



HARSHITA GLOBAL EDUCATIONAL ACADEMY
COLLEGE OF PHARMACY
BOKARO, JHARKHAND

SYLLABUS

Second Year Diploma in Pharmacy
As per ER 2020

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PHARMACOLOGY – THEORY

Course Code: ER20-21T

75 Hours (3 Hours/week)

Chapter	Topic	Hours
1	General Pharmacology <ul style="list-style-type: none"> ● 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 <ul style="list-style-type: none"> ● Steps involved in neurohumoral transmission ● Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> ● Miotics Mydriatics Drugs used in Glaucoma 	2
4	Drugs Acting on the Central Nervous System Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> General anaesthetics Hypnotics and sedatives Anti-Convulsant drugs Anti-anxiety drugs Anti-depressant drugs Anti-psychotics Nootropic agents Centrally acting muscle relaxants Opioid analgesics 	
5	Drugs Acting on the Cardiovascular System Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Hematinic agents Anti-coagulants Anti-platelet agents Thrombolytic drugs 	4
7	Definition, classification, pharmacological actions, dose, indications, and contraindications of <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Diuretics Anti-Diuretics 	2
10	Hormones and Hormone Antagonists ;Physiological and pathological role and clinical uses of <ul style="list-style-type: none"> Thyroid hormones Anti-thyroid drugs Parathormone Calcitonin Vitamin D Insulin Oral hypoglycemic agents Estrogen Progesterone Oxytocin Corticosteroids 	8

11	<p>Autocoids</p> <ul style="list-style-type: none"> • Physiological role of Histamine, 5 HT and Prostaglandins • Classification, clinical uses, and adverse effects of antihistamines and 5 HT antagonists 	3
12	<p>Chemotherapeutic Agents: Introduction, basic principles of chemotherapy of infections, infestations and neoplastic diseases, Classification, dose, indication and contraindications of drugs belonging to following classes:</p> <p>Penicillins Cephalosporins Aminoglycosides Fluoroquinolones Macrolides Tetracyclines - -</p> <p>Sulphonamides Anti-tubercular drugs Anti-fungal drugs Anti-viral drugs Anti-amoebic agents Anthelmintics Anti-malarial agents Anti-neoplastic agents</p>	12
13	<p>Biologicals</p> <p>Definition, types, and indications of biological agents with examples</p>	2

PHARMACOLOGY – PRACTICAL

Course Code: ER20-21P

50 Hours (2 Hours/week)

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

COMMUNITY PHARMACY AND MANAGEMENT – THEORY

Course Code: ER20-22T

75 Hours (3 Hours/week)

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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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

8	Over The Counter (OTC) Medications <ul style="list-style-type: none"> ● 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
9	Community Pharmacy Management <ul style="list-style-type: none"> ● 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, Cashbook ● 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)

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)

Chapter	Topic	Hours
1	Introduction to biochemistry: Scope of biochemistry in pharmacy; Cell and its biochemical organization.	2
2	Carbohydrates <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• 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	<p>Lipids</p> <ul style="list-style-type: none"> • 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	<p>Nucleic acids</p> <ul style="list-style-type: none"> • 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	<p>Enzymes</p> <ul style="list-style-type: none"> • 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	<p>Vitamins</p> <ul style="list-style-type: none"> • Definition and classification with examples • Sources, chemical nature, functions, coenzyme form, recommended dietary requirements, deficiency diseases of fat-and water-soluble vitamins 	6
8	<p>Metabolism (Study of cycle/pathways without chemical structures)</p> <ul style="list-style-type: none"> • 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 	20
9	<p>Minerals: Types, Functions, Deficiency diseases, recommended dietary requirements</p>	05
10	<p>Water and Electrolytes</p> <ul style="list-style-type: none"> • 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	<p>Organ function tests</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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
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BIOCHEMISTRY & CLINICAL PATHOLOGY – PRACTICAL

Course Code: ER20-23P

50 Hours (2 Hours/week)

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)

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 Parkinson's disease Alzheimer's disease Stroke Migraine	8
	(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)

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)

HOSPITAL AND CLINICAL PHARMACY – THEORY

Course Code: ER20-25T

75 Hours (3 Hours/week)

S. No.	Topic	Hours
1	Hospital Pharmacy <ul style="list-style-type: none"> ● 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 <ul style="list-style-type: none"> ● 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 	4
4	Supply Chain and Inventory Control <ul style="list-style-type: none"> ● 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 <ul style="list-style-type: none"> ● 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	<p>Clinical Pharmacy: Definition, scope, and development - in India and other countries</p> <p>Technical definitions, common terminologies used in clinical settings and their significance such as Paediatrics, Geriatric, Anti-natal Care, Post-natal Care, etc.</p> <p>Daily activities of clinical pharmacists: Definition, goal, and procedure of</p> <ul style="list-style-type: none"> • Ward round participation • Treatment Chart Review • Adverse drug reaction monitoring • Drug information and poisons information • Medication history • Patient counselling • Interprofessional collaboration <p>Pharmaceutical care: Definition, classification of drug related problems. Principles and procedure to provide pharmaceutical care</p> <p>Medication Therapy Management, Home Medication Review</p>	12
10	<p>Clinical laboratory tests used in the evaluation of disease states - significance and interpretation of test results</p> <ul style="list-style-type: none"> • Haematological, Liver function, Renal function, thyroid function tests • Tests associated with cardiac disorders • Fluid and electrolyte balance • Pulmonary Function Tests 	10
11	<p>Poisoning: Types of poisoning: Clinical manifestations and Antidotes</p> <p>Drugs and Poison Information Centre and their services – Definition, Requirements, Information resources with examples, and their advantages and disadvantages</p>	6
12	<p>Pharmacovigilance</p> <ul style="list-style-type: none"> • Definition, aim and scope • Overview of Pharmacovigilance 	2
13	<p>Medication errors: Definition, types, consequences, and strategies to minimize medication errors, LASA drugs and Tallman lettering as per ISMP</p> <p>Drug Interactions: Definition, types, clinical significance of drug interactions</p>	6

HOSPITAL AND CLINICAL PHARMACY – PRACTICAL

Course Code: ER20-25P

25 Hours (1 Hour / Week)

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 clinicalcase (2 cases)
3. Filling up IPC's ADR Reporting Form and perform causality assessments usingvarious 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, 2DECHO, 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)

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	<p>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.</p>	
	<p>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.</p> <p>Study of schedule C and C1, G, H, H1, K, P, M, N, and X.</p> <p>Sale of Drugs – Wholesale, Retail sale and Restricted license, Records to be kept in a pharmacy Drugs Prohibited for manufacture and sale in India</p> <p>Administration of the Act and Rules – Drugs Technical Advisory Board, Central Drugs Laboratory, Drugs Consultative Committee, Government analysts, licensing authorities, controlling authorities, Drug Inspectors.</p>	23
4	<p>Narcotic Drugs and Psychotropic Substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.</p>	2
5	<p>Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.</p>	2
6	<p>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.</p>	2
7	<p>Poisons Act-1919: Introduction, objective, definition, possession, possession for sales and sale of any poison,import of poisons</p>	2
8	<p>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</p>	2
9	<p>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)</p>	5
10	<p>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.</p>	5
11	<p>Medical Termination of Pregnancy Act and Rules – basic understanding, salient features, and Amendments</p>	2
12	<p>Role of all the government pharma regulator bodies –Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)</p>	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 Medicine.