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Unit	:	2 (Part I)
Topic	:	Detailed Study of Schedule
Sub-topic	:	Schedule G, H, M, N, P, T, U, V, X, Y, Part XII B

DETAILED STUDY OF SCHEDULE

SCHEDULE 'G'

- List of substances required **to be used under medical supervision** and labelled accordingly.
- Labelled with the words 'Caution: **It is dangerous to take this preparation except under medical supervision'** – conspicuously printed and surrounded by a line within which there shall be no other words.

SCHEDULE 'H'

- List of substances **(prescription)** that should be sold by retail only on prescriptions of **R.M.P**.
- Labelled with the symbol **Rx** and conspicuously displayed on the left top corner of the label.
- Labelled with the following words '**To be sold by retail on the prescription of a Registered Medical Practitioner only'.**

Schedule 'M'

Requirements of manufacturing premises, **GMP requirements** of factory premises, plants and equipment's. It includes-

General requirements

- Location and surroundings- Free from open sewage, public lavatory, dust, smoke, excessive soot, obnoxious odour, chemical or biological emission.
- Buildings and premises- Designs suitable for manufacturing operation and maintain hygiene.
- Water system- Validated system for water treatment to make it usable and free from microbial growth.
- Disposal of wastes- Disposal shall be according to Environment Pollution Control Board and as per.

Warehousing area- Designs allow sufficient and orderly warehousing of various categories of materials and products.

Production area- Area shall be designed to allow the production preferably in uniflow with logical sequence of operation and avoiding the risk of cross contamination.

Ancillary area- Rest and refreshment rooms shall be separate with changing storing clothes facilities. Washing and toilet purposes shall be easily accessible.

Quality control area- Lab independent of production area with separate and adequate space for each type of testing.

Manufacturing operation- All operations shall be carried out under supervision of technical staff approved by Licensing Authority.

Documentation and record- It shall specify the title, nature and purpose and laid out in orderly fashion.

Schedule 'M1'

Requirements of factory premises for manufacture of **Homeopathic medicines.**

Schedule 'M2'

Requirements of factory premises for manufacture of **cosmetics.**

Schedule 'M3'

Requirements of factory premises for manufacture of **medical devices**

SCHEDULE 'N'

- List of minimum equipment for the efficient running of a pharmacy
- *Entrance shall bear an inscription "Pharmacy" in front*
- *Premises shall be separated from rooms for private use and it should be well built, dry, well-lit and ventilated and of sufficient dimension to keep the goods separately.*

SCHEDULE 'P'

Life period of drugs

- Period in months (unless otherwise specified) between date of manufacture and date of expiry which the labelled potency period of the drug shall not exceed under the conditions of storage specified.

SCHEDULE 'P-1'

Packing of drugs

- The pack sizes of drugs meant for retail sale shall be as prescribed.
  Ex; The pack sizes for liquid Oral preparations shall be 30ml (paediatric only) 60 ml/100 ml/200 ml/450 ml.

SCHEDULE 'T'

Requirements (GMP) of factory premises for **Ayurvedic, Siddha, Unani** drugs.

- For getting a certificate of 'Good Manufacturing Practices' of Ayurveda, Siddha-Unani drugs, the applicant shall made application on plain paper, providing the information on existing infrastructure of the manufacturing unit, and the licensing authority shall after verification of the requirements as per Schedule **'T'** issue the certificate within a period of 3 months in form 26-E.

SCHEDULE 'U'

Manufacturing, raw materials and analytical records of **drugs.**

- Lot of the raw material used for the manufacture of products and also each batch of the final product and shall maintain records.
- The records or registers shall be retained for a period of 5 years from the date of manufacture.

SCHEDULE 'U (1)'

Manufacturing, raw materials and analytical records of cosmetics

- The licensee shall keep records of the details of each batch of cosmetic manufactured by him and of raw materials used therein as per particulars specified in Schedule U (1).
- Such records shall be retained for a period of three years.

SCHEDULE 'V'

- The standards for patent or proprietary medicines shall be those laid down in Schedule V and such medicines shall also comply with the standards laid down in the Second Schedule to the Act.

SCHEDULE 'X'

List of narcotic drugs and psychotropic substances

- Symbol XRX in red on left hand top corner.

- Labelled with warnings: - To be sold on prescription of RMPs only.
- Drugs under this schedule may be imported under license or permit.

SCHEDULE 'Y'

Requirement and guidelines on clinical **trials** for import and manufacture of new drugs

It includes:

- Application for permission Clinical trial Studies in special population Post Marketing Surveillance.

Schedule F Part XII B – Subpart I

Requirements for Blood Bank / Blood Components.

- List of Equipment's
- Special Reagents
- Testing of whole blood
- Records
- Labels.

Schedule F Part XII B – Subpart II

Blood Donation Camps

A. Permission for camps to:

• Licensed designated Regional Blood Transfusion Centre

• Licensed Govt. Blood Bank

• Indian Red Cross Society

• Licensed blood bank run by registered voluntary or charitable organisations recognised by SBTC

B. Personnel for out-door camps

C. Equipment

Schedule F Part XII B – Subpart III

Processing of Blood Components

A. Accommodation

B. Equipment

C. Personnel

D. Testing facility

E. Categories of Blood Components

1. Concentrated Red Blood Cells

2. Platelet concentrate

3. Granulocytes

4. FFP

5. Cryo-precipitate

F. Apheresis

Donor Criteria

Monitoring

Reference:

Yadav, A., Remeth Dias, Vijay Havaldar, and Kailas Mali. Pharmaceutical Jurisprudence, 2012.