Hospital & Clinical Pharmacy (Theory)

ER20-25T

For D.Pharm II Year Students

As per PCI Syllabus

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Preface

Hospital and Clinical Pharmacy (ER20-25T) is the course in which the diploma pharmacist meets the hospital as a working system: a place where medicines are selected, bought, stored, distributed, compounded and, finally, used in patients whose response must be watched. This book follows the course exactly as the Pharmacy Council of India has framed it in the Education Regulations 2020, unit by unit and in the same order, so that a student who reads it through has covered every topic on which the university examination can set a question.

The treatment is deliberately balanced between paragraphs and points. Each topic opens with a precise definition and a short explanation of why the practice exists; the enumerations that examiners expect (functions, advantages, steps, composition) then follow as numbered or bulleted points that can be revised quickly. Figures and tables are used wherever a process, a classification or a comparison is easier to see than to read, and every one of them has been drawn afresh for this book.

The hospital pharmacy chapters (1 to 7) build from organisation and committees to the supply chain, distribution, compounding, radiopharmaceuticals and computer applications. The clinical pharmacy chapters (8 to 12) then turn to the patient: the daily activities of the clinical pharmacist, pharmaceutical care, the interpretation of laboratory tests, poisoning and drug information, pharmacovigilance, medication errors and drug interactions. Regulatory facts, standards and reference values have been checked against current official sources; where a laboratory or an institution sets its own value, the text says so.

Each chapter closes with a short summary and a self-assessment set of multiple choice, short-answer and long-answer questions with answers or answer outlines, framed in the pattern of the D.Pharm examination. Suggestions from teachers and students for improving later editions will be received gratefully.

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Syllabus: Hospital and Clinical Pharmacy (ER20-25T)

Course Code: ER20-25T **Hours:** 75 (3 hours per week)

Scope: This course is designed to impart fundamental knowledge and professional skills required for facilitating various hospital and clinical pharmacy services.

Course Objectives: This course will discuss and train the students in the following:

1. Hospital and hospital pharmacy organisation and set-ups.
2. Basics of hospital pharmacy services including the procurement, supply chain, storage of medicines and medical supplies.
3. Basics of clinical pharmacy including introduction to comprehensive pharmaceutical care services.
4. Basic interpretations of common laboratory results used in clinical diagnosis towards optimising the drug therapy.

Course Outcomes: Upon successful completion of this course, the students will be able to:

CO1 Explain the basic concepts of hospital pharmacy administration.

CO2 Manage the supply chain and distribution of medicines within the hospital settings.

CO3 Assist the other healthcare providers in monitoring drug therapy and address drug-related problems.

CO4 Interpret common lab investigation reports for optimising drug therapy.

Syllabus units, teaching hours and the chapters of this book

Unit	Topic	Hours	Chapter
1	Hospital Pharmacy: definition, scope, national and international scenario; organisational structure; professional responsibilities, qualification and experience requirements, job specifications, workload requirements and inter-professional relationships; Good Pharmacy Practice (GPP) in hospital; Hospital Pharmacy Standards (FIP Basel Statements, AHSP); introduction to NAQS guidelines and NABH accreditation and role of pharmacists	6	1
2	Different Committees in the Hospital: Pharmacy and Therapeutics Committee (objectives, composition and functions); Hospital Formulary (definition, procedure for development and use); Infection Control Committee (role of pharmacist in preventing antimicrobial resistance)	4	2
4	Supply Chain and Inventory Control: drug lists (high-risk, emergency, Schedule H1, NDPS drugs, reserved antibiotics); procedures of drug purchase (drug selection, short term, long term, tender/e-tender, quotations); inventory control techniques (EOQ, reorder level, inventory turnover); inventory management of the central drug store (storage conditions, methods of storage, distribution, cold chain, refrigerator, ILR, walk-in cold rooms); FEFO, FIFO; expiry drug removal, handling and disposal; disposal of narcotics and cytotoxic drugs; documentation of purchase and inventory	14	3

Unit	Topic	Hours	Chapter
5	Drug Distribution (in-patients and out-patients): individual prescription order, floor stock, unit dose and drug basket methods; distribution to ICCU/ICU/NICU/emergency wards; automated drug dispensing systems and devices; distribution and storage of narcotic and psychotropic substances	7	4
6	Compounding in Hospitals: bulk compounding, IV admixture services and incompatibilities, total parenteral nutrition	4	5
7	Radiopharmaceuticals: storage, dispensing and disposal	2	6
8	Application of computers in hospital pharmacy practice, electronic health records, software used in hospital pharmacy	2	7
9	Clinical Pharmacy: definition, scope and development in India and other countries; technical definitions and common terminologies; daily activities of clinical pharmacists; pharmaceutical care and drug-related problems; Medication Therapy Management; Home Medication Review	12	8
10	Clinical laboratory tests used in the evaluation of disease states: haematological, liver function, renal function and thyroid function tests; tests associated with cardiac disorders; fluid and electrolyte balance; pulmonary function tests	10	9
11	Poisoning: types, clinical manifestations and antidotes; Drug and Poison Information Centre and its services	6	10
12	Pharmacovigilance: definition, aim and scope; overview	2	11
13	Medication errors (definition, types, consequences, strategies, LASA drugs and Tall Man lettering as per ISMP); drug interactions (definition, types, clinical significance)	6	12

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Chapter 1: Hospital Pharmacy

Learning Outcomes

After studying this chapter, the student will be able to:

- *Define a hospital and hospital pharmacy, classify hospitals, and state the objectives, functions and scope of hospital pharmacy in India and abroad.*
- *Describe the organisational structure of a hospital and of its pharmacy department with the help of organograms.*
- *List the professional responsibilities, qualifications, job specifications and workload determinants of hospital pharmacy staff, and explain their inter-professional relationships.*
- *Explain Good Pharmacy Practice (GPP) in the hospital using the four roles of the FIP/WHO guidelines.*
- *Outline the FIP Basel Statements and the practice standards of ASHP.*
- *Explain NQAS and NABH accreditation and the role of the pharmacist in each.*

1.1 Introduction

A **hospital**, as described by a World Health Organization (WHO) expert committee, is an integral part of a social and medical organisation whose function is to provide the population with complete health care, both curative and preventive, with out-patient services that reach the family in its home; the hospital is also a centre for training health workers and for biosocial research.

Hospital pharmacy is the department of the hospital, under the direction of a registered and professionally competent pharmacist, that procures, stores, prepares, dispenses and distributes medicines and medical supplies, and that advises prescribers, nurses and patients on their safe and rational use. The definition joins a supply service to a clinical one, and modern practice is judged on both.

> **Hospital case:** A 300-bed government district hospital in central India is to face its first National Quality Assurance Standards assessment in four months. A preliminary walk-through of the pharmacy finds expired ampoules on the same shelf as current stock, no daily temperature record for the medicine refrigerator, look-alike insulin vials stored side by side, and no written record of patient counselling. The Medical Superintendent asks the chief pharmacist to lead the pharmacy's preparation.

1.1.1 Classification of hospitals

Hospitals are classified on four common bases, shown as a tree in Figure 1.1: ownership, size, the type of care offered and teaching status.

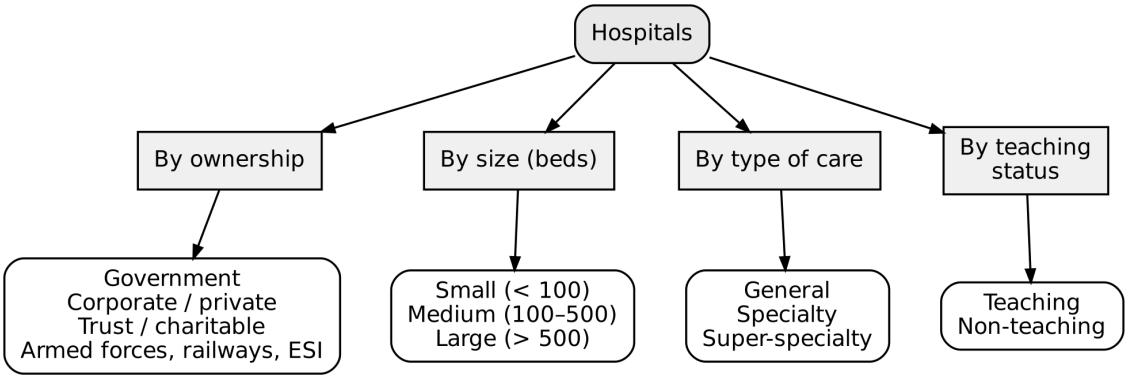


Figure 1.1: Classification of hospitals by ownership, size, type of care and teaching status.

- Ownership: government hospitals (central, state, municipal), corporate or private hospitals, trust and charitable hospitals, and hospitals of special agencies such as the armed forces, railways and the Employees' State Insurance scheme.
- Size: a common teaching convention treats hospitals of fewer than 100 beds as small, 100–500 beds as medium and more than 500 beds as large. Bed strength drives pharmacy staffing and stock levels.

- Type of care: general hospitals treat all common conditions; specialty hospitals concentrate on one field (e.g., cancer, eye, maternity); super-specialty hospitals offer advanced sub-specialties such as cardiothoracic surgery and transplantation.
- Teaching status: teaching hospitals are attached to a medical college and train students; non-teaching hospitals provide service only.

1.2 Definition, Scope, National and International Scenario

1.2.1 Objectives and functions of hospital pharmacy

The objective of hospital pharmacy is to supply the right medicine, of assured quality, to the right patient at the right time and acceptable cost, and to see that it is used well. Its functions follow.

- Annual drug requirement, purchase through approved procedures and stock-keeping in a Central Drug Store under correct storage conditions.
- Out-patient dispensing and supply to wards, theatres and intensive care units through a defined distribution system.
- Manufacture and compounding of preparations that are not available commercially or are cheaper to make in-house (e.g., sterile irrigation fluids, oral liquids for children, IV admixtures).
- Legal and statutory records, including registers for Schedule H1 drugs and for substances controlled under the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985.
- Membership (often as secretary) of the Pharmacy and Therapeutics Committee (PTC) and preparation of the Hospital Formulary.
- Drug information, patient counselling, adverse drug reaction (ADR) reporting and ward-based clinical services.
- Teaching students, nurses and junior staff, and research on drug use.

1.2.2 Scope

The scope of hospital pharmacy has moved steadily from the dispensary counter to the ward. Its present scope covers supply-chain management, sterile and non-sterile compounding, radiopharmacy in larger centres, clinical pharmacy, therapeutic drug monitoring, drug and poison information, pharmacovigilance, antimicrobial stewardship and the management of the hospital information system (HIS) as it applies to medicines.

1.2.3 National scenario

India delivers public health care through a referral pyramid (Figure 1.2). Sub-centres, now developed as Ayushman Arogya Mandirs, refer to Primary Health Centres (PHCs); PHCs refer to Community Health Centres (CHCs); CHCs refer to sub-district and district hospitals; and district hospitals refer to medical college and other tertiary hospitals. A pharmacist post exists at the PHC level and upwards, and the pharmacy grows in size and range of services at each step. Alongside this public network, the private sector (corporate chains, trust hospitals and nursing homes) provides a large share of hospital care, especially in cities.



Figure 1.2: The public health care referral chain in India, from the sub-centre to the tertiary hospital.

The legal base of the profession is the Pharmacy Act, 1948. Under it, a person must be registered with the State Pharmacy Council to practise, and Section 42 restricts the compounding, preparing, mixing and dispensing of medicines on a prescription to a registered pharmacist. The Pharmacy Practice Regulations, 2015, framed by the Pharmacy Council of India (PCI) under Sections 10 and 18 of the Act, define the hospital pharmacist, set rules for patient counselling and records, and list the job responsibilities of pharmacists, senior pharmacists and chief pharmacists at hospital sites. Smaller public facilities remain