Quadri
- Karabadin Kabir
- Karabadin Azam

- ❖ Second Schedule: Standards to be complied with by imported drugs & by drugs manufactured for sale, sold, stocked or exhibited for sale or distribute
- ❖ Schedules to the Rule
  - ✓ A: List of forms for making applications for issuing licences, granting licences, sending memorandum
  - ✓ B: Fees for test or analysis by the Central Drugs Laboratory
  - ✓ C: List Of biological and special products (Injectable) applicable to special provisions.

- ✓ C1: List of other special products whose import, sale, distribution and manufacture are governed by special provisions
- ✓ D: Classes of exempted drugs which are exempted from certain provisions applicable to import of drugs
- ✓ E(1): List of poisonous substances under the Ayurvedic, Siddha, and Unani poisons
- ✓ F: Provisions applicable to blood bank (Requirements and licencing process)

- ✓ F (I) : Provisions applicable to other biological and special products such as vaccines, antigens, diagnostic antigens, tuberculin, etc. regarding their production, testing, storage, packing, etc.
- ✓ F (II) :Standards for Surgical dressings and bandage cloth.
- ✓ F (III): Standard for umbilical tapes.
- ✓ FF: Standards for ophthalmic preparations.
- ✓ G: List of substances required to be used under medical supervision and labelled accordingly.
- ✓ H: List of substances (prescription) that should be sold by retail only on prescriptions of R.M.P

- ✓ J: List of diseases and ailments that drug should not claim to cure
- ✓ K: List of drugs that are exempted from certain provisions regarding manufacture
- ✓ M: Good manufacturing requirement of factory premises, plants and equipments
- ✓ M1: Requirements of factory premises for manufacture of homeopathic medicines
- ✓ M2: Requirements of factory premises for manufacture of cosmetics
- ✓ M3: Requirements of factory premises for manufacture of medical devices

- ✓ N: List of equipment to run a pharmacy
- ✓ O: standards for disinfectant fluids
- ✓ P: Life period(expiry) of drugs
- ✓ P 1: Pack size of certain drugs.
- ✓ Q: List of coaltar colours permitted to be used in drug and cosmetics
- ✓ R: Standards for mechanical contraceptives
- ✓ R1: Standards for medical devices
- ✓ S: Standards for cosmetics
- ✓ T: Requirements (GMP) of factory premises for ayurvedic, siddha, unani drugs

- ✓ U: Manufacturing and analytical records of drugs
- ✓ U1: Manufacturing and analytical records of cosmetics
- ✓ V: Standards for patent or proprietary medicines
- ✓ W: List of drugs marketed under generic names
- ✓ X: List of narcotic drugs and psychotropic substances
- ✓ Y: Requirement and guidelines on clinical trials for import and manufacture of new drugs