



SATHYABAMA

INSTITUTE OF SCIENCE AND TECHNOLOGY
(DEEMED TO BE UNIVERSITY)

Accredited "A" Grade by NAAC | 12B Status by UGC | Approved by AICTE
www.sathyabama.ac.in

SCHOOL OF PHARMACY

Agenda

1. Welcome speech by Chairperson.
2. To discuss about the introduction of new courses for B.Pharm Seventh Semester as per PCI syllabus (Regulation 2014) from the academic year 2022-23 onwards.
3. To discuss about the introduction of new courses for D. Pharm (Education Regulation 2020) from the academic year 2022-23 onwards.
4. To discuss about the examination pattern.
5. To discuss about academic calendar.
6. Vote of thanks by chairman.



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SCHOOL OF PHARMACY

03.06.2022

MINUTES OF THE MEETING - BOARD OF STUDIES

The Board of studies members meeting was conducted in the premises School of Pharmacy Sathyabama Institute of Science and Technology, Chennai on 03.06.2022 at 11:00 A.M, with the Chairman of Dr. B. Bharathi.

The Board of Chairman, Board of Studies- Pharmacy welcomed the members and explained about the agenda and programmes.

The Secretary presented about the syllabus and curriculum of B.Pharm and D. Pharm in detail in the committee. The Board of studies unanimously decided to introduce new courses as per PCI Syllabus for the Seventh semester B. Pharm and Second year D. Pharm without any changes in it.

The BOS recommended the following

- The Board of study decided to conduct the examination as per PCI norms. According to PCI norms for B.Pharm in semester pattern and D.Pharm will be annual pattern.
- The D. Pharm students requires more knowledge about Computer, First aid, Communication skills and handling of Drugs
- The Institution should make MOU with Hospital and Industry for training of students of B.Pharm and D.Pharm

The secretary also presented the academic calendar in the committee. The committee approved the academic calendar and they decided to forward the academic calendar for further approval in academic council.

At the end Chairman of Board of Studies proposed vote of thanks.



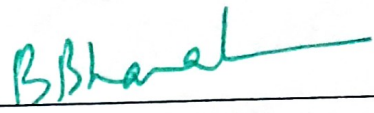
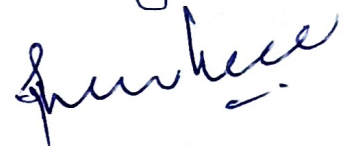
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SCHOOL OF PHARMACY

BOARD OF STUDY- PHARMACY

Name	Designation	Signature
Dr. B. Bharathi Dean Academics, SIST, Chennai.	Chairman	
Dr. P. Shanmugapandiyan M Pharm., Ph.D., Dean, School of Pharmacy SIST, Chennai.	Member Secretary	
Dr. S. Arunkumar M Pharm., Ph.D., Associate Professor, School of Pharmacy SIST, Chennai.	Internal Member	
Dr. P. Muthusamy M Pharm., Ph.D., Associate Professor College of Pharmacy, Madras Medic College Chennai-600001	External Member	
Dr. B. Selvaraj M. Pharm., Ph.D., Sr.DGM (R & D) TTK Health care Ltd Pallavaram, Chennai-600043	External Member	



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SCHOOL OF PHARMACY

Agenda

1. Welcome speech by Chairperson.
2. To discuss about the introduction of new courses for B.Pharm Eight Semester as per PCI syllabus (Regulation 2014) from the academic year 2022-23 onwards.
3. To discuss about the examination pattern.
4. To discuss about academic calendar.
5. Vote of thanks by chairman.



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SCHOOL OF PHARMACY

04.11.2022

MINUTES OF THE MEETING - BOARD OF STUDIES

The Board of studies members meeting was conducted in the premises School of Pharmacy Sathyabama Institute of Science and Technology, Chennai on 04.11.2022 at 11:00 A.M, with the Chairman of Dr. B. Bharathi.

The Board of Chairman, Board of Studies- Pharmacy welcomed the members and explained about the agenda and programmes.

The Secretary presented about the syllabus and curriculum of B.Pharm in detail in the committee. The board of studies unanimously decided to introduce new courses as per PCI Syllabus for the Eighth semester B. Pharm without any changes in it.

The BOS recommended the following

- The board of study decided to conduct the examination as per PCI norms. According to PCI norms for B.Pharm in semester pattern.
- The D.Pharm students require more knowledge about Computer, First aid, Communication skills and handling of Drugs
- The Institution should make MoU with Hospital and Industry for training of students of B.Pharm and D.Pharm

The secretary also presented the academic calendar in the committee. The committee approved the academic calendar and they decided to forward the academic calendar for further approval in academic council.

At the end Chairman of Board of Studies proposed vote of thanks.



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SCHOOL OF PHARMACY

BOARD OF STUDY- PHARMACY

Name	Designation	Signature
Dr. B. Bharathi Dean Academics, SIST, Chennai.	Chairman	
Dr. P. Shanmugapandiyan M Pharm., Ph.D., Dean, School of Pharmacy SIST, Chennai.	Member Secretary	
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SCHOOL OF PHARMACY

New courses introduced across all programs offered during the year 2022 - 23

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BP701T. INSTRUMENTAL METHODS OF ANALYSIS (Theory)

45 Hours

Course Content:

UNIT -I

10 Hours

UV Visible spectroscopy: Electronic transitions, chromophores, auxochromes, spectral shifts, solvent effect on absorption spectra, Beer and Lambert's law, Derivation and deviations.

Instrumentation - Sources of radiation, wavelength selectors, sample cells, detectors-Photo tube, Photomultiplier tube, Photo voltaic cell, Silicon Photodiode.

Applications- Spectrophotometric titrations, Single component and multi component analysis.

Fluorimetry: Theory, Concepts of singlet, doublet and triplet electronic states, internal and external conversions, factors affecting fluorescence, quenching, instrumentation and applications.

UNIT-II

10 Hours

IR spectroscopy: Introduction, fundamental modes of vibrations in poly atomic molecules, sample handling, factors affecting vibrations.

Instrumentation- Sources of radiation, wavelength selectors, detectors - Golay cell, Bolometer, Thermocouple, Thermister, Pyroelectric detector and applications.

Flame Photometry- Principle, interferences, instrumentation and applications.

Atomic absorption spectroscopy- Principle, interferences, instrumentation and applications.

Nephelo-turbidimetry- Principle, instrumentation and applications.

UNIT-III

10 Hours

Introduction to chromatography: Adsorption and partition column chromatography- Methodology, advantages, disadvantages and applications.

Thin layer chromatography- Introduction, Principle, Methodology, Rf values, advantages, disadvantages and applications.

Paper chromatography- Introduction, methodology, development techniques, advantages, disadvantages and applications.

Electrophoresis- Introduction, factors affecting electrophoresis mobility, Techniques of paper, gel, capillary electrophoresis, applications.

UNIT-IV

08 Hours

Gas chromatography - Introduction, theory, instrumentation, derivatization, temperature programming, advantages, disadvantages and applications.

High performance liquid chromatography (HPLC)- Introduction, theory, instrumentation, advantages and applications.

UNIT-V

07 Hours

Ion exchange chromatography- Introduction, classification, ion exchange resins, properties, mechanism of ion exchange process, factors affecting ion exchange, methodology and applications.

Gel chromatography- Introduction, theory, instrumentation and applications.

Affinity chromatography- Introduction, theory, instrumentation and applications.

New Course

BP702T INDUSTRIAL PHARMACY-II (Theory)

45 Hours

Course Content

UNIT-I

10 Hours

Pilot plant scale up techniques: General considerations - including significance of personnel requirements, space requirements, raw materials, Pilot plant scale up considerations for solids, liquid orals, semi solids and relevant documentation, SUPAC guidelines, Introduction to platform technology

UNIT-II

10 Hours

Technology development and transfer: WHO guidelines for Technology Transfer(TT): Terminology, Technology transfer protocol, Quality risk management, Transfer from R & D to production (Process, packaging and cleaning), Granularity of TT Process (API, excipients, finished products, packaging materials) Documentation, Premises and equipments, qualification and validation, quality control, analytical method transfer, Approved regulatory bodies and agencies, Commercialization - practical aspects and problems (case studies), TT agencies in India - APCTD, NRDC, TIFAC, BCIL, TBSE / SIDBI; TT related documentation - confidentiality agreement, licensing, MoUs, legal issues

UNIT-III

10 Hours

Regulatory affairs: Introduction, Historical overview of Regulatory Affairs, Regulatory authorities, Role of Regulatory affairs department, Responsibility of Regulatory Affairs Professionals

Regulatory requirements for drug approval: Drug Development Teams, Non-Clinical Drug Development, Pharmacology, Drug Metabolism and Toxicology, General considerations of Investigational New Drug (IND) Application, Investigator's Brochure (IB) and New Drug Application (NDA), Clinical research / BE studies, Clinical Research Protocols, Biostatistics in Pharmaceutical Product Development, Data Presentation for FDA Submissions, Management of Clinical Studies.

UNIT-IV

08 Hours

Quality management systems: Quality management & Certifications: Concept of Quality, Total Quality Management, Quality by Design (QbD), Six Sigma concept, Out of Specifications (OOS), Change control, Introduction to ISO 9000 series of quality systems standards, ISO 14000, NABL, GLP

UNIT-V

07 Hours

Indian Regulatory Requirements: Central Drug Standard Control Organization (CDSCO) and State Licensing Authority: Organization, Responsibilities, Certificate of Pharmaceutical Product (COPP), Regulatory requirements and approval procedures for New Drugs.



New Course

BP703T. PHARMACY PRACTICE (Theory)

45 Hours

Course Content:

Unit-I

10 Hours

Hospital and its organization: Definition, Classification of hospital- Primary, Secondary and Tertiary hospitals, Classification based on clinical and non-clinical basis, Organization Structure of a Hospital, and Medical staffsinvolved in the hospital and their functions.

Hospital pharmacy and its organization

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

Adverse drug reaction

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

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

Unit-II

10 Hours

Drug distribution system in a hospital

Dispensing of drugs to inpatients, types of drug distribution systems, charging policy and labeling. Dispensing of drugs to ambulatory patients and dispensing of controlled drugs. **Hospital formulary** Definition, contents of hospital formulary, Differentiation of hospital formulary and Drug list, preparation and revision, and addition and deletion of drug from hospital formulary.

Therapeutic drug monitoring

Need for Therapeutic Drug Monitoring, Factors to be considered during the Therapeutic Drug Monitoring, and Indian scenario for Therapeutic Drug Monitoring.

Medication adherence: Causes of medication non-adherence, pharmacist role in the medication adherence andmonitoring of patient medication adherence.

Patient medication history interview: Need for the patient medication history interview, medication interview forms. Community pharmacy management: Financial, materials, staff, and infrastructure requirements.

Unit-III

10 Hours

Pharmacy and therapeutic committee : Organization, functions, Policies of the pharmacy and therapeutic committee in including drugs into formulary, inpatient and outpatient prescription, automatic stop order, and emergency drug list preparation.

Drug information services: *Drug and Poison information centre, Sources of drug information, Computerized services, and storage and retrieval of information.*

Patient counselling

Definition of patient counselling; steps involved in patient counselling, and Special cases that require the pharmacist

New Course

Education and training program in the hospital

Role of pharmacist in the education and training program, Internal and external training program, Services to the nursing homes/clinics, Code of ethics for community pharmacy, and Role of pharmacist in the interdepartmental communication and community health education.

Prescribed medication order and communication skills

Prescribed medication order- interpretation and legal requirements, and Communication skills-

communication with prescribers and patients.

Unit-IV

8 Hours

Budget preparation and implementation: Budget preparation and implementation. **Clinical Pharmacy:** Introduction to Clinical Pharmacy, Concept of clinical pharmacy, functions and responsibilities of clinical pharmacist, Drug therapy monitoring- medication chart review, clinical review, pharmacist intervention, Ward round participation, Medication history and Pharmaceutical care. Dosing pattern and drug therapy based on Pharmacokinetic & disease pattern.

Over the counter (OTC) sales: Introduction and sale of over the counter and rational use of common over the counter medications.

Unit-V

7 Hours

Drug store management and inventory control

Organization of drug store, types of materials stocked and storage conditions, Purchase and inventory control: principles, purchase procedure, purchase order, procurement and stocking, Economic order quantity, Reorder quantity level, and Methods used for the analysis of the drug expenditure.

Investigational use of drugs

Description, principles involved, classification, control, identification, role of hospital pharmacist, advisory committee.

Interpretation of Clinical Laboratory Tests Blood chemistry, haematology and urine analysis



New Course

BP704T. NOVEL DRUG DELIVERY SYSTEMS (NDDS) (Theory)

45 Hours

Course content:

Unit-I

10 Hours

Controlled drug delivery systems: Introduction, terminology/definitions and rationale, advantages, disadvantages, selection of drug candidates. Approaches to design-controlled release formulations based on diffusion, dissolution and ion exchange principles. Physicochemical and biological properties of drugs relevant to controlled release formulations.



Polymers: Introduction, classification, properties, advantages and application of polymers in formulation of controlled release drug delivery systems.

Unit-II

10 Hours

Microencapsulation: Definition, advantages and disadvantages, microspheres /microcapsules, microparticles, methods of microencapsulation, applications.

Mucosal Drug Delivery system: Introduction, Principles of bioadhesion/mucoadhesion, concepts, advantages and disadvantages, transmucosal permeability and formulation considerations of buccal delivery systems.

Implantable Drug Delivery Systems: Introduction, advantages and disadvantages, concept of implants and osmotic pump.

Unit-III

10 Hours

Transdermal Drug Delivery Systems: Introduction, Permeation through skin, factors affecting permeation, permeation enhancers, basic components of TDDS, formulation approaches.

Gastro-retentive drug delivery systems: Introduction, advantages, disadvantages, approaches for GRDDS– Floating, high density systems, inflatable and gastro-adhesive systems and their applications.

Naso-pulmonary drug delivery system: Introduction to Nasal and Pulmonary routes of drug delivery, Formulation of Inhalers (dry powder and metered dose), nasal sprays, nebulizers.

Unit-IV

08 Hours

Targeted drug Delivery: Concepts and approaches advantages and disadvantages, introduction to liposomes, niosomes, nanoparticles, monoclonal antibodies and their applications

Unit-V

07 Hours

Ocular Drug Delivery Systems: Introduction, intra ocular barriers and methods to overcome– Preliminary study, ocular formulations and ocuserts.



New Course

BP705P INSTRUMENTAL METHODS OF ANALYSIS

- 1 Determination of absorption maxima and effect of solvents on absorption maxima of organic compounds
- 2 Estimation of dextrose by colorimetry
- 3 Estimation of sulfanilamide by colorimetry
- 4 Simultaneous estimation of ibuprofen and paracetamol by UV spectroscopy

- 5 Assay of paracetamol by UV- Spectrophotometry
- 6 Estimation of quinine sulfate by fluorimetry
- 7 Study of quenching of fluorescence
- 8 Determination of sodium by flame photometry
- 9 Determination of potassium by flame photometry
- 10 Determination of chlorides and sulphates by Nephlo Turbidometry
- 11 Separation of amino acids by paper chromatography
- 12 Separation of sugars by thin layer chromatography
- 13 Separation of plant pigments by column chromatography
- 14 Demonstration experiment on HPLC
- 15 Demonstration experiment on Gas Chromatography



New Course

BP 706 PS. PRACTICE SCHOOL

150 Hours

Course content

Every candidate shall undergo practice school for a period of 150 hours evenly distributed throughout the semester. The student shall opt any one of the domains. Every student shall submit a printed report (in triplicate) on the practice school he/she attended (not more than 25 pages).

Domains (anyone to be opted):

- Phytomedicine
- Formulation development
- Quality control and quality assurance
- Drug design and process chemistry
- Pharmaceutical software
- Artificial intelligence
- 3D printing
- Neutraceuticals
- Cosmeceuticals
- Alternative medicine



New Course

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 pharmacodynamics
2. Enlist the various classes and drugs of choice for any given disease condition
3. Advise 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 metabolism • Excretion of drugs - Definition, routes of drug excretion	10

New Course

	General mechanisms of drug action and factors modifying drug action	
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	6

New Course

	• Congestive heart failure	
6	Drugs Acting on Blood and Blood Forming Organs	4
	Definition, classification, pharmacological actions, dose, indications and contraindications of • Hematinic agents • Anti-coagulants • Anti-platelet agents • Thrombolytic drugs	
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	8

New Course

	• Corticosteroids	
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 • 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



New Course

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 Study of pharmacological effects of drugs like local anaesthetics, mydriatic and mitotic on rabbit eye

1. Screening the effects of various drugs acting in the central nervous system
2. Study of drug effects on isolated organs / tissues
3. 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).

- Study of local anaesthetics on rabbit eye
- Study of Mydriatic effect on rabbit eye
- Study of Mitotic effect on rabbit eye

New Course

- Effect of analgesics using Analgesiometer
- Study of analgesic activity by writhing test
- Screening of anti-convulsant using Electro Convulsiometer
- Screening of Muscle relaxants using Rota-Rod apparatus
- Screening of CNS stimulants and depressants using Actophotometer
- Study of anxiolytic activity using elevated plus maze method
- Study of effect of drugs (any 2) on isolated heart
- Effect of drugs on ciliary motility on frog's buccal cavity
- 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. Newer techniques in experimental pharmacology
2. Introduction to High Throughput screening
3. Introduction to ELISA test
4. Intro to Allergy Testing
5. Intro to Toxicity Studies
6. Drugs available as paediatric formulations
7. Drug Facts Labels of USFDA
8. Antimicrobial Resistance
9. Introduction to Bioassays
10. Pre-clinical studies in new drug development



New Course

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 counseling on diseases, prescription and or non-prescription drugs 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 drugs
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, Health 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 pharmaceutical care services in the simulated community pharmacy.

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

1. Professional handling and filling prescriptions
2. Patient counseling on diseases and minor ailments
3. Patient counseling on prescription and / or non-prescription drugs
4. Preparation of counseling 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 drugs
4. Design and prepare patient information leaflets
5. Perform basic health screening tests

Practical's

Note: The following practical's 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

New Course

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 drugs
5. Preparation of window / shelf display materials for the model community pharmacy
6. Software available for retail pharmacy management including
7. billing, inventory, etc.
8. Dosage / Medication Reminder Aids
9. Overview on the operations and marketing strategies of various online pharmacies
10. Overview on the common fixed dose combinations
11. Overview on the medications require special storage conditions
12. Roles of Community Pharmacists in preventing Antimicrobial Resistance
13. Jan Aushadhi and other Generic Medicine initiatives in India
14. Overview of various professional associations of Pharmacy / Pharmacists in India
15. Community Pharmacy Practice Standards: Global Vs. Indian Scenario Overview on Pharma Marketing

Field Visit

The students shall be taken in groups to visit community pharmacies (both retail and wholesale) to understand and witness the professional activities of the community pharmacists. Individual reports from each student on their learning experience from the field visit shall be submitted.



New Course

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 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	Minerals: Functions, Deficiency diseases, recommended dietary requirements of calcium, phosphorus, iron, sodium and chloride	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

New Course

BIOCHEMISTRY & CLINICAL PATHOLOGY – PRACTICAL

Course Code: ER20-23P

75 Hours (3 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)



New Course

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

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)	10
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	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



New Course

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 the 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)
1. 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)



New Course

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

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 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	4
3	development and use of hospital formulary • 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, shortterm, 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 their disposal methodse.g., Narcotics • 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, DrugBasket Method. • Distribution of drugs to ICCU/ICU/NICU/Emergency wards. • Automated drug dispensing systems and devices • Distribution of Narcotic and Psychotropic substancesand their storage	7
6	Compounding in Hospitals. Bulk compounding, IV admixtureservices 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 - inIndia and other countries Technical definitions, common terminologies used in clinicalsettings 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



New Course

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 the common laboratory reports to understand the need for optimizing the dosage regimen
3. How to report the suspected adverse drug reactions to the concerned authorities
4. Uses and methods of handling various medical/surgical aids and devices
5. How to interpret the 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) Filling up IPC's ADR Reporting Form and perform causality assessments using various scales (2 cases)
3. 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.
4. Case studies on drug-drug interactions (any 2 cases)
5. Wound dressing (simulated cases and role play – any 2 cases)
6. Vaccination and injection techniques (IV, IM, SC) using mannequins (5 activities)

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 Fumigation and pesticide control in hospitals
4. Genesis and development of Drug / Poison Information centres in India
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
9. Diagnostic Kits - Pregnancy Test
10. Measures to be taken in hospitals, ICUs to minimize the Antimicrobial Resistance
11. Antimicrobial Stewardship Program

Field Visit

The students shall be taken in groups to visit a Govt / 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.



New Course

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. Manufacture of drugs – Prohibition of manufacture and	23
	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, X and Y. 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,	

New Course

	licensing authorities, controlling authorities, Drug Inspectors.	
4	Medicinal and Toilet Preparations Act 1955: Objectives, Definitions, Licensing, Offences and Penalties	2
5	Narcotic Drugs and psychotropic substances Act 1985 and Rules Objectives, Definitions, Authorities and Officers, Prohibition, Control and Regulation, Offences and Penalties.	2
6	Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties.	2
7	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
8	Poisons Act-1919: Introduction, objective, definition, possession, possession for sales and sale of any poison, import of poisons	2
9	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
10	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,	5
11	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
12	Medical Termination of Pregnancy Act and Rules –basic understanding/salient features	2
13	Role of all the government pharma regulator bodies – Central Drugs Standards Control Organization (CDSCO), Indian Pharmacopoeia Commission (IPC)	1
14	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

15	Introduction to BCS system of classification, Basic concepts of Clinical Trials, ANDA, NDA, New Drug development, Schedule Y. Brand v/s Generic, Trade name concept, Introduction to Patent Law and Intellectual Property Rights, Emergency Use Authorization	5
16	Blood bank – basic requirements and functions	2
17	Clinical Establishment Act and Rules – Aspects related to Pharmacy	2
18	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
19	Bioethics - Basic concepts, history and principles. Brief overview of ICMR's National Ethical Guidelines for Biomedical and Health Research involving human participants	2
20	Introduction to the Consumer Protection Act	2
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 from the literature / media
5. Schedule H1 drugs and its implementation in India
6. Counterfeit / Spurious medicines
7. Drug Testing Labs in India
8. Generic Medicines
9. Before or after food/Medicines and Meals



New Course

BP801T. BIOSTATISTICS AND RESEARCH METHODOLOGY (Theory)

45 Hours

Course content:

Unit-I

10 Hours

Introduction: Statistics, Biostatistics, Frequency distribution.

Measures of central tendency: Mean, Median, Mode- Pharmaceutical examples.

Measures of dispersion: Dispersion, Range, standard deviation, Pharmaceutical problems.

Correlation: Definition, Karl Pearson's coefficient of correlation, multiple correlation-Pharmaceuticals examples.

Unit-II

10 Hours

Regression: Curve fitting by the method of least squares, fitting the lines $y = a + bx$ and $x = a + by$, Multiple regression, standard error of regression- Pharmaceutical examples. **Probability:** Definition of probability, Binomial distribution, Normal distribution, Poisson's distribution, properties- problems.

Sample, Population, large sample, small sample, Null hypothesis, alternative hypothesis, sampling, essence of sampling, types of sampling, Error-I type, Error-II type, Standard error of mean (SEM) - Pharmaceutical examples.

Parametric test: t-test (Sample, Pooled or Unpaired and Paired), ANOVA, (One way and Two way), Least Significance difference.

Unit-III

10 Hours

Non-Parametric tests: Wilcoxon Rank Sum Test, Mann-Whitney U test, Kruskal-Wallis test, Friedman Test.

Introduction to Research: Need for research, Need for design of Experiments, Experiential Design Technique, Plagiarism.

Graphs: Histogram, Pie Chart, Cubic Graph, response surface plot, Counter Plot graph

Designing the methodology: Sample size determination and Power of a study, Report writing and presentation of data, Protocol, Cohorts studies, Observational studies, Experimental studies, Designing clinical trial, various phases.

Unit-IV

8 Hours

Blocking and confounding system for Two-level factorials.

Regression modeling: Hypothesis testing in Simple and Multiple regression models

Introduction to Practical components of Industrial and Clinical Trials Problems: Statistical Analysis Using Excel, SPSS, MINITAB[®], Design of experiment, R- Online Statistical Software's to Industrial and Clinical trial approach.

Unit-V

7 Hours

Design and Analysis of experiments:

Factorial Design: Definition, 2^2 , 2^3 design. Advantages of factorial design.

Response Surface methodology: Central composite design, Historical design, Optimization Techniques.

BP802T. SOCIAL AND PREVENTIVE PHARMACY (Theory)

45 Hours

Course content:

Unit-I

10 Hours

Concept of health and disease: Definition, concepts and evaluation of public health. Understanding the concept of prevention and control of disease, social causes of diseases and social problems of the sick.

Social and health education: Food in relation to nutrition and health, Balanced diet, Nutritional deficiencies, Vitamin deficiencies, Malnutrition and its prevention.

Sociology and health: Socio cultural factors related to health and disease, Impact of urbanization on health and disease, Poverty and health.

Hygiene and health: personal hygiene and health care; avoidable habits.

Unit-II

10 Hours

Preventive medicine: General principles of prevention and control of diseases such as cholera, SARS, Ebola virus, influenza, acute respiratory infections, malaria, chicken guinea, dengue, lymphatic filariasis, pneumonia, hypertension, diabetes mellitus, cancer, drug addiction-drug substance abuse.

Unit-III

10 Hours

National health programs, its objectives, functioning and outcome of the following: HIV AND AIDS control programme, TB, Integrated disease surveillance program (IDSP), National leprosy control programme, National mental health program, National programme for prevention and control of deafness, Universal immunization programme, National programme for control of blindness, Pulse polio programme.

Unit-IV

08 Hours

National health intervention programme for mother and child, National family welfare programme, National tobacco control programme, National Malaria Prevention Program, National programme for the health care for the elderly, Social health programme; role of WHO in Indian national program.

Unit-V

07 Hours

Community services in rural, urban and school health: Functions of PHC, Improvement in rural sanitation, national urban health mission, Health promotion and education in school.

New Course

BP804ET. PHARMACEUTICAL REGULATORY SCIENCE (Theory)

45Hours

Course content:

Unit-I

10 Hours

New Drug Discovery and development

Stages of drug discovery, Drug development process, pre-clinical studies, non-clinical activities, clinical studies, Innovator and generics, Concept of generics, Generic drug product development.

Unit-II

10 Hours

Regulatory Approval Process

Approval processes and timelines involved in Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA). Changes to an approved NDA / ANDA.

Regulatory authorities and agencies

Overview of regulatory authorities of India, United States, European Union, Australia, Japan, Canada (Organization structure and types of applications).

Unit-III

10 Hours

Registration of Indian drug product in overseas market

Procedure for export of pharmaceutical products, Technical documentation, Drug Master Files (DMF), Common Technical Document (CTD), electronic Common Technical Document (eCTD), ASEAN Common Technical Document (ACTD) research.

Unit-IV

08 Hours

Clinical trials

Developing clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process and procedures, GCP obligations of Investigators, sponsors & Monitors, Managing and Monitoring clinical trials, Pharmacovigilance - safety monitoring in clinical trials.

Unit-V

07 Hours

Regulatory Concepts

Basic terminology, guidance, guidelines, regulations, Laws and Acts, Orange book, Federal Register, Code of Federal Regulatory, Purple book.

New Course

BP805ET. PHARMACOVIGILANCE (Theory)

45Hours

Course Content

Unit-I

10 Hours

Introduction to Pharmacovigilance

History and development of Pharmacovigilance □ Importance of safety monitoring of Medicine □ WHO international drug monitoring programme □ Pharmacovigilance Program of India (PvPI).

Introduction to adverse drug reactions

Definitions and classification of ADRs □ Detection and reporting □ Methods in Causality assessment □ Severity and seriousness assessment □ Predictability and preventability assessment, Management of adverse drug reactions. 10 hours

Drug and disease classification

Anatomical, therapeutic and chemical classification of drugs □ International classification of diseases □ Daily defined doses □ International Non-proprietary names for drugs.

Drug dictionaries and coding in pharmacovigilance

WHO adverse reaction terminologies □ MedDRA and Standardized MedDRA queries □ WHO drug dictionary □ EudraVigilance medicinal product dictionary.

Information resources in pharmacovigilance

Basic drug information resources □ Specialized resources for ADRs.

Unit-III

10 Hours

Vaccine safety surveillance

Vaccine Pharmacovigilance □ Vaccination failure, Adverse events following immunization.

Pharmacovigilance methods

Passive surveillance – Spontaneous reports and case series □ Stimulated reporting □ Active surveillance– Sentinel sites, drug event monitoring and registries □ Comparative observational studies– Cross sectional study, case control study and cohort study. Targeted clinical investigations.

Communication in pharmacovigilance

Effective communication in Pharmacovigilance □ Communication in Drug Safety Crisis management □ Communicating with Regulatory Agencies, Business Partners, Healthcare facilities & Media.

Unit-IV

8 Hours

Safety data generation: Pre clinical phase, Clinical phase, Post approval phase (PMS).

ICH Guidelines for Pharmacovigilance: Organization and objectives of ICH, Expedited reporting, Individual case safety reports, Periodic safety update reports, Post approval expedited reporting, Pharmacovigilance planning, Good clinical practice in pharmacovigilance studies

Unit-V

7 Hours

Pharmacogenomics of adverse drug reactions: Genetics related ADR with example focusing PK parameters.

Drug safety evaluation in special population: Paediatrics, Pregnancy and lactation, Geriatrics..

CDSCO (India) and Pharmacovigilance: D & C Act and Schedule Y, Differences in Indian and global pharmacovigilance requirements.