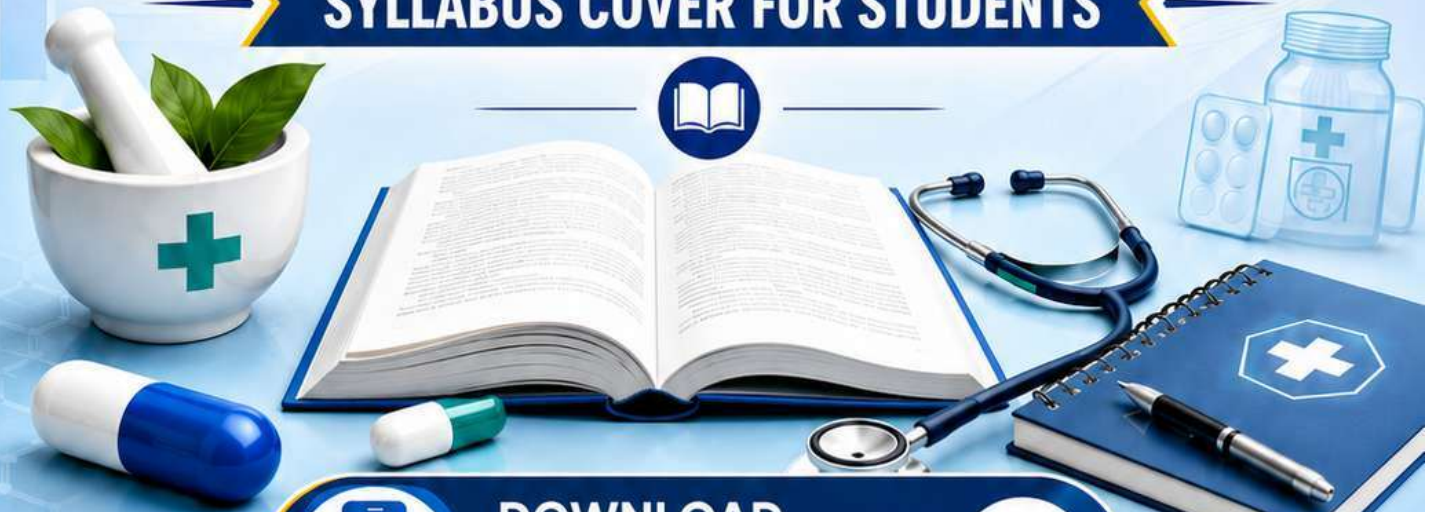
Pharmacy India

D.PHARM 2ND YEAR SYLLABUS

(PCI)

SYLLABUS COVER FOR STUDENTS



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8. ER-2020 D.Pharm Syllabus – Part II

S. No.	Course Code	Name of the Course	Total Theory / Practical Hours	Total Tutorial Hours	Theory / Practical Hours per Week	Tutorial Hours per Week
1.	ER20-21T	Pharmacology – Theory	75	25	3	1
2.	ER20-21P	Pharmacology – Practical	50	-	2	-
3.	ER20-22T	Community Pharmacy & Management – Theory	75	25	3	1
4.	ER20-22P	Community Pharmacy & Management – Practical	75	-	3	-
5.	ER20-23T	Biochemistry & Clinical Pathology – Theory	75	25	3	1
6.	ER20-23P	Biochemistry & Clinical Pathology – Practical	50	-	2	-
7.	ER20-24T	Pharmacotherapeutics – Theory	75	25	3	1
8.	ER20-24P	Pharmacotherapeutics – Practical	25	-	1	-
9.	ER20-25T	Hospital & Clinical Pharmacy – Theory	75	25	3	1
10.	ER20-25P	Hospital & Clinical Pharmacy – Practical	25	-	1	-
11.	ER20-26T	Pharmacy Law & Ethics	75	25	3	1

PHARMACOLOGY – THEORY

Course Code: ER20-21T **75 Hours (3 Hours/week)**

Scope: This course provides basic knowledge about different classes of drugs available for the pharmacotherapy of common diseases. The indications for use, dosage regimen, routes of administration, pharmacokinetics, pharmacodynamics, and contraindications of the drugs discussed in this course are vital for successful professional practice.

Course Objectives: This course will discuss the following:

1. General concepts of pharmacology including pharmacokinetics, pharmacodynamics, routes of administration, etc.
2. Pharmacological classification and indications of drugs
3. Dosage regimen, mechanisms of action, contraindications of drugs
4. Common adverse effects of drugs

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

1. Describe the basic concepts of pharmacokinetics and pharmacodynamics2. Enlist the various classes and drugs of choices for any given disease condition
3. Advice the dosage regimen, route of administration and contraindications for a given drug
4. Describe the common adverse drug reactions

Chapter	Topic	Hours
1	**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	10

2	**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)	**11**
3	**Drugs Acting on the Eye** Definition, classification, pharmacological actions, dose, indications and contraindications of • Miotics • Mydriatics • Drugs used in Glaucoma	**2**
4	**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 • Centrally acting muscle relaxants • Opioid analgesics	**8**
5	**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	**6**

6	**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	4
7	Definition, classification, pharmacological actions, dose, indications, and contraindications of • Bronchodilators • Expectorants • Anti-tussive agents • Mucolytic agents	2
8	**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	5
9	**Drugs Acting on the Kidney** Definition, classification, pharmacological actions, dose, indications, and contraindications of • Diuretics • Anti-Diuretics	2
10	**Hormones and Hormone Antagonists** Physiological and pathological role and clinical uses of • Thyroid hormones • Anti-thyroid drugs • Parathormone • Calcitonin • Vitamin D • Insulin • Oral hypoglycemic agents • Estrogen • Progesterone • Oxytocin • Corticosteroids	8

11	**Autocoids** • Physiological role of Histamine, 5 HT and Prostaglandins • Classification, clinical uses, and adverse effects of antihistamines and 5 HT antagonists	**3**
12	**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	**12**
13	**Biologicals** Definition, types, and indications of biological agents with examples	**2**

PHARMACOLOGY – PRACTICAL

Course Code: ER20-21P **50 Hours (2 Hours/week)**

Scope: This course provides the basic understanding about the uses, mechanisms of actions, dose dependent responses of drugs in simulated virtual animal models and experimental conditions.

Course Objectives: This course will demonstrate / provide hands-on experience in the virtual platform using appropriate software on the following

1. Study of pharmacological effects of drugs like local anaesthetics, mydriatic and mitotic on rabbit eye
2. Screening the effects of various drugs acting in the central nervous system
3. Study of drug effects on isolated organs / tissues
4. Study of pyrogen testing on rabbit

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

1. Study and report the local anaesthetic, mydriatic and mitotic effects of the given drug on the rabbit eye
2. Choose appropriate animal experiment model to study the effects of the given drugs acting on the central nervous system and submit the report
3. Perform the effects of given tissues (simulated) on isolated organs / tissues and interpret the results
4. Interpret the dose dependent responses of drugs in various animal experiment models

Practicals

Introduction to the following topics pertaining to the experimental pharmacology have to be discussed and documented in the practical manuals.

1. Introduction to experimental pharmacology
2. Study of laboratory animals
   (a) Mice; (b) Rats; (c) Guinea pigs; (d) Rabbits
3. Commonly used instruments in experimental pharmacology
4. Different routes of administration of drugs in animals
5. Types of pre-clinical experiments: In-Vivo, In-Vitro, Ex-Vivo, etc.
6. Techniques of blood collection from animals

Experiments

Note: Animals shall not be used for doing / demonstrating any of the experiments given. The given experiments shall be carried- out / demonstrated as the case may be, ONLY with the use of software program(s) such as 'Ex Pharm' or any other suitable software

1. Study of local anaesthetics on rabbit eye
2. Study of Mydriatic effect on rabbit eye
3. Study of Miotic effect on rabbit eye
4. Effect of analgesics using Analgesiometer
5. Study of analgesic activity by writhing test
6. Screening of anti-convulsant using Electro Convulsiometer
7. Screening of Muscle relaxants using Rota-Rod apparatus
8. Screening of CNS stimulants and depressants using Actophotometer
9. Study of anxiolytic activity using elevated plus maze method
10. Study of effect of drugs (any 2) on isolated heart
11. Effect of drugs on ciliary motility on frog's buccal cavity
12. Pyrogen testing by rabbit method

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Introduction to Allergy Testing
2. Introduction to Toxicity Studies
3. Drug Facts Labels of US FDA
4. Pre-clinical studies in new drug development
5. Medicines and meals: Before or After food
6. Pre-clinical studies in new drug development
7. Drugs available as paediatric formulations
8. Drug information apps

PHARMACY INDIA

COMMUNITY PHARMACY AND MANAGEMENT – THEORY

Course Code: ER20-22T **75 Hours (3 Hours/week)**

Scope: The course is designed to impart basic knowledge and skills to provide various pharmaceutical care services to patients and general practitioners in the community setup.

Course Objectives: This course will discuss the following:

1. Establishing and running a community pharmacy and its legal requirements
2. Professional aspects of handling and filling prescriptions
3. Patient counselling on diseases, prescription and or non-prescription medicines
4. Scope for performing basic health screening in community pharmacy settings

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

1. Describe the establishment, legal requirements, and effective administration of a community pharmacy
2. Professionally handle prescriptions and dispense medications
3. Counsel patients about the disease, prescription and or non-prescription medicines
4. Perform basic health screening on patients and interpret the reports in the community pharmacy settings

Chapter	Topic	Hours
1	**Community Pharmacy Practice** – Definition, history and development of community pharmacy - International and Indian scenarios	2
2	Professional responsibilities of community pharmacists Introduction to the concept of Good Pharmacy Practice and SOPs.	3
3	**Prescription and prescription handling** • 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	7

4	**Communication skills** • 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	6
5	**Patient counselling** • 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	10
6	**Medication Adherence** Definition, factors influencing non-adherence, strategies to overcome non-adherence	2
7	**Health Screening Services in Community Pharmacy** Introduction, scope, and importance of various health screening services - for routine monitoring of patients, early detection, and referral of undiagnosed cases	5
9	**Over The Counter (OTC) Medications** • 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)	15

10	**Community Pharmacy Management** • 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	**25**

COMMUNITY PHARMACY AND MANAGEMENT – PRACTICAL

Course Code: ER20-22P **75 Hours (3 Hours/week)**

Scope: The course is designed to train the students and improve professional skills to provide various pharmaceuticalcare services in community pharmacy.

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

1. Professional handling and filling prescriptions
2. Patient counselling on diseases and minor ailments
3. Patient counselling on prescription and / or non-prescription medicines
4. Preparation of counselling materials such as patient information leaflets
5. Performing basic health screening tests

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

1. Handle and fill prescriptions in a professional manner
2. Counsel patients on various diseases and minor ailments
3. Counsel patients on prescription and or non-prescription medicines
4. Design and prepare patient information leaflets
5. Perform basic health screening tests

Practicals

Note: The following practicals shall be carried out in the model community pharmacy with appropriate simulated scenarios and materials. Students shall be trained through role plays wherever necessary. The activities of the students shall be assessed / evaluated using a structured objective assessment form.

1. Handling of prescriptions with professional standards, reviewing prescriptions, checking for legal compliance and completeness (minimum 5)
2. Identification of drug-drug interactions in the prescription and follow-up actions (minimum 2)
3. Preparation of dispensing labels and auxiliary labels for the prescribed medications (minimum 5)
4. Providing the following health screening services for monitoring patients / detecting new patients (one experiment for each activity)

   Blood Pressure Recording, Capillary Blood Glucose Monitoring, Lung function assessment using Peak Flow Meter and incentive spirometer, recording capillary oxygen level using Pulse Oximeter, BMI measurement
5. Providing counselling to simulated patients for the following chronic diseases / disorders including education on the use of devices such as insulin pen, inhalers, spacers, nebulizers, etc. where appropriate (one experiment for each disease)

   Type 2 Diabetes Mellitus, Primary Hypertension, Asthma, Hyperlipidaemia, Rheumatoid Arthritis
6. Providing counselling to simulated patients for the following minor ailments (any three)

   Headache, GI disturbances (Nausea, Vomiting, Dyspepsia, diarrhoea, constipation), Worm infestations, Pyrexia, Upper Respiratory Tract infections, Skin infections, Oral and dental disorders.
7. Appropriate handling of dummy dosage forms with correct administration techniques - oral liquids with measuring cup/cap/dropper, Eye Drops, Inhalers, Nasal drops, Insulin pen, nebulizers, different types of tablets, patches, enemas, suppositories
8. Use of Community Pharmacy Software and digital health tools

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. SOPs for various activities in Community Pharmacy (as discussed in Theory and Practical)

2. List out the various abbreviations, short forms used in prescriptions and their interpretation
3. Patient Information Leaflet for a given chronic disease / disorder
4. Patient Information Leaflet for prescription / non-prescription medicines
5. Preparation of window / shelf display materials for the model community pharmacy
6. Overview of Software available for retail pharmacy management including billing, inventory, etc.
7. Dosage / Medication Reminder Aids
8. Overview on the operations and marketing strategies of various online pharmacies
9. Overview on the common fixed dose combinations
10. Overview on the medications requiring special storage conditions
11. Role of Community Pharmacists in preventing Antimicrobial Resistance
12. Jan Aushadhi and other Generic Medicine initiatives in India
13. Global Overview of Online Pharmacies
14. Community Pharmacy Practice Standards: Global Vs. Indian Scenario
15. Overview of pharmacy associations in India

Field Visit

The students shall be taken in groups to visit community pharmacies and medicine distributors to understand and witness the professional activities of the community pharmacists, and supply chain logistics. Individual reports from each student on their learning experience from the field visit shall be submitted.

BIOCHEMISTRY & CLINICAL PATHOLOGY – THEORY

Course Code: ER20-23T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge on the study of structure and functions of biomolecules and the chemical processes associated with living cells in normal and abnormal states. The course also emphasizes on the clinical pathology of blood and urine.

Course Objectives: This course will discuss the following at the fundamental level

1. Structure and functions of biomolecules
2. Catalytic activity, diagnostic and therapeutic importance of enzymes
3. Metabolic pathways of biomolecules in health and illness (metabolic disorders)
4. Biochemical principles of organ function tests and their clinical significance
5. Qualitative and quantitative determination of biomolecules / metabolites in the biological sample
6. Clinical pathology of blood and urine

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

1. Describe the functions of biomolecules
2. Discuss the various functions of enzymes in the human system
3. Explain the metabolic pathways of biomolecules in both physiological and pathological conditions
4. Describe the principles of organ function tests and their clinical significances
5. Determine the biomolecules / metabolites in the given biological samples, both qualitatively and quantitatively
6. Describe the clinical pathology of blood and urine

Chapter	Topic	Hours
1	**Introduction to biochemistry**: Scope of biochemistry in pharmacy; Cell and its biochemical organization.	2
2	**Carbohydrates** • 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	5

3	**Proteins** • 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.	**5**
4	**Lipids** • 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	**5**
5	**Nucleic acids** • Definition, purine and pyrimidine bases • Components of nucleosides and nucleotides with examples • Structure of DNA (Watson and Crick model), RNA and their functions	**4**
6	**Enzymes** • Definition, properties and IUB and MB classification • Factors affecting enzyme activity • Mechanism of action of enzymes, Enzyme inhibitors • Therapeutic and pharmaceutical importance of enzymes	**5**
7	**Vitamins** • Definition and classification with examples • Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins	**6**
8	**Metabolism** (Study of cycle/pathways without chemical structures) • Metabolism of Carbohydrates: Glycolysis, TCA cycle and glycogen metabolism, regulation of blood glucose	**20**

	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	
9	**Minerals**: Types, Functions, Deficiency diseases, recommended dietary requirements	**05**
10	**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	**05**
11	Introduction to Biotechnology	**01**
12	**Organ function tests** • 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	**06**
13	**Introduction to Pathology of Blood and Urine** • Lymphocytes and Platelets, their role in health and disease • Erythrocytes - Abnormal cells and their significance • Normal and Abnormal constituents of Urine and their significance	**06**

BIOCHEMISTRY & CLINICAL PATHOLOGY – PRACTICAL

Course Code: ER20-23P **50 Hours (2 Hours/week)**

Scope: This course is designed to train the students in the qualitative testing of various biomolecules and testing of biological samples for determination of normal and abnormal constituents

Course Objectives: This course will train and provide hands-on experiences on the following

1. Qualitative determination of biomolecules / metabolites in simulated biological samples
2. Determination of normal and abnormal constituents of simulated blood and urine samples

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

1. Qualitatively determine the biomolecules / metabolites in the given biological samples
2. Determine the normal and abnormal constituents in blood and urine samples and interpret the results of such testing

Practicals

1. Qualitative analysis of carbohydrates (4 experiments)
2. Qualitative analysis of Proteins and amino acids (4 experiments)
3. Qualitative analysis of lipids (2 experiments)
4. Qualitative analysis of urine for normal and abnormal constituents (4 experiments)
5. Determination of constituents of urine (glucose, creatinine, chlorides) (2 experiments)
6. Determination of constituents of blood/serum (simulated) (Creatine, glucose, cholesterol, Calcium, Urea, SGOT/SGPT) (5 experiments)
7. Study the hydrolysis of starch from acid and salivary amylase enzyme (1 experiment)

Assignments

The students shall be asked to submit written assignments on Various Pathology Lab Reports (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

PHARMACOTHERAPEUTICS - THEORY

Course Code: ER20-24T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge on etiopathogenesis of common diseases and their management along with quality use of medicines.

Course Objectives: This course will discuss about

1. Etiopathogenesis of selected common diseases and evidence-based medicine therapy
2. Importance of individualized therapeutic plans based on diagnosis
3. Basic methods for assessing the clinical outcomes of drug therapy

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

1. Help assessing the subjective and objective parameters of patients in common disease conditions
2. Assist other healthcare providers to analyse drug related problems and provide therapeutic interventions
3. Participate in planning the rational medicine therapy for common diseases
4. Design and deliver discharge counselling for patients

Chapter	Topic	Hours
1	Pharmacotherapeutics – Introduction, scope, and objectives. Rational use of Medicines, Evidence Based Medicine, Essential Medicines List, Standard Treatment Guidelines (STGs)	**8**
2	**Definition, etiopathogenesis, clinical manifestations, non-pharmacological and pharmacological management of the diseases associated with**	
	(a) Cardiovascular System • Hypertension • Angina and Myocardial infarction • Hyperlipidaemia • Congestive Heart Failure	**8**
	(b) Respiratory System • Asthma • COPD	**4**
	(c) Endocrine System • Diabetes • Thyroid disorders - Hypo and Hyperthyroidism	**5**
	(d) Central Nervous System • Epilepsy	**8**

	• Parkinson's disease • Alzheimer's disease • Stroke • Migraine	
	(e) Gastro Intestinal Disorders • Gastro oesophageal reflux disease • Peptic Ulcer Disease • Alcoholic liver disease • Inflammatory Bowel Diseases (Crohn's Disease and Ulcerative Colitis)	**8**
	(f) Haematological disorders • Iron deficiency anaemia • Megaloblastic anaemia	**4**
	(g) Infectious diseases • Tuberculosis • Pneumonia • Urinary tract infections • Hepatitis • Gonorrhoea and Syphilis • Malaria • HIV and Opportunistic infections • Viral Infections (SARS, CoV2)	**12**
	(h) Musculoskeletal disorders • Rheumatoid arthritis • Osteoarthritis	**3**
	(i) Dermatology • Psoriasis • Scabies • Eczema	**3**
	(j) Psychiatric Disorders • Depression • Anxiety • Psychosis	**4**
	(k) Ophthalmology • Conjunctivitis (bacterial and viral) • Glaucoma	**2**
	(l) Anti-microbial Resistance	**2**
	(m) Women's Health • Polycystic Ovary Syndrome • Dysmenorrhea • Premenstrual Syndrome	**4**

PHARMACOTHERAPEUTICS – PRACTICAL

Course Code: ER20-24P **25 Hours (1 Hour/week)**

Scope: This course is designed to train the students in the basic skills required to support the pharmaceutical care services for selected common disease conditions.

Course Objectives: This course will train the students on

1. How to prepare a SOAP (Subjective, Objective, Assessment and Plan) note for clinical cases of selected common diseases
2. Patient counselling techniques/methods for common disease conditions

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

1. Write SOAP (Subjective, Objective, Assessment and Plan) notes for the given clinical cases of selected common diseases
2. Counsel the patients about the disease conditions, uses of drugs, methods of handling and administration of drugs, life-style modifications, and monitoring parameters.

Practicals

I. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions.

1. Hypertension
2. Angina Pectoris
3. Myocardial Infarction
4. Hyperlipidaemia
5. Rheumatoid arthritis
6. Asthma
7. COPD
8. Diabetes
9. Epilepsy
10. Stroke
11. Depression
12. Tuberculosis
13. Anaemia (any one type as covered in theory)
14. Viral infection (any one type as covered in theory)
15. Dermatological conditions (any one condition as covered in theory)

II. Patient counselling exercises using role plays based on the real / hypothetical clinical case scenarios. The students are expected to provide counselling on disease condition, medications, life-style modifications, monitoring parameters, etc. and the same shall be documented. (Minimum 5 cases)

III. Simulated cases to enable dose calculation of selected drugs in paediatrics, and geriatrics under various pathological conditions. (Minimum 4 cases)

PHARMACY INDIA

HOSPITAL AND CLINICAL PHARMACY – THEORY

Course Code: ER20-25T **75 Hours (3 Hours/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 organization 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 optimizing the drug therapy

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

1. Explain about the basic concepts of hospital pharmacy administration
2. Manage the supply chain and distribution of medicines within the hospital settings
3. Assist the other healthcare providers in monitoring drug therapy and address drug related problems
4. Interpret common lab investigation reports for optimizing drug therapy

S. No.	Topic	Hours
1	**Hospital Pharmacy** • Definition, scope, national and international scenario • Organisational 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, AHSP) • Introduction to NAQS guidelines and NABH Accreditation and Role of Pharmacists	6
2	**Different Committees in the Hospital** • Pharmacy and Therapeutics Committee - Objectives, Composition, and functions • Hospital Formulary - Definition, procedure for development and use of hospital formulary	4

	• Infection Control Committee – Role of Pharmacist in preventing Antimicrobial Resistance	
4	**Supply Chain and Inventory Control** • Preparation of Drug lists - High Risk drugs, Emergency drugs, Schedule H1 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	**14**
5	**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	**7**
6	Compounding in Hospitals. Bulk compounding, IV admixture services and incompatibilities, Total parenteral nutrition	**4**
7	**Radio Pharmaceuticals -** Storage, dispensing and disposal of radiopharmaceuticals	**2**
8	Application of computers in Hospital Pharmacy Practice, Electronic health records, Softwares used in hospital pharmacy	**2**
9	**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, Anti-natal Care, Post-natal Care, etc.	**12**

	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 counselling • Interprofessional collaboration **Pharmaceutical care**: Definition, classification of drug related problems. Principles and procedure to provide pharmaceutical care **Medication Therapy Management, Home Medication Review**	
10	**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	**10**
11	**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	**6**
12	**Pharmacovigilance** • Definition, aim and scope • Overview of Pharmacovigilance	**2**
13	**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	**6**

HOSPITAL AND CLINICAL PHARMACY – PRACTICAL

Course Code: ER20-25P **25 Hours (1 Hour / Week)**

Scope: This course is designed to train the students to assist other healthcare providers in the basic services of hospital and clinical pharmacy.

Course Objectives: This course will train the students with hands-on experiences, simulated clinical case studies in the following:

1. Methods to systematically approach and respond to drug information queries
2. How to interpret common laboratory reports to understand the need for optimizing dosage regimens
3. How to report suspected adverse drug reactions to the concerned authorities
4. Uses and methods of handling various medical/surgical aids and devices
5. How to interpret drug-drug interactions in the treatment of common diseases.

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

1. Professionally handle and answer the drug information queries
2. Interpret the common laboratory reports
3. Report suspected adverse drug reactions using standard procedures
4. Understand the uses and methods of handling various medical/surgical aids and devices
5. Interpret and report the drug-drug interactions in common diseases for optimizing the drug therapy

Note: Few of the experiments of Hospital and Clinical Pharmacy practical course listed here require adequate numbers of desktop computers with internet connectivity, adequate drug information resources including reference books, different types of surgical dressings and other medical devices and accessories. Various charts, models, exhibits pertaining to the experiments shall also be displayed in the laboratory.

Practicals

1. Systematic approach to drug information queries using primary / secondary / tertiary resources of information (2 cases)
2. Interpretation of laboratory reports to optimize the drug therapy in a given clinical case (2 cases)
3. Filling up IPC's ADR Reporting Form and perform causality assessments using various scales (2 cases)
4. Demonstration / simulated / hands-on experience on the identification, types, use / application /administration of
    - Orthopaedic and Surgical Aids such as knee cap, LS belts, abdominal belt, walker, walking sticks, etc.

- Different types of bandages such as sterile gauze, cotton, crepe bandages, etc.
- Needles, syringes, catheters, IV set, urine bag, RYLE's tube, urine pots, colostomy bags, oxygen masks, etc.

5. Case studies on drug-drug interactions (any 2 cases)
6. Wound dressing (simulated cases and role play –minimum 2 cases)
7. Vaccination and injection techniques (IV, IM, SC) using mannequins (5 activities)
8. Use of Hospital Pharmacy Software and various digital health tools

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Typical profile of a drug to be included in the hospital formulary
2. Brief layout and various services of the Central Sterile Supplies Department (CSSD)
3. Various types of sterilizers and sterilization techniques used in hospitals
4. Fumigation and pesticide control in hospitals
5. Role of Pharmacists in Transition of Care: Discharge cards, post hospitalization care, medicine reconciliation activities in developed countries
6. Total parenteral nutrition and IV admixtures and their compatibility issues
7. Concept of electronic health records
8. Invasive and Non-invasive diagnostic tests - HRCT, MRI, Sonography, 2D ECHO, X-rays, Mammography, ECG, EMG, EEG
9. Home Diagnostic Kits - Pregnancy Test, COVID testing etc
10. Measures to be taken in hospitals to minimize Antimicrobial Resistance
11. Role and responsibilities of a pharmacist in public hospital in rural parts of the country
12. Safe waste disposal of hospital waste

Field Visit

The students shall be taken in groups to visit a Government / private healthcare facility to understand and witness the various hospital and clinical pharmacy services provided. Individual reports from each student on their learning experience from the field visit shall be submitted.

PHARMACY LAW AND ETHICS – THEORY

Course Code: ER20-26T **75 Hours (3 Hours/week)**

Scope: This course is designed to impart basic knowledge on several important legislations related to the profession of pharmacy in India

Course Objectives: This course will discuss the following

1. General perspectives, history, evolution of pharmacy law in India
2. Act and Rules regulating the profession and practice of pharmacy in India
3. Important code of ethical guidelines pertaining to various practice standards
4. Brief introduction to the patent laws and their applications in pharmacy

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

1. Describe the history and evolution of pharmacy law in India
2. Interpret the act and rules regulating the profession and practice of pharmacy in India
3. Discuss the various codes of ethics related to practice standards in pharmacy
4. Interpret the fundamentals of patent laws from the perspectives of pharmacy

Chapter	Topics	Hours
1	General Principles of Law, History and various Acts related to Drugs and Pharmacy profession	2
2	**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**	5
3	**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.	23

	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.	
4	**Narcotic Drugs and Psychotropic Substances Act 1985 and Rules** Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.	**2**
5	**Drugs and Magic Remedies (Objectionable Advertisements) Act 1954** Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.	**2**
6	**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.	**2**
7	**Poisons Act-1919**: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons	**2**
8	**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	**2**

9	**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)	**5**
10	**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.	**5**
11	Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments	**2**
12	Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	**1**
13	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	**3**
14	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	**7**
15	Blood bank – basic requirements and functions	**2**
16	Clinical Establishment Act and Rules – Aspects related to Pharmacy	**2**
17	Biomedical Waste Management Rules 2016 – Basic aspects, and aspects related to pharma manufacture to disposal of pharma / medical waste at homes, pharmacies, and hospitals	**2**
18	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	**2**
19	Introduction to the Consumer Protection Act	**1**
20	Introduction to the Disaster Management Act	**1**
21	Medical Devices – Categorization, basic aspects related to manufacture and sale	**2**

Assignments

The students shall be asked to submit written assignments on the following topics (One assignment per student per sessional period. i.e., a minimum of THREE assignments per student)

1. Requirements for Ayurvedic, Homeopathic manufacturing, sale, and licensing requirements
2. Layout and contents of official websites of various agencies regulating the profession of pharmacy in India: e.g., CDSCO, SUGAM portal, PCI, etc.
3. Licenses required, application processes (online/offline), drug regulatory office website of the respective state
4. Case studies – actions taken on violation of any act / rule related to pharmacy
5. Schedule H1 drugs and its implementation in India
6. Counterfeit / Spurious medicines
7. Drug Testing Labs in India
8. Overview of Pharma marketing practices
9. Generic Medicines

PHARMACY INDIA

D.PHARMA 2ND YEAR

PHARMACY INDIA

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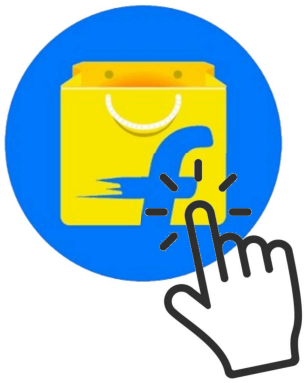

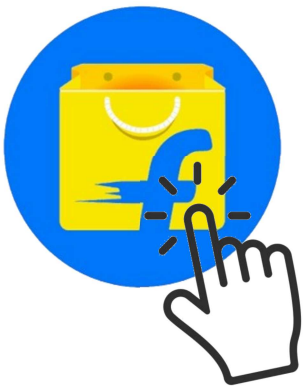

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