# Unit-2
# Pharmaceutical Jurisprudence

## B.Pharma 5th Sem Notes

## Unit: 2

**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)
- Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties
- Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties.
- Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs
- Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors.

**Drugs and Cosmetics Act, 1940 and its rules 1945:**

# Introduction:

The Drugs and Cosmetics Rules, 1945 are the rules which the government of India established for the implementation of the Drugs and Cosmetics Act, 1940. These rules classify drugs under given schedules and present guidelines for the storage, sale, display and prescription of each schedule.

- The modern medicines have been imported by India till after the first word war which made India mostly dependent.
- In August 1930, the Government of India, under the chairmanship of R.N. Chopra appointed a Drug Enquiry Committee for the quality & standard of drugs sold and recommendation for control measure.
- In 1937, a bill was introduced to give effect to the recommendations of the Drugs Enquiry Committee in the Central Legislative Assembly for a more comprehensive measure for the uniform control of import, manufacture, distribution and sale of drugs was desirable.
- In 1939, the Drug Import Bill was prepared & placed for consideration before the Central Legislative Assembly.
- In 10th April, 1940 the bill was passed & received assent of the Governor General in Council & became the Drugs and Cosmetics Act.
- In 1945, the related Drugs Rules were passed & since 1940, a number of amendments have been done in the Act and is currently known as the Drugs and Cosmetics Act, 1940.

# Objective of the Act

The primary objectives of the Act include:

- The act visualizes the regulatory control over the drugs imported in the country by central government while the manufacture sale and distribution of drugs is primarily regulated by the state drug control authorities appointed by the respective state governments.
- The primary objective of the act is to ensure that the drugs and cosmetic sold in India are safe, effective and conform to state quality standards and to make available standard quality drug/ cosmetic to consumer.
- The manufacture and sale of the drugs is regulated through a system of licensing and inspection by the licensing authorities.
- The Central Drugs Standard Control Organization (CDSCO), headed by the Drugs Controller General, India is concerned with the regulatory control over the quality of drugs & cosmetics.

## Schedules:

- The Drugs and Cosmetics Rules, 1945 has provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule.
- The Rule 67 details the conditions of licenses. The Rule 97 contains the labeling regulations.

The notable Schedules include:

**Schedule G:**

- These drugs include hormonal medications (excluding sex hormone medications), antineoplastic drugs, anticonvulsants (e.g. 2,4-oxazolidinediones, ureides), hypoglycemic drugs (e.g. sulfonylureas, biguanides), antihistamines, etc.
- The drug label must display the text "Caution: It is dangerous to take this preparation except under medical supervision" prominently. Examples of substances under this schedule: All insulin preparations, testolactone, hydroxyurea, daunorubicin, metformin, diphenhydramine, carbutamide, primidone etc.

**Schedule H:**

- Each drug's label must prominently display the symbol "Rx" and a red-boxed warning "**Schedule H drug. Warning:** "Not to be sold by Retail without the prescription of a Registered Medical Practitioner".
- It can only be supplied to licensed parties. It cannot be sold without a prescription and only the amount specified in the prescription should be sold.
- The time and date of prescription must be noted. Examples: androgenic, anabolic, oestrogenic and progestational substances; Alprazolam (Xanax), Hepatitis B vaccine, Ibuprofen, Vasopressin etc.
- If a Schedule H drug also comes under the purview of Narcotic Drugs and Psychotropic Substances Act, 1985, the drug's label must prominently display the symbol "NRx" and a red-boxed warning "**Schedule H drug. Warning**: "Not to be sold by Retail without the prescription of a Registered Medical Practitioner".

**Schedule H1:**

- Notified in 2013,[5] this list includes third and fourth generation antibiotics, some psychotropic drugs and anti-TB drugs.
- A separate register is to be maintained to track supply of these drugs and labelling requirements are of the symbol "Rx" and the red boxed warning : "**Schedule H1 Drug-Warning:** It is dangerous to take this preparation except in accordance with the medical advice. -Not to be sold by retail without the prescription of a Registered Medical Practitioner."

**Schedule M:**

- This schedule outlines the Good Manufacturing Practices (GMP) for pharmaceutical manufacturing units in India.
- It focuses on maintaining quality standards within the manufacturing facility, covering aspects like manufacturing premises, plant, and equipment.
- Recent revisions emphasize product quality review, pharmaceutical quality systems, quality risk management, and computerized storage systems.

**Schedule N:**

- This schedule specifies the requirements for the premises and essential equipment needed to run a pharmacy efficiently.
- This includes adequate space, ventilation, sanitation, proper storage for medicines, and necessary furniture and apparatus for dispensing.

**Schedule P:**

- Contains regulations regarding life period and storage of various drugs.

**Schedule P-I:**

- Contains regulations regarding retail package size of various drugs.

**Schedule T:**

- This schedule provides specific guidelines for Good Manufacturing Practices (GMP) for Ayurvedic, Siddha, and Unani (ASU) drugs.
- It covers the requirements for manufacturing units, machinery, equipment, and minimum manufacturing premises needed for different categories of ASU drugs, ensuring the authenticity and quality of these traditional medicines.

**Schedule U:**

- This schedule contains regulations related to the particulars that must be recorded for raw materials, manufacturing processes, analytical testing, and finished product packaging for various drug products.
- It also lays down the requirements for operating a blood bank, including necessary facilities, personnel, equipment, testing procedures, and record-keeping.

**Schedule V:**

- This schedule contains standards for drug patents. It also mentions that drugs under this schedule must prominently display the caution: "It is dangerous to take this preparation except under medical supervision." Examples include insulin preparations, testolactone, hydroxyurea, and metformin.

**Schedule X:**

- This schedule lists a special category of prescription drugs that are highly regulated due to their potential for addiction and abuse.
- These drugs cannot be sold without a valid prescription from a registered medical practitioner, and retailers must maintain a record of these prescriptions for two years.
- Many narcotic drugs fall under this category.

**Schedule Y:**

- This schedule provides guidelines for the conduct of clinical trials of new drugs in India.
- It covers all aspects of clinical trial conduct, including study design, ethical review, informed consent, data management, and reporting, ensuring the safety and efficacy of new drugs before they are approved for use in India.

**Part XII B of Schedule F:**

- This part pertains to the import and export of narcotic drugs and psychotropic substances. It prohibits such activities except with a valid import certificate or export authorization issued under the relevant rules.

**Schedule F:**

- This schedule contains regulations for blood banks and blood components.
- It specifies the requirements for premises, including air-conditioned areas for various activities like blood collection, component preparation, testing (blood group serology and tests for blood transmissible diseases), sterilization, and storage.
- It also details the necessary reagents and solutions and their testing frequencies.

**DMR (OA):**

- This refers to the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.
- This act controls the advertising of drugs in India and prohibits the advertisement of drugs and remedies that claim to possess magical properties or make false claims.
- Violations of this act are considered a cognizable offense.

# Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties

## Sale of Drugs:

The **Drugs and Cosmetics Act, 1940** regulates the import, manufacture, distribution, and sale of drugs and cosmetics in India. It ensures that drugs sold to the public meet required standards of safety, efficacy, and quality.

The **sale of drugs** in India is classified into:

- **Wholesale Sale**
- **Retail Sale**
- **Sale under Restricted License**

**Wholesale:** From stockist to shopkeepers.

**Retail sale:** From shopkeepers (drug store, chemists and druggists, pharmacy or dispensing chemist) to patients.

**Wholesale of Drugs**

- Wholesale means a dealer or his agent or stockiest engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency.

**Drugs other than these specified in schedule C, C1 and X:**

- Issued in form 20B licensee
- Drug should be purchased only form a dully Licensesd dealer or manufacture.
- Schedule X drugs — Licenses issued in Form 20G.

**Drug specified in schedule C & C1 but not included in schedule X:—**

- License issued in the form 21B.

**Drugs specified in schedule C & C1 from motor vehicle:**

- License issued in the form 21BB.

## Retail Sale:

For retail Sale two types of Licensess are issued,

1. General
2. Restricted

General licenses are granted to persons who have premises for the business and who engage the services of a qualified person to supervise the sale of drugs and do the Compounding and dispensing.

**Conditions:**

- Licenses should be displayed in a prominent place in a part of the premises open to public.
- License should comply with provisions of Drugs and Cosmetics Act and Ruler in force.
- Any change in the qualified staff in charge should be steparted by licensee to licensing authority with in 1 month
- Any change in Constitution of licensed firm should be informed to licensing authority with in 3 months and in the meantime fresh Licenses should be obtained in the home of the firm with changed Constitution.

## Restricted licenses

- Licenses for restricted sale of drugs other than those specified in Schedule C, $C_1$ and X and those specified in Schedule C, and C1 but not in Schedule X are issued in the form 20A and 21A Respectively.

**Condition for Best Restricted Licenses: -**

- Licensee must have adequate premises equipped with facilities for proper storage of drugs to which Licenses applies provided that this condition does not apply to vendors.
- Licensee should comply with provisions of Drugs and Cosmetics Act and rules in force.
- Drugs should be purchased only from a duly licensed dealer or manufacturer.
- If licensee is a vendor having no fined place of business, he should buy drugs from dealers specified in his Licenses.

**Drugs should be sold in their original containers.**

- Labeling and Packing of Drugs
- The Containers of all the drugs including patent or proprietary medicine are to be labelled in accordance with the Drugs and Cosmetics Rules 1945.

**Following particulars should be either printed on written in indelible ink and should appear in a conspicuous manner on label of the inner most container of any drug and every other Covering in which the Container is packed: -**

- Proper name of the drug should be printed in a more conspicuous manner than the trade name, if any.
- A Correct statement of the net contents in term of weight, measure, volume, number of units of activity as the Case of units of may be are expressed in motrin system.
- The name and address of manufactured. In case of the drug contained in an example or a similar small container it is enough if only the name of the manufacturer and his principal place of business is shown.
- Manufacturing Licenses Number, or mfg. Lic. No, or M. L.
- A distinctive batch number, the figuere reperesenting the batch number being preceded by the words 'Batch No, or B. No, or Lot No, or Lot.

**Expiry particulars.**

- Precautionary information related to care in handling, use, distribution etc.
- Information suclated to storage all manner af use.
- General information such as 'physician's sample, not for sale etc.

**Packing of Drugs**

- The pack size of drugs meant for retail sale shall be as prescribed schedule P1 to the rules and for in Other drugs given bellow.

1) less than 10 Tablets/ Capsules: Packing by integral number

- More than 10 Tablets / Capsules: Multiples of 5

2) Liquid oral pereparation: - 30ml (paediatric only) 60ml /100ml/200ml/450ml

3) Paediatric oral drops: 5ml/10ml/15ml

4) Eye / Ear / nasal drops: 3ml | 5ml | 10ml

5) Eye ointment: 3 gm / 5gml / 10gm.

**However these provisions shall not apply to**

i. Imparted formulations in finished form
ii. Preparations for veterinary use
iii. Preparations for export.
iv. Vitamins / tonics | Cough preparations) antacids | laxatives in liquid oral forms / unit dose forms.
v. Physician's samples, pack sizes of dosage forms af for retail sale to hospitals.
vi. Pack sizes of large valume IV fluids.

**The Schedule X drugs shall be marketed in packing not exceeding: -**

i. 100 unit doses in the case of tablets / Capsules.

ii. 300ml in the case of aral liquid preparations.
iii. 5ml in case of injections.

**License & their Form No:**

| License Issued | Drugs Other than Schedule C, C1 & X drugs | Schedule C & Ca drugs | Schedule X drugs. |
|---|---|---|---|
| **Retail** | 20 | 21 | 20-F |
| **Wholesale** | 20-B | 21-B | 20-G |
| **Wholesale from Motor** | 20-BB | 21-BB | - |
| **Restricted** | 20-A | 21-A | - |

**Offences:**

- Sale, stocking, exhibition or offer for sale of drugs which may cause death or serious hurt as per section 320 of IPC.
- Sale, stocking, exhibition or offer for sale of spurious drugs.
- Sale, stocking, exhibition or offer of sale in contravention of any other provision.
- Sale, stocking, exhibition or offer for sale of adulted drugs.

**Penalties:**

| First conviction | Second conviction |
|---|---|
| Upto 5 years and extending upto lifetime and fine of not less than 10,000 | Upto 10 years or fine upto 20,000 or both |
| 1-3 years and fine of not less than 5,000 | 2-4 years/ fine upto 10,000 |
| Less than a year and a lesser fine. | Not less than 2 years /fine upto 10,000 |
| 3-5 years/fine of not less than 5,000. | Notless than 6-10 years/ fine upto 10,000. |
| Imprisonment from 1-2 years and fine. | Imprisonment for 2 4 years / fine upto 5,000 or both. |
| Fine upto 500 | Upto 10 years /with fine or both |

## Labelling and Packing of Drugs and Cosmetics in India

- The labelling and packing of drugs and cosmetics in India are governed by the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945, which were further updated by the Cosmetics Rules, 2020. These regulations are implemented and overseen by the Central Drugs Standard Control Organization (CDSCO). The primary aim of these regulations is to ensure the safety, efficacy, quality, and proper use of drugs and cosmetics, and to provide consumers with adequate information to make informed decisions.

## Labelling of Drugs

Drug labelling in India is strictly regulated, and all labels must conform to the specifications outlined in the Drugs and Cosmetics Rules, 1945. Key requirements for drug labels include:

- **Name of the Drug:** The proper name of the drug or fixed-dose combination (up to two drugs) must be clearly printed in a font size at least two sizes larger than the brand name or trade name. For combinations with three or more drugs, the brand name or trade name should be conspicuously displayed below or after the proper name.
- **Quantity of Active Ingredients:** The label must clearly state the quantity of each active ingredient present in the formulation.
- **Manufacturer Details:** The name and address of the manufacturer must be mentioned on the label. For imported drugs, the name and address of the importer should also be included. A manufacturing license number must also be present.
- **Batch Number:** Each batch of drugs manufactured must have a unique batch number mentioned on the label.
- **Date of Manufacture and Expiry:** The manufacturing date and the date of expiry of the drug must be clearly stated.
- **Dosage Form and Strength:** The label should specify the dosage form (e.g., tablet, capsule, syrup) and the strength of the drug.
- **Directions for Use:** Adequate directions for the safe and effective use of the drug must be provided. For prescription drugs, this information is often detailed in the package insert.
- **Storage Conditions:** Specific storage conditions (e.g., temperature, humidity) that need to be maintained for the drug's stability should be mentioned.
- **Caution or Warning:** Depending on the drug's schedule (Schedule G, H, H1, or X), specific cautions or warnings must be prominently displayed on the label in a legible black font within a red rectangular box.
- **For External Use Only:** If a drug is meant for external application, this must be clearly indicated on the label.
- **MRP:** The Maximum Retail Price (inclusive of all taxes) should be printed on the label.

### Packing of Drugs

The packaging of drugs is also regulated to ensure the drug's quality and prevent contamination. Key regulations for drug packing in India include:

- **Pack Sizes:** Rule 105 of the Drugs and Cosmetics Rules, 1945, specifies pack sizes for various drug types. For instance, tablets and capsules should have pack sizes that either

match the number of units (if less than 10) or are multiples of 5 (if above 10). Liquid oral preparations, paediatric oral drops, eye/ear/nasal drops, and eye ointments have predefined pack sizes.

- **Schedule X Drugs:** Rule 105A outlines specific packaging criteria for Schedule X drugs to ensure appropriate quantities, with some exceptions for hospital and dispensary supplies.
- **Prohibition of Misleading Claims:** Rule 106 prohibits any claims on drug packaging that suggest prevention or cure for diseases listed in Schedule J of the Drugs and Cosmetics Rules, 1945.
- **Child-Resistant Packaging:** For certain medications, child-resistant packaging may be required to prevent accidental ingestion by children.

**Labelling of Cosmetics**

The labelling of cosmetics in India is governed by the CDSCO's Cosmetic Rules, 2020, and also considers the Legal Metrology Rules, 2011 for general packaging regulations. Key labelling requirements for cosmetics include:

- **Name and Address of the Manufacturer:** The label must clearly state the name and address of the manufacturer. For imported cosmetics, the name and address of the importer must also be provided.
- **Country of Origin:** For imported cosmetics, the country of origin must be declared on the label.
- **List of Ingredients:** All ingredients used in the cosmetic product must be listed on the label in descending order of weight or volume. Specific requirements exist for the declaration of certain ingredients like colours and preservatives.
- **Net Quantity:** The net quantity of the cosmetic product (in terms of weight, volume, or number) must be clearly mentioned.
- **Date of Manufacture and Expiry Date:** The manufacturing date and expiry date or the period after opening (PAO) symbol with the relevant timeframe should be displayed.
- **Batch Number:** A batch number or lot number must be present to facilitate traceability.
- **Directions for Use and Warnings:** Instructions for the safe and intended use of the cosmetic, along with any necessary warnings or precautions (e.g., "For external use only," "Avoid contact with eyes"), must be provided.
- **Use Before Date/Best Before Date:** Depending on the nature of the product, either a "Use Before" date or a "Best Before" date should be mentioned.
- **Label Language:** The information on the label should be in English or Hindi, or both, and must be clear and easily readable with an adequate font size and style.

- **Product Information File (PIF):** Manufacturers are required to maintain a Product Information File (PIF) containing detailed information about the product's safety, ingredients, and labelling.
- **Certification Marks:** If applicable, certification marks like BIS standards or ISO can be mentioned.
- **Exemptions for Small Packages:** For very small cosmetic packages (under 5 grams or 5 millilitres), some labelling requirements, like the complete ingredient list, may be relaxed, but key information like the product name, manufacturing date, and expiry date must still be present.

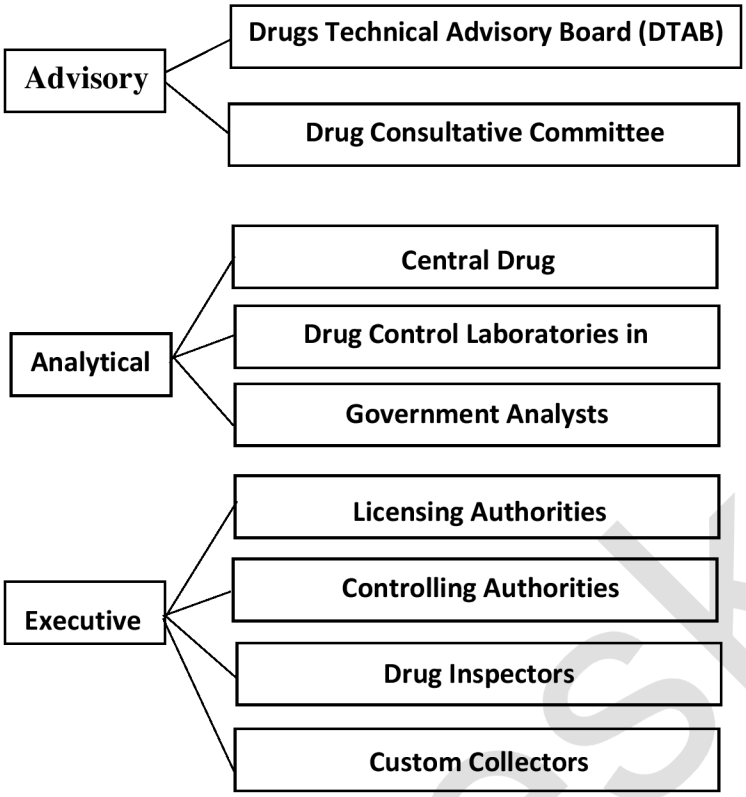
**Packing of Cosmetics**

The packing of cosmetics in India must ensure the product's integrity and prevent leakage or damage. Specific regulations regarding packing are often linked to ensuring proper labelling and preventing misleading claims. Key considerations for cosmetic packing include:

- **Material of Packaging:** The packaging material should be compatible with the cosmetic product and should not alter its quality or safety.
- **Tamper-Evident Packaging:** For certain cosmetic products, tamper-evident packaging might be necessary to ensure product safety and authenticity.
- **Prohibition of Misleading Claims:** Similar to drugs, cosmetic packaging must not contain any false or misleading claims about the product's benefits or ingredients.
- **Inner and Outer Labels:** For products with both inner and outer packaging, both must comply with the relevant labelling regulations. However, if the information is fully displayed on the outer label, some details may be relaxed on the inner label for very small containers.
- **Batch Number for Larger Quantities:** For solid and semi-solid cosmetics above 10 gm and liquids above 25 ml, the batch number must be mentioned on the product label. For liquids above 60 ml and solid/semi-solid above 30 gm, the product weight and volume should be mentioned.

## Administration of the Act and Rules:

For the efficient administration of the Act and the Rules, the Following agencies have been




**Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs**

**Drug Technical Advisory Board (DTAB):**

- DTAB is constituted the Central Government to advise the Central and State Governments on technical matters arising out of the administration of this Act.
- It consists of 18 members, of whom are ex-officio, 5 nominated and 5 elected members, as follows:

**I. Ex- officio members:**

a. Director General of Health Services (chairman)
b. Drug Controller of India.
c. Director, Central Drug laboratory, Kolkata
d. Director, Central Research Institute, Kasauli
e. Director, Indian Veterinary Research Institute, Izatnagar
f. President, Pharmacy Council of India
g. President, medical Council of India

h. Director, Central Drug Research Institute, Lucknow.

**II. Nominated members:**

- Two Persons nominated by the Central Government from amongst persons who are incharge of drugs Control in states.
- One person from the Pharmaceutical industry, nominated by the Central Government
- Two Government analyst, nominated by the Central Government.

**III. Elected members:**

- A teacher in Pharmacy or Pharmaceutical Chemistry or Pharmacognosy on the staff of an Indian University or an affiliated - College, elected by the Executive Committee of the Pharmacy Council of India.
- A teacher in medicine or therapeutic on the staff of an Indian University or an affiliated college, elected by the Executive Committee of the medical Council of India.
- One Pharmacologist elected by the Governing body of the Indian Council of medical Research.
- One Person elected by the Council of the central medical Association.
- One Person to be elected the Council of the Indian Pharmaceutical Association.

**Function:**

- Advices the central and state government.
- It makes modification and amendments in the act by consulting the board.
- It carries out the other function assigned by the act.

## Drug Consultative Committee (DCC):

- The drugs Consultative Committee is constituted by the Central Government. It is an advisory committee for the Central and State governments and the DTAB.
- It Consists of two representatives nominated by the central Government and one nominee of each of state Governments.
- The Committee meets when required by Central Government to do so and is empowered to regulate its own procedure.

**Function:**

- It advises the central government the state government and the DTAB on any matter trending to secure uniformity throughout India in secure uniformity throughout India in the administration of this act.
- When required it regulate its own procedure.

**Central Drug Laboratory**

- The Act provides for the establishment of a Central Drug Laboratory under the Control of a director appointed by Central Government. This laboratory established in Kolkata has been entrusted with the following functions.
- To analyse or test samples of drugs or Cosmetics send to it by the Customs Collectors or Courts.
- To carry out such other duties as entrusted to it by the Central Government or with its permission by the State Government after Consultation with the DTAB.
- The functions of the laboratory in respect of sera, Solutions of serum proteins for injection, vaccines, toxins antigens, antitoxins, sterilised surgical ligature and sutures and bacteriophages are carried out at the Central Research Institute Kasauli.

**Function:**

- To analyses the sample of drugs or cosmetic sent to it by custom collector or courts.
- It carried out the analytical Q.C of the imported samples.
- To carry out such other duties as many be assigned to it by central gov or state gov. with the permission of central gov after consultation with DTAB.
- If some drugs test are not carried out in CDL at Kolkata then it send to other labs.

**Government Analysts:**

- Government Analysts are appointed by the Central Government or a State Government V/S 33-F in relation to Ayurvedic, Siddha or Unani drugs and UV 20 in relation to any other drug or Cosmetic.
- The Central Government may also similarly appoint Government Analysts, in respect of such drugs, classes of drugs, Cosmetic, classes of Cosmetics, as specified.

**Qualification of Government Analysts:**

A graduate in medicine/ science / Pharmacy / Pharmaceutical Chemistry of a recognized university and have five years past graduate experience in the testing of drugs in a laboratory under the Control of

a) A Government Analyst:
b) Head of an approved institution or testing laboratory or has completed two years training testing of drugs, including items stated in Schedule C in Central Drugs Laboratory.
c) A post graduate in medicine | science / Pharmacy / Pharmaceutical Chemistry of a recognized University or Associate ship Diploma of the Institution of Chemists (India) obtained by Passing the said examination with Analysis of Drugs and Pharmaceuticals as one of the subjects with at least three years' experience in the testing of drugs in a laboratory under the Control.

**Duties of Government Analysts:**

- To cause to be analysed or tested sample of drugs or cosmetics sent to under the act and to furnish reports of the results of test or analysis.
- Forward to the Government from time to time, reports giving the results of analysis work and research with a view to their publication at the discretion of Government.

**Licensing Authorities**

- Any Application for the grant or renewal of a licence for the import, manufacture, sale, distribution etc. Drug or of any Cosmetic is to be made to LA.
- The Qualification of a licensing authority has been prescribe under "Rule 49A" by the Drugs and Cosmetics Rules 1989.

**Qualification: -**

No person shall be qualified to be a licensing authority under the Act unless

1) He is graduate in Pharmacy /pharmaceutical chemistry, medicine with specialization in Clinical Pharmacology/ microbiology, from a recognised university.
2) He has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years.

**Controlling Authorities:**

- Drug Inspectors appointed under the Act are under the control of a Controlling authority.
- The qualification of a controlling authority has been Prescribed Under "Rule 50 A" by the Drugs and Cosmetics Rules, 1989.

**Qualification:**

- No Person shall be qualified to be a Controlling authority under the Act unless.
- He is a graduate in Pharmacy / Pharmaceutical Chemistry/ medicine with specialization in Clinical Pharmacology/ microbiology, from a recognised university.
- He has experience in the manufacture or testing of drugs or enforcement of the provisions of the Act for a minimum period of five years.

## Drug Inspectors:

- In relation to Ayurvedic, Siddha or Unani drug an Inspector appointed by the Central Government or a state Government V/S 33-G.
- In relation to any other drug or Cosmetic an Inspector appointed by the Central Government or a State Government v/s 21.
- The Central & State Governments are empowered to appoint Drug Inspectors and to assign them definite areas. Any person having financial interest in the import, manufacture or sale of the drugs or Cosmetics not be appointed as drugs Inspector.
- Drug Inspectors are deemed to be public servants and are officially subordinate to the controlling Authority.

**Qualification of Drug Inspectors: -**

For appointment as Drug Inspectors a person must have a degree in Pharmacy as pharmaceutical Science or medicine with specialization in clinical Pharmacology or microbiology from an Indian University.

For Inspection of the manufacture of substances in Schedule C the persons appointed as Drug Inspectors must have-

- At least 18 month experience in the manufacture of at least one of the substances specified in schedule C.
- At least 18 month experience in the testing of at least one of the substances in schedule C in an Approved testing laboratory.
- Gained experience of not less than three years in the inspection of firms manufacturing any of the substances in Schedule C during the tenure of their service as Drug Inspectors.

**Powers of Inspectors:**

- Inspection of premises where any drug or Cosmetic is being manufactured and the means employed for standardising and testing the drug or Cosmetic.
- Inspection of premises where any drug is being sold, or Stocked on exhibited or afforded for sale or distributed.
- Taking samples of any drug or cosmetic which is being manufacture or being sold/Stocked/exhibited/affered for sale being distributed.
- Taking samples of drug or Cosmetic from any person Conveying delivering or preparing to deliver such Drug or Cosmetic to a purchaser as a consignee.
- Examine any record, register, document or any other material object with any person or in any place mentioned above and size the same if it is likely to furnish the evidence of an offence.
- Require any person to produce any record, register or other document relating to manufacture, sale or distribution of any drug or cosmetic in respect of which on offence has been or is being committed.

**Duties of Drug Inspectors:**

**A. Inspection of Premises licensed for sale:**

- Inspect not less than once a year all establishments licenced for the sale of drugs with in the area assigned to him and to satisfy himself that the conditions of the license are being observed.
- Procure and send for test or analysis if necessary imparted packages which he has reason to suspect contain drugs being sold in contravention of the provisions of the Act or the rules there under.
- Investigate any complaint made to him in writing and to institute prosecutions in respect of preaches of the "Act or Rules there under.
- Maintain a record of all inspections made and action taken by him in the performance of his duties, including the taking of sample and the seizure of stocks and to submit copies of such records to the controlling authority.
- Make such enquiries and inspections as may be necessary to detect the sale of drugs in contravention of the Act.
- When so authorised by the State Government to detain imported packages which he has reason to suspect contain drugs the import of which is prohibited.

**B. Inspection of manufacture of drugs or cosmetics.**

- To inspect not less than once a year all premises licensed for the manufacture of drugs with in the area allotted to him and to satisfy himself that the conditions of the license and the provisions of the Act and Rules there under are being observed.
- In the case of establishments licensed to manufacture products specified in Schedule C and C1 to inspect the plant and the process of manufacture the means employed for standardizing and testing the drug, the methods and place of storage, the technical qualifications of the staff employed and all details of location, construction and administration of the establishment likely to effect the pokncy or purity of the product.
- To send to the controlling Authority after each inspection a detailed report indicating the condition of the license and provisions of the Act and rules.
- To take the samples of the drugs manufactured on the premises and send them for test or analysis.
- To institute prosecution in respect of breaches of the Act and Rules.