As Per PCI Regulation

GDC PUBLICATION

A Text Book of PHARMACOLOGY

Diploma in Pharmacy

ER20-21T

2nd YEAR
Diploma in Pharmacy

Dr. Abhishek Tripathi
Mr. Jitesh Kumar Patwa
Mr. Krishna Kant Jangde
Ms. Jyoti Yadav

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PHARMACOLOGY

DIPLOMA IN PHARMACY

As per the PCI Education Regulation (ER-2020)

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A Text Book of Pharmacology

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Preface

The field of pharmacology plays a crucial role in healthcare by providing the foundation for the development of new medications and the improvement of existing ones. It involves information's related to drugs, their action and adverse effects. By delving into the complexities of pharmacology, the students, pharmacist and healthcare professionals can expand their knowledge of various drugs, its interactions and found to be more effective in optimizing the therapeutic benefits of the medicine. This book will explore the diverse aspects of pharmacology, including its impact on drug development, clinical practice, and patient care.

It is a matter of great pleasure for us to present this book to our esteemed readers. This book comprehensively covers the entire syllabus of D. Pharm 2nd year as accordance with the E.R. 2020 guidelines. It has been written to meet the requirements of students of second year in D. Pharm. Some of the special features of the book are as follows:

1. Full coverage of the revised syllabus as per PCI regulation for Diploma students.
2. Comprehensive chapters with detailed and pointwise explanation about each topics.
3. Complete book with colourful diagrams, tables and important points.
4. Proposed MCQ's, short and long answer questions in each and every chapter.
5. Modern, lucid and simple language have been used to make the book readable.

Keeping in view the scope of the subject, we have tried to present the information as comprehensive and updated with various sources as possible. It is hoped that the book will be of great importance in understanding the concept of each and every topics and easily assimilate the information by the readers.

We are very grateful to GDC Publication who have rendered all possible assistance in finalizing and successfully completing this book. We wish to acknowledge our deep gratitude towards the technical and non-tech staff who assisted in preparing this book. Any suggestions including criticism from the reader shall be appreciated and considered.

"Never regard study as a duty, but as the enviable opportunity to learn."

Authors

★★★

Syllabus

Chapter 1 **(10 Hours)**

General Pharmacology

- Introduction and scope of Pharmacology
- Various routes of drug administration - advantages and disadvantages
- Drug absorption - definition, types, factors affecting drug absorption
- Bioavailability and the factors affecting bioavailability
- Drug distribution - definition, factors affecting drug distribution
- Biotransformation of drugs - Definition, types of biotransformation reactions, factors influencing drug metabolisms
- Excretion of drugs - Definition, routes of drug excretion
- General mechanisms of drug action and factors modifying drug action

Chapter 2 **(11 Hours)**

Drugs Acting on the Peripheral Nervous System

- **Steps involved in neurohumoral transmission,**
- **Definition, classification, pharmacological actions, dose, indications, and contraindications of**
  a) Cholinergic drugs
  b) Anti-Cholinergic drugs
  c) Adrenergic drugs
  d) Anti-adrenergic drugs
  e) Neuromuscular blocking agents
  f) Drugs used in Myasthenia gravis
  g) Local anaesthetic agents
  h) Non-Steroidal Anti-Inflammatory drugs (NSAIDs)

Chapter 3 **(2 Hours)**

Drugs Acting on the Eye

Definition, classification, pharmacological actions, dose, indications and contraindications of

- Miotics
- Mydriatics
- Drugs used in Glaucoma

Chapter 4 **(8 Hours)**

Drugs Acting on the Central Nervous System

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- General anaesthetics
- Hypnotics and sedatives
- Anti-Convulsant drugs
- Anti-anxiety drugs
- Anti-depressant drugs
- Anti-psychotics
- Nootropic agents

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- Centrally acting muscle relaxants
- Opioid analgesics
- Distribution of Narcotic and Psychotropic Substances and their Storage.

Chapter 5 **(6 Hours)**

Drugs Acting on the Cardiovascular System

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- Anti-hypertensive drugs
- Anti-anginal drugs
- Anti-arrhythmic drugs
- Drugs used in atherosclerosis and
- Congestive heart failure
- Drug therapy for shock

Chapter 6 **(4 Hours)**

Drugs Acting on Blood and Blood Forming Organs

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- Hematinic agents
- Anti-coagulants
- Anti-platelet agents
- Thrombolytic drugs

Chapter 7 **(2 Hours)**

Drugs Acting on the Respiratory system

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- Bronchodilators
- Expectorants
- Anti-tussive agents
- Mucolytic agents

Chapter 8 **(5 Hours)**

Drugs Acting on the Gastro Intestinal Tract

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- Anti-ulcer drugs
- Anti-emetics
- Laxatives and purgatives
- Anti-diarrheal drugs

Chapter 9 **(2 Hours)**

Drugs Acting on the Kidney

Definition, classification, pharmacological actions, dose, indications, and contraindications of

- Diuretics
- Anti-Diuretics

Chapter 10 **(8 Hours)**

Hormones and Hormone Antagonists

Physiological and pathological role and clinical uses of

- Thyroid hormones
- Anti-thyroid drugs
- Parathormone
- Calcitonin
- Vitamin D
- Insulin
- Oral hypoglycaemic agents
- Estrogen
- Progesterone
- Oxytocin
- Corticosteroids

Chapter 11 **(3 Hours)**

Autocoids

- Physiological role of Histamine, 5 HT and Prostaglandins
- Classification, clinical uses, and adverse effects of antihistamines and 5-HT antagonists

Chapter 12 **(12 Hours)**

Chemotherapeutic Agents

Introduction, basic principles of chemotherapy of infections, infestations and neoplastic diseases, Classification, dose, indication and contraindications of drugs belonging to following classes:

- Penicillins
- Cephalosporins
- Aminoglycosides
- Fluoroquinolones
- Macrolides
- Tetracyclines
- Sulphonamides
- Anti-tubercular drugs
- Anti-fungal drugs
- Anti-viral drugs
- Anti-amoebic agents
- Anthelmintics
- Anti-malarial agents
- Anti-neoplastic agents

Chapter 13 **(2 Hours)**

Biologicals

Definition, types, and indications of biological agents with examples

Index

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Chapter 1

A A AN

1.1. INTRODUCTION AND SCOPE OF PHARMACOLOGY

- Pharmacology is the science of drugs (Greek: *Pharmacon* means drug; *logos* means discourse in).
- Pharmacology is the science that deals with study of drugs and their interaction with the living systems.
- In a broad sense, it deals with interaction of exogenously administered chemical molecules in living systems.

1.1.1 Historical Background

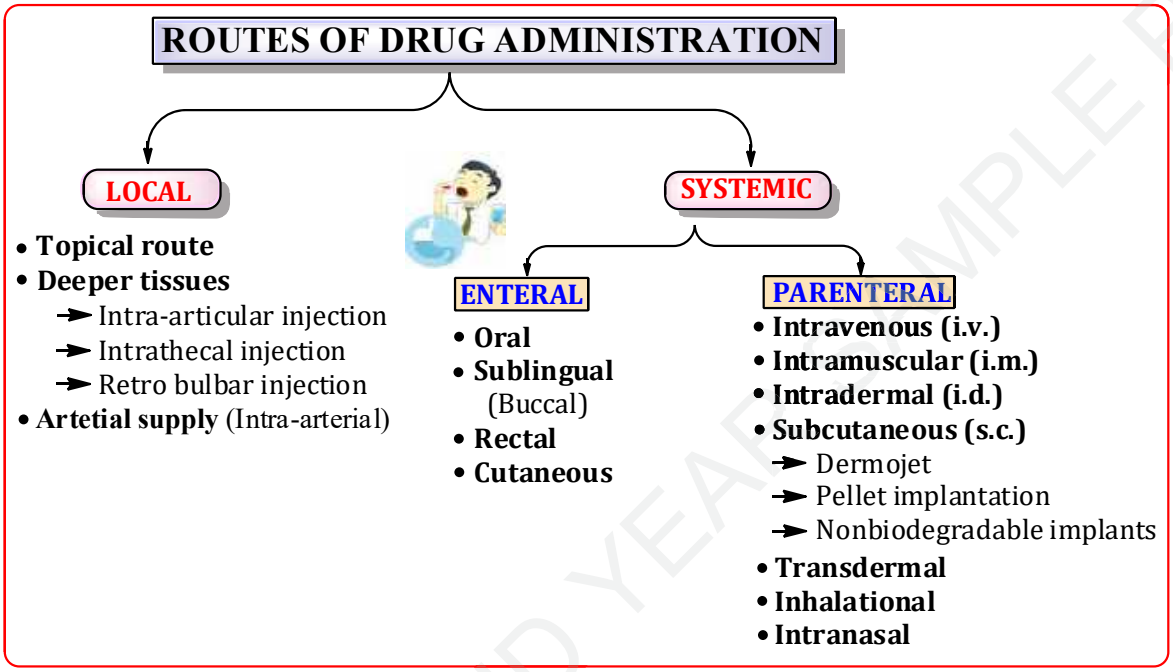
- India's earliest pharmacological writings are from 'Vedas' like Rigveda (3000 BC).
- **Hippocrates** is a Greek physician, studied the 'cause of disease'. He is the father of medicine.
- **Galen** is a Greek physician, described that, "Diseases are due to an imbalance of blood-fluids, phlegm, black bile and yellow bile" and considered as "First Pharmacist".
- **Oswald Schmiedeberg** regarded as 'Father of pharmacology'.
- **Sir Ram Nath Chopra** was an Indian Medical Service officer and a doyen of science and medicine of India. Sir Ram Nath Chopra considered as the Father of Indian Pharmacology.
- **Paul Ehrlich** was a Nobel Prize-winning German physician and scientist who worked in the fields of haematology, immunology, and antimicrobial chemotherapy and he coined the term "Chemotherapy" and he gave the concept of Magic Bullet.
- **Mahadeva Lal Schroff** is known as the father of Indian pharmacy because of his contribution to Pharmacy education in India.

1.1.2 Branches and terminologies related to pharmacology

- **Pharmacy:** It is the **art and science** of compounding and dispensing drugs or preparing suitable dosage forms for administration of drug to humans or animals.
- **Pharmacokinetics:** (What the body does to the drugs) It deals with the study of absorption, distribution, metabolism, excretion (ADME) of drugs.
- **Pharmacodynamics:** (What the drug does to the body) It deals with the mechanism of action and pharmacological effect of drug.
- **Pharmacoeconomics:** Deals with the cost, i.e., economic aspects of drugs used

- Emergency/routine use.
- Site of action of the drug (local or systemic).
- Condition of the patient (Unconscious, Vomiting, Diarrhoea).
- Age of the patients.
- Effect of gastric pH, digestive enzymes and first pass metabolism.

1.2.1 Classification of routes of drug administration



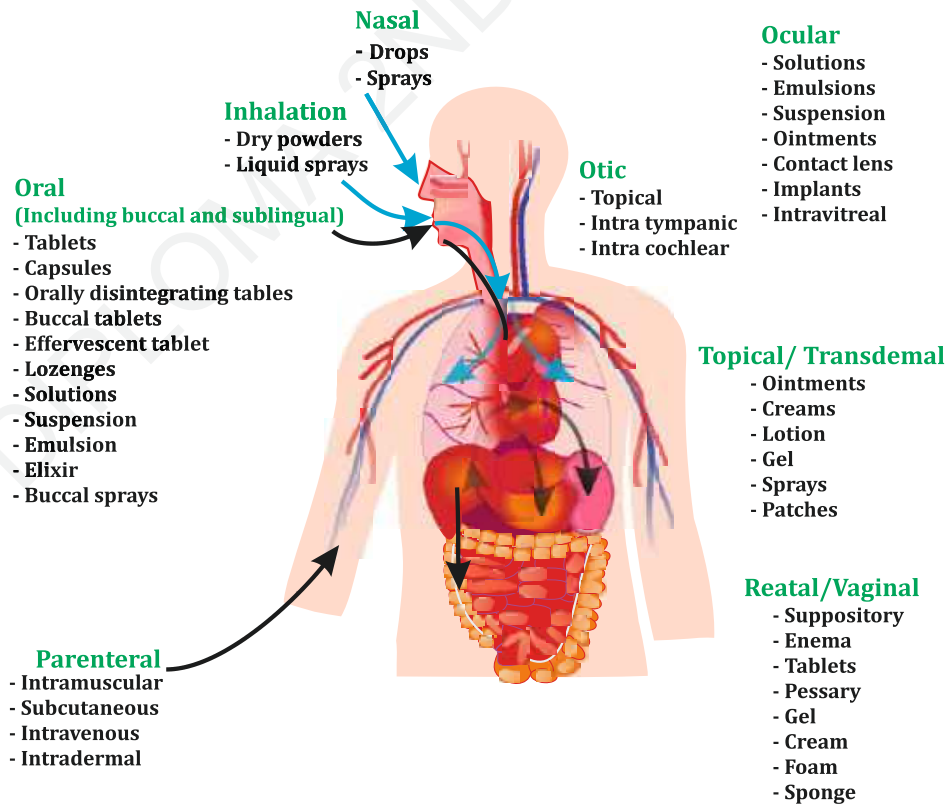


Fig.1.1: Routes of drug administration

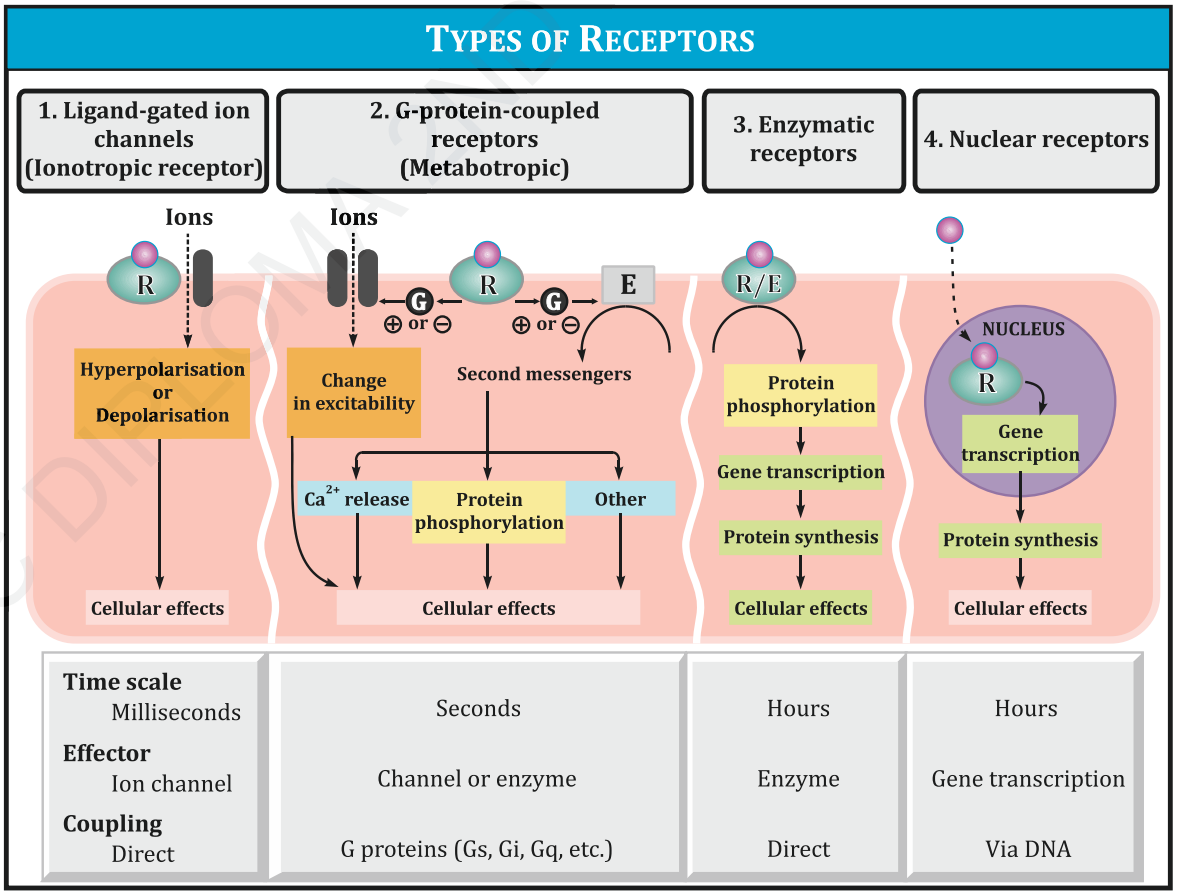
2. **G-protein coupled receptors (Metabotropic receptor, serpentine receptor):** G Protein are membrane proteins and have three subunits (α, β, γ), heterotrimeric, when all are Joined together G-Protein is inactive. G-Protein - Coupled receptor (GPCRs) control cell function via, Adenyl cyclase, Phospholipase C, and Ion channel when drug bind to the receptor which in turn activates G Protein. eg. α and β receptor and muscarinic receptor.

3. **Transmembrane enzymatic receptors (Kinase-linked receptor):** Enzymes are stimulated at the **outer end**. The drug binds to the extracellular sites. The intracellular site has enzymatic activity. eg. Prolactine, Insulin and growth hormone.

- **Enzymatic receptors are transmembrane protein having two sites:**
  (1) Extracellular domain (site) for ligand binding.
  (2) Intracellular domain for catalytic activity.

4. **Nuclear receptors:** Only **lipid soluble drugs** can act on nuclear receptor.
   Drug binds with nuclear receptor → Binds with DNA → Regulate Translation, Transcription and Replication.

- **Two types of nuclear receptor**
  (a) Cytoplasmic receptor - Glucocorticoids, Mineralocorticoids, Progestin.
  (b) Nuclear receptor - T_3, T_4, Estrogen, vitamin A, vitamin D, Estrogen.



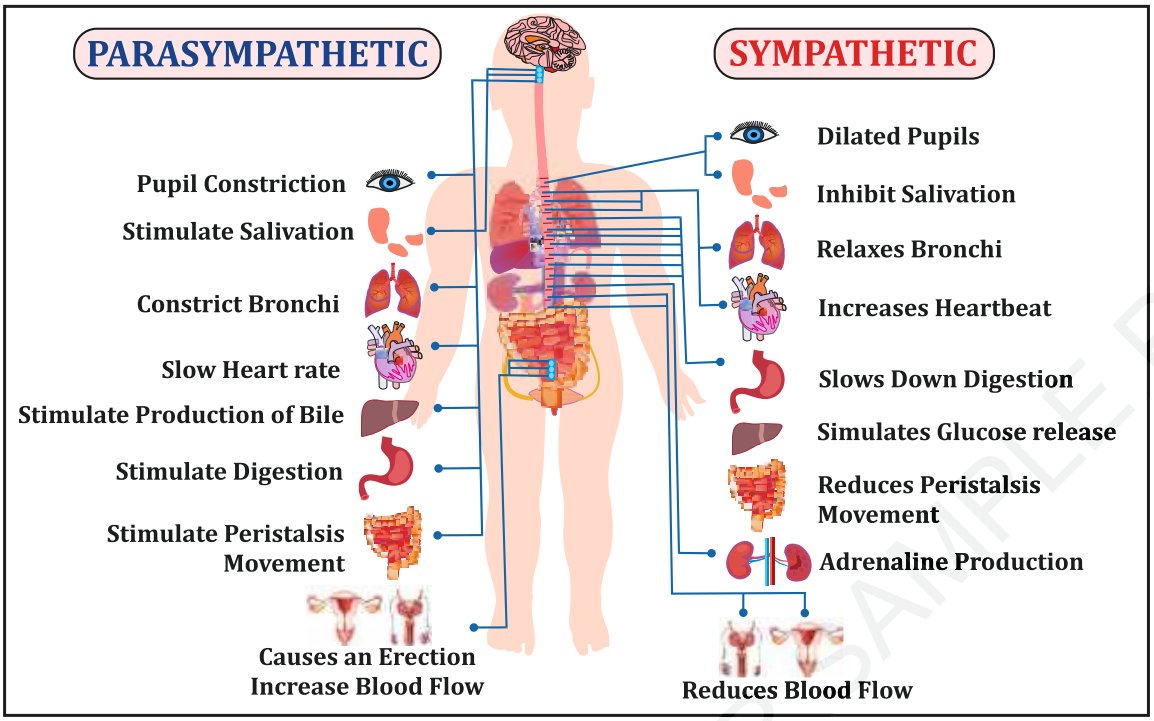


Fig. 2.3: Difference between parasympathetic and sympathetic nervous system

2.2.2 Physiology of Autonomic nervous system

Table. 2.1 Physiology of ANS

ORGAN	SYMPATHETIC STIMULATION	PARASYMPATHETIC STIMULATION
Eye ✓ Pupils ✓ Lachrymal glands ✓ Ciliary muscles	• Dilation of pupil (mydriasis) • No effect • Paralysis of accommodation	• Constriction of pupil (miosis) • Increased secretion • Constriction: spasm of accommodation
Lungs	• Bronchodilation decreased secretions	• Bronchospasm increased secretions
Heart	• Increased heart rate • Increased myocardial contractility • Therefore, Increased BP	• Decreased heart rate • Decreased myocardial contractility • Therefore, Decreased BP
Blood vessels Coronary vessels ✓ Skeletal muscle blood vessels ✓ Others	• Dilation • Constriction	• Constriction • Dilation
Glands ✓ Intestinal gastric glands and bile secretions ✓ Sweat gland ✓ Adrenal gland	• Decreased secretion • Increased sweating • Increased secreting	• Increased secretion • No effect • No effect

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COMMUNITY PHARMACY AND MANAGEMENT

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Dr. Vibhor Kumar Jain
Dr. Pranav Kumar Upadhyay
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Syllabus

Chapter 1

Community Pharmacy Practice – Definition, history and development of community pharmacy International and Indian scenarios **(2 Hours)**

Chapter 2

Professional responsibilities of community pharmacists
Introduction to the concept of Good Pharmacy Practice and SOPs **(3 Hours)**

Chapter 3

Prescription and prescription handling **(7 Hours)**

- Definition, parts of prescriptions, legality of prescriptions, prescription handling, labelling of dispensed medications (Main label, ancillary label, pictograms), brief instructions on medication usage
- Dispensing process, Good Dispensing Practices, dispensing errors and strategies to minimize them

Chapter 4

Communication skills **(6 Hours)**

- Definition, types of communication skills
- Interactions with professionals and patients
- Verbal communication skills (one-to-one, over the telephone)
- Written communication skills
- Body language
- Patient interview techniques

Chapter 5

Patient counselling **(10 Hours)**

- Definition and benefits of patient counselling
- **Stages of patient counselling -** Introduction, counselling content, counselling process, and closing the counselling session
- **Barriers to effective counseling -** Types and strategies to overcome the barriers
- **Patient counselling points for chronic diseases/disorders -** Hypertension, Diabetes, Asthma, Tuberculosis, Chronic obstructive pulmonary disease, and AIDS
- **Patient Package Inserts -** Definition, importance and benefits, Scenarios of PPI use in India and other countries
- **Patient Information leaflets -** Definition and uses

Chapter 6

Medication Adherence **(2 Hours)**
Definition, factors influencing non- adherence, strategies to overcome non-adherence

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Chapter 7

Health Screening Services in Community Pharmacy **(5 Hours)**

Introduction, scope, and importance of various health screening services - for routine monitoring of patients, early detection, and referral of undiagnosed cases

Chapter 8

Over the Counter (OTC) Medications **(15 Hours)**

- Definition, need and role of Pharmacists in OTC medication dispensing
- OTC medications in India, counseling for OTC products
- Self-medication and role of pharmacists in promoting the safe practices during self-medication
- Responding to symptoms, minor ailments, and advice for self-care in conditions such as - Pain management, Cough, Cold, Diarrhea, Constipation, Vomiting, Fever, Sore throat, Skin disorders, Oral health (mouth ulcers, dental pain, gum swelling)

Chapter 9

Community Pharmacy Management **(25 Hours)**

- Legal requirements to set up a community pharmacy
- Site selection requirements
- Pharmacy designs and interiors
- Vendor selection and ordering
- Procurement, inventory control methods, and inventory management
- Financial planning and management
- Accountancy in community pharmacy – Day book, Cash book
- Introduction to pharmacy operation softwares – usefulness and availability
- Customer Relation Management (CRM)
- Audits in Pharmacies
- SOP of Pharmacy Management
- Introduction to Digital Health, mHealth and Online pharmacies

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Chapter 1

N A AN AN N

1.1 DEFINITION

- Community pharmacy, also known as retail pharmacy, is the most common type of pharmacy that allows the public access to their medications and advice about their health. Traditionally known as a 'chemist', it is the healthcare facility that is responsible for the provision of pharmaceutical service to a specific community group or region.

- "Community pharmacy is the term used to describe the provision of pharmaceutical care by pharmacists in primary healthcare settings".
- Community pharmacy is a diverse, dynamic and constantly changing practice environment comprising several different practice settings and offering many opportunities for pharmacy practitioners.
- It is a major pharmacy practice area where the medications and other healthcare needs of community (society) are fulfilled. In India, these are privately owned practice settings popularly known as drug stores/medical stores/ chemists and druggists/pharmacy, etc.
- As opposed to hospital pharmacy, these settings are flexible to adopt advances in technology, medicines and accordingly modify to fulfil the expectations of community.
- The pharmacist can also assist the physician by providing patient education and counselling about medicines, and strategies to improve blood pressure control in an effort to reinforce the physician's treatment plan.
- Community pharmacists are considered to be the most accessible health professionals to the public, as they are available to provide personalized advice about health and medicine on a walk-in basis, without the need for an appointment.
- Pharmacy is the health profession that links the health sciences with the chemical sciences, and it is charged with ensuring the safe and effective use of medication.
- A community pharmacy is a pharmacy that deals directly with people in the local area. It has responsibilities including compounding, counselling, checking and dispensing of prescription drugs to the patients with care, accuracy and legality.
- "Community pharmacy is a link between the community and health." It is a healthcare service.

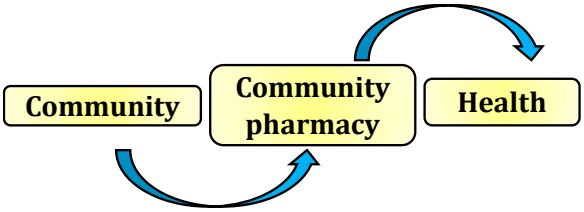

Fig. 1.1: Linkage of Community Pharmacy

- In 1945, PhD in Pharmaceutical Sciences was started at BHU.
- In 1948, the Pharmacy Act was enacted on 4 march 1948 by PCI to regulate the practice, education and profession of pharmacy.
- PCI, the central council made the first education regulations in 1953 prescribing the minimum standard of education as Diploma in pharmacy for qualification as a registered pharmacist.
- The subsequent Diploma in pharmacy regulations made by PCI were E.R. 1972, E.R. 1981, E.R. 1991, and most recently the E.R. 2020.
- During 1980-1990's consequence of drug misuse, poor outcomes of therapy, ADRs, economic, losses, antibiotics resistance etc. were acknowledged. the need of pharmacist's, contribution was realized.
- After independence, the Indian Pharmacopoeia Committee was constituted in 1948, for publication of IP as its main function. The Indian Pharmacopoeia editions are as follows:
  - ✓ Indian Pharmacopoeia 1955 - First edition, followed by supplement in 1960;
  - ✓ Indian Pharmacopoeia 1966 - Second edition, followed by supplement in 1975;
  - ✓ Indian Pharmacopoeia 1985 - Third edition, followed by its addendum in 1989 and 1991;
  - ✓ Indian Pharmacopoeia 1996 - Fourth edition, followed by its addendum 2000, supplement 2000 for Veterinary Products, addendum 2002 and addendum 2005;
  - ✓ Indian Pharmacopoeia 2007 - Fifth edition, followed by addendum 2008;
  - ✓ Indian Pharmacopoeia 2010 - Six edition with DVD followed by its addendum 2012;
  - ✓ Indian Pharmacopoeia 2014 – Seventh edition with DVD followed by its addendum 2015 and addendum 2016;
  - ✓ Indian Pharmacopoeia 2018 with DVD - Eighth edition.
  - ✓ Indian Pharmacopoeia 2022 - Ninth edition.

- In 1980, there were 11 universities and 26 colleges for B. Pharma and M. Pharm.
- In 1996, the M. Pharm program in pharmacy practice was introduced at JSS College of Pharmacy at Mysore and at Ooty in 1997.
- National Institute of Pharmaceutical Education and Research (NIPER) was established in 1998.
- Indian Government has set up 7 National Institutes of Pharmaceutical Education and Research (NIPERs) offering M.S. (Pharm), M. Tech. (Pharm) and higher-level de grees.
- Pharmacy council of India introduced Pharm. D. program regulations in 2008.
- In 2010, there were less than 900 pharmacy colleges in country.
- In 2014, through PCI regulation, the B. Pharm and M. Pharma curriculum was made uniform throughout the nation.
- In 2015, the pharmacy colleges were increased from 2000 colleges to 6000 colleges with 4 lakh students.

Chapter 2

A M N A AN

2.1 INTRODUCTION

- The professional role of the community pharmacist has been largely concerned with preparing and dispensing prescriptions.
- There are many professional scopes and roles in various health care services, from counselling of patients to dispensing of prescribed drug including informative advice regarding drug and it's use, compatibility, adverse drug reaction and side effect.
- "Community pharmacist is the professional who dispenses medicine with a prescription and in certain cases without a prescription where applicable (OTC drugs)".
- The aim of pharmacy services is to ensure optimal drug therapy both by contributing to the preparation, supply, and control of medicines and by providing information and advice to those who prescribe or use the pharmaceutical products.

2.2 ROLE OF COMMUNITY PHARMACIST IN ENSURING BETTER HEALTHCARE

- Counselling the patients regarding the use of the drugs and dosage forms.
- Providing up-to-date information on drugs/dosage forms to the patients, as well as, medical staff.
- Maintaining patient records and history.
- Involved in guiding patients in the usage of self-diagnostic kits for disorders such as diabetes, hypertension etc.
- Providing a supply of home care dosage forms.
- A community pharmacist can also advise on the administration of the medication, provide information on the storage of the medication and wherever necessary he can counsel the patient. Education regarding the disadvantage of polypharmacy can also be given to the patient.

2.3 PROFESSIONAL RESPONSIBILITIES OF COMMUNITY PHARMACISTS

- The role of the pharmacist has evolved greatly and is now deeply involved in a number of other health initiatives.
- The responsibilities of community pharmacist, can be categorized based on area of practice into the following categories:

Table 2.1: Standards for the Elements Suggested By GPP

ELEMENTS OF GPP	STANDARDS NEEDED
1. Health promotion, ill-health prevention and achieving health objectives.	i. Facility for independent counselling area that ensures privacy. ii. Provision of general advice on health matters. iii. Involvement in health, related campaigns. iv. Quality assurance of equipment use and advice given in diagnostic testing.
2. Supply and use of medication and other healthcare products. a. Receiving prescription and confirmation of integrity of communication.	 i. Facilities ii. Procedures iii. Personnel
b. Assessment of prescription by the pharmacist: i. Therapeutic aspects ii. Appropriateness for individual iii. Social, legal, economic aspects	 i. Information sources ii. Competence of Pharmacist iii. Medication records
c. Assembly of prescribed items	i. Sources of supply of medicines, manufacture of medicines. ii. Storage. iii. Condition at time of supply to patient. iv. Personnel involved. v. Equipment required. vi. Facilities and workplace required.
d. Advice to ensure that patient receives and understand information to derive maximum benefit from the treatment	i. Facilities for confidential conversation that can not be overhead by others. ii. Information sources. iii. Procedure to be followed and appropriate documentation. iv. Competence of the personnel involved.
e. Following up of the effect of prescribed treatment	i. Procedure to be followed in regular, systematic evaluation of outcomes of treatment. ii. Access to necessary monitoring equipment and facilities. iii. Quality assurance of monitoring facilities.
f. Documentation of professional activities	i. Recording of professional activities and pertinent data. ii. Procedures for self-assessment of professional activities.

MULTIPLE CHOICE QUESTIONS

1. Professional responsibilities of the Community Pharmacist include
(a) Processing prescriptions
(b) Checking for drug interactions
(c) Dispensing medications
(d) All of these

2. GPP requires that a pharmacist's first concern in all settings is the
(a) Documentation
(b) Welfare of patients
(c) Measurement of the biological marker in blood
(d) All of these

3. GPP is the practice of pharmacy that responds to
(a) The needs of the people
(b) Administration of medication, when required
(c) The monitoring of the effects of medication use
(d) None of these

4. FIP is
(a) Pharmaceutical Federation of India
(b) Indian Pharmaceutical Federation
(c) International Pharmaceutical Federation
(d) None of these

5. Which of the following is under the drug products related responsibilities
(a) Dispensing of medicines
(b) Special products
(c) Supply of medical devices
(d) All of these

6. Which should be maintained for commonly made extemporaneous preparations
(a) Temperature
(b) Humidity
(c) Cleanliness
(d) Standard operating procedures

7. A separate list of important medicines including _____should be prepared
(a) Vaccines and Sera
(b) OTC medications and baby oils
(c) Life-saving drugs and Vaccines
(d) Essential and life-saving medicines

8. SOPs stands for
(a) Safety Operating Procedures
(b) Standard Operating Procedures
(c) Safety Operating Policy
(d) Standard Operating Policy

9. Which of the Pharmacy should be equipped with appropriate apparatus required for the preparation
(a) Counselling room
(b) Compound section
(c) Compounding section
(d) Medicine storage area

10. Elements of Good Pharmacy Practice is Except
(a) Self-care
(b) Supply and use of medication and other healthcare products
(c) Assembly of unprescribed drugs
(d) Health promotion, ill-health prevention and achieving health objectives

11. SOPs should include
(a) The date of preparation
(b) A full and clear description of each part of the process and how it should be carried out
(c) Activities that must be carried out by the pharmacist
(d) All of these

12. Which is a requirement in both hospital and community pharmacy to ensure the safe and effective provision of pharmacy services
(a) SOPs
(b) Counselling section
(c) Doctors
(d) Trainers

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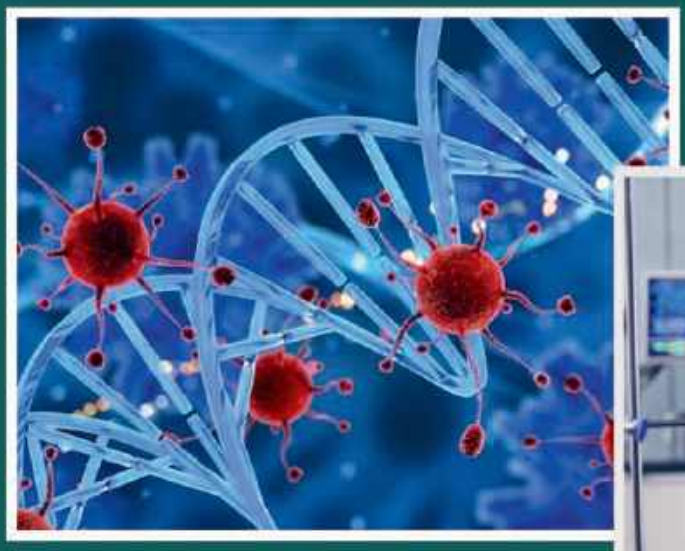
BIOCHEMISTRY AND CLINICAL PATHOLOGY

Diploma in Pharmacy



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Syllabus

Chapter 1

Introduction to biochemistry **(2 Hours)**

- Scope of biochemistry in pharmacy; Cell and its biochemical organization

Chapter 2

Carbohydrates **(5 Hours)**

- Definition, classification with examples, chemical properties
- Monosaccharides - Structure of glucose, fructose, and galactose
- Disaccharides - structure of maltose, lactose, and sucrose
- Polysaccharides - chemical nature of starch and glycogen
- Qualitative tests and biological role of carbohydrates

Chapter 3

Proteins **(5 Hours)**

- Definition, classification of proteins based on composition and solubility with examples
- Definition, classification of amino acids based on chemical nature and nutritional requirements with examples
- Structure of proteins (four levels of organization of protein structure)
- Qualitative tests and biological role of proteins and amino acids
- Diseases related to malnutrition of proteins

Chapter 4

Lipid **(5 Hours)**

- Definition, classification with examples
- Structure and properties of triglycerides (oils and fats)
- Fatty acid classification - Based on chemical and nutritional requirements with examples
- Structure and functions of cholesterol in the body
- Lipoproteins - types, composition and functions in the body
- Qualitative tests and functions of lipids

Chapter 5

Nucleic acids **(4 Hours)**

- Definition, purine and pyrimidine bases
- Components of nucleosides and nucleotides with examples
- Structure of DNA (Watson and Crick model), RNA and their functions

Chapter 6

Enzymes **(5 Hours)**

- Definition, properties and IUB and MB classification
- Factors affecting enzyme activity
- Mechanism of action of enzymes, Enzyme inhibitors
- Therapeutic and pharmaceutical importance of enzymes

Chapter 7

Vitamins **(6 Hours)**

- Definition and classification with examples
- Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins

Chapter 8

Metabolism (Study of cycle/pathways without chemical structures) **(20 Hours)**

Metabolism of Carbohydrates: Glycolysis, TCA cycle and glycogen metabolism, regulation of blood glucose level. Diseases related to abnormal metabolism of Carbohydrates

Metabolism of lipids: Lipolysis, β-oxidation of Fatty acid (Palmitic acid) ketogenesis and ketolysis. Diseases related to abnormal metabolism of lipids such as Ketoacidosis, Fatty liver, Hypercholesterolemia

Metabolism of Amino acids (Proteins): General reactions of amino acids and its significance– Transamination, deamination, Urea cycle and decarboxylation. Diseases related to abnormal metabolism of amino acids, Disorders of ammonia metabolism, phenylketonuria, alkaptonuria and Jaundice

Biological oxidation: Electron transport chain and Oxidative phosphorylation

Chapter 9 **(5 Hours)**

Minerals: Types, Functions, Deficiency diseases, recommended dietary requirements

Chapter 10 **(5 Hours)**

Water and Electrolytes

- Distribution, functions of water in the body
- Water turnover and balance
- Electrolyte composition of the body fluids, Dietary intake of electrolyte and Electrolyte balance
- Dehydration, causes of dehydration and oral rehydration therapy

Chapter 11 **Introduction to Biotechnology** **(1 Hours)**

Chapter 12

Organ function tests **(6 Hours)**

- Functions of kidney and routinely performed tests to assess the functions of kidney and their clinical significances
- Functions of liver and routinely performed tests to assess the functions of liver and their clinical significances
- Lipid profile tests and its clinical significances

Chapter 13

Introduction to Pathology of Blood and Urine **(6 Hours)**

- Lymphocytes and Platelets, their role in health and disease
- Erythrocytes - Abnormal cells and their significance
- Normal and Abnormal constituents of Urine and their significance

Index

Chapter 1

U N M N

1.1 INTRODUCTION

- Biochemistry can be defined as **"chemistry of the living cells ".**
- Biochemistry is the science concerned with studying the various molecules that occur in living cells and organisms and with their chemical reactions.
- It bridges the study of chemistry and biology.
- The living matter is composed of mainly six elements - **Carbon, Hydrogen, Oxygen, Nitrogen, Phosphorus and Sulfur**. These elements constitute about 90% of dry weight of human body.

1.2 HISTORY OF BIOCHEMISTRY

- The name Biochemistry was **coined in 1903** by a German chemist named **Carl Neuberg**.
- During the later part of 19th century, scientists contributed in the field of chemistry of fats, proteins and carbohydrates.
- Study of nucleic acid is central to the knowledge of life but its fusion with biochemistry started with works of **Frederick Sanger** and **Har Gobind Khorana**. In 1990, the structural details of cell organization was given.


Carl Neuberg

- The field of molecular biochemistry was also progressing at an almost unstoppable speed having expanded its horizons beyond human imagination with the introduction of PCR, creating waves of appreciation from every field of medicine and then established better therapies for various diseases by the introduction of gene therapy.

Table 1.1 Scientists and their Discoveries

SCIENTIST	DISCOVERIES
Friedrich Wohler	Friedrich Wohler was first to synthesize an organic compound from an inorganic substance. conversion of ammonium cyanate into urea.
Eduard Buchner	Yeast extract with no living yeast fungi can form alcohol from a sugar solution.
Hans Krebs	Discovery of the Tricarboxylic acid cycle - "Krebs cycle".
Avery and Macleod	DNA is a genetic material.
Albert Lehninger	He identified the TCA cycle in mitochondria.
Watson and crick	Watson and Crick described double helical model.
M. W. Nirenberg	Genetic code in mRNA.

2.	**Cell membrane**	Cell is enveloped by a rigid cell wall	Cell is enveloped by a flexible plasma membrane
3.	**Sub-cellular organelles**	Absent	Distinct organelles are found (e.g., mitochondria, nucleus, lysosomes)
4.	**Nucleus**	Not well defined; DNA is found as nucleoid, histones are absent	Nucleus is well defined, surrounded by a membrane; DNA is associated with histones
5.	**Energy metabolism**	Mitochondria absent, enzymes of energy metabolism bound to membrane	Enzymes of energy metabolism are located in mitochondria
6.	**Cell division**	Usually, fission and no mitosis	Mitosis
7.	**Cytoplasm**	Organelles and cytoskeleton absent	Contains organelles and cytoskeleton (a network of tubules and filaments)
8.	**Membrane bound organelles**	Absent	Present
9.	**Ribosome**	70s ribosome present	80s ribosome present

1.5.2 Cell Organelles

1. Cell Membrane (Plasma Membrane)

- The plasma membrane forms the cells flexible outer surface, separating the cell's internal environment from the external environment.
- It is a selective barrier that regulates the flow of materials into and out of the cell.
- Plasma membrane is best described by using fluid mosaic model by **S.J. Singer and G. L. Nicolson.**
- The basic structural framework of the plasma membrane is the lipid bilayer.

✓ **Function**

- Acts as a barrier separating inside and outside of the cell.
- Controls the flow of substances into and out of cell.
- Helps identify the cell to other cells.
- Participates in intercellular signaling.

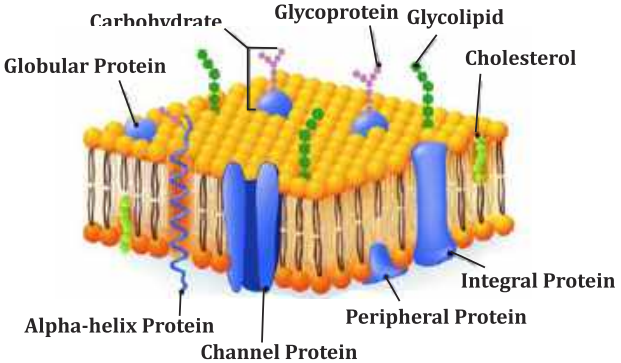


Fig.1.2: Structure of Cell Membrane

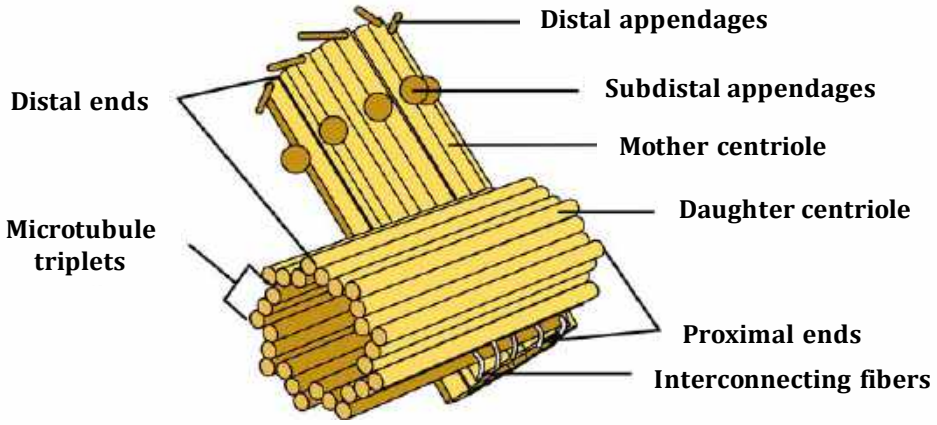


Fig. 1.9: Structure of Centrosome

✓ Function

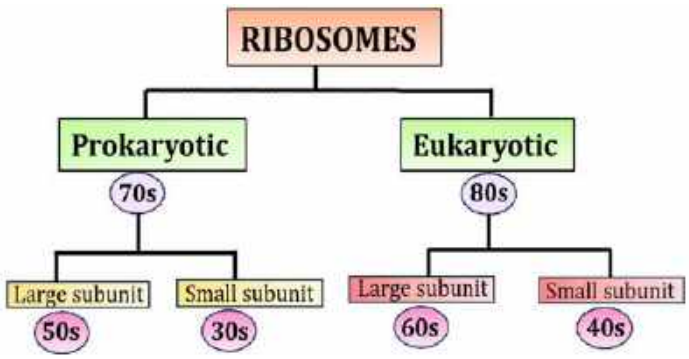
- The pericentriolar material of the centrosome contains tubulins that build microtubules in nondividing cell.
- The pericentriolar material of the centrosome forms the mitotic spindle during cell division.

11.Flagella and Cilia

CHARACTERISTICS	FLAGELLA	CILIA
Definition	Flagella are long, thread like appendages on the surface of a living cell.	Cilia are short, hair like appendages extending from the surface of a living cell.
Length	Long	Shorter than flagella.
Motion	Wave-like, undulating sinusoidal, slow movement.	Rotational, like a motor very fast moving.
Density	Fewer in number.	Many per cell.
Found in	Both in eukaryotes and prokaryotes.	Eukaryotes
Function	Help in locomotion only.	Help in locomotion, feeding.

12.Ribosome

- Ribosomes are composed of a ribonucleic protein.
- They are granular in structure and are made up of two parts - A large subunit and a small subunit.



- In 70S and 80S ribosomes, 'S' refers to Svedberg's Unit which stands for sedimentation coefficient.

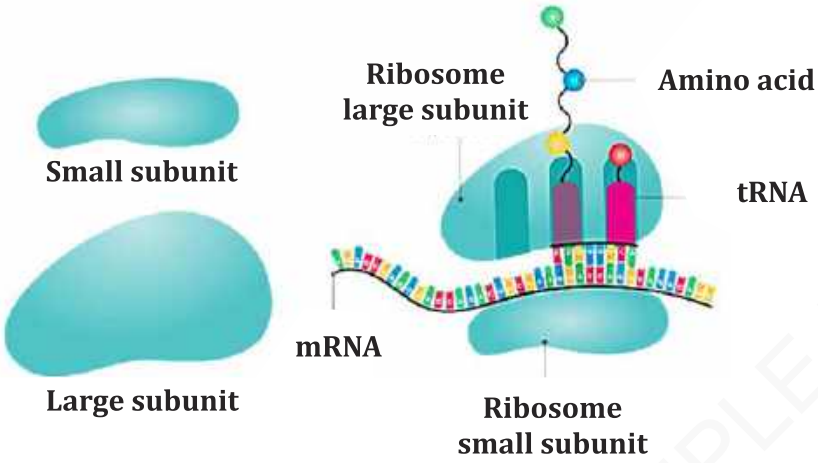


Fig.1.10: Structure of Ribosome

✓ **Function**

- Ribosome associated with endoplasmic reticulum synthesizes proteins for insertion in the plasma membrane or secretion from the cell. Free ribosomes **synthesize protein** used in the cytosol.

MULTIPLE CHOICE QUESTIONS

1. What is Biochemistry

(a) Study of chemistry of human body
(b) Study of chemistry of carbon compounds
(c) Study of chemistry of living things
(d) Study of all matter

2. Which of the following is the most correct and complete description of Medical Biochemistry

(a) Study of size, shape and beauty of human body
(b) Study of gross and microscopic structure of human body
(c) Study of functions of human body at cell, tissue or organ level
(d) Study of structure and function of human body at the molecular level

3. Cell term was given by

(a) Robert Hooke (b) Tatum
(c) Schwann (d) De Bary

4. Which is called as power house of cell

(a) Nucleus
(b) Mitochondria
(c) Endoplasmic reticulum
(d) Lysosome

5. Which do not have nucleus

(a) Mature RBCs
(b) Sperm cell
(c) Motor neuron cell
(d) Adipose cell

6. The largest organelle in cell is

(a) Endoplasmic reticulum
(b) Chromosomes
(c) Nucleus
(d) Golgi bodies

7. The energy currency of the cell is

(a) ATP (b) DNA
(c) Calories (d) Joule

As Per PCI Regulation

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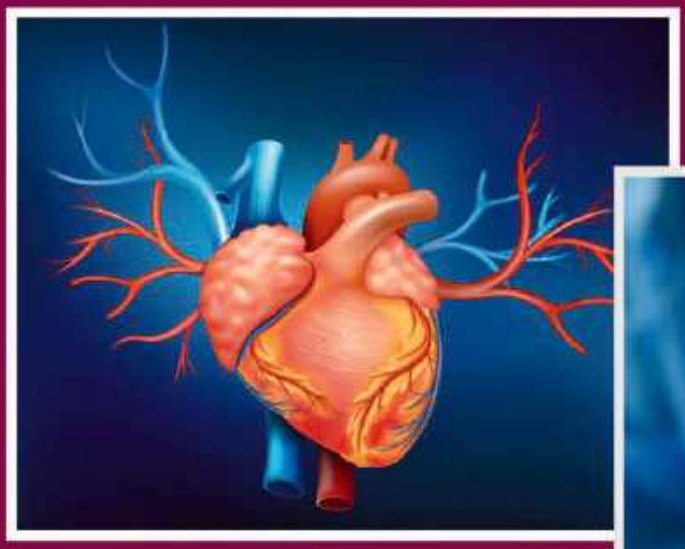
A Text Book of

PHARMACOTHERAPEUTICS

Diploma in Pharmacy



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Syllabus

Chapter 1 **(8 Hours)**

Pharmacotherapeutics

- Introduction, scope, and objectives. Rational use of Medicines, Evidence Based Medicine, Essential Medicines List, Standard Treatment Guidelines (STGs)

Chapter 2

Definition, etiopathogenesis, clinical manifestations, non-pharmacological and pharmacological management of the diseases associated with

(a) Cardiovascular System **(8 Hours)**

- Hypertension
- Angina and Myocardial infarction
- Hyperlipidaemia
- Congestive Heart Failure

(b) Respiratory System **(4 Hours)**

- Asthma
- COPD

(c) Endocrine System **(5 Hours)**

- Diabetes
- Thyroid disorders - Hypo and Hyperthyroidism

(d) Central Nervous System **(8 Hours)**

- Epilepsy
- Parkinson's disease
- Alzheimer's disease
- Stroke
- Migraine

(e) Gastro Intestinal Disorders **(8 Hours)**

- Gastro oesophageal reflux disease
- Peptic Ulcer Disease
- Alcoholic liver disease
- Inflammatory Bowel Diseases (Crohn's Disease and Ulcerative Colitis)

(f) Haematological disorders **(4 Hours)**

- Iron deficiency anaemia
- Megaloblastic anaemia

(g) Infectious diseases **(12 Hours)**

- Tuberculosis
- Pneumonia

- Urinary tract infections
- Hepatitis
- Gonorrhoea and Syphilis
- Malaria
- HIV and Opportunistic infections
- Viral Infections (SARS, CoV2)

(h) Musculoskeletal disorders **(3 Hours)**

- Rheumatoid arthritis
- Osteoarthritis

(i) Dermatology **(3 Hours)**

- Psoriasis
- Scabies
- Eczema

(j) Psychiatric Disorders **(4 Hours)**

- Depression
- Anxiety
- Psychosis

(k) Ophthalmology **(2 Hours)**

- Conjunctivitis (bacterial and viral)
- Glaucoma

(l) Anti-microbial Resistance **(2 Hours)**

(m) Women's Health **(4 Hours)**

- Polycystic Ovary Syndrome
- Dysmenorrhea
- Premenstrual Syndrome

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Chapter 1

A AN A N

1.1 INTRODUCTION TO PHARMACOTHERAPEUTICS

- Pharmacotherapeutics is branch of pharmacology that deals with the therapeutic application and effect of drugs.
- Pharmacotherapeutics refers to the use of drugs for the prevention, treatment, diagnosis, and modification of normal functions.
- Pharmacotherapeutics is the clinical purpose or indication for giving a drug.

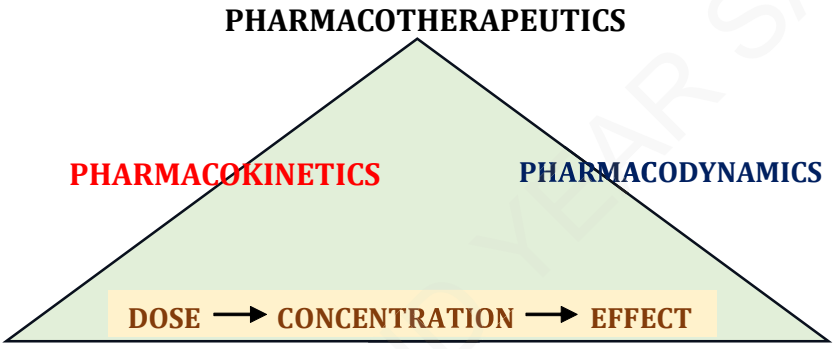

Fig. 1.1: Pharmacotherapeutics and its components

1.2 SCOPE OF PHARMACOTHERAPEUTICS

The scope of Pharmacotherapeutics is broad and encompasses several key aspects:

1. **Disease Treatment:** The use of medications to treat, manage, or cure illnesses is known as Pharmacotherapeutics. This covers both acute and long-term conditions from a range of medical specialties, including psychology, infectious diseases, cardiology, and oncology.
2. **Symptom Management:** Medications are frequently used to improve patients' quality of life by easing the symptoms of illnesses. This can involve controlling pain, reducing inflammation, managing nausea, and improving other symptoms.
3. **Prevention of Diseases:** Pharmacotherapeutics includes the use of drugs for prophylactic antibiotics, chemoprevention, and immunization as preventive measures. The goal of preventive pharmacotherapy is to lower the likelihood of contracting specific diseases.
4. **Individualized Treatment:** The profession acknowledges the value of customized or individualized treatment, accounting for a patient's age, gender, genetic makeup, and general state of health. This method assists in customizing Pharmacotherapeutics treatments to meet the demands of individual patients.

- We, the undersigned, hereby establish this charter to encourage the responsible use of medications, acknowledging the critical role that these drugs play in the health and well-being of individuals and communities. Assuring the responsible stewardship of healthcare resources, reducing risks, and attaining optimal health outcomes all depend on the prudent use of medications.

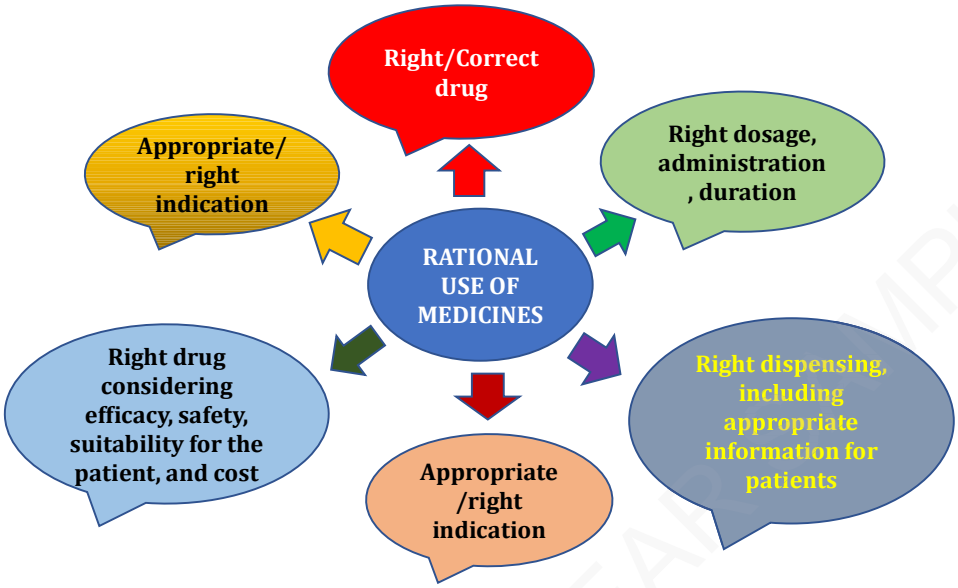

Fig. 1.2 Rational use of medicines

1.4.1 Process

The process of rational prescribing typically involves several key steps:

- Patient Assessing and Diagnosis
- Establishing Treatment Goals
- Choosing the Most Effective Medicine
- Patient Factors to be Considered
- Dosage and Administration
- Monitoring and Follow-up
- Educating the Patient
- Analyzing and Modifying the Treatment Plan
- Consideration of Cost-Effectiveness
- Documentation

1.4.2 Irrational Use of Medicines

Here are some common examples and reasons for the irrational use of medicines:

1. **Overuse of Antibiotics:** Antibiotic abuse or misuse is one notable example. When they are not required, like in the case of viral illnesses, antibiotics are frequently administered. Antibiotic resistance may result from this, gradually decreasing the effectiveness of these medications.
2. **Self-Medication:** It is possible for people to self-diagnose and self-prescribe drugs without seeking medical advice. This may result in the usage of improperly prescribed medications, dosage errors, and possible drug interactions.

PHARMACOTHERAPEUTICS

(d) Infection

5. Non-Pharmacological Management include

(a) Use of medicine
(b) Do not use of medicine
(c) Etiology
(d) None of these

6. Pharmacological Management of disease involve

(a) Use of medicine (b) Diet change
(c) Physical activity (d) None of these

7. Scope of Pharmacotherapeutics include

(a) Pathophysiology of disease
(b) Therapeutics management of disease
(c) Therapeutics of disease
(d) All of these

8. In which year WHO released the first Essential Medicine List

(a) 1986 (b) 1967
(c) 1977 (d) 1958

9. Aspects of NLEM consist of

(a) Cost (b) Safety
(c) Efficacy (d) All of these

10. Full form of NLEM is

(a) National list of essential medicine
(b) National list of exceptional medicine
(c) National list of excess medicine
(d) None of these

ANSWER KEY

1 - c 2 - a 3 - c 4 - b 5 - b 6 - a 7 - d 8 - c 9 - d 10 - a

THEORETICAL QUESTIONS

Short answer questions (Each question carries 4 marks)

Q1. Define rational use of medicine.

Q2. State the steps involve in the process of Rational prescribing.

Q3. What are the key features involved in standard treatment guideline.

Q4. What are the factors considered for the selection of essential medicine.

Q5. What are the scopes in Pharmacotherapeutics.

Long answer questions (Each question carries 8 marks)

Q1. What is the concept and advantages of essential medicine list.

Q2. Give a brief description of standard treatment guidelines.

Q3. Describe the evidence-based medicines and steps involved in it.

Q4. Give a brief description on rational use of medicine.

Q5. Define Pharmacotherapeutics and its objectives.

9. Combination Medications:

Some individuals may require a combination of medications from different classes to achieve optimal blood pressure control.

2.2.7 Diagnosis of Hypertension

- Urinalysis may show protein, red blood cells, or white blood cells (WBCs), suggesting renal disease; or glucose, suggesting diabetes mellitus.
- Excretory urography may reveal renal atrophy, indicating chronic renal disease.
- Serum potassium levels less than 3.5 mEq/L may indicate adrenal dysfunction.
- Blood urea nitrogen (BUN) levels that are elevated to more than 20 mg/dL.
- ECG may show left ventricular hypertrophy or ischemia.

2.3 ANGINA

2.3.1 Definition of Angina

- Angina is *a symptom of coronary artery disease*. Angina is also called angina pectoris.
- Angina pectoris is the result of myocardial ischemia caused by an imbalance between myocardial blood supply and oxygen demand.
- Angina is usually a sign of coronary artery disease (CAD), a disorder in which plaque- a mixture of fatty deposits, cholesterol, and inflammatory cells - builds up in the coronary arteries, narrowing or blocking them. Angina symptoms can be brought on by activities that raise the workload on the heart, such as physical activity or emotional stress, which reduce blood flow to the heart muscle.

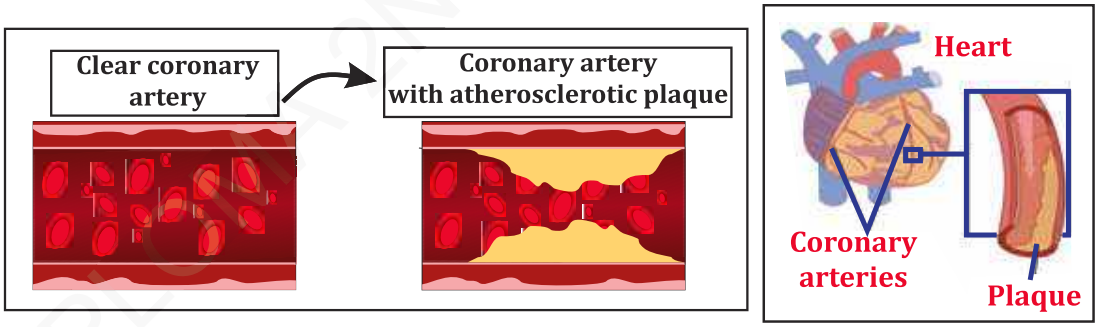

Fig. 2.3: Showing normal artery and artery during plaque formation

2.3.2 Etiopathogenesis of Angina

Angina is discomfort or soreness in the chest brought on by a decrease in blood supply to the heart muscle. It is frequently a sign of underlying coronary artery disease (CAD), in which the heart muscle's blood supply is impeded or constricted by the coronary arteries. Among the principal etiopathogenic factors of angina are:

1. **Atherosclerosis:** This disorder, which is defined by the accumulation of plaque in the coronary arteries, is the most frequent cause of angina. The inflammatory cells, cholesterol, and fatty deposits that make up these plaques cause the artery lumen to constrict.

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A Text Book of

HOSPITAL AND CLINICAL PHARMACY

2nd YEAR

DIPLOMA IN PHARMACY

As per the PCI Education Regulation (ER-2020)

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Syllabus

Chapter 1 **(6 Hours)**

Hospital Pharmacy

- Definition, scope, national and international scenario.
- Organizational structure.
- Professional responsibilities, Qualification and experience requirements, Job specifications, work load requirements and inter professional relationships.
- Good Pharmacy Practice (GPP) in Hospital.
- Hospital Pharmacy Standards (FIP Basel Statements, ASHP).
- Introduction to NQAS guidelines and NABH Accreditation and Role of Pharmacists.

Chapter 2 **(4 Hours)**

Different Committees in the Hospital

- Pharmacy and Therapeutics Committee - Objectives, Composition and Functions.
- Hospital Formulary - Definition, procedure for development and use of hospital formulary.
- Infection Control Committee - Role of Pharmacist in preventing Antimicrobial Resistance

Chapter 3 **(14 Hours)**

Supply Chain and Inventory Control

- Preparation of Drug Lists - High Risk drugs, Emergency Drugs, Schedule H_1 Drugs, NDPS Drugs, Reserved Antibiotics.
- Procedures of Drug Purchases- Drug selection, short-term, long-term and tender/e-tender process, quotations, etc.
- Inventory control techniques - Economic Order Quantity, Reorder Quantity Level, Inventory Turnover etc.
- Inventory Management of Central Drug Store - Storage conditions, Methods of storage, Distribution, Maintaining Cold Chain, Devices used for cold storage (Refrigerator, ILR, Walk-in-Cold Rooms).
- FEFO, FIFO Methods.
- Expiry drug removal and handling, and disposal. Disposal of narcotics, cytotoxic drugs.
- Documentation - purchase and inventory.

Chapter 4 **(7 Hours)**

Drug Distribution

- Drug Distribution (in-patients and out-patients) - Definition, advantages and disadvantages of individual prescription order method, Floor stock method, Unit Dose Drug Distribution Method, Drug Basket Method.
- Distribution of Drugs to ICCU/ICU/NICU/Emergency Wards.
- Automated drug dispensing systems and devices.
- Distribution of Narcotic and Psychotropic Substances and their Storage.

Chapter 5 **(4 Hours)**

Compounding in Hospitals: Bulk compounding, IV Admixture, services and incompatibilities, Total parenteral nutrition.

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Chapter 6 **(2 Hours)**

Radio Pharmaceuticals: Storage, dispensing and disposal of radiopharmaceuticals.

Chapter 7 **(2 Hours)**

Application of Computers in Hospital Pharmacy Practice, Electronic Health Records, Softwares used in hospital pharmacy.

Chapter 8 **(12 Hours)**

- **Clinical Pharmacy:** Definition, Scope and Development in India and other countries.
- Technical definitions, common terminologies used in clinical settings and their significance such as Paediatrics, Geriatric, Antenatal Care, Post-natal Care, etc.
- **Daily activities of clinical pharmacists**: Definition, goal and procedure of:
  - ✓ Ward round participation
  - ✓ Treatment chart review
  - ✓ Adverse drug reaction monitoring
  - ✓ Drug information and poisons information
  - ✓ Medication history
  - ✓ Patient counseling
  - ✓ Interprofessional collaboration
- **Pharmaceutical Care**: Definition, classification of drug related problems. Principles and procedure to provide pharmaceutical care.
- **Medication Therapy Management, Home Medication Review**.

Chapter 9 **(10 Hours)**

Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results

- Haematological, Liver function, Renal function, Thyroid function tests.
- Tests associated with cardiac disorders.
- Fluid and electrolyte balance.
- Pulmonary function tests.

Chapter 10 **(6 Hours)**

Poisoning: Types of Poisoning: Clinical Manifestations and Antidotes.

Drugs and Poison Information Centre and their Services - Definition, Requirements, Information resources with examples, and their advantages and disadvantages.

Chapter 11 **(2 Hours)**

Pharmacovigilance

- Definition, aim and scope.
- Overview of Pharmacovigilance.

Chapter 12 **(6 Hours)**

Medication errors - Definition, Types, Consequences, and Strategies to Minimize Medication Errors, LASA Drugs and Tallman Lettering as per ISMP.

Drug Interactions - Definition, types, clinical significance of drug interactions.

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Index

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Chapter 1

A A AN

1.1 INTRODUCTION

- Health care is the process of providing or receiving medical treatment. Receiving health care helps prevent and treat diseases that can impact individuals' quality of life as well as the length of their life.
- The healthcare services that are provided to the patient are two types: ambulatory patient care services and institutional patient care services.

Table 1.1 – Ambulatory and Institutional patient care services

AMBULATORY PATIENT CARE SERVICES	INSTITUTIONAL PATIENT CARE SERVICES
The ambulatory patient is referred to a patient who are not bedridden and receives healthcare services from a general or specialist clinical practitioner in their clinics.	The institutional patient is referred to any patient who receives healthcare services in the hospital. This includes patients admitted to the hospital or ambulatory patients.
Community pharmacies provide pharmaceutical services to such patients.	Hospital pharmacies provide pharmaceutical services in the hospitals department to such patients.

1.2 HOSPITAL

- Hospital is a healthcare institution that provides specialized medical and surgical treatment and nursing care for sick and injured people.
- Hospitals are equipped with medical equipment and all facilities, including operating theaters where medical professionals conduct major surgical procedures.

1.2.1 Classification of Hospital

Table 1.2 – Classification of Hospital

<table>
<tr><th colspan="4">CLASSIFICATION OF HOSPITAL</th></tr>
<tr><th colspan="2">BASED ON LENGTH OF PATIENT STAY</th><th colspan="2">BASED ON OWNERSHIP</th></tr>
<tr><td colspan="2">• Short term stay hospital (stay less than 30 days)
• Long term stay hospital (stay more than 30 days)</td><td colspan="2">• Public Hospital
• Voluntary Hospital
• Private Hospital
• Corporate Hospital</td></tr>
<tr><th colspan="2">BASED ON CLINICAL BASIS</th><th colspan="2">BASED ON THE OBJECTIVES</th></tr>
<tr><td colspan="2">• Psychiatric Hospitals
• Orthopaedic Hospitals
• Maternity Hospitals</td><td colspan="2">• Teaching-cum research Hospital
• General Hospital
• Specialised Hospital
• Isolation Hospital</td></tr>
<tr><th colspan="2">BASED ON COST</th><th colspan="2">BASED ON SIZE</th></tr>
<tr><td>Elite Hospital</td><td>Like five-star hospitals e.g. Jaslok and Hinduja Hospital</td><td>Large Hospital</td><td>Beds 1000 and above</td></tr>
<tr><td rowspan="2">Budget Hospital</td><td rowspan="2">e.g. Civil Hospitals, Corporation Hospital</td><td>Medium Hospital</td><td>Beds between 500 - 1000</td></tr>
<tr><td>Small Hospital</td><td>Beds between 100 - 500</td></tr>
<tr><td colspan="2"></td><td>Very small Hospital</td><td>Less than 100 Beds</td></tr>
</table>

- **Secondary care:** Secondary health care is the specialist treatment and support provided by doctors and other health professionals for patients who have been referred to them for specific expert care, such as oncologists or endocrinologists.
- **Tertiary care:** The patient is referred by primary and healthcare providers when they require advanced medical procedures such as major surgeries, transplants, replacements, and long-term medical care management for diseases.

  Examples: Coronary artery bypass surgery, neurosurgery, plastic surgery.
- **Quaternary care:** Quaternary care is an extension of tertiary care in reference to advanced levels of medicine that are highly specialized and not widely accessed, such as experimental medicine and uncommon diagnostic or surgical procedures.

1.2.7 Difference between Hospital Pharmacy and Community Pharmacy

Table 1.4 – Difference between Hospital Pharmacy and Community Pharmacy

HOSPITAL PHARMACY	COMMUNITY PHARMACY
The practice of pharmacy in hospital.	A retail pharmaceutical establishment.
It is the organisation or department of hospital to manage the procurement, storage, preservation, packaging, sterilization, compounding, preparation, dispensing of medicine in the hospital.	Community pharmacy means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or prescription orders are compounded and dispensed other than hospital pharmacy.
A hospital pharmacy is located inside a hospital and serves inpatients.	A community pharmacy is accessible to the public and is usually located outside or near hospital.
Activities are interrelated such that physician – pharmacist – nurse – patient.	Activities are interrelated such that physician – pharmacist – patient.
Co-ordination with other department in hospital.	Co-ordination with only prescribing physician.
Interaction with clinical practitioners, nursing staff and pathologist.	Limited interaction with other healthcare professionals.
More complex clinical medication management issues.	More complex business and customer relations issues.

1.3 HOSPITAL PHARMACY

1.3.1 Definition

- The actual practice of pharmacy in the hospital is known as hospital pharmacy.
- It is the area of the hospital where legally qualified and professionally competent pharmacist distributes, manufactures, compounds, distributes, preserves, buys, stores, assays, and packages medications for inpatients and outpatients.

1.3.2 Function of Hospital Pharmacy

- Coordinating with the financial plan of operation for a hospital.
- Participate in studies or research designed for the improvement of patient's healthcare.
- To provide medication-related education to healthcare professionals and patients.
- To provide quality care to patients and support their recovery.
- Implement the philosophy, objectives, policies, and standards of the hospital.
- To develop and maintain an effective system of clinical and administrative records and reports.
- To fulfill the requirements for facilities, supply any equipment's.

- **Education**: Provides in-service education and training programs to health professionals.
- **Co-ordination**: Provides good ambulatory patient care by coordinating all activities.
- **Drug Information**: Provides adequate drug information to all health professionals.

➢ **Inpatient care area:**

- Helps the physician and nursing staff in the selection of drug therapy, and dose regimen.
- Obtaining patient medication histories and identifying drugs brought by them to the hospital to ensure that patients receive right treatment and avoid drug interactions.
- Inspection of the medication area of the nursing unit is necessary for the proper supply and storage of drugs.

1.7 QUALIFICATION AND EXPERIENCE REQUIREMENTS FOR HOSPITAL PHARMACIST

To become a hospital pharmacist, an individual must possess the following qualification:

- **Education:** The individual must hold a Bachelor of Pharmacy (B.Pharm), Master of Pharmacy (M.Pharm), or Doctor of Pharmacy (Pharm.D) degree from an institution accredited by the Pharmacy Council of India (PCI).
- **Training:** Upon completing their degree, the candidate must undergo the training period mandated by PCI, which typically lasts for at least one year.
- **Registration:** After completing the required training, the candidate must register with the State Pharmacy Council in the state where they intend to practice.
- **License:** Following registration, the candidate must obtain a license from the Drugs Controller General of India (DCGI), provided they meet all necessary qualifications to legally practice as a pharmacist.

1.7.1 Abilities Required of Hospital Pharmacists

- A well-qualified hospital pharmacist must have the following abilities:

Table 1.7 - Abilities Required of Hospital Pharmacists

ABILITIES	DESCRIPTION
Administrative and Managerial ability	• Organisation of hospital • Plan, organize, direct and control function • Preparing • Budget, inventory control ✓ Cost-review, cost-effectiveness ✓ Audit, maintenance of record & report • Personal manager
Technical ability	• Knowledge of drugs • Knowledgeable: Pharmacology, toxicology, pathophysiology, therapeutics and patient care techniques.
Manufacturing ability	• Develop formulations • Cost-benefit analysis
Research ability	• Participate in clinical research • Conduct pharmaceutical research himself • Information: Pharmacology, toxicology
Ability to control	• Quality assurance programme • Distribution of drug
Academic ability	• Training of new personnel • Training programmes

Name of patient _____

ADVERSE DRUG REACTION REPORT

1. Name of the drug _____
2. Type of reaction _____
3. Age _____ 4. Sex _____ 5. Weight _____
6. Daily dose _____ 7. Date (a) Started _____ (b) Ended _____
8. Source of drug _____ (a) Prescription _____ (b) Over the counter _____
   (c) Other _____

2.1.9 Role of PTC in "Emergency drug list"

- The time factor is necessary for the Pharmacy and Therapeutics Committee of a hospital to prepare boxes containing emergency drugs which should always be available for use at the bedside.
- Committees should develop a list of these medications and other supplies, which should then be placed in "Emergency Kits."
- After the emergency boxes have been placed in the wards, it is very essential and compulsory that a system be developed. The nursing supervisor in charge of the ward or the hospital pharmacists check them every day.

2.1.10 Role of PTC in Drug Utilization Review

- Drug utilization encompasses the prescribing, dispensing, administering, and consumption of prescribed medications. This is a crucial function of the hospital committee.
- The hospital pharmacist should gather the medication history, including the following details:

✓ Medications administered at the time of admission, during the hospital stay, and over-the-counter (OTC) remedies used at home.

✓ Drug allergies and idiosyncrasies related to food products, etc.

The purposes of collecting this information include:

- Enhancing drug prescribing practices by encouraging the safe and rational use of medications.
- Identifying and preventing potential drug interactions.
- Detecting and preventing adverse drug reactions, especially in sensitive patients.
- Identifying and preventing incompatibilities in intravenous (IV) additives.
- Recognizing drug-induced diseases.
- Detecting possible drug-induced diseases.
- Identifying potential drug toxicities.

2.1.11 Automatic Stop Order Policy

- In order to promote the safe and efficacious use of antibiotics, an automatic stop order is established.
- It is an order to hold medication for an unspecified period of time will result in the discontinuation of the medication.
- The automatic stop and review orders are important for two reasons:

1. To review patient's medication regimen to help avoid potential toxicity or dependence (resulting from prolonged use).
2. To avoid the development of resistant organisms to antibiotics.

- This policy is specially required for medications having the potential to cause toxicity, dependence, or emergence of resistant organisms e.g. Heparin, Narcotics, Sedative hypnotics, Antibiotics, Chronic pain management.

As Per PCI Regulation

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Diploma in Pharmacy

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Diploma in Pharmacy

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Syllabus

Chapter 1 (2 Hours)

General Principles of Law, History and various Acts related to Drugs and Pharmacy profession

Chapter 2 (5 Hours)

Pharmacy Act, 1948 and Rules: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils, Registration of Pharmacists, Offences and Penalties.

Pharmacy Practice Regulations, 2015

Chapter 3 (23 Hours)

Drugs and Cosmetics Act, 1940 and Rules, 1945 and New Amendments

Objectives, Definitions, Legal definitions of schedules to the Act and Rules

Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit.

Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

Study of schedule C and C1, G, H, H1, K, P, M, N, and X.

Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India

Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.

Chapter 4 (2 Hours)

Narcotic Drugs and Psychotropic Substances Act, 1985 and Rules

Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.

Chapter 5 (2 Hours)

Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.

Chapter 6 (2 Hours)

Prevention of Cruelty to Animals Act, 1960: Objectives, Definitions, CPCSEA - brief overview, Institutional Animal Ethics Committee, Breeding and Stocking of Animals, Performance of Experiments, Transfer and Acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties.

Chapter 7 (2 Hours)

Poisons Act, 1919: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons.

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Chapter 8 **(2 Hours)**

FSSAI (Food Safety and Standards Authority of India) Act and Rules: brief overview and aspects related to manufacture, storage, sale, and labelling of Food Supplements.

Chapter 9 **(5 Hours)**

National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO) - 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, Pharmaceutical Policy 2002, National List of Essential Medicines (NLEM).

Chapter 10 **(5 Hours)**

Code of Pharmaceutical Ethics: Definition, ethical principles, ethical problem solving, registration, code of ethics for Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath.

Chapter 11 **(2 Hours)**

Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments.

Chapter 12 **(1 Hour)**

Role of all the government pharma regulator bodies –Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC).

Chapter 13 **(3 Hours)**

Good Regulatory Practices (documentation, licenses, renewals, e-governance) in Community Pharmacy, Hospital pharmacy, Pharma Manufacturing, Wholesale business, inspections, import, export of drugs and medical devices.

Chapter 14 **(7 Hours)**

Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, New Drugs and Clinical Trials Rules, 2019. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization.

Chapter 15 **(2 Hours)**

Blood Bank – basic requirements and functions.

Chapter 16 **(2 Hours)**

Clinical Establishment Act and Rules – Aspects related to Pharmacy.

Chapter 17 **(2 Hours)**

Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals.

Chapter 18 **(2 Hours)**

Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants.

Chapter 19 **(1 Hour)**

Introduction to the Consumer Protection Act.

Chapter 20 **(1 Hour)**

Introduction to the Disaster Management Act.

Chapter 21 **(2 Hours)**

Medical Devices – Categorization, basic aspects related to manufacture and sale.

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Chapter 1

A AN NA A U A

1.1 INTRODUCTION

- Concept of law and principles of interpretation of statutes lay down the foundation of forensic pharmacy. It includes the knowledge of law and technically it is the science of the first principles of civil law.
- **Jurisprudence :** It is the study of fundamental legal principles and is also science and philosophy of law.
- **Pharmaceutical Jurisprudence :** It is a branch of pharmacy which deals with the knowledge of laws relating to drugs and pharmaceuticals and about pharmacy profession. It is also concerned with the laws related to drugs, medicines, cosmetics, pharmacist.
- Law intends to regulate and control various aspects of social life.
- The function of law is to achieve justice, stability and peaceful change in a society.
- The purpose of pharmaceutical legislation is to ensure that the patients receive drugs of required quality, tested and evaluated for safety as well as efficacy for their intended use. It means that Pharmaceutical Legislation is associated with the health of society.

1.2 PRINCIPLES OF LAW

- Laws and regulations govern almost all aspects of the profession of pharmacy.
- These have been developed over many years in order to guide the safe and effective delivery of medications to patients.
- These laws lay down permitted and prohibited conduct for pharmacists, pharmacies and organizations.
- The laws and regulations establish the pharmacist's responsibilities for operating a pharmacy, dispensing prescription medications, and providing other pharmacist services such as counselling patients about their prescription medications and assisting patients with selecting appropriate over-the-counter medications.
- They establish the requirements for information that must be on the prescription label, such as the name and quantity of the prescribed medication, directions for use, and other information.

- This Drug Enquiry Committee was later known by the name 'Chopra Committee'
- This committee published its report in 1931.
- It was reported that there was no recognized specialized profession of Pharmacy.
- The Committee was asked to make enquiries in the said matter and then to make recommendations for smooth control of manufacture, import, distribution and sale of drugs in the interest of public health.

✓ **The Committee recommended the following:**

1. There should be a central legislation to control drugs and pharmacy.
2. Setting up of testing laboratories in all the states so as to control quality of production of drugs and pharmaceuticals and also imported drugs.
3. Appointment of an Advisory Board to advise the Government in making Rules
4. Registration of every patent and proprietary medicine of undisclosed formula manufactured in India or imported from outside the country.
5. Setting up of courses for training in pharmacy and prescribing minimum qualification for registration as a pharmacist.
6. Crude single drugs as well as compounded medications utilized in the traditional medical systems should be under control.
7. Development of drug industries in India.
8. Manufacturing in medical stores depots should be gradually reduced.
9. Steps should be taken to compile an Indian pharmacopoeia.
10. The Cinchona department should cultivate cinchona.

✓ **In response to the above recommendation in 1931 by Chopra committee the following development was seen:**

- In 1932, The First Department of Pharmaceutics was started at Banaras Hindu University (BHU).
- In 1935, Pharmaceutical Association was organised, now it is known as IPA (Indian Pharmaceutical Association).
- Government introduced the Import of Drugs Bill in the Legislative Assembly in 1937 and subsequently the Drug Bill was introduced in 1940 in the Legislative Assembly.
- In 1939, Indian Journal of Pharmacy was started by Prof. M.L. Schroff.
- In 1940, Indian Pharmaceutical Association organised an All India Pharmaceutical Conference.
- The Pharmacy Bill was introduced by the Government of India in 1945 to regulate the profession and practice of pharmacy.
- In 1948 a full-fledged Indian Pharmacopoeia Committee was constituted under the chairmanship of Dr. B.N. Ghosh of Calcutta
- In 1943, the Government of India appointed a Health Survey and Development Committee to make recommendations for future developments under the chairmanship of Sir Joseph Willliam Bhore. Hence, termed as Bhore committee.

6. **Registered Pharmacist:** A person whose name is for the time being entered in the register of the State in which he is for the time being residing or carrying on his profession or business of pharmacy.
7. **University Grants Commission:** University Grants Commission established under section 4 of the University Grants Commission Act, 1956.

2.4 PHARMACY COUNCIL OF INDIA (PCI)

- Central Council (PCI) is constituted by the Central Government.
- First Pharmacy Council of India was constituted in the year 1949.
- Reconstituted every five years.

2.4.1 Constitution of Pharmacy Council of India

Table 2.1 Members of Pharmacy Council of India

Elected member: (Total= 8)	(a) Six members including at least one teacher each in pharmaceutical chemistry, pharmacology and pharmacognosy on the teaching staff of an Indian University or an affiliated college granting a degree or diploma in pharmacy. These members are elected by the University Grants Commission. (b) One member elected by Medical Council of India from amongst its members. (c) One member shall be registered pharmacist to represent each state elected by each State Council from amongst its members.
Nominated member: (Total= 9)	(a) Six members including at least four person possessing degree or diploma in pharmacy and engaged in the practice of pharmacy or pharmaceutical chemistry, nominated by the Central Government. (b) One from UGC and one from AICTE. (c) One registered pharmacist to represent each state nominated by State Government.
Ex-officio member: (Total= 3)	(a) Director General of Health Services. (b) Director of Central Drugs Laboratory. (c) Drug Controller of India.

✓ **President and Vice President of Central Council**

- President and vice president of the council shall be elected by the members of the council amongst themselves.
- They hold office for a term not exceeding five years and not extending beyond the expiry of his term, as a member of Central council.
- If his term as a member of Central Council expires before the expiry of the full term for which he is elected as President or Vice President; and if he is re-elected or re-nominated as a member of Central Council, he can continue to hold office as President or Vice President for the full term for which he is elected.

5. How many members from Medical Council of India are there in Pharmacy council of India

(a) One (b) Three
(c) Five (d) Zero

6. In State Pharmacy Council all following are ex officio members except

(a) President of India
(b) Chief Administrator Medical Officer of State
(c) The Officer in Charge of Drug Control Organization
(d) Government Analyst

7. Pharmacy Council of India has _____ state government nominated member(s)

(a) 1 (b) 2
(c) 3 (d) 4

8. Pharmacy Council of India is reconstituted

(a) Every 2 Years (b) Every 3 Years
(c) Every 5 Years (d) Every 6 Years

9. Offences of Pharmacy Act are

(a) Falsely claiming to be a registered pharmacist
(b) Failure to surrender certificate of registration
(c) Dispensed by unregistered person
(d) All of these

10. Every year the Register of State Pharmacy Council is required to print the registers

(a) 1st January (b) 1st March
(c) 1st April (d) 1st June

11. The penalties prescribed for falsely claiming to be a registered pharmacist on first conviction

(a) A fine upto Rs. 1,500
(b) A fine up to Rs. 500
(c) A fine upto Rs. 1,000
(d) Imprisonment upto 6 months

12. Minimum age limit for registration as pharmacist is

(a) 18 Years (b) 21 Years
(c) 19 Years (d) 25 Years

13. Ex - Officio member of central council is

(a) Officer in charge of Drug Control Administrative
(b) Government Analyst of each state
(c) Chief Medical Officer
(d) The Drug Controller of India

14. The Pharmacy Council of India is constituted by the

(a) Central Government
(b) State Government
(c) Cabinet Health Minister
(d) Legislative Assembly

15. Pharmacy Act was passed in 1948 with the objecting of

(a) Regulating pharmacy education in India
(b) Regulating practice of pharmacy in India
(c) To survey Facilitation on technical cell
(d) For approval of institutions

16. In Elected member of PCI, six member elected by

(a) Central Council (b) UGC
(c) AICTE (d) All of these

17. Pharmacy Council of India has _____ State Government nominated member(s)

(a) One (b) Two
(c) Three (d) Four

18. Central Register of Pharmacists is maintained by

(a) State Health Ministry
(b) Pharmacy Council of India
(c) State Pharmacy Council
(d) Drug Controller of India