

Drugs and Cosmetics Act, 1940 and its rules 1945

Detailed Study of Schedules G, H, M, N, P, T, U, V, X, Y, Part XII B, Schedule F & DMR (OA)

- The **Schedules** in the Drugs and Cosmetics Act classify drugs based on various criteria, including their potential for abuse, control measures, and prescribing regulations.

Detailed Study of Important Schedules and Parts in The Drugs and Cosmetics Rules, 1945

Schedule G

Scope:

- Lists drugs that must carry the legend: "Caution: It is dangerous to take this preparation except under medical supervision" on their label.

Examples:

- Certain hormones, sulfonamides, and other drugs with significant adverse effects if used without medical guidance.

Importance:

- Ensures the necessity for medical supervision and warns consumers about the risks of unsupervised use.

Schedule H

Scope:

- Includes prescription drugs that can only be sold by retail on the prescription of a Registered Medical Practitioner (RMP).

Labeling Requirement:

- Must display: "Schedule H drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only."

Importance:

- Controls misuse of potent medications and ensures dispensing only on valid prescriptions.

Schedule M

Scope:

- Provides Good Manufacturing Practices (GMP) requirements for pharmaceuticals, including plant design, standards for premises, equipment, and operations.

Key Components:

- Quality control systems.

- Qualification and responsibilities of technical staff.
- Hygiene requirements.
- Self-inspection and quality audit protocols.

Importance:

- Ensures consistent manufacturing standards for drugs to maintain safety, efficacy, and quality.

Schedule N

Scope:

- Prescribes requirements for machinery, equipment, and premises for efficiently running a pharmacy.

Examples of Requirements:

- Adequate space for storage and dispensing.
- Proper facilities for cleanliness and order.

Importance:

- Ensures pharmacies meet minimum standards to safely store and dispense drugs.

Schedule P

Scope:

- Specifies the life period or shelf-life of drugs.

Key Details:

- Defines the duration a drug remains fit for consumption under recommended storage conditions.

Importance:

- Ensures consumers use drugs within safe time frames, reducing risks of degradation or reduced efficacy.

Schedule T

Scope:

- Provides Good Manufacturing Practices for Ayurvedic, Siddha, and Unani medicines.

Focus:

- Requirements for manufacturing premises and hygiene.
- Quality control for traditional medicine preparation.

Importance:

- Protects consumers by ensuring consistent quality in Indian traditional medicine systems.

Schedule U

Scope:

- Specifies particulars to be shown in manufacturing records and records to be maintained by manufacturers of drugs.

Key Points:

- Batch manufacturing records.
- Analytical reports.
- Distribution records.

Importance:

- Facilitates traceability and quality checks, aiding in batch recalls or investigations of quality complaints.

Schedule V

Scope:

- Covers standards for patent or proprietary medicines, including vitamin and mineral preparations.

Key Provisions:

- Minimum requirements for vitamin and mineral content.
- Labeling standards for patent or proprietary medicines.

Importance:

- Ensures OTC products meet minimum standards of quality and labeling.

Schedule X

Scope:

- Lists drugs requiring additional strict controls due to potential for abuse (e.g., psychotropic substances).

Requirements:

- Strict control on manufacturing and distribution.
- Special record-keeping for production, stocking, and sale.
- Sold only against prescription (similar to Schedule H but more stringent).

Importance:

- Prevents misuse or illegal trafficking of potent or habit-forming drugs.

Schedule Y

Scope:



FREE PREVIEW

[Click here to visit our website](#)

PHARMACY PREMIUM NOTES

Complete subject
and semesters are
available on
FirstHope app only.



[Scan or click here](#)

Click here to get the app



Available on Google Play

JOIN THE FIRSTHOPE COMMUNITY

Join our Telegram channel

Click here to join Telegram



[Scan or click here](#)

@FirstHopeNotes

Instagram

@firsthope.official

[Click here to follow >](#)

YouTube channel

FirstHope-Pharmacy / Live streams

[Click here to watch >](#)

WhatsApp channel

Follow FirstHope on WhatsApp

[Click here to join >](#)

FirstHope website

firsthopenotes.com

[Click here to visit >](#)

B.Pharm / D.Pharm / M.Pharm / Pharm.D

Preview notes. Complete subjects and semesters in the FirstHope app.