

Unit-1

Pharmacy Practice

B.Pharma 7 Sem Notes

Unit: 1

1. Hospital and it's organization

- Hospital and it's organization Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non- clinical basis, Organization Structure of a Hospital, and Medical staffs involved in the hospital and their functions

2. Hospital pharmacy and its organization

- Definition, functions of hospital pharmacy, Organization structure, Location, Layout and staff requirements, and Responsibilities and functions of hospital pharmacists.

3. Adverse drug reaction

- Classifications – Excessive pharmacological effects, secondary pharmacological effects, idiosyncrasy, allergic drug reactions, genetically determined toxicity, toxicity following sudden withdrawal of drugs, Drug interaction- beneficial interactions, adverse interactions, and pharmacokinetic drug interactions, Methods for detecting drug interactions, spontaneous case reports and record linkage studies, and Adverse drug reaction reporting and management

4. Community Pharmacy

- Organization and structure of retail and wholesale drug store, types and design, Legal requirements for establishment and maintenance of a drug store, Dispensing of proprietary products, maintenance of records of retail and wholesale drug store.

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Hospital and Its Organization

Definition of Hospital

■ DEFINITION

A hospital is a healthcare institution providing patient treatment with specialized medical and nursing staff and medical equipment. According to the World Health Organization (WHO), a hospital is an integral part of a social and medical organization whose function is to provide complete healthcare — both curative and preventive — to the population.

In simple words, a hospital is a place where sick and injured people are given medical care, diagnosis, and treatment. Hospitals also play a role in medical education, research, and training of healthcare professionals.

Classification of Hospitals

Hospitals can be classified in many ways depending on the type of service, ownership, size, and level of care provided. The most common classification is based on the level of healthcare delivery.

A) Based on Level of Care

- **Primary Hospitals:** These are the first point of contact between the patient and the healthcare system. They provide basic medical care, preventive services, vaccination, first aid, and treatment of common illnesses. Usually found in villages and small towns (e.g., Primary Health Centres - PHCs). They have general physicians and limited beds.
- **Secondary Hospitals:** These hospitals provide specialized medical care and accept patients referred from primary hospitals. They have specialists like surgeons, gynecologists, pediatricians, and facilities like operation theatres, labs, and X-ray. District hospitals and Community Health Centres (CHCs) are examples.
- **Tertiary Hospitals:** These are highly specialized hospitals offering advanced treatment and super-specialty services like cardiology, neurology, oncology, and organ transplantation. They have advanced equipment (MRI, CT, cath lab), teaching facilities, and research units. Examples include AIIMS, PGI Chandigarh, and large medical college hospitals.

B) Based on Clinical Basis

- Treats all types of diseases and has departments like medicine, surgery, ortho, ENT, etc. (General Hospital).
- Treats only one type of disease or patient group, e.g., cancer hospital, maternity hospital, TB hospital, psychiatric hospital (Specialty Hospital).
- Attached to medical colleges for teaching and training of medical and pharmacy students (Teaching Hospital).



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C) Based on Non-Clinical Basis

This classification is based on ownership, management, and size.

Basis	Types
Ownership	Government, Private, Trust, Corporate, Voluntary
Size (beds)	Small (<100), Medium (100–300), Large (>300)
Length of stay	Short-term (<30 days), Long-term (>30 days)
Purpose	General, Specialty, Teaching, Research

Organization Structure of a Hospital

A hospital works through a well-organized hierarchical structure where each department has defined duties. Good organization ensures smooth patient care, efficient use of resources, and proper coordination among staff.

The typical structure is as follows:

- **Board of Trustees / Governing Body:** Highest authority that frames policies and takes major decisions.
- **Medical Superintendent / Hospital Administrator:** The chief executive who manages overall functioning of the hospital.
- **Medical & Nursing Staff:** Handles clinical work — doctors, surgeons, specialists, and nurses.
- **Paramedical / Supportive Departments:** Includes pharmacy, radiology, laboratory, physiotherapy, and dietary departments.
- **Administrative & Non-Medical Staff:** Handles accounts, purchase, stores, HR, maintenance, housekeeping, and security.

Medical Staff and Their Functions

Staff	Main Function
Medical Superintendent	Overall administration and decision making
Doctors / Physicians	Diagnose and treat diseases of patients
Surgeons	Perform surgical operations
Specialists	Treat specific diseases (cardiologist, neurologist etc.)
Resident Medical Officer	24-hour availability for emergency care
Nursing Staff	Patient care, giving medicines, assisting doctors
Pharmacists	Dispensing, drug information, compounding, drug store



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Staff	Main Function
Lab Technicians	Perform diagnostic tests
Radiologists	X-ray, CT, MRI and imaging services
Dietitian	Plans nutrition and diet for patients

Hospital Pharmacy and Its Organization

Definition

■ DEFINITION

Hospital pharmacy is that branch of pharmacy which deals with the procurement, storage, compounding, dispensing, manufacturing, testing, packaging, and distribution of drugs and medical supplies inside a hospital to provide better patient care. It is an essential department working under the direct control of the hospital administration.

Functions of Hospital Pharmacy

- Procurement and purchase of quality medicines and surgical items.
- Proper storage and inventory control of drugs.
- Dispensing medicines to inpatients and outpatients as per doctor's prescription.
- Compounding and small-scale manufacturing of preparations like lotions, ointments, mixtures, and IV fluids.
- Providing drug information to doctors, nurses, and patients.
- Maintaining records of narcotics, scheduled drugs, and stock registers.
- Participating in the Pharmacy and Therapeutics Committee (PTC).
- Monitoring Adverse Drug Reactions (ADR) and promoting rational drug use.
- Teaching and training of pharmacy students and nurses.

Organization Structure of Hospital Pharmacy

The hospital pharmacy is headed by a Chief Pharmacist (Director of Pharmacy) and is organized into different sections for efficient work.

- Chief Pharmacist / Director of Pharmacy — overall in-charge.
- Deputy / Assistant Chief Pharmacist — supports chief pharmacist.
- Staff Pharmacists — dispensing, compounding, IV admixtures.
- Pharmacy Technicians and Helpers — support and labelling work.
- Clerical and Store staff — accounts, records, and inventory.



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Location and Layout

Location

The hospital pharmacy should be located on the ground floor, near the OPD and emergency block, so that patients can easily collect their medicines. It should be away from noisy areas but well-connected to wards and stores.

Layout Requirements

- Separate sections for dispensing, compounding, bulk store, and office.
- Proper ventilation, lighting, temperature, and humidity control.
- Refrigerator for thermolabile drugs (vaccines, insulin).
- Cupboards and racks for systematic storage.
- Separate narcotic cupboard with double lock.
- Wash-basin, fire extinguisher, and emergency exit.
- Adequate space for patient waiting area and counselling.

Staff Requirements

As per guidelines, the minimum staff depends on the number of beds. A general rule is one pharmacist for every 50 beds, with additional technicians and support staff. A 200-bed hospital usually requires 1 chief pharmacist, 2–3 staff pharmacists, and 2–3 technicians.

Responsibilities and Functions of Hospital Pharmacist

- Dispensing medicines accurately and safely.
- Compounding extemporaneous preparations.
- Maintaining drug stock and ensuring availability of essential medicines.
- Providing drug information services to medical staff.
- Participating in ward rounds and patient counselling.
- Ensuring rational drug use and monitoring ADRs.
- Checking expiry dates and disposing expired drugs properly.
- Maintaining records of narcotics and scheduled drugs as per law.
- Acting as a member of PTC, Infection Control Committee, etc.
- Training students, nurses, and junior staff.



Adverse Drug Reaction (ADR)

Definition

■ DEFINITION

According to WHO, an Adverse Drug Reaction (ADR) is "any response to a drug which is noxious, unintended, and occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function." In short, ADR means any harmful or unwanted effect of a medicine at normal doses.

Classification of ADRs

1) Excessive Pharmacological Effects

- These occur when a drug shows more than the expected action due to higher dose, increased sensitivity, or altered metabolism. For example, hypoglycemia due to high dose of insulin, or bleeding due to overdose of warfarin.

2) Secondary Pharmacological Effects

- These are unwanted effects that occur along with the main therapeutic effect. They are not due to overdose but due to the drug's own nature. For example, drowsiness with antihistamines, or dry mouth with atropine.

3) Idiosyncrasy

- It is an abnormal and unexpected response to a drug seen only in certain individuals, usually due to genetic factors. For example, hemolysis in G6PD-deficient patients after taking primaquine.

4) Allergic Drug Reactions

- These are immune-mediated reactions. Prior exposure (sensitization) is needed. Examples include skin rashes, urticaria, asthma, and anaphylaxis with penicillin. They are not dose-related.

5) Genetically Determined Toxicity

- Some people have genetic variation in drug-metabolizing enzymes, leading to toxicity. For example, slow acetylators of isoniazid are more prone to peripheral neuritis.

6) Toxicity Following Sudden Withdrawal of Drugs

- Stopping certain drugs suddenly can cause a rebound or withdrawal reaction. For example, sudden stop of beta-blockers can cause rebound hypertension; stopping corticosteroids abruptly may cause adrenal insufficiency.

Drug Interactions

- A drug interaction occurs when the effect of one drug is changed by the presence of another drug, food, or chemical. Interactions may be beneficial or harmful.

A) Beneficial Interactions



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- Levodopa + Carbidopa — Carbidopa prevents peripheral breakdown of levodopa in Parkinson's disease.
- Penicillin + Probenecid — Probenecid increases penicillin level by blocking its excretion.
- Sulfamethoxazole + Trimethoprim — synergistic antibacterial action.

B) Adverse Interactions

- Aspirin + Warfarin — increases risk of bleeding.
- MAO inhibitors + Tyramine-rich food — hypertensive crisis.
- Antacids + Tetracycline — reduces absorption of tetracycline.

C) Pharmacokinetic Drug Interactions

These occur when one drug affects the absorption, distribution, metabolism, or excretion (ADME) of another drug.

- **Absorption:** Antacids decrease absorption of iron and tetracycline.
- **Distribution:** Aspirin displaces warfarin from plasma proteins, increasing its free form.
- **Metabolism:** Rifampicin induces liver enzymes and reduces the level of oral contraceptives.
- **Excretion:** Probenecid decreases renal excretion of penicillin.

Methods for Detecting Drug Interactions

- **Spontaneous Case Reports:** Doctors, pharmacists, or patients report suspected reactions to regulatory authorities. It is simple but may miss rare events.
- **Record Linkage Studies:** Patient records from hospitals are linked with drug prescription data to identify unusual patterns of reactions. It is useful for long-term studies.
- Other methods include cohort studies, case-control studies, clinical trials, and hospital-based ADR monitoring programs.

ADR Reporting and Management

Reporting

In India, ADR reporting is done under the Pharmacovigilance Programme of India (PvPI), coordinated by IPC Ghaziabad. Pharmacists, doctors, and nurses can fill the Suspected ADR Reporting Form (Yellow form) and send it to the nearest ADR Monitoring Centre (AMC).

Management of ADR

- Immediately stop or reduce the dose of the suspected drug.
- Provide symptomatic treatment (e.g., antihistamines for rash, adrenaline for anaphylaxis).
- Replace with an alternative safer drug.
- Counsel the patient about the drug and avoid re-exposure.
- Record and report the ADR for future prevention.



Community Pharmacy

Introduction

■ DEFINITION

A community pharmacy (also called a retail or chemist shop) is a pharmacy where medicines and healthcare products are dispensed to the general public on the basis of prescription or over-the-counter (OTC) sale. It is the most visible and accessible face of the pharmacy profession.

Organization and Structure

A) Retail Drug Store

A retail drug store sells medicines directly to patients in small quantities based on a prescription. It is the final link between the manufacturer and the patient. It usually has a pharmacist, assistants, and support staff.

Main functions of a retail drug store:

- Dispensing prescription medicines accurately.
- Selling OTC products, cosmetics, and surgical items.
- Counselling patients about medicine use.
- Maintaining stock and records of Schedule H, H1, and X drugs.
- Providing first aid and basic health advice.

B) Wholesale Drug Store

A wholesale drug store purchases medicines in bulk directly from manufacturers and sells them in smaller quantities to retail pharmacies, hospitals, dispensaries, and nursing homes. It does not sell to the general public.

Main functions of a wholesale drug store:

- Bulk purchase and bulk storage of medicines.
- Distribution to retailers and hospitals.
- Maintaining proper purchase and sale records.
- Ensuring proper storage conditions for sensitive drugs.

Types of Drug Stores

- Sells medicines to the public.
- Supplies in bulk to retailers.
- Owned by hospitals to supply their patients.
- Runs under co-operative societies.
- Chain pharmacies such as Apollo, MedPlus, 1mg, Netmeds, etc.

Design and Layout of a Drug Store



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A good drug store should be planned in a way that ensures easy handling of medicines, proper storage, and smooth customer service.

- Total area of at least 10 square meters for a retail store and 15 square meters for a combined retail + wholesale shop.
- Proper shelves, racks, and cupboards for systematic storage.
- Refrigerator for vaccines, insulin, and other thermolabile drugs (kept at 2–8°C).
- Separate narcotic and poison cupboard with lock and key.
- Good ventilation, lighting, and pest-free environment.
- Dispensing counter for pharmacist-patient interaction.
- Waiting area for customers and a clean display section for OTC products.

Legal Requirements for Establishment and Maintenance

The establishment of a drug store in India is governed by the Drugs and Cosmetics Act, 1940 and Rules 1945. Important legal requirements are as follows:

- **Qualified Person:** A registered pharmacist (registered with State Pharmacy Council) must be present at the premises.
- **Drug License Application:** Form 19 for retail sale and Form 19A for restricted license. Wholesale requires a separate license (Form 20B / 21B).
- **License Forms:** Issued by the State Drug Control Authority on Form 20 (general), 20B (wholesale), 21 (Schedule C & C1), and 21B (wholesale of Schedule C).
- **Area:** Minimum 10 sq. m. for retail or wholesale (15 sq. m. if both).
- **Storage:** Refrigerator, air conditioner (if needed), and adequate storage facilities are mandatory.
- **Validity:** Drug license is valid for 5 years and must be renewed on time.
- **Records:** Cash memo, purchase bills, and stock registers must be maintained. Schedule H, H1, and X drugs have strict record rules.
- **Inspection:** Periodic inspection is done by the Drug Inspector.

Dispensing of Proprietary Products

Proprietary products are medicines manufactured and sold under a brand name by a particular company (e.g., Crocin, Dolo-650, Combiflam). While dispensing such products the pharmacist should:

- Check the prescription carefully for patient name, drug name, strength, dose, and doctor's signature.
- Verify the expiry date and physical condition of the product.
- Confirm that the brand dispensed matches the prescribed one, or if substitution is allowed, use a bio-equivalent brand.
- Label the product with dosage instructions if required.
- Counsel the patient about dose, timing, food instructions, and side effects.
- Charge the correct MRP and issue a proper cash memo/bill.
- Record the sale in the relevant register (especially for Schedule H1 and narcotic drugs).



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Maintenance of Records

Every drug store must maintain proper records as per the Drugs and Cosmetics Rules. The important registers are:

Register / Record	Purpose
Purchase Register	Records of drugs purchased from wholesalers/manufacturers
Sales Register	Records of drugs sold to customers / retailers
Cash Memo / Bill Book	Issued to customers at the time of sale
Prescription Register	Records of prescriptions dispensed
Schedule H1 Register	Record of antibiotics and habit-forming drugs
Narcotic Register	Record of narcotic and psychotropic drugs
Stock Register	Daily stock position of medicines
Expiry Register	List of expired drugs and their disposal
License File	Original drug license and renewal papers





These records must be preserved for at least 2 years (or as specified in the rules) and produced during inspection by the Drug Inspector.



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