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PHARMACEUTICAL JURISPRUDENCE

UNIT 2

TOPIC :

- **Drugs and Cosmetics Act, 1940 and its rules 1945.**

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

Drugs and Cosmetics Act, 1940 and its rules 1945.

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

Schedule G – Prescription Drugs (Drugs to be taken only under medical supervision)

- Schedule G of the Drugs and Cosmetics Rules, 1945 lists certain drugs that must be used only under medical supervision.
- These drugs are not safe for self-medication because they may cause serious side effects, toxic reactions, or require periodic monitoring by a registered medical practitioner.
- The main purpose of Schedule G is to ensure safe and rational use of potent drugs that affect vital systems like the endocrine, nervous, and reproductive systems.

Legal Requirement

According to the Drugs and Cosmetics Rules, the following provisions apply to all Schedule G drugs:

- Labeling Requirement:
  Each container of Schedule G drug must bear the following cautionary label printed in red color:

  ⚠"Caution: It is dangerous to take this preparation except under medical supervision."

- Prescription Requirement:
  These drugs should not be sold without the prescription of a registered medical practitioner (RMP).
- Storage and Sale:
  - Schedule G drugs are usually sold by licensed pharmacies only.

- Pharmacists must maintain proper records of purchase and sale.

Examples of Schedule G Drugs

Below are some common examples of drugs that fall under Schedule G:

Category	Drug Examples	Use
Hormones	Thyroxine, Methyltestosterone, Stilboestrol	Endocrine disorders
Cytotoxic/Anticancer agents	Chlorambucil, Busulfan	Cancer treatment
CNS acting drugs	Phenobarbitone, Carbamazepine	Epilepsy and seizures
Antidepressants	Amitriptyline, Imipramine	Depression and anxiety
Antithyroid agents	Carbimazole, Propylthiouracil	Hyperthyroidism
Antihistamines (some)	Promethazine	Allergic conditions
Corticosteroids	Prednisolone, Hydrocortisone	Inflammatory conditions
Vitamins (in high doses)	Vitamin D, Vitamin A	Nutritional therapy under supervision

Purpose and Importance of Schedule G

- To prevent misuse and overuse of potent drugs.
- To ensure medical supervision during administration.
- To reduce the risk of adverse drug reactions and drug interactions.
- To ensure rational prescribing by qualified professionals.

Labeling Format Example

Every label of a Schedule G drug must look like this:
Caution: It is dangerous to take this preparation except under medical supervision.

- The warning should be conspicuous, legible, and printed in red on the outer label.

- The name of the drug, manufacturer, batch number, manufacturing date, and expiry date must also be clearly mentioned as per labeling rules.

Schedule H – Prescription Drugs

- Schedule H is one of the most important schedules under the Drugs and Cosmetics Rules, 1945.
- It contains a list of drugs that can be sold only on the prescription of a registered medical practitioner (RMP).
- These drugs are potent and may cause serious adverse effects or dependence if used without proper medical advice.
- The main objective of Schedule H is to regulate the sale and use of prescription-only medicines to prevent misuse, overuse, and self-medication.

Legal Definition

According to Rule 65 and Rule 97 of the Drugs and Cosmetics Rules, 1945:

Schedule H drugs shall be sold by retail only on and in accordance with the prescription of a registered medical practitioner, and each container of such drugs must be labeled with a specific caution.

Labeling Requirement

Each container of a Schedule H drug must bear the following warning label printed conspicuously in red:

⚠"Schedule H Drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only."

Additional labeling rules:

- The symbol "Rx" must be printed conspicuously on the top left corner of the label.

- No advertisement or promotional material for Schedule H drugs is allowed to the general public.
- These drugs must be kept under lock and key in a licensed pharmacy.

Sales and Record Requirements

- Retail sale of Schedule H drugs is permitted only by a registered pharmacist.
- The pharmacist must ensure the prescription is genuine and signed by a registered medical practitioner.
- Although maintaining a sale record is not compulsory (unlike Schedule X), prescriptions must be kept for reference for a reasonable period.
- Drugs must be stored securely to prevent misuse.

Examples of Schedule H Drugs

Category	Examples	Therapeutic Use
Antibiotics	Amoxicillin, Ciprofloxacin, Cephalexin	Bacterial infections
Antihypertensives	Atenolol, Amlodipine	High blood pressure
Antidiabetics	Metformin, Glibenclamide	Diabetes mellitus
Corticosteroids	Prednisolone, Dexamethasone	Inflammatory conditions
Antiepileptics	Phenytoin, Carbamazepine	Seizures and epilepsy
Antidepressants	Fluoxetine, Amitriptyline	Depression
Antipsychotics	Chlorpromazine, Haloperidol	Schizophrenia
Hormones	Insulin, Thyroxine	Endocrine disorders
Cardiac drugs	Digoxin, Propranolol	Heart diseases
Anticancer drugs	Cyclophosphamide, Methotrexate	Cancer therapy

Objective and Purpose

- To prevent irrational and unsafe use of potent medicines.
- To ensure that such drugs are used only under medical supervision.
- To protect the public from harmful effects of self-medication.

- To promote rational drug therapy and avoid drug abuse.
- To help regulatory authorities monitor the use and distribution of prescription drugs.

Schedule M – Good Manufacturing Practices (GMP) and Requirements of Premises, Plant, and Equipment for Pharmaceutical Products

- Schedule M of the Drugs and Cosmetics Rules, 1945 prescribes the Good Manufacturing Practices (GMP) and requirements for premises, plant, and equipment used in the manufacture of drugs and pharmaceuticals.
- Its main purpose is to ensure that drugs are consistently produced and controlled to meet the quality standards appropriate for their intended use.
- The Schedule ensures that manufacturing operations are scientifically designed, hygienic, and properly maintained to avoid contamination or errors.

Objective of Schedule M

The primary objectives of Schedule M are:

1. To maintain quality, safety, purity, and efficacy of pharmaceutical products.
2. To establish standard procedures for manufacturing, processing, packaging, and labeling.
3. To ensure hygienic conditions and proper maintenance of the manufacturing unit.
4. To prevent cross-contamination and mix-ups in production.
5. To ensure trained personnel and qualified supervision in every manufacturing process.

Legal Reference

- Authority: Central Drugs Standard Control Organization (CDSCO).
- Legal Basis: Issued under Rule 71, Rule 74, and Rule 76 of the Drugs and Cosmetics Rules, 1945.

- Applicability: Applies to all drug manufacturers in India producing:
  - Allopathic drugs
  - Homeopathic medicines
  - Veterinary medicines
  - Cosmetics and related products

Main Components / Parts of Schedule M

Schedule M is divided into different parts (A–M), each dealing with specific aspects of drug manufacturing.

Part	Subject / Title
Part I	General requirements for premises and materials
Part IA	Requirements for sterile products (e.g., injectables, ophthalmic preparations)
Part IB	Requirements for biological and biotechnological products
Part IC	Requirements for medical devices
Part II	Requirements for plant and equipment for various dosage forms
Part III	Requirements for testing and quality control
Part IV	Requirements for manufacture of cosmetics
Part V–M	Cover specific product types and special conditions

Key Provisions of Schedule M

(A) Location and Surroundings

- The factory must be located in a clean and sanitary environment, away from dust, smoke, or chemical fumes.
- Surroundings must be free from open drains, stagnant water, and other contamination sources.

(B) Building Design and Construction

- Building should be of sound construction with smooth, washable surfaces.
- Walls, ceilings, and floors must be easy to clean and disinfect.
- Adequate ventilation, lighting, and temperature control must be provided.

- Areas must be clearly divided into sections for:
  - Manufacturing
  - Quality control
  - Packaging
  - Storage
  - Administrative offices

(C) Water Supply

- Potable water and purified water systems must be available.
- Water used in production must comply with pharmacopoeial standards.

(D) Equipment

- All equipment must be made of non-reactive materials (e.g., stainless steel).
- Equipment should be cleaned, maintained, and calibrated regularly.
- Each machine must have logbooks and maintenance records.

(E) Personnel

- Manufacturing must be carried out under the active direction of competent technical staff.
- Personnel must be trained in GMP, hygiene, and safety practices.
- Proper clothing (gowns, gloves, caps, masks) must be used.

(F) Documentation and Records

- Proper documentation ensures traceability and accountability.
- Records include:
  - Master formula record
  - Batch manufacturing record
  - Batch packing record
  - Standard operating procedures (SOPs)
  - Equipment cleaning and calibration logs

(G) Manufacturing Operations

- Steps must follow SOPs to prevent contamination and mix-ups.
- Separate areas for penicillin, hormones, and cytotoxic products.
- Proper labeling and in-process quality checks are mandatory.

(H) Quality Control System

- A separate Quality Control (QC) department must exist with qualified staff.
- QC should test:
  - Raw materials
  - Intermediate products
  - Finished products
- Stability testing and validation of methods are mandatory.

(I) Packaging and Labeling

- Materials used for packaging must be clean, non-reactive, and tamper-proof.
- Labeling must comply with legal and pharmacopoeial standards.

(J) Storage

- Storage areas must maintain controlled temperature and humidity.
- Drugs should be stored in well-ventilated, clean, and organized shelves.

(K) Sanitation and Hygiene

- The premises must be cleaned regularly using approved disinfectants.
- Waste must be disposed of safely to avoid contamination.
- Periodic pest control is mandatory.

(L) Self-Inspection and Audits

- Manufacturers must conduct periodic internal audits to ensure compliance.
- Deviations and corrective actions must be documented.

Good Manufacturing Practices (GMP) – Core Principles

Schedule M emphasizes the following five pillars of GMP:

1. People – Trained, qualified, and responsible staff.
2. Premises – Hygienic, well-designed, and maintained facilities.
3. Processes – Validated manufacturing procedures.
4. Products – Consistent quality meeting pharmacopeial standards.

5. Procedures – Proper documentation for all operations.

Importance of Schedule M

- Ensures uniform quality of drugs throughout the country.
- Protects patients from substandard or contaminated medicines.
- Helps Indian manufacturers meet international quality standards (WHO-GMP).
- Forms the basis for licensing and inspection of manufacturing units.
- Strengthens public confidence in the safety and quality of pharmaceuticals.

Penalties for Non-Compliance

- Non-compliance may lead to:
  - Suspension or cancellation of manufacturing license.
  - Fines and imprisonment under the Drugs and Cosmetics Act.
  - Rejection of product batches during inspection.

Schedule N – Requirements for Premises and Equipment for Sale of Drugs

- Schedule N of the Drugs and Cosmetics Rules, 1945 specifies the minimum requirements of premises, furniture, and equipment to be maintained by pharmacies, chemist shops, and wholesale drug stores.
- It ensures that storage, handling, and sale of drugs are done under hygienic, safe, and controlled conditions.
- The main aim of Schedule N is to maintain the quality, potency, and safety of drugs during storage and sale until they reach the consumer.

Legal Basis

- Prescribed under Rule 65(1) and Rule 64 of the Drugs and Cosmetics Rules, 1945.
- It is applicable to all persons or establishments involved in the retail and wholesale sale of drugs and pharmaceuticals.
- It forms an important criterion for grant of license to sell drugs by retail or wholesale.

Objectives of Schedule N

1. To ensure that drugs are stored properly to maintain their quality and efficacy.
2. To prescribe standard requirements for premises and equipment of pharmacies.
3. To maintain sanitary conditions in drug stores.
4. To ensure availability of adequate facilities for the safe handling and dispensing of medicines.
5. To safeguard public health by preventing deterioration and contamination of drugs.

Key Provisions of Schedule N

A. Premises Requirements

- The premises must be well-constructed, clean, and hygienic.
- Minimum area required:
  - Retail pharmacy: at least 10 square meters.
  - Wholesale pharmacy: at least 15 square meters.
  - Combined retail and wholesale outlet: at least 15 square meters.
- The premises must have adequate lighting, ventilation, and cleanliness.
- It should be free from dust, dampness, and rodents.
- Flooring must be impervious and easy to clean.

B. Storage Facilities

- Drugs must be stored in proper conditions to maintain stability and potency.
- Storage areas must be well-ventilated and protected from direct sunlight.
- Separate storage for:
  - Schedule X drugs – under lock and key in a cupboard.
  - Poisonous drugs – in a separate cupboard marked "POISON".
  - Biological and thermolabile products – in refrigerators (2°C–8°C).
- Drugs should be arranged systematically with labeling and stock rotation (FIFO – First In, First Out).

C. Furniture and Equipment Requirements

Every pharmacy must be equipped with:

1. Dispensing counter – smooth, clean, and large enough for preparation.
2. Refrigerator – for storing vaccines, insulin, sera, and other biologicals.
3. Weighing balance – sensitive and properly calibrated for accurate weighing.
4. Dispensing apparatus – pestle and mortar, spatula, funnels, measuring cylinders, beakers, etc.
5. Glassware and containers – clean and suitable for dispensing preparations.
6. Shelves and cupboards – to store drugs in an organized and safe manner.
7. Sink with running water – for cleaning apparatus.

D. Personnel

- A qualified registered pharmacist must be present during business hours in retail outlets.
- The pharmacist must personally supervise the dispensing of medicines.
- Proper records must be maintained of all sales involving prescription drugs.

E. Sanitary Conditions

- The premises should be kept clean daily.
- Waste materials must be disposed of properly.
- There should be no accumulation of dust, garbage, or spillage.
- Proper pest control measures must be implemented.
- Drinking water and sanitary facilities must be available for staff.

F. Display and Labeling

- The name of the pharmacy and license number should be conspicuously displayed.
- "Pharmacy" or "Chemist and Druggist" signboards must be clearly visible.
- The license certificate issued by the licensing authority must be displayed in the premises.

G. Record and Documentation

- Maintain proper records of:
    - Sale of Schedule H, H1, and X drugs.
    - Purchase invoices and supplier details.
    - Prescriptions (especially for controlled drugs).
    - Expiry date monitoring and stock register.
- Records should be kept for at least 2 years for inspection.

Licensing Requirements (as per Schedule N)

- A pharmacy must meet Schedule N requirements to obtain a retail or wholesale drug license.
- License types include:
  - Form 20/21 – for retail sale of drugs other than Schedule X.
  - Form 20-B/21-B – for wholesale sale.
  - Form 20-F/21-F – for Schedule X drugs.
- The license may be suspended or cancelled if Schedule N standards are not maintained.

Importance of Schedule N

- Maintains drug integrity during storage and sale.
- Ensures hygienic and safe environment for drug handling.
- Helps in quality assurance at the distribution level.
- Protects the public from substandard or degraded medicines.
- Ensures compliance with legal and ethical pharmacy practices.

Schedule P – Life Period and Storage Conditions of Drugs

- Schedule P of the Drugs and Cosmetics Rules, 1945 specifies the life period (shelf life or expiry period) and storage conditions for various drugs and pharmaceutical preparations.
- It ensures that drugs are safe, effective, and stable until their expiry date when stored under prescribed conditions.
- The schedule helps manufacturers, pharmacists, and regulatory authorities maintain the quality and potency of medicines throughout their intended shelf life.

Legal Basis

- Prescribed under Rule 96 and Rule 105-B of the Drugs and Cosmetics Rules, 1945.
- Applies to all pharmaceutical manufacturers, wholesalers, and retailers in India.
- It defines the period between the date of manufacture and the date of expiry for each drug.

Objective of Schedule P

1. To define the official shelf life or life period of each drug.
2. To ensure drugs are stored under proper temperature and humidity.
3. To prevent degradation, contamination, or potency loss during storage.
4. To guide manufacturers and pharmacists in labeling correct expiry dates.
5. To ensure that patients receive safe and effective medicines up to the date of expiry.

Key Provisions of Schedule P

(A) Life Period

- The life period (also called shelf life) is the time interval between the date of manufacture and expiry date under specified storage conditions.
- Different drugs have different shelf lives depending on their stability and formulation type.
- Example:
  - Tablets and capsules → usually 3 to 5 years
  - Antibiotic syrups → 1 to 2 years
  - Vaccines and sera → few months only

(B) Storage Conditions

Schedule P specifies the exact temperature and humidity required for each drug to maintain its stability.

Common storage conditions include:

Storage Condition	Temperature Range / Requirement
Cold storage	Between 2°C and 8°C (in refrigerator)
Cool place	Between 8°C and 25°C
Room temperature	Up to 30°C
Protection from light	Stored in amber or opaque containers
Dry place	Protection from moisture and humidity
Freezer storage	Below 0°C (for certain biological products)

Labeling Requirements (as per Schedule P)

- Every drug label must mention:
  1. Date of manufacture
  2. Date of expiry or "Use before" date
  3. Storage conditions (e.g., "Store in a cool and dry place", "Protect from light")
- The expiry date must not exceed the period specified in Schedule P unless special permission is granted by the licensing authority.

Typical Examples of Drugs under Schedule P

Drug / Formulation	Life Period (Approx.)	Storage Condition
Aspirin tablets	3 years	Store in a cool, dry place
Paracetamol tablets	3 years	Below 30°C, protect from moisture
Vitamin C tablets	2 years	Cool, dry, and airtight container
Penicillin injection	1 year	Below 8°C, protect from light
Tetanus toxoid vaccine	6 months	Between 2°C and 8°C
Insulin injection	1 year	Refrigerator (2°C–8°C)
Oral rehydration salts (ORS)	2 years	Dry place
Eye drops (ophthalmic solution)	1 month (after opening)	Cool, sterile conditions

Responsibilities under Schedule P

Manufacturers:

- Must determine stability by accelerated stability studies.
- Must ensure labeling shows correct expiry date and storage conditions.
- Must provide batch records confirming compliance with Schedule P standards.

Pharmacists / Distributors:

- Must store drugs as per prescribed temperature and humidity.
- Should regularly check for expiry dates and discard expired drugs.
- Maintain proper stock rotation (FIFO – First In, First Out).

Importance of Schedule P

- Protects consumers from ineffective or harmful drugs due to improper storage.
- Helps in maintaining uniform quality standards for all marketed drugs.
- Acts as a legal guideline for drug labeling and expiry declaration.
- Ensures that temperature-sensitive products (like vaccines, antibiotics, hormones) are properly preserved.
- Supports rational distribution and storage practices in pharmacies.

Schedule T – Good Manufacturing Practices (GMP) for Ayurvedic, Siddha and Unani (ASU) Medicines

- Schedule T was inserted in the Drugs and Cosmetics Rules, 1945 in 2000 to ensure Good Manufacturing Practices (GMP) for Ayurvedic, Siddha, and Unani (ASU) medicines.
- It lays down minimum requirements of premises, plant, equipment, hygiene, documentation, and quality control to ensure that traditional medicines are safe, pure, and of consistent quality.
- It parallels Schedule M (for allopathic drugs) but is tailored to the unique nature of herbal and traditional formulations.

Legal Basis

- Framed under Rule 157 of the Drugs and Cosmetics Rules, 1945.
- Enforced by the Ministry of AYUSH, Government of India.
- Applicable to all licensed manufacturers of Ayurvedic, Siddha, and Unani medicines in India.

Objectives of Schedule T

1. To establish standardized production and quality systems for ASU drugs.
2. To ensure safety, efficacy, purity, and uniformity of traditional medicines.
3. To minimize contamination, adulteration, and mix-ups during manufacture.
4. To ensure scientific documentation and proper labeling.
5. To integrate traditional practices with modern quality assurance.

Structure of Schedule T

Schedule T is divided into two main parts:

Part	Title / Coverage
Part I	Good Manufacturing Practices (GMP) for ASU drugs
Part II	List of Machinery, Equipment, and Premises required for various categories of ASU formulations

Part I – Good Manufacturing Practices (GMP)

A. Location and Surroundings

- Factory must be located in a clean, hygienic environment, away from smoke, dust, and pollution.
- Surroundings should permit proper drainage and waste disposal.

B. Building and Layout

- Premises must be well-constructed, ventilated, and illuminated.
- Separate areas for:
  - Raw-material storage
  - Manufacturing and processing
  - Quality-control section
  - Packaging and labeling
  - Finished-product storage
  - Office and record keeping
- Floors and walls must be smooth, washable, and easy to clean.

C. Water Supply

- Must have potable, clean, and adequate water for washing, manufacturing, and cleaning purposes.

D. Equipment

- Equipment should be made of non-reactive, corrosion-resistant materials.
- Separate sets for metallic, mineral, herbo-mineral, and Rasa (preparations containing mercury or heavy metals).
- Regular cleaning, calibration, and maintenance records required.

E. Personnel

- Manufacturing must be supervised by qualified technical staff:
  - BAMS / BUMS / BSMS graduates or persons recognized by AYUSH.
- Workers should be trained in hygiene, equipment handling, and GMP.

F. Health, Clothing, and Hygiene

- Personnel must undergo periodic health check-ups.

- Clean protective clothing, head caps, masks, and gloves are mandatory.
- Smoking, eating, or drinking is strictly prohibited in production areas.

G. Raw Materials

- Only authentic, quality-tested herbs and raw materials should be used.
- Each batch of raw materials must be tested, labeled, and stored properly.
- Raw-material stores should have bins or containers labeled with source, batch, and date.

H. Manufacturing Process Control

- Each process (e.g., churna, taila, bhasma, asava-arishta) must have standardized operating procedures (SOPs).
- In-process quality checks should be performed at each step.
- Cross-contamination between different preparations must be prevented.

I. Packaging and Labeling

- Containers must be clean, dry, and non-reactive.
- Label must contain:
    - Product name and batch number
    - Date of manufacture and expiry
    - Net contents and dosage
    - Storage conditions
    - Manufacturer's name and license number

J. Storage

- Finished products must be stored in a cool, dry, and well-ventilated place.
- Products requiring refrigeration (e.g., certain arishtas or lehyas) must be stored accordingly.

K. Quality Control System

Each factory must have a Quality Control (QC) section, either inside the premises or at a recognized testing laboratory.
QC activities include:

1. Raw-material identification and authentication.
2. In-process and finished-product testing (organoleptic, chemical, and biological tests).
3. Stability and shelf-life studies.
4. Maintaining reference standards and documentation.

L. Record Keeping and Documentation

- Every batch must have:
  - Batch Manufacturing Record (BMR)
  - Batch Packing Record (BPR)
  - Distribution Record
- Proper documentation is essential for traceability and accountability.

M. Self-Inspection and Audits

- Periodic internal audits must be conducted to check GMP compliance.
- Corrective actions should be documented and implemented.

Part II – Machinery, Equipment, and Premises Requirements

This part specifies minimum equipment and space required for different dosage forms.

Dosage Form	Essential Equipment / Facilities
Churna (powder)	Pulverizer or grinder, sieves, blender, weighing balance
Asava–Arishta (fermented liquids)	Fermentation vessels, filters, storage tanks
Bhasma (calcined preparations)	Furnace, crucibles, muffle furnace
Taila/Ghrita (oils and ghee)	Steam-jacketed kettle, filtering unit, filling unit
Tablet (Vati/Gutika)	Mixer, granulator, tablet press, drying oven
Syrup (Avaleha/Leha)	Heating vessel, mixer, homogenizer
Eye/Ear drops (Netra / Karna prapara)	Laminar-flow area, sterilizer, filtration unit
Unani formulations	Separate area for Jawarish, Majoon, Arq

	preparations

Importance of Schedule T

- Establishes uniform national standards for ASU medicine manufacture.
- Improves credibility and international acceptance of traditional medicines.
- Ensures patient safety and therapeutic consistency.
- Promotes scientific documentation and quality control.
- Encourages integration of traditional knowledge with modern GMP practices.

Penalties for Non-Compliance

- Suspension or cancellation of manufacturing license.
- Seizure of drugs and prosecution under the Drugs and Cosmetics Act, 1940.
- Rejection of non-conforming product batches during inspection.

Schedule U – Records of Manufacture and Standardisation of Drugs

- Schedule U was introduced to ensure that accurate and detailed records of every batch of drug manufactured are maintained, verified, and traceable.
- It defines what documents, data, and test results must be recorded for each batch of allopathic drugs (and partly adapted for others).
- It ensures accountability, quality consistency, and regulatory compliance throughout the manufacturing process.

Legal Basis

- Provided under Rule 74 and Rule 78 of the Drugs and Cosmetics Rules, 1945.
- Applies to licensed manufacturers of allopathic formulations and bulk drugs.
- It complements Schedule M (Good Manufacturing Practices) by focusing on record maintenance and product standardisation.

Objectives of Schedule U

1. To maintain complete traceability of each batch of a drug manufactured.
2. To ensure that every product conforms to prescribed standards of strength, quality, and purity.
3. To record tests, inspections, and analytical results during production.
4. To facilitate regulatory audits and investigations.
5. To prevent mix-ups, contamination, and errors in labeling and packaging.
6. To support product recall in case of complaints or defects.

Scope of Schedule U

- Applies to every manufacturer who produces:
  - Bulk drugs (Active Pharmaceutical Ingredients)
  - Formulations (tablets, capsules, injections, ointments, etc.)
- It specifies the types of records that must be maintained and how long they must be preserved.

Classification of Records under Schedule U

Schedule U divides the manufacturing documentation into two major parts:

Part	Details
Part I	Records of Manufacture
Part II	Records of Standardisation (Testing and Analysis)

Part I – Records of Manufacture

These are the Batch Manufacturing Records (BMRs) containing full details of each batch of drug produced.

A. Details to be Recorded

1. Name of the drug and its dosage form.
2. Batch/Lot number.
3. Date of manufacture and date of expiry.
4. Size of the batch.
5. List of raw materials with quantity and code number.
6. Manufacturing process details:
    - Step-wise procedure used.
    - Temperatures, pressures, time, and conditions maintained.
    - Equipment and machinery used.
7. In-process controls and yield at each stage.
8. Name and signature of the responsible technical staff.
9. Packaging and labeling particulars.
10. Final yield and reconciliation of quantities.
11. Storage conditions and distribution records.

B. Authentication

- Every entry must be dated and signed by the production and quality-control personnel.
- Corrections must be countersigned to avoid tampering.

C. Preservation

- All batch-related records must be preserved for at least 5 years from the date of manufacture or one year after expiry, whichever is later.

Part II – Records of Standardisation

This section covers the testing and analysis carried out to ensure product quality.

A. Raw Material Testing

- Source and identification of materials.
- Specifications, test results, and certificate of analysis.
- Date of receipt, lot number, and status (approved/rejected).

B. In-Process Testing

- Physical and chemical control tests during manufacturing.
- Intermediate product specifications (e.g., granule moisture, pH, viscosity).

C. Finished Product Testing

- Complete analytical data verifying that the batch meets pharmacopoeial standards.
- Tests include:
    - Appearance, weight variation, disintegration, dissolution, pH, sterility, assay, etc.
- Results are entered in the Analytical Record Register.

D. Stability Studies

- Periodic testing for shelf-life determination and confirmation of expiry period.

E. Reference Samples

- Representative samples of each batch and of raw materials must be retained for re-testing or verification.

Supporting Records Required under Schedule U

Type of Record	Purpose
Master Formula Record (MFR)	Approved manufacturing and packaging formula for each product.
Batch Manufacturing Record (BMR)	Step-wise documentation of a particular batch.
Batch Packaging Record (BPR)	Details of labeling, coding, and packing operation.
Equipment Cleaning & Maintenance Log	To ensure cleanliness and performance of machinery.
Deviation and Change Control Records	To record any change from approved process.
Distribution Records	To trace every batch supplied to market.
Recall Records	For effective product recall when required.
Complaint and Adverse Reaction Reports	For pharmacovigilance and corrective actions.

Retention of Records

- Finished product records: Minimum 5 years after batch release.
- Raw-material records: Minimum 3 years after batch release.
- Sterile product records: Minimum 1 year after expiry date.

Importance of Schedule U

1. Maintains complete traceability from raw material to final product.
2. Ensures accountability of staff in manufacturing and testing.
3. Provides data for investigations, recalls, and audits.
4. Helps maintain uniform product quality.
5. Serves as legal evidence in case of regulatory inspection.

Penalties for Non-Compliance

- Suspension or cancellation of manufacturing licence.
- Seizure or destruction of non-compliant batches.
- Legal prosecution under the Drugs and Cosmetics Act, 1940.
- Loss of GMP certification and export authorisation.

Schedule V – Standards for Patent and Proprietary Medicines

- Schedule V of the Drugs and Cosmetics Rules, 1945 lays down the standards for patent and proprietary medicines, particularly those not included in any official pharmacopoeia such as the Indian Pharmacopoeia (IP), British Pharmacopoeia (BP), or United States Pharmacopoeia (USP).
- It ensures that all new, innovative, or proprietary formulations meet minimum quality, safety, and efficacy standards before being marketed.
- It applies to both Ayurvedic, Siddha, Unani (ASU) and Allopathic proprietary medicines.

Legal Basis

- Framed under the Drugs and Cosmetics Rules, 1945 in accordance with the Drugs and Cosmetics Act, 1940.
- Enforced through Rules 75, 76, 78, and 150 of the Drugs and Cosmetics Rules.
- Implemented by the Central Drugs Standard Control Organization (CDSCO) and State Licensing Authorities.

Definition

Patent or Proprietary Medicine

- Defined under Section 3(h) of the Drugs and Cosmetics Act, 1940:

  "Patent or Proprietary medicine" means a drug which is not included in the official pharmacopoeia of India or any other country, but which is a formulation containing one or more drugs with known therapeutic value and is invented, developed, or manufactured under a brand name by a manufacturer.

Objective of Schedule V

1. To establish quality standards for drugs not listed in official pharmacopoeias.
2. To ensure that such formulations are safe, effective, and stable.
3. To guide manufacturers in fixing standards for ingredients, dosage, and labeling.
4. To prevent misleading, substandard, or unsafe formulations from entering the market.
5. To maintain uniformity in quality and therapeutic value of proprietary medicines across India.

Scope of Schedule V

- Applies to patent and proprietary medicines of:
  - Allopathic system of medicine
  - Ayurvedic, Siddha, and Unani (ASU) systems
- Covers non-pharmacopoeial formulations, i.e., those not described in IP, BP, or USP.
- Specifies minimum requirements for:
  - Formula composition
  - Strength and dosage
  - Methods of preparation
  - Tests and assays for quality
  - Labeling and presentation

Requirements under Schedule V

A. Composition and Formula

- Each formulation must clearly specify the ingredients with their quantities per dosage unit.
- Ingredients must be official (pharmacopoeial) wherever possible, or well-characterized non-official substances.
- The therapeutic justification of each ingredient must be established.

B. Standards for Ingredients

- Active ingredients and excipients should:
  - Conform to recognized standards (e.g., IP, BP, USP, or AOAC).
  - Be pure, stable, and safe for use.
  - Have known pharmacological actions and not be harmful in prescribed doses.

C. Manufacturing Standards

- Manufacture must comply with Good Manufacturing Practices (GMP) as per Schedule M (for allopathic) or Schedule T (for ASU drugs).
- Each product should be manufactured under expert supervision by qualified technical staff.

D. Quality Control Tests

- Every formulation must undergo:
  - Physicochemical testing (pH, weight variation, disintegration, dissolution).
  - Chemical analysis (assay of active ingredients).
  - Microbiological testing (sterility, bacterial count, pyrogen test where applicable).

E. Labelling Requirements

- The label must bear:
  1. Name of the medicine (brand name and common name if any).
  2. Complete list of active ingredients with their strengths per dose.
  3. Name and address of the manufacturer.
  4. Batch number, manufacturing date, and expiry date.
  5. Storage conditions and cautionary statements.
  6. License number and drug code.

F. Safety and Efficacy Documentation

- Before approval, the manufacturer must submit:
  - Pre-clinical and clinical trial data (for new drugs).
  - Toxicological safety data.
  - Evidence of therapeutic efficacy.
  - Stability and shelf-life data.

G. Color, Flavor, and Additives

- Only approved colors, preservatives, and flavoring agents listed in Schedule Q (for colors) or Schedule F (for preservatives) may be used.
- Additives must be non-toxic and safe for human use.

Special Provisions for Ayurvedic, Siddha, and Unani Drugs

For ASU patent or proprietary medicines:

- They must contain only ingredients mentioned in authoritative texts listed in the First Schedule of the Drugs and Cosmetics Act.
- Combinations or modifications of traditional formulations must be scientifically justified.
- Safety and efficacy must be demonstrated through classical evidence or clinical data.

Approval and Licensing Procedure

1. Manufacturer submits the complete formula and process details to the Licensing Authority.
2. Quality Control and Analytical Data are verified.
3. Authority ensures compliance with Schedule M / T (GMP).
4. Product license is granted only after satisfying Schedule V standards.
5. Post-approval, periodic testing and revalidation are required.

Importance of Schedule V

1. Ensures uniform quality and safety of all proprietary medicines.
2. Prevents adulteration or irrational combinations in formulations.
3. Provides scientific basis for the approval of new or modified traditional formulations.
4. Protects consumers from substandard and spurious drugs.
5. Promotes innovation with regulatory safety assurance.
6. Supports standardization and global acceptance of Indian medicines.

Penalties for Non-Compliance

- Suspension or cancellation of manufacturing license.
- Confiscation of products and prosecution under Drugs and Cosmetics Act, 1940.
- Manufacturer may be blacklisted or fined for producing substandard or misbranded drugs.

Schedule X – Control of Narcotic and Psychotropic Substances

- Schedule X of the Drugs and Cosmetics Rules, 1945 contains a list of habit-forming, narcotic, and psychotropic substances that require special control in manufacture, storage, sale, and distribution.
- These drugs have a high potential for abuse, addiction, and misuse, hence are placed under strict regulatory supervision.
- Schedule X is closely linked with the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985.

Legal Basis

- Derived from the Drugs and Cosmetics Rules, 1945 under Rules 61, 97, and 122E.
- It works in conjunction with the NDPS Act, 1985 and the Drugs and Cosmetics Act, 1940.
- Administered by the Central Drugs Standard Control Organization (CDSCO) and State Drug Control Departments.

Definition

Schedule X drugs are:

"Drugs that have a high potential for abuse and dependence, and whose manufacture, sale, possession, and distribution are subject to special restrictions under the Drugs and Cosmetics Rules, 1945."

Objective of Schedule X

1. To prevent misuse and illegal trafficking of narcotic and psychotropic substances.
2. To ensure that these drugs are used strictly for medical and scientific purposes.
3. To maintain complete records of manufacture, sale, and prescriptions.
4. To ensure safe storage and dispensing under authorized supervision.
5. To protect public health and prevent drug dependence.

Examples of Drugs Listed in Schedule X

Category	Examples of Drugs
Narcotic Analgesics	Morphine, Codeine, Methadone
Barbiturates	Pentobarbital, Amobarbital, Secobarbital
Benzodiazepines (some)	Diazepam, Lorazepam, Nitrazepam
CNS Stimulants	Amphetamine, Dextroamphetamine, Methylphenidate
Others	Cocaine, Pethidine, Ketamine, Buprenorphine, Phenobarbital

Main Provisions of Schedule X

A. Licensing for Manufacture and Sale

- Separate licence required for manufacture, sale, and distribution of Schedule X drugs.
- The license must be obtained from the State Licensing Authority.
- Manufacturers and dealers must maintain strict stock and distribution records.

B. Prescription Requirement

- Schedule X drugs can be sold only on the prescription of a Registered Medical Practitioner (RMP).
- The prescription must:
  - Be written in duplicate (two copies).
  - Contain name, address, and registration number of the prescriber.
  - Mention drug name, dosage, and quantity clearly.
- One copy of the prescription is retained by the pharmacist for at least 2 years.

C. Record Keeping

- Retailers and wholesalers must maintain a register of all sales and stocks of Schedule X drugs.
- Details recorded include:
  - Name of the drug
  - Quantity received and sold
  - Name and address of the purchaser
  - Date of transaction
  - Doctor's prescription details
- Records must be preserved for at least 2 years and made available for inspection.

D. Storage

- Schedule X drugs must be stored in a locked cupboard or safe in the pharmacy.
- Access is allowed only to the pharmacist or authorized personnel.
- Storage areas must prevent pilferage, loss, or unauthorized access.

E. Labeling Requirements

- The label must carry the following warnings:
  1. "Schedule X Drug – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only."
  2. Manufacturer's name, address, batch number, and expiry date.
  3. Drug code and license number.
  4. Red 'X' mark on the label for easy identification.

F. Import and Export Restrictions

- Import or export of Schedule X drugs is strictly prohibited without prior approval from the Central Government or Drug Controller General of India (DCGI).
- Such drugs are also regulated under the Customs Act, 1962.

G. Disposal of Expired or Damaged Drugs

- Expired or damaged Schedule X drugs must be destroyed in the presence of a Drug Inspector with proper documentation and signatures.

Penalties for Violation

Violation of Schedule X provisions is a serious offence under the Drugs and Cosmetics Act and the NDPS Act.

Offence	Penalty
Unauthorized manufacture or sale	Imprisonment up to 3 years and/or fine
Possession without prescription	Seizure and prosecution
Tampering with records or illegal sale	License cancellation and criminal charges
Repeated offence	Stricter punishment including imprisonment up to 10 years

Difference Between Schedule H and Schedule X

Feature	Schedule H	Schedule X
Type of Drugs	Prescription drugs	Narcotic and psychotropic drugs
Potential for Abuse	Moderate	Very high
Prescription Copies	Single copy	Duplicate copy (one kept by pharmacist)
Storage Condition	Normal storage	Locked and secure storage
Record Keeping	Not mandatory	Mandatory (2 years minimum)
Label Marking	"Rx"	"XRx" (Red 'X' symbol)
Penalty for Violation	Moderate	Severe (includes imprisonment)

Importance of Schedule X

1. Prevents illegal drug trafficking and abuse.
2. Ensures responsible medical use of habit-forming drugs.
3. Protects the public from addiction and misuse.
4. Promotes controlled distribution and storage in pharmacies.
5. Provides traceability of every transaction involving narcotic substances.
6. Ensures legal accountability of prescribers and pharmacists

Schedule Y – Requirements and Guidelines for Clinical Trials for New Drugs

- Schedule Y of the Drugs and Cosmetics Rules, 1945 deals with the requirements and guidelines for conducting clinical trials, import, and manufacture of new drugs in India.
- It provides the legal framework for testing new drugs on humans to ensure their safety, efficacy, and quality before marketing.
- This schedule aligns Indian standards with international guidelines (ICH-GCP) for ethical and scientific conduct of clinical trials.

Objective of Schedule Y

1. To regulate clinical trials of new drugs in India.
2. To ensure protection of human subjects during clinical trials.
3. To ensure that data generated from trials are scientifically valid and ethically acceptable.
4. To define responsibilities of sponsors, investigators, and ethics committees.
5. To establish guidelines for import, manufacture, and marketing approval of new drugs.

Legal Basis

- Governed under Rule 122A, 122B, 122DA, 122DAA, 122DAB, 122DAC, 122DD and 122E of the Drugs and Cosmetics Rules, 1945.
- The detailed provisions are listed in Schedule Y.
- Central Drugs Standard Control Organization (CDSCO), under the Drugs Controller General of India (DCGI), is the competent authority to approve and monitor clinical trials.

Definition of Important Terms

Term	Meaning
New Drug	A drug not used in India before or a new dosage form, combination, or indication of an existing drug.
Clinical Trial	Any systematic study of new drug(s) in human subjects to evaluate safety, efficacy, and dosage.
Sponsor	Individual, company, or institution that takes responsibility for initiating and managing a clinical trial.
Investigator	Qualified person (usually a medical professional) responsible for conducting the clinical trial.
Ethics Committee (EC)	Independent body that ensures the rights, safety, and well-being of trial participants.

Phases of Clinical Trials as per Schedule Y

Phase	Description	Purpose
Phase I	Conducted on 20–80 healthy volunteers	To determine safety, tolerance, and pharmacokinetics
Phase II	Conducted on 100–300 patients with the target disease	To evaluate efficacy and dose range
Phase III	Conducted on 1,000–3,000 patients across multiple centers	To confirm efficacy, monitor side effects, and compare with standard therapy
Phase IV (Post-Marketing Surveillance)	Conducted after marketing approval	To detect rare or long-term adverse effects

Documents Required for Clinical Trial Approval

As per Schedule Y, the sponsor must submit the following to DCGI for approval:

1. Application Form (Form 44).
2. Preclinical (animal) data – toxicity, pharmacology, and pharmacokinetic studies.
3. Investigational New Drug (IND) Dossier – complete information on manufacturing, chemistry, and quality.
4. Clinical Trial Protocol – detailed plan of how the trial will be conducted.
5. Investigator's Brochure (IB) – details about the drug's preclinical and clinical data.
6. Informed Consent Form (ICF) and Patient Information Sheet (PIS).
7. Ethics Committee approval letter.
8. Insurance and compensation plan for subjects in case of injury or death.

Responsibilities under Schedule Y

A. Sponsor's Responsibilities

- Ensure scientific and ethical conduct of the trial.
- Provide necessary information to investigators and regulatory authority.
- Ensure insurance coverage and compensation for trial-related injuries.

B. Investigator's Responsibilities

- Conduct the study as per the approved protocol.
- Obtain informed consent from all participants.
- Report adverse drug reactions (ADRs) immediately to the sponsor and ethics committee.
- Maintain accurate records and case report forms.

C. Ethics Committee (EC) Responsibilities

- Review and approve the trial protocol before initiation.
- Ensure protection of participants' rights, safety, and privacy.
- Monitor ongoing studies for compliance with ethical standards.

Key Ethical Requirements

Schedule Y emphasizes compliance with Good Clinical Practice (GCP) principles:

1. Informed Consent – Participants must be fully informed about risks and benefits.
2. Voluntary Participation – No coercion or undue influence is allowed.
3. Confidentiality – Participant identity and medical records must be protected.
4. Compensation – Must be provided in case of injury or death due to trial.
5. Ethical Review – All trials must be reviewed by an independent Ethics Committee.

Import and Manufacture of New Drugs

- Import license is required for testing or marketing new drugs.
- Manufacturers must submit data from clinical trials conducted as per Schedule Y.
- No new drug can be imported, manufactured, or marketed without DCGI approval.

Post-Marketing Surveillance (PMS)

- Also known as Phase IV trials.
- Conducted to monitor long-term safety and rare adverse effects after drug approval.
- Reports must be submitted periodically to the licensing authority (DCGI).

Amendments to Schedule Y

- Major revision in 2005: Introduced Good Clinical Practice (GCP) guidelines and ethical framework.
- Recent updates include electronic submission of trial data, compensation rules, and mandatory registration of clinical trials on the Clinical Trials Registry of India (CTRI).

Importance of Schedule Y

1. Ensures ethical and scientific integrity in human drug testing.
2. Protects human volunteers and patients during clinical trials.
3. Maintains international standards of clinical research.
4. Ensures transparency, accountability, and reliability of clinical data.
5. Builds public trust in the safety and efficacy of new drugs.

Schedule F – Biological Products and Their Requirements

- Schedule F of the Drugs and Cosmetics Rules, 1945 specifies the standards, requirements, and conditions for manufacturing, storing, and testing biological products in India.
- These products are derived from living organisms (plants, animals, or microorganisms) and are used in the prevention, diagnosis, or treatment of diseases.
- Because biological products are sensitive and complex, strict quality control and aseptic manufacturing conditions are required to ensure their safety and effectiveness.

Legal Basis

- Issued under the Drugs and Cosmetics Rules, 1945, framed under the Drugs and Cosmetics Act, 1940.
- The provisions of Schedule F are mandatory for the manufacture, distribution, and sale of biological and special products.
- The rules are enforced by the Central Drugs Standard Control Organization (CDSCO) under the Drugs Controller General of India (DCGI).

Objective of Schedule F

1. To ensure uniform standards of strength, purity, and quality of biological products.
2. To lay down the conditions of licensing for the manufacture of biological and special products.
3. To ensure that these products are safe, potent, and sterile.
4. To regulate manufacturing, labeling, storage, and testing of all biological preparations.
5. To prevent contamination, degradation, and variability in biological products.

Products Covered Under Schedule F

Schedule F mainly covers biological and special preparations, including:

Category	Examples
Vaccines	Tetanus toxoid, Diphtheria vaccine, BCG vaccine, Rabies vaccine, Polio vaccine, Typhoid vaccine
Sera	Antitetanus serum, Antisnake venom serum, Diphtheria antitoxin, Antirabies serum
Toxins and Antitoxins	Tetanus toxoid, Diphtheria antitoxin
Bacterial and Viral Vaccines	Cholera vaccine, Typhoid-paratyphoid vaccine, Smallpox vaccine, Measles vaccine
Diagnostic Biological Products	Tuberculin, Mallein, Gonococcal diagnostic antigens
Immunological Products	Insulin, Growth hormone, Interferon, and similar biotechnological products

Key Provisions of Schedule F

A. Manufacturing Requirements

- Manufacturing must be done under aseptic conditions in sterile, dust-free, and temperature-controlled rooms.
- Separate manufacturing sections must exist for bacterial and viral products to prevent cross-contamination.
- Raw materials and finished products must be free from harmful microorganisms.

B. Building and Equipment

- The factory should have:
  - Sterile rooms with controlled temperature and humidity.
  - Clean air supply systems (HEPA filters).
  - Autoclaves, incubators, laminar airflow cabinets, and other sterile equipment.
  - Animal houses for testing biological potency and safety.

C. Personnel Requirements

- The manufacturing process must be supervised by a qualified and experienced person with:
  - A degree in medicine, veterinary science, pharmacy, microbiology, or biological science.
  - Adequate training in aseptic techniques and biological testing.

D. Storage Requirements

- Biological products are temperature-sensitive and must be stored under specific conditions.
- Commonly required conditions:
  - Cold storage: Between 2°C and 8°C (refrigerator).
  - Protection from light and moisture.
  - No freezing for certain vaccines (e.g., toxoids).

E. Labeling Requirements

Each biological product must have a label containing:

1. Name of the product and manufacturer.
2. Batch number and date of manufacture.
3. Expiry date and storage conditions.
4. Type of preservative used (if any).
5. Statement of potency and dosage form.
6. Warning such as “For Intramuscular Use Only” or “Store Between 2°C and 8°C” as applicable.

F. Testing Requirements

- Each batch must undergo the following tests:
  1. Sterility test – ensures product is free from microorganisms.
  2. Safety test – ensures it does not cause harmful reactions.
  3. Potency test – ensures desired biological activity.

4. Pyrogen test – checks for fever-producing substances (especially for injectables).

Licensing Provisions

- A special manufacturing license is required for biological products.
- Application must include:
  - Manufacturing plan and layout,
  - List of equipment,
  - Qualifications of technical staff, and
  - Quality control facilities.
- License may be suspended or cancelled if conditions of Schedule F are not followed.

Importance of Schedule F

1. Ensures production of safe and potent biological products.
2. Prevents outbreaks or health hazards from contaminated vaccines or sera.
3. Maintains international quality standards for biological preparations.
4. Helps manufacturers and regulators maintain quality consistency.
5. Protects public health by ensuring proper labeling, handling, and storage.

Distinction Between Schedule F and F(1)

Schedule	Subject
Schedule F	Standards for biological and special products (vaccines, sera, etc.)
Schedule F(1)	Standards for cosmetics (e.g., soaps, creams, powders)
Schedule F(II)	Standards for surgical dressings (e.g., gauze, bandages)

Part XII-B – Requirements for the Manufacture, Testing and Control of Medical Devices

- Part XII-B of the Drugs and Cosmetics Rules, 1945 specifies the regulatory requirements for manufacturing, testing, quality control, labeling, and storage of medical devices in India.
- It was introduced to ensure that medical devices are safe, effective, and of good quality, just like pharmaceutical products.
- This part provides a legal framework for Good Manufacturing Practices (GMP) and Quality Management Systems (QMS) for medical devices.

Legal Basis

- Governed under the Drugs and Cosmetics Act, 1940 and the Rules of 1945, specifically Part XII-B (Rules 109A to 109X).
- The Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare is the national regulatory authority responsible for implementing these rules.
- The Drugs Controller General of India (DCGI) acts as the licensing authority for medical devices.

Objective of Part XII-B

1. To ensure safety, performance, and quality of medical devices used in healthcare.
2. To prescribe standards and conditions for the manufacture, testing, storage, and labeling of medical devices.
3. To align Indian device regulations with international standards such as ISO 13485 (Quality Management System for medical devices).
4. To ensure protection of public health by minimizing risks from faulty or substandard devices.

Meaning of "Medical Device"

According to the Rules, a medical device means any instrument, apparatus, appliance, material, implant, or reagent used for:

- Diagnosis, prevention, monitoring, treatment, or alleviation of diseases or injuries.
- Supporting or sustaining life (e.g., pacemakers).
- Disinfection of medical devices.
- Control of conception (e.g., intrauterine devices).

Examples: Syringes, catheters, stents, heart valves, orthopedic implants, X-ray machines, blood pressure monitors, etc.

Scope of Part XII-B

Part XII-B lays down requirements for:

1. Manufacture of medical devices.
2. Testing and calibration of equipment.
3. Quality control and documentation.
4. Storage and distribution of devices.
5. Labeling and packaging.
6. Record keeping and recall procedures.

Classification of Medical Devices (Based on Risk)

To ensure proper regulation, medical devices are classified into four risk-based categories:

Class	Risk Level	Examples
Class A	Low risk	Thermometers, stethoscopes, surgical gloves
Class B	Low–moderate risk	Hypodermic needles, suction equipment
Class C	Moderate–high risk	Ventilators, dialysis machines
Class D	High risk	Heart valves, pacemakers, implantable defibrillators

Key Provisions of Part XII-B

A. Manufacturing Premises

- Premises must be clean, well-ventilated, and properly designed to prevent contamination.
- Separate areas for manufacture, testing, and packaging.
- Use of validated and calibrated equipment.
- Facilities must meet Good Manufacturing Practice (GMP) standards similar to pharmaceutical plants.

B. Personnel Requirements

- Staff must be qualified and trained in medical device manufacturing and quality control.
- Technical head should have a degree in engineering, pharmacy, or science with experience in production or testing of medical devices.

C. Quality Management System (QMS)

- Manufacturer must implement QMS in line with ISO 13485.
- QMS covers:
  - Design and development control
  - Risk management
  - Corrective and preventive actions (CAPA)
  - Documentation and internal audits
  - Validation of production processes

D. Testing and Quality Control

- Devices must undergo routine quality checks for performance, safety, and sterility (where applicable).
- Each device should conform to the Indian Standards (BIS) or ISO/IEC standards.
- Calibration of instruments must be done periodically and recorded.

E. Labeling Requirements

As per Rule 109A and subsequent rules, every medical device label must include:

1. Name of the device and manufacturer.
2. Batch number / Lot number / Serial number.
3. Manufacturing and expiry dates.
4. Storage conditions (if applicable).
5. Instructions for use (IFU).
6. Warning or caution statements (e.g., “For single use only”, “Sterile unless package opened”).
7. Import license number, if imported.

F. Storage and Distribution

- Devices must be stored in clean, dry, and temperature-controlled areas.
- Distribution should ensure product integrity is maintained.
- Damaged or expired products must be removed and disposed of safely.

G. Record Maintenance

- Manufacturers must maintain detailed records of production, testing, and sale.
- Records should be retained for at least 2 years after expiry of the device or as prescribed.
- Documentation must allow traceability of every batch or unit manufactured.

H. Product Recall Procedure

- In case of any defect, adverse event, or safety concern, the manufacturer must recall the defective batch immediately.

- The recall must be reported to CDSCO and State Licensing Authority.

Licensing Provisions

- No person shall manufacture a medical device without obtaining a license from the State Licensing Authority or DCGI (depending on the class of device).
- Separate licenses are required for:
  - Manufacture (Form MD-5)
  - Loan license (Form MD-6)
  - Import (Form MD-15)

Inspection and Audits

- The licensing authority may conduct periodic inspections or audits of manufacturing sites.
- Non-compliance may lead to suspension or cancellation of license.
- Corrective actions must be implemented within the specified time.

Importance of Part XII-B

1. Ensures safe and effective medical devices for public use.
2. Reduces risks of device failure or patient injury.
3. Brings Indian regulations in harmony with global standards.
4. Promotes quality assurance and accountability among manufacturers.
5. Enhances patient confidence in the reliability of healthcare devices.

DMR (OA) – Drug Manufacturing Records for Ophthalmic and Antibiotic Preparations

- DMR (OA) stands for Drug Manufacturing Records (Ophthalmic and Antibiotic preparations).
- It refers to the set of mandatory records and documentation that a manufacturer must maintain while producing ophthalmic (eye) and antibiotic preparations.
- These records ensure that the manufacturing process is controlled, standardized, and traceable, maintaining the quality, safety, and efficacy of the products.
- DMR (OA) requirements are part of the Good Manufacturing Practices (GMP) under the Drugs and Cosmetics Rules, 1945.

Objective of DMR (OA)

The main objectives are:

1. To ensure each batch of ophthalmic and antibiotic preparations is manufactured as per approved specifications.
2. To maintain complete traceability from raw materials to finished product.
3. To ensure quality consistency between batches.
4. To provide documentary evidence for regulatory audits and quality assurance.
5. To detect and prevent errors, contamination, or deviations during production.
6. To facilitate recall of any defective batch if necessary.

Legal Basis

- Governed under the Drugs and Cosmetics Rules, 1945, in relation to Schedule M (Good Manufacturing Practices) and Schedule F (Biological and Special Products).
- Rule 74 and Rule 78 emphasize maintenance of Batch Manufacturing Records (BMR) and Batch Packaging Records (BPR) for every batch of drugs.

- DMR (OA) specifically focuses on Ophthalmic and Antibiotic formulations, which require aseptic conditions and special handling.

Scope of DMR (OA)

DMR (OA) covers all manufacturing records related to:

1. Ophthalmic preparations – sterile eye drops, eye ointments, eye lotions.
2. Antibiotic preparations – penicillin, cephalosporin, tetracycline, erythromycin, etc.

These products are highly sensitive and require aseptic environments to prevent contamination.

Importance of DMR (OA)

Reason	Explanation
Safety	Prevents contamination that can cause serious infections in the eye or body.
Quality Assurance	Confirms every batch meets purity, potency, and sterility standards.
Regulatory Compliance	Fulfills legal requirements under Drugs and Cosmetics Act.
Accountability	Identifies who performed, checked, and approved each stage of production.
Traceability	Helps track any defect back to its origin (raw material or process step).

Components of DMR (OA)

The Drug Manufacturing Record (DMR) must contain comprehensive details for each batch produced.

Below are the essential components of DMR (OA):

A. General Information

- Name of the product (generic and brand name).
- Batch number, batch size, and manufacturing date.
- Formula reference number (master formula record).
- License number and manufacturing unit details.
- Manufacturing and expiry dates.

B. Master Formula Record (MFR)

- Contains complete formulation details for ophthalmic or antibiotic preparations, including:
  - List and quantity of raw materials.
  - Equipment used.
  - Step-by-step manufacturing procedure.
  - Environmental requirements (temperature, pressure, aseptic area conditions).

C. Raw Material Record

- Name, code, and batch number of each ingredient used.
- Quantity weighed and issued by the store.
- Certificate of Analysis (CoA) confirming raw material quality.

D. Equipment and Area Record

- Cleaning and sterilization log of equipment (e.g., autoclave, filling machine, filtration unit).
- Environmental monitoring data for sterile areas.

- Record of area clearance before starting manufacturing.

E. Manufacturing Process Record

- Step-by-step record of each stage of production, such as:
  - Dissolution, filtration, filling, sealing, sterilization, labeling, and packing.
- Record of process parameters like temperature, pressure, and time.
- Signatures of production and quality assurance (QA) personnel.

F. In-Process Quality Control (IPQC) Record

- Parameters checked during production:
  - Clarity, pH, volume, fill weight, viscosity, sterility, potency, and particle contamination.
- Sampling records and acceptance/rejection decisions.

G. Sterilization Record

- Details of sterilization method used (autoclaving, dry heat, membrane filtration, etc.).
- Sterilization cycle number, date, temperature, and duration.

H. Packaging and Labeling Record

- Details of the container, closure, and packaging material used.
- Label sample with batch number, manufacturing date, expiry date, and storage instructions.
- Verification of correct labeling by QA department.

I. Finished Product Testing Record

- Results of all finished product quality control tests:
  - Sterility test
  - Assay (potency)
  - pH

- Clarity / Absence of particulate matter
- Pyrogen test (for injectables)
- Physical appearance

J. Batch Release and Distribution Record

- QA release approval with date and signature.
- Quantity of batch released for sale.
- Details of distributors, markets, or hospitals supplied.
- Retention samples stored for future reference.

Special Requirements for Ophthalmic and Antibiotic Preparations

A. Ophthalmic Preparations

- Must be sterile and free from particles.
- Containers must be tamper-proof, airtight, and dropper-type.
- Use of preservatives must be justified and within permissible limits.
- No re-use of containers or droppers allowed.

B. Antibiotic Preparations

- Separate facilities are required for penicillin and non-penicillin antibiotics to prevent cross-contamination.
- Air filtration (HEPA) and environmental monitoring must be ensured.
- Potency must be checked by microbiological assay methods.
- Labels must indicate potency units per dose and storage conditions (e.g., below 25°C or refrigerated).

Retention of Records

- DMR (OA) must be preserved for at least 5 years from the date of manufacture or 1 year after the expiry date (whichever is later).

- Records must be easily retrievable for inspection by the Drug Control Authority.

Inspection and Auditing

- Regulatory inspectors may verify DMR (OA) during GMP audits.
- Non-compliance (missing or falsified records) can lead to:
  - Suspension of manufacturing license
  - Product recall or destruction
  - Legal prosecution under the Drugs and Cosmetics Act.

Importance of Documentation (DMR)

Proper DMR ensures:

- Accountability at every stage of manufacturing.
- Compliance with GMP and Schedule M requirements.
- Traceability of all batches produced.
- Assurance of product safety and efficacy.