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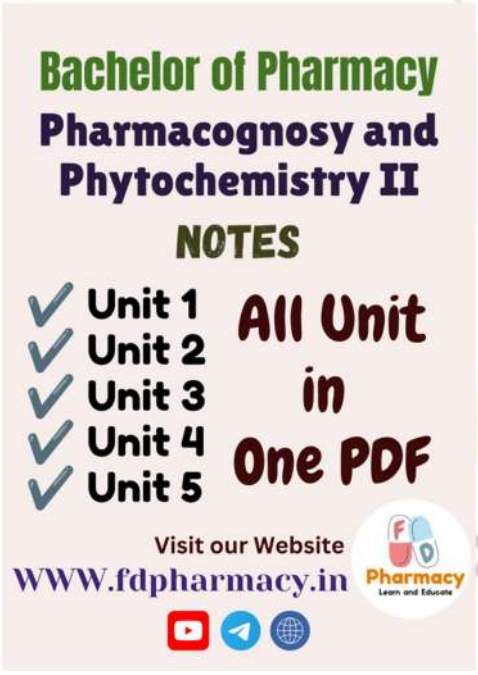
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PHARMACEUTICAL JURISPRUDENCE

UNIT 2

TOPIC :

- **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

Administration of the Drugs and Cosmetics Act and Rules

- The **Drugs and Cosmetics Act, 1940**, along with the **Rules, 1945**, ensures that drugs and cosmetics sold in India are safe, effective, and of standard quality.
- To implement and enforce the provisions of this Act, several administrative authorities and technical bodies are established.
- These authorities help in regulation, standardization, inspection, licensing, and control of drugs and cosmetics throughout India.

Administrative Machinery under the Act

The administration of the Act is divided between:

1. Central Government – Deals with import, overall control, and coordination.
2. State Governments – Responsible for manufacture, sale, distribution, and enforcement within the state.

Key administrative bodies include:

1. Drugs Technical Advisory Board (DTAB)
2. Drugs Consultative Committee (DCC)
3. Central Drugs Laboratory (CDL)
4. Licensing Authorities
5. Government Drug Analysts
6. Controlling Authorities
7. Drugs Inspectors

Drugs Technical Advisory Board (DTAB)

(Under Section 5 of the Drugs and Cosmetics Act, 1940)

- The Drugs Technical Advisory Board (DTAB) is the highest technical advisory body under the Drugs and Cosmetics Act, 1940.
- It advises the Central Government and the State Governments on technical matters related to drugs and cosmetics.
- It ensures that the standards of quality, safety, and efficacy of drugs and cosmetics in India are maintained according to scientific and international norms.
- It is a statutory body — meaning it is established by law (Section 5 of the Act).

Legal Provision

- Constituted under Section 5 of the Drugs and Cosmetics Act, 1940.
- It functions as a technical advisory committee to assist in:
  - Formulation of rules.
  - Amendment of schedules.
  - Regulation of manufacture, import, sale, and distribution of drugs and cosmetics.

Composition of DTAB

The Board consists of ex-officio, nominated, and elected members representing various scientific and professional fields.

Category	Members
Chairman	Director General of Health Services (DGHS)
Ex-officio Members	- Drugs Controller, India (CDSCO) - Director, Central Drugs Laboratory (CDL), Kolkata - Director, Central Research Institute (Kasauli) - Director, Indian Veterinary Research Institute (IVRI) - President, Medical Council of India (MCI) - President, Pharmacy Council of India (PCI)
Nominated Members (by Central Government)	- Two pharmacologists - Two experts in pharmacy - One expert in drug industry - One expert in medical research - One representative of the cosmetic industry
Elected Members	- One representative elected by the Medical Council of India - One representative elected by the Pharmacy Council of India - One representative elected by the Indian Pharmaceutical Association (IPA) - One representative elected by the Central Council of Indian Medicine (AYUSH)

The Board thus represents all major sectors of healthcare, pharmacy, medicine, veterinary, and cosmetics.

Tenure of Members

- Members hold office for a period of three years.
- They are eligible for re-nomination or re-election.
- Ex-officio members continue as long as they hold their official posts.

Meetings of the Board

- The DTAB meets at least once a year.
- The Chairman presides over the meeting.
- The Drugs Controller General of India (DCGI) acts as the Member Secretary of the Board.
- Minutes of the meeting and recommendations are forwarded to the Central Government for approval and implementation.

Functions of DTAB

The DTAB performs the following key functions:

1. Advisory Role – Advises the Central and State Governments on all technical matters related to drugs and cosmetics.
2. Regulatory Suggestions – Recommends amendments to the Drugs and Cosmetics Act and Rules.
3. Standardization – Suggests standards for drugs, cosmetics, and biologicals, and their testing methods.
4. Schedule Revision – Recommends inclusion or deletion of drugs from various Schedules (e.g., H, X, M, etc.).
5. Safety and Quality – Ensures that drugs marketed in India are safe, effective, and of good quality.
6. Harmonization – Helps in harmonizing Indian drug standards with international norms (e.g., WHO, USFDA).
7. Advises on Import and Manufacture – Provides expert opinions on import, testing, and manufacturing practices.
8. Evaluation of Cosmetics – Advises the government regarding standards, safety, and labeling of cosmetics.

Drugs Consultative Committee (DCC)

- The Drugs Consultative Committee (DCC) is a central coordinating body established to ensure uniform administration of the Drugs and Cosmetics Act, 1940 throughout India.
- It works under the Central Government and serves as a liaison between the Centre and the States on all matters relating to drug control.
- While the Drugs Technical Advisory Board (DTAB) gives *technical* advice, the DCC focuses on *administrative coordination and enforcement*.

Legal Provision

- The DCC is constituted under Section 7 of the Drugs and Cosmetics Act, 1940.
- It is a statutory advisory committee that assists the Central Government in securing uniformity in the enforcement of the Act and Rules across all States and Union Territories.

Composition of DCC

Category	Members
Chairman	Director General of Health Services (DGHS)
Member-Secretary	Drugs Controller General of India (DCGI) (or any person appointed by the Central Government)
Members	Representatives nominated by: – The Central Government – Each State Government (usually the State Drugs Controller or State Licensing Authority)

Thus, the DCC includes representatives from both Central and State Drug Control Departments, ensuring nationwide coordination.

Tenure of Members

- Members generally hold office for three years.

- They can be re-nominated or re-appointed after completion of their term.

Meetings of the DCC

- The Committee meets as often as necessary, usually twice a year.
- Meetings are convened by the Chairman.
- Decisions are taken by majority vote.
- Minutes of meetings are recorded and submitted to the Central Government for consideration and further action.

Functions of the Drugs Consultative Committee (DCC)

The DCC performs administrative and advisory functions to ensure effective and uniform drug control across India.

A. Coordination Functions

1. Ensures uniform implementation of the Drugs and Cosmetics Act and Rules in all States.
2. Promotes cooperation between Central and State drug control authorities.
3. Provides a platform for discussion of problems faced in enforcement at the State level.

B. Advisory Functions

1. Advises the Central and State Governments on administrative and enforcement matters.
2. Recommends improvements or amendments to rules for better uniformity.
3. Reviews inspection systems, licensing procedures, and drug sampling methods.
4. Suggests policy measures to prevent manufacture or sale of spurious, adulterated, or misbranded drugs.
5. Coordinates training programs for Drug Inspectors, Analysts, and licensing officers.

Central Drugs Laboratory (CDL)

- The Central Drugs Laboratory (CDL) is the national drug testing and research laboratory of India.
- It functions as the apex laboratory for the analysis and quality control of drugs and cosmetics.
- CDL serves as a scientific and technical arm of the Central Government to ensure that all drugs and cosmetics marketed in India meet the required standards of quality, safety, and efficacy.
- It also provides expert opinion, testing services, and reference standards for State Drug Control Laboratories and other testing institutions.

Legal Provision

- The Central Drugs Laboratory is established under Section 6 of the Drugs and Cosmetics Act, 1940.
- Its functions and responsibilities are elaborated in Rule 3 of the Drugs and Cosmetics Rules, 1945.

Location

- The main Central Drugs Laboratory is located at Kolkata (West Bengal).
- Additionally, certain other specialized laboratories have been designated as Central Drugs Laboratories for specific categories of products:
    - Central Research Institute (Kasauli, Himachal Pradesh) – for sera, vaccines, and toxoids.
    - Pasteur Institute of India (Coonoor, Tamil Nadu) – for vaccines.
    - Central Indian Pharmacopoeia Laboratory (Ghaziabad, Uttar Pradesh) – for analytical standards.
    - Laboratory of the Director, Biologicals, Kasauli – for biological products.

Administrative Control

- CDL functions under the administrative control of the Central Government, specifically under the Ministry of Health and Family Welfare.
- It operates under the Central Drugs Standard Control Organization (CDSCO).
- The Director of CDL acts as the Head of the Laboratory and is responsible for its overall functioning.

Divisions of CDL

The CDL is divided into several specialized divisions to perform a wide range of testing and analytical tasks:

Division	Major Functions
Chemical Division	Analysis of chemical drugs, raw materials, finished formulations, and impurities.
Pharmaceutical Division	Evaluation of dosage forms, stability studies, and physicochemical properties.
Microbiological Division	Testing of antibiotics, antiseptics, vaccines, and sterility.
Biological Division	Testing of sera, vaccines, toxins, antitoxins, and blood products.
Pharmacological Division	Pharmacological and toxicity testing of new drugs.
Instrumental Analysis Division	Uses advanced instruments like HPLC, GC, UV-Vis spectrophotometer for drug analysis.
Reference Standard Division	Preparation and distribution of Indian Pharmacopoeia Reference Standards (IPRS).
Documentation & Information Division	Maintenance of data, records, and reports related to analysis and research.

Functions of Central Drugs Laboratory (CDL)

The functions of the CDL are comprehensive and serve both regulatory and scientific purposes.

A. Analytical and Testing Functions

1. Serves as the National Drug Testing Laboratory for all drugs and cosmetics under the Act.
2. Performs testing and analysis of:
    - Drugs and cosmetics sent by the Central or State Drug Control Authorities.
    - Samples referred by courts of law in case of disputes.
    - Drugs for export certification and licensing.
3. Ensures compliance with pharmacopoeial standards (e.g., Indian Pharmacopoeia).
4. Conducts bioassay, sterility, pyrogen, and toxicity tests for biological products.

B. Reference and Standardization Functions

1. Prepares, maintains, and distributes reference standards for drugs and pharmaceuticals (known as IP Reference Standards).
2. Acts as the custodian of Indian Pharmacopoeia Standards.
3. Provides technical guidance to State Drug Testing Laboratories and private testing facilities.
4. Calibrates instruments and verifies analytical methods.

C. Research and Development Functions

1. Conducts research on analytical methods, drug stability, and formulation development.
2. Develops new techniques for detecting spurious, adulterated, or misbranded drugs.
3. Carries out studies related to pharmacopoeial updates and drug quality enhancement.

D. Training and Advisory Functions

1. Provides training to Drug Analysts, Inspectors, and other regulatory officers.
2. Offers technical advice to the Central Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC).
3. Acts as a reference authority for resolving analytical disputes among laboratories.

E. Quality Control of Biological Products

1. Responsible for testing of biologicals like sera, vaccines, toxins, and blood products.
2. Certifies each batch of vaccines before release for public use.
3. Ensures biological safety and potency of these products.

Licensing Authorities

Licensing Authorities are government-appointed officers responsible for granting, renewing, suspending, or canceling licenses related to the manufacture, sale, and distribution of drugs and cosmetics in India.

- Their primary objective is to ensure that only qualified manufacturers, sellers, and distributors handle drugs and cosmetics that meet quality, safety, and efficacy standards.
- These authorities ensure that all provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945 are implemented uniformly across the country.

Legal Provision

- Licensing authorities are appointed under the provisions of:
  - Section 33 of the Drugs and Cosmetics Act, 1940
  - Rule 21 to 24 of the Drugs and Cosmetics Rules, 1945
- These rules define the powers, duties, and jurisdiction of licensing authorities for different classes of drugs and cosmetics.

Appointment of Licensing Authorities

- The Central Government and State Governments appoint Licensing Authorities for different purposes:

Authority	Appointed By	Scope / Jurisdiction
Central Licensing Authority (CLA)	Central Government	For manufacture, import, and approval of new drugs, vaccines, and blood products.
State Licensing Authority (SLA)	State Government	For manufacture, sale, and distribution of drugs and cosmetics within the state.

Hence, licensing control is a shared responsibility between Central and State Governments.

Types of Licenses Granted by Licensing Authorities

Category	License Type	Issuing Authority
Manufacture of Drugs	License for manufacture of drugs (other than biologicals)	State Licensing Authority
Manufacture of Biologicals (e.g., vaccines, sera)	License for biological products	Central Licensing Authority
Manufacture for Testing/Examination/Analysis	License for laboratory use	State Licensing Authority
Loan License	For manufacturing using another's facilities	State Licensing Authority
Repacking License	For repacking bulk drugs into smaller packs	State Licensing Authority
Import License	For importing drugs or cosmetics	Central Licensing Authority
Sale License	For retail, wholesale, or restricted sale	State Licensing Authority
Cosmetics License	For manufacture or sale of cosmetics	State Licensing Authority

Qualifications and Eligibility of Licensing Authority

- Must be a qualified person with a degree in Pharmacy, Pharmaceutical Chemistry, Medicine, or Science.
- Should have adequate experience in drug regulation, inspection, and quality assurance.
- Appointed officially by the Government notification in the Official Gazette.

Powers and Duties of Licensing Authorities

A. Grant or Refusal of Licenses

1. To grant or renew licenses for manufacture, sale, and distribution of drugs and cosmetics.
2. To refuse license if the applicant fails to comply with prescribed standards (e.g., premises, equipment, qualified staff).

B. Suspension and Cancellation

1. To suspend or cancel a license if conditions are violated.
2. Must provide a show-cause notice and an opportunity to the licensee before suspension/cancellation.

C. Inspection and Supervision

1. To conduct inspection of manufacturing and selling premises either personally or through Drug Inspectors.
2. To verify records, machinery, sanitation, and personnel qualifications.
3. To ensure compliance with Good Manufacturing Practices (GMP) under Schedule M.

D. Quality Control and Enforcement

1. To ensure that drugs and cosmetics conform to standards specified in the Indian Pharmacopoeia or other recognized standards.
2. To take regulatory action against manufacturers or sellers dealing with spurious, adulterated, or misbranded drugs.

E. Record Maintenance

1. To maintain records of all licenses issued, renewed, or canceled.
2. To send annual reports and statistics to the Central Government.

F. Collaboration and Reporting

1. To work in coordination with Drug Inspectors, Government Analysts, and Central Licensing Authorities.
2. To report violations and participate in joint inspections with CDSCO officials when required.

Conditions for Grant of License

The Licensing Authority must ensure that the applicant fulfills all the following conditions before granting a license:

1. Premises are adequate and comply with Schedule M (for drugs) or Schedule M-II (for cosmetics).
2. Qualified technical staff is employed (Registered Pharmacist or competent technical person).
3. Equipment and facilities are suitable for the type of drug or cosmetic to be handled.
4. Proper storage arrangements exist for temperature-sensitive products.
5. Compliance with all provisions of the Act and Rules.

Important Rules Related to Licensing

Rule No.	Subject
Rule 21	Defines Licensing Authorities
Rule 22	Application for license
Rule 23	Procedure for grant of license
Rule 24	Validity and renewal of license
Rule 25	Conditions attached to license
Rule 27	Suspension and cancellation of license
Rule 71 & 71A	Conditions for manufacture of drugs
Rule 74 & 74A	Conditions for sale of drugs
Rule 78	Conditions for repacking of drugs

Examples of Central Licensing Functions

The Central Licensing Authority (CLA) handles:

- Approval of new drugs and clinical trials.
- Licensing of blood products, vaccines, sera, and other biologicals.
- Import and export licenses for drugs and cosmetics.
- Coordinating with the Central Drugs Laboratory (CDL) for product testing.

Government Drug Analysts

- A Government Drug Analyst is a qualified scientific officer appointed by the Central or State Government to analyze and test drugs and cosmetics.
- Their main responsibility is to ensure the quality, purity, and safety of drugs and cosmetics available in the market.
- They play a key role in the enforcement of the Drugs and Cosmetics Act, 1940, by examining samples sent by Drug Inspectors or Courts, and providing expert analytical reports.

Legal Provision

- The appointment and functions of Government Analysts are governed by:
  - Section 20 of the Drugs and Cosmetics Act, 1940, and
  - Rules 44 to 49 of the Drugs and Cosmetics Rules, 1945.

These provisions define their qualifications, duties, powers, and the legal value of their reports.

Appointment

- The Central Government or a State Government may, by notification in the Official Gazette, appoint:
  - Central Government Analysts (for central laboratories)
  - State Government Analysts (for state drug testing laboratories)
- Their names, designations, and places of work are officially published for public information.

Qualifications of Government Analysts (Rule 44)

A person shall not be appointed as a Government Analyst unless he/she has the following qualifications:

A. Academic Qualifications

1. A graduate degree in Pharmacy, Pharmaceutical Chemistry, Medicine, or Science from a recognized university, and
2. Postgraduate qualification or specialized training in the analysis of drugs and pharmaceuticals.

B. Experience

- At least 5 years of practical experience in the testing or analysis of drugs.
- Experience may be gained in a pharmaceutical industry, testing laboratory, or research institution.

C. Other Requirements

- Should possess sound knowledge of analytical instruments such as HPLC, GC, UV-Vis, IR spectrophotometers, etc.
- Should not have any financial interest in the import, manufacture, or sale of drugs or cosmetics (to avoid conflict of interest).

Duties and Functions of Government Drug Analysts

Category	Description of Duties
1. Analytical Work	To analyze and test samples of drugs and cosmetics sent by Drug Inspectors, Courts, or Licensing Authorities.
2. Quality Control	To check whether the samples conform to the standards specified in the Indian Pharmacopoeia or other official pharmacopoeias.
3. Reporting	To prepare and issue certified analytical reports (Form 13) stating whether the sample is standard, substandard, adulterated, or spurious.
4. Expert Evidence	To appear in courts of law as an expert witness in cases related to drug quality or violations of the Act.
5. Advisory Role	To advise Drug Inspectors and Licensing Authorities on analytical methods, standardization, and interpretation of results.
6. Maintenance of Records	To maintain detailed records of all samples tested, analytical methods used, and reports issued.
7. Research and Development	To conduct research on improved analytical techniques, drug stability, and standardization procedures.
8. Coordination	To cooperate with the Central Drugs Laboratory (CDL) and State Drug Testing Laboratories for uniformity in drug testing.

Powers of Government Analysts

- May receive and analyze any drug or cosmetic sample sent by a Drug Inspector, Licensing Authority, or Court.
- May request additional information from the person from whom the sample was taken (e.g., manufacturing formula, batch records).
- May refuse to test a sample if it is not in a proper condition or if it was not collected properly (must record reasons in writing).
- May certify reports which are legally valid under the Act.

Procedure for Analysis and Reporting

1. Receipt of Sample:
    - Samples are received from the Drug Inspector or Court with a memorandum in Form 18.
2. Testing and Analysis:
    - The sample is analyzed according to official pharmacopoeial methods (e.g., Indian Pharmacopoeia, BP, USP).
3. Preparation of Report:
    - The result is recorded in Form 13.
4. Submission of Report:
    - One copy of the report is sent to the authority who submitted the sample (Inspector or Court).
5. Retention of Records:
    - A copy of the report and all related documents are retained for five years for record purposes.

Legal Value of the Analyst's Report

- The report signed by a Government Analyst under Section 25(1) of the Act is admissible as conclusive evidence in a court of law regarding the quality of the drug or cosmetic.
- The report may only be challenged if the accused applies to the court for a re-analysis by the Central Drugs Laboratory (CDL).
- Hence, the Analyst's report carries strong legal authority and forms the basis for legal proceedings under the Act.

Limitations / Restrictions

- A Government Analyst cannot test or certify any sample in which he/she has financial or personal interest.
- Analysts must maintain confidentiality and integrity in all testing activities.
- Must follow standard operating procedures (SOPs) and ensure accuracy in results.

Controlling Authorities

Under the Drugs and Cosmetics Act, 1940, the Controlling Authorities are responsible for the supervision and administration of licensing and inspection activities related to the manufacture, sale, and distribution of drugs and cosmetics in India.
Their main objective is to ensure that quality standards, safety, and efficacy of drugs and cosmetics are maintained throughout the country.

Definition:

A Controlling Authority is a government officer (appointed by the Central or State Government) who oversees and controls the work of Licensing Authorities and Drugs Inspectors within their jurisdiction to ensure proper implementation of the Act and Rules.

Appointment:

- The State Government appoints the Controlling Authority under Rule 50A of the Drugs and Cosmetics Rules, 1945.
- Generally, the Director of Health Services or Drugs Control Administration acts as the State Controlling Authority.
- The Central Government may also appoint controlling authorities for specific classes of drugs like vaccines, sera, and biological products.

Functions of Controlling Authorities:

(a) ***Supervision of Licensing Authorities:***

- They supervise the activities of all licensing authorities in the state.
- Ensure that licenses are granted, renewed, suspended, or cancelled only as per the provisions of the Act and Rules.

(b) ***Inspection and Monitoring:***

- They monitor the inspections conducted by Drugs Inspectors.

- Ensure that manufacturing and sale premises comply with Good Manufacturing Practices (GMP) and Good Storage Practices (GSP).

(c) ***Implementation of the Act and Rules:***

- Ensure uniform enforcement of the Drugs and Cosmetics Act, 1940 and Rules, 1945 within their jurisdiction.
- Issue circulars or instructions to maintain standard practices in enforcement.

(d) ***Coordination:***

- Act as a link between Licensing Authorities, Drugs Inspectors, and Central/State Government.
- Coordinate with Central Drugs Standard Control Organization (CDSCO) and other agencies for regulatory functions.

(e) ***Control over Drugs Inspectors:***

- Direct and supervise the work of Drugs Inspectors.
- Approve or review inspection reports and guide them in enforcement procedures.

(f) ***Quality Control:***

- Ensure that only drugs of standard quality are manufactured and sold.
- Take necessary actions if substandard, adulterated, or spurious drugs are found.

(g) ***Advisory Role:***

- Advise the government on technical and administrative issues related to drug regulation and control.

Powers of Controlling Authorities:

- Power to inspect records, call reports, or order re-inspections.
- Power to suspend or cancel licenses in case of violations.
- Power to recommend prosecution against offenders for serious violations.
- Power to coordinate testing of drugs and cosmetics in government laboratories.

Importance of Controlling Authorities:

- Ensure proper regulation of the drug industry.
- Maintain public health safety by preventing circulation of substandard drugs.
- Ensure that manufacturing units and retail outlets comply with legal and quality norms.
- Maintain uniformity in drug enforcement across states.

Example:

In India,

- Central Controlling Authority:
  - *Drugs Controller General of India (DCGI)* – supervises licensing and control of drugs at the national level.
- State Controlling Authority:
  - *State Drugs Controller* or *Director of Drugs Control* – supervises state-level enforcement activities.

Drugs Inspectors

A Drugs Inspector is a key regulatory officer appointed by the Central or State Government under the Drugs and Cosmetics Act, 1940.
They are responsible for ensuring that the manufacture, sale, distribution, and storage of drugs and cosmetics comply with the legal standards of quality, safety, and labeling.
Their primary aim is to protect public health by preventing the sale of spurious, adulterated, or substandard drugs.

Legal Provisions:

- Section: 21 to 23 of the Drugs and Cosmetics Act, 1940
- Rules: 49 to 52 of the Drugs and Cosmetics Rules, 1945

Appointment:

- Drugs Inspectors are appointed by:
  - Central Government – for matters related to the manufacture and import of drugs.
  - State Government – for matters related to sale and distribution of drugs within the state.
- They work under the supervision of the Controlling Authority and Licensing Authority.

Qualifications :

To be eligible for appointment as a Drugs Inspector, a person must:

1. Hold a degree in Pharmacy, Pharmaceutical Sciences, or Medicine with specialization in Clinical Pharmacology or Microbiology from a recognized university.
2. Have at least 18 months of experience in manufacturing or testing of drugs, or 3 years' experience in inspection under a qualified Drugs Controller.
3. Possess good knowledge of the Drugs and Cosmetics Act, Rules, and GMP (Good Manufacturing Practices).

Powers of Drugs Inspectors :

A Drugs Inspector has several statutory powers to enforce the law effectively:

(a) ***Inspection Powers:***

- Inspect any premises where drugs or cosmetics are manufactured, sold, or stocked for sale.
- Verify compliance with the Act and Rules.

(b) ***Sampling Powers:***

- Take samples of drugs or cosmetics for testing and analysis.
- Send samples to Government Analysts or Central Drugs Laboratory for quality testing.

(c) ***Search and Seizure:***

- Enter and search any premises if there is reason to believe that an offence under the Act has been committed.
- Seize drugs or cosmetics that appear to be substandard, spurious, misbranded, or adulterated.

(d) ***Investigation:***

- Investigate complaints regarding violation of the Act.
- Examine records, registers, or documents related to manufacture and sale.

(e) ***Authority to Stop Sale:***

- Stop the distribution or sale of any drug suspected to be harmful or substandard until test results are received.

(f) ***Initiation of Prosecution:***

- File prosecution reports in court for offences under the Act.
- Give evidence in court as an expert witness.

Duties and Responsibilities of Drugs Inspectors:

(a) ***Inspection of Manufacturing Units:***

- Inspect manufacturing premises at regular intervals (at least once every year).
- Check adherence to Good Manufacturing Practices (GMP) and sanitary conditions.

(b) ***Inspection of Sale Premises:***

- Visit retail and wholesale drug stores to ensure that drugs are sold only under valid licenses.
- Check that Schedule H and X drugs are sold on prescription only.

(c) ***Sampling and Testing:***

- Collect random samples from different markets and verify their identity, purity, and strength.
- Ensure that drugs meet Pharmacopoeial standards.

(d) ***Verification of Records:***

- Examine records, batch manufacturing records, purchase invoices, and sales registers.
- Verify that proper documentation is maintained for controlled drugs.

(e) ***Control of Spurious and Adulterated Drugs:***

- Identify and report cases involving counterfeit or substandard drugs.
- Take immediate legal action to remove them from circulation.

(f) ***Public Health Protection:***

- Ensure that only safe, effective, and quality drugs are available to the public.

(g) ***Enforcement of Labeling Rules:***

- Check that the labeling and packaging of drugs comply with Schedule F, G, H, X, and Y requirements.

(h) ***Education and Guidance:***

- Educate manufacturers, wholesalers, and pharmacists about proper drug handling and compliance with laws.

Procedure for Sampling :

1. Divide the sample into four portions.
2. Seal and label each portion.
3. Distribute the samples as follows:
    - One to the Government Analyst.
    - One to the person from whom the sample is taken.
    - One to the court (if prosecution is launched).
    - One retained by the Drugs Inspector.

Restrictions on Powers :

- Drugs Inspectors cannot disclose confidential information obtained during the course of duty.
- They must present a written authorization when entering any premises for inspection.
- They cannot arbitrarily seize goods without reasonable cause or due process.

Reports and Documentation:

- After inspection, the Drugs Inspector submits:
    - Inspection reports to the Controlling Authority.
    - Test reports to the Licensing Authority and the concerned manufacturer or seller.
    - Prosecution reports in case of violations.