SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.PHARMACY (PHARMACY PRACTICE)
R25 COURSE STRUCTURE AND SYLLABUS
Effective from Academic Year 2025-26 Admitted Batch

I YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-I	Pharmacotherapeutics – I	3	1	0	4
Professional Core-II	Clinical Pharmacy Practice	3	1	0	4
Professional Elective-I	1. Clinical Toxicology 2. Hospital and Community Pharmacy 3. Clinical Research and Pharmacovigilance	3	1	0	4
Professional Elective-II	1. Molecular Biology 2. Advances in Preclinical Evaluation 3. Drug Regulatory Affairs	3	1	0	4
	Research methodology and IPR	2	0	0	2
Laboratory-I	Pharmacotherapeutics – I Lab	0	0	6	3
Laboratory-II	Clinical Pharmacy Practice Lab	0	0	6	3
Audit - I	Audit Course - I	2	0	0	0
	Seminar & Assignment	0	0	4	2
	Total	**16**	**4**	**16**	**26**

I YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Professional Core-III	Pharmacotherapeutics – II	3	1	0	4
Professional Core-IV	Clinical Pharmacokinetics and Drug monitoring	3	1	0	4
Professional Elective-III	1. Biopharmaceutics and Pharmacokinetics 2. Clinical Research 3. Quality use of Medicines	3	1	0	4
Professional Elective-IV	1. Principles of Drug Discovery 2. Cellular and Molecular Pharmacology 3. Nutraceuticals	3	1	0	4
Laboratory- III	Pharmacotherapeutics – II Lab	0	0	6	3
Laboratory- IV	Clinical Pharmacokinetics and Drug Monitoring Lab	0	0	6	3
	Mini Project	2	0	0	2
Audit - II	Audit Course- II	2	0	0	0
	Seminar & Assignment	0	0	4	2
	Total	**16**	**4**	**16**	**26**

II YEAR I Semester

Course Code	Course Title	L	T	P	Credits
Professional Elective-V	1. Biostatistics 2. Pharmacoepidemiology and Pharmacoeconomics 3. Phytopharmaceuticals	3	1	0	4
Open Elective	Open Elective	3	1	0	4
	Comprehensive Viva voce	0	0	8	4
	Dissertation Work Review - II	0	0	24	12
	Total	**6**	**2**	**32**	**24**

II YEAR II Semester

Course Code	Course Title	L	T	P	Credits
Dissertation	Dissertation Work Review - III	0	0	24	12
Dissertation	Dissertation Viva-Voce	0	0	20	10
	Total	**0**	**0**	**44**	**22**

***For Dissertation Work Review - I, Please refer R25 Academic Regulations.**

Audit Courses I & II:

1. English for Research Paper Writing
2. Disaster Management
3. Sanskrit for Technological Learning
4. Value Education
5. Constitution of India
6. Pedagogy Studies
7. Stress Management by Yoga
8. Personality Development through Life Enlightenment Skills

Open Electives:

1. Entrepreneurship Management
2. Pharmaceutical administration
3. Cosmetic Science
4. Environmental and Health safety
5. Vaccines and Biologicals

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (PHARMACY PRACTICE)
PHARMACOTHERAPEUTICS- I (Professional Core - I)

Course Objective: This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

CO 1. Explain pathophysiology, etiology, and therapeutic rationale of diseases affecting cardiovascular, respiratory, gastrointestinal, endocrine, musculoskeletal, and dermatologic systems.
CO 2. Develop individualized therapeutic care plans using evidence-based guidelines.
CO 3. Analyze patient-specific data to optimize pharmacotherapy and monitor therapeutic outcomes.
CO 4. Identify potential drug interactions and adverse effects to ensure rational drug use.
CO 5. Demonstrate clinical decision-making and communication skills in multidisciplinary care.

UNIT- I
Cardiovascular System: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias. Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders

UNIT- II
Respiratory System: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases

UNIT- III
Gastrointestinal System: Peptic ulcer diseases, Reflux esophagitis, inflammatory bowel diseases, Jaundice, & hepatitis, Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease

UNIT-IV
Bone And Joint Disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis

UNIT-V
Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders
Ophthalmology: Conjunctivitis, Glaucoma

REFERENCE BOOKS:

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs-LWW
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Clinical Pharmacy and Pharmacotherapeutics by Ravi Shankar, Pharma med Press
10. Pharmacotherapeutics by laxmi, Pharmamed Press.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year I Sem (PHARMACY PRACTICE)

CLINICAL PHARMACY PRACTICE (Professional Core - II)

Course Objective: This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

CO1. Describe the scope, objectives, and elements of clinical pharmacy and pharmaceutical care.
CO 2. Collect and interpret patient medical and medication histories for effective therapeutic management.
CO 3. Provide accurate and evidence-based drug and poison information.
CO 4. Perform patient counseling and assess medication adherence strategies.
CO 5. Document and evaluate clinical pharmacy interventions for quality improvement.

UNIT- I

Introduction to Clinical Pharmacy: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical MPP, Pharmaceutical care Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

UNIT - II

Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counseling, Drug utilization evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services.

UNIT - III

Patient Data Analysis: Patient Data & Practice Skills: Patient's case history – its structure and significances in drug therapy management, Common medical abbreviations, and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services. Lab Data Interpretation: Hematological tests, Renal function tests, Liver function tests

UNIT - IV

Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

UNIT - V

Medicines & Poisons Information Services:

Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, establishing a drug information centre.

Poisons Information Service: Definition, need, organization and functions of poison information centre.

REFERENCE BOOKS:

1. A Textbook of Clinical MPP – Essential concepts and skills –Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia

3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Thomas J Johnson, Critical Care Pharmacotherapeutics
5. Collen D L, Sneha B S, Fundamental Skills for Patient Care in MPP
6. Patient Assessment in Pharmacy, by Yolanda M H
7. Patient Communication for Pharmacy : A Case-Study Approach on Theory and Practice, Min Liu, Lakesha M. Butler
8. 11. Fundamental Skills for Patient Care in Pharmacy Practice by Colleen Doherty Lauster, Sneha Baxi Srivastava
9. Relevant review articles from recent medical and pharmaceutical literature
10. Fundamentals of Clinical Pharmacy Practice by D. Sudheer Kumar, Dr. J. Krishnaveni

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (PHARMACY PRACTICE)
CLINICAL TOXICOLOGY (Professional Elective – I)

Course Objective: In the current scenario of accidental, homicidal and suicidal excessive consumption of drugs, pesticides, heavy metals and other poisonings, this elective helps the students to acquire the required knowledge and skills in the management of poisoning.

Course Outcome: At the end of the course the student is equipped with

CO 1. Explain the principles of toxicology, classification of poisons, and mechanisms of toxicity.
CO 2. Describe clinical symptoms and management of common poisoning cases.
CO 3. Discuss antidotes and their mechanisms of action in poisoning management.
CO 4. Evaluate laboratory data and design treatment plans for poisoned patients.
CO 5. Apply preventive strategies and patient education in toxicology.

UNIT - I
General principles involved in the management of poisoning, antidotes and the clinical applications.

UNIT - II
Supportive care in clinical toxicology. Gut decontamination, elimination enhancement and toxicokinetics.

UNIT - III
Clinical symptoms and management of acute poisoning with the following agents –
a) Pesticide poisoning: organophosphorus compounds, carbamates, organochlorines, pyrethroids. b) Opiates overdose. c) Antidepressants d) Barbiturates and benzodiazepines. e) Alcohol: ethanol, methanol. f) Paracetamol and salicylates. g) Non-steroidal anti-inflammatory drugs. h) Hydrocarbons: Petroleum products and PEG. i) Caustics: inorganic acids and alkalis. j) Radiation poisoning

UNIT - IV
Clinical symptoms and management of chronic poisoning with the following agents –
a) Heavy metals: Arsenic, lead, mercury, iron, copper b) Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries. c) Plants poisoning. Mushrooms, Mycotoxins. d) Food poisonings e) Envenomations – Arthropod bites and stings.

UNIT - V
Substance Abuse:
Signs and symptoms of substance abuse and treatment of dependence
a) CNS stimulants: amphetamine
b) Opioids
c) CNS depressants
d) Hallucinogens: LSD
e) Cannabis group
f) Tobacco

REFERENCE BOOKS:
1. Matthew j ellenhorn. Ellenhorns medical toxicology – diagnosis and treatment of poisoning. Second edition. Williams and willkins publication, london b.
2. 2. V V Pillay. Handbook of forensic medicine and toxicology. Thirteenth edition 2003 paras publication, Hyderabad

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (PHARMACY PRACTICE)

HOSPITAL & COMMUNITY PHARMACY (Professional Elective - I)

Course Objective: This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

CO 1. Explain the structure, organization, and operation of hospital and community pharmacies.
CO 2. Describe drug procurement, inventory control, and distribution systems.
CO 3. Demonstrate preparation and maintenance of hospital formulary and therapeutic committees.
CO 4. Perform patient counseling and health promotion in community settings.
CO 5. Apply principles of rational drug use and medication safety in both settings.

UNIT- I

Introduction to Hospitals: Definition, classification, organizational structure Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH

UNIT- II

Hospital Formulary Guidelines: And its development, Developing Therapeutic guidelines, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management

UNIT- III

Education and Training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. Community MPP: Definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers. Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

UNIT- IV

Prescription: Legal requirements & interpretation, prescription related problems Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy, OTC medication: Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence Patient referrals to the doctors ADR monitoring in community pharmacies

UNIT- V

Health Promotion: Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care. National Health Programs- Role of Community Pharmacist in Malaria and TB

control programs Home Medicines review program – Definition, objectives, Guidelines, method and outcomes Research in community MPP

REFERENCE BOOKS:

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice– Ramesh Adepu, BSP Publishers, Hyderabad
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (PHARMACY PRACTICE)

CLINICAL RESEARCH AND PHARMACOVIGILANCE (Professional Elective - I)

Course Objectives: This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will teach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in pre-clinical, clinical phases of drug development and post market surveillance.

Course Outcomes: Upon completion of the course, the student shall be able to;

CO1. Explain clinical trial phases, protocol design, and ethical considerations.
CO 2. Discuss roles and responsibilities of clinical research personnel and ethics committees.
CO 3. Demonstrate understanding of pharmacovigilance systems and ADR reporting methods.
CO 4. Analyze clinical data to assess drug safety and effectiveness.
CO 5. Apply GCP, GLP, and regulatory guidelines in clinical research and pharmacovigilance.

UNIT - I
Regulatory Perspectives of Clinical Trials:
Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH- GCP) guidelines Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant-Schedule Y, ICMR, Informed Consent Process: Structure and content of an Informed Consent Process Ethical principles governing informed consent process

UNIT - II
Clinical Trials: Types and Design:
Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional Clinical Trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.

UNIT - III
Clinical Trial Documentation:
Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring-Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity and seriousness assessment. predictability and preventability assessment. Management of adverse drug reactions; Terminologies of ADR.

UNIT - IV
Basic aspects, terminologies and establishment of pharmacovigilance:
History and progress of pharmacovigilance, Significance of safety monitoring, Pharmacovigilance in India and international aspects, WHO international drug monitoring Program, WHO and Regulatory terminologies of ADR, evaluation of medication safety, establishing pharmacovigilance centers in Hospitals, Industry and National Programs related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.

UNIT - V

Methods, ADR reporting and tools used in pharmacovigilance:

International classification of diseases, International Nonproprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety
data.

REFERENCE BOOKS:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice. E6; May 1996.230
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
6. Handbook of clinical Research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
8. Textbook of Pharmacovigilance: Concept and Practice. G.P. Mohanta and P. K. Manna. 2016, Pharma Med Press.
9. A textbook of Clinical Pharmacy Practice: Essential Concepts and Skills. Second Edition, 2012, University Press
10. A Textbook of Clinical Research and Pharmacovigilance by KPR Chowdary, Pharmamed Press

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (PHARMACY PRACTICE)S

MOLECULAR BIOLOGY (Professional Elective - II)

Course Objective: This subject will provide the knowledge about nucleic acid-DNA and RNA structures, DNA Topology, organization of DNA into chromosomes, mutation problems. This subject also provides knowledge about transcription and translation processes occur in molecular biology.

Course Outcome: Upon completion of the course, the student shall be able to,

CO 1. Describe the structure and function of nucleic acids and genetic material.
CO 2. Explain molecular mechanisms involved in gene expression and regulation.
CO 3. Discuss applications of molecular biology in disease diagnosis and therapy.
CO 4. Perform analysis of genetic and protein data for biomedical applications.
CO 5. Apply molecular biology techniques in pharmacogenomics and personalized medicine.

UNIT - I

Introduction to Molecular biology

Nucleic acids - DNA and RNA structure and functions, DNA as genetic material. Griffth, Avery-McCarty-MCLeod, Hershy- Chase, Franklin Conrat Experiments

DNA Structure: Chemistry of DNA, Forces stabilizing DNA structure, Helix parameters, Forms of DNA (A,B,C,D,T and Z), Watson – Crick and Hoogsteen base pairing , Physical Properties of ds DNA (UV absorption spectra Denaturation and renaturation), Chemical that react with DNA.

UNIT - II

DNA topology: DNA supercoiling, Supercoiled form of DNA, Super helical density, Energetic of supercoiled DNA, Biology of supercoiled DNA (Topological domain of DNA, DNA topoisomerases, Mechanisms of supercoiling in cells, mechanisms of action of topoisomerase I and II, effect of supercoiling on structure of DNA and role of supercoiling in gene expression and DNA replication).

Organization of DNA into chromosomes: Packaging of DNA and organization of chromosome in bacteria and eukaryotic cells; packaging of DNA in eukaryotic nucleosome and chromatin condensation assembly of nucleosomes upon replication. Chromatin modification and genome expression.

UNIT - III

Mutations- molecular mechanism - types of DNA mutations and its significance. DNA repair - repair mechanisms - need of DNA repairs, DNA recombination – molecular mechanism of recombination-relationship between repair and recombination, SOS mechanism. Proteins and enzymes involved DNA repair and recombination.

DNA – Protein Interactions: General features interaction of Helix- turn Helix motif, B sheet, Zn- DNA binding domain etc with DNA.

UNIT - IV

DNA Replication: Mechanism of DNA polymerase catalyzed synthesis of DNA, types of DNA polymerases in bacteria and their role. Initiation of chromosomal DNA replication and its regulation in prokaryotes assembly of replisome and progress of replication fork, termination of replication. Types and function of eukaryotic DNA polymerases initiation of replication in eukaryotes, role of telomerases in replication of eukaryotic chromosomes. Inhibitor of DNA replication (Blocking precursor synthesis nucleotide polymerization, altering DNA structure).

Transcription: RNA polymerases, features of prokaryotic and eukaryotic promoters. Strong and weak promoters. Assembly of transcription initiation complex in prokaryotes and eukaryotes and its regulation; synthesis and processing of prokaryotic and eukaryotic transcripts. Transport of RNA within eukaryotic cell. Regulatory elements of genes-promoters. Fate of mRNA.

UNIT - V

Translation- Synthesis and Processing of Proteome: Structure and role of tRNA in protein synthesis, ribosome structure, basic feature of genetic code and its deciphering, translation (initiation, elongation and termination in detail in prokaryotes as well as eukaryotes), Post translational processing of protein (protein folding, processing by proteolytic cleavage, processing by chemical modification, inteins). Protein degradation.

Regulation of Gene expression in prokaryotes and eukaryotes: Positive and negative regulation. lac-, ara-, his- and trp- operon regulation; antitermination, global regulatory responses; Regulation of gene expression in eukaryotes: Transcriptional, translational and processing level control mechanisms.

DNA- transposable elements- types of transposable elements, its importance in variation and evolution. Possible origin of virus, Oncogenes.

REFERENCE BOOKS:

1. Cell & Molecular Biology: Cell and Molecular Biology: Concepts and Experiments, Gerald Karp, John Wiley, NY
2. Molecular Cell Biology, H.S. Bramrah, Anmol Publications Pvt. Ltd., New Delhi
3. Advanced Molecular Biology, H.S. Bhamrah Viva Books, Pvt. Ltd., New Delhi
4. Plant Biochemistry and Molecular Biology, Hans Walter Held, Oxford, NY
5. Molecular Biology of the Gene, Watson, Baker, Bell, Gann Levine, Losick, Pearson Education Pvt. Ltd., New Delhi
6. Essential Molecular Biology: A Practical Approach, TA Brown, oxford.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (PHARMACY PRACTICE)

ADVANCES IN PRECLINICAL EVALUATION – I (Professional Elective-II)

Course Objective: This course is designed to impart basic knowledge and skills that are required animals and their regulatory requirements. The students will know about screening programmes, preclinical and clinical models to perform activities.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

CO 1. Describe preclinical drug development stages and evaluation parameters for efficacy and safety.
CO 2. Explain animal models used to assess pharmacological activity and toxicology.
CO 3. Interpret experimental data to predict clinical outcomes.
CO 4. Discuss ethical and regulatory requirements for preclinical testing.
CO 5. Apply modern techniques in preclinical screening and biomarker identification.

UNIT - I

Care, handling and breeding techniques of laboratory animals. Regulations for laboratory animal care and ethical requirement. Knowledge of the CPCSEA proforma for performing experiments on animals.

UNIT - II

Organization of preclinical screening programme (Blind screening)

UNIT - III

Drug Discovery Process: Principles, techniques and strategies used in drug discovery. High throughput screening, human genomics.

UNIT - IV

Preclinical and clinical models employed in the screening of new drugs belonging to following categories.

1. Drugs acting on Autonomic nervous system: Sympathomimetics, Parasympathomimetics, Anticholinesterages, anticholinergics, adrenolytics. Muscle relaxants (peripheral)
2. Cardiovascular Pharmacology: Cardiac glycosides, antiarrhythmics, antihypertensives, antiatherosclerotics.
3. Screening of free radical scavenging activity
4. Immunopharmacology: Specific (Cell and humoral mediated) and non-specific methods.
5. Drugs for metabolic disorders: Anti-diabetic agents, Hepatoprotective agents, Anti-hyperlipidemic agents

UNIT - V

Principles of Toxicological evaluations, ED50, LD50 and TD values, acute, sub-acute and chronic toxicity studies.

REFERENCE BOOKS:

1. Biological standardization by J. H. Burn D.J. Finney and I.G. Goodwin
2. Screening methods in Pharmacology by Robert Turner. A
3. Evaluation of drugs activities by Laurence and Bachrach
4. Methods in Pharmacology by Arnold Schwartz.
5. Fundamentals of experimental Pharmacology by M. N. Ghosh
6. Pharmacological experiment on intact preparations by Churchill Livingstone
7. Drug discovery and Evaluation by Vogel H.G.
8. Experimental Pharmacology by R. K. Goyal.
9. Preclinical evaluation of new drugs by S. K. Gupta

10. Pharmacological screening methods and Toxicology by A. Srinivasa Rao
11. Handbook of Experimental Pharmacology, S K. Kulkarni
12. Practical Pharmacology and Clinical Pharmacy, S K. Kulkarni, 3rd Edition.
13. David R. Gross. Animal Models in Cardiovascular Research, 2nd Edition, Kluwer Academic Publishers, London, UK.
14. Screening Methods in Pharmacology, Robert A. Turner.
15. Rodents for Pharmacological Experiments, Dr. Tapan Kumar chatterjee.
16. Practical Manual of Experimental and Clinical Pharmacology by Bikash Medhi (Author), Ajay Prakash (Author)

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (PHARMACY PRACTICE)

DRUG REGULATORY AFFAIRS (Professional Elective - II)

Course Objective: The topics which are present in the Drug regulatory affairs are very much useful which increases the knowledge regarding the regulatory aspects in the pharmaceutical industries.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

CO 1. Explain the role of national and international regulatory bodies in drug approval.
CO 2. Describe requirements for IND, NDA, ANDA filings and clinical trial applications.
CO 3. Discuss documentation and dossier preparation for regulatory submissions.
CO 4. Evaluate ethical and legal aspects of drug promotion and post-marketing surveillance.
CO 5. Apply global regulatory guidelines for drug development and export.

UNIT I

Drug Regulatory Aspects (India)

1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective)
3. Special emphasis – Schedule M and Y
4. New drugs – Importation, Registration, development, Clinical Trials, BE NOC& BE studies
5. Various Licences – Test Lic., Import lic., for testing of drugs and API's, Manufacturing Contract and Loan licence manufacturing.

UNIT II

Good Manufacturing Practices (GMP)

1. Indian GMP certification, WHO GMP certification.
2. ICH guidelines for stability testing and other relevant ones (Q1-Q10)
3. Export permissions and manufacturing for semi-regulated countries
4. Understanding of the plant layouts with special emphasis on the environment & safety (HVAC, Water Systems, Stores Managemant, Effluent etc.)
5. Quality Assurance and Qulaity Control – Basic understanding for in-built quality.

UNIT III

Global Regulatory Affairs

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA, Europe and Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations. Regulatory aspects of pharmaceutical and bulk drug manufacture, regulatory drug analysis.

UNIT IV

Good Documentation Practices

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.
Quality, safety and legislation for cosmetic products and herbal products.

UNIT V

Governing Regulatory Bodies across the globe.

Country Authority Submission

a. U.S Food & Drug Administration USDMF
b. Canada Therapeutic Product DirectorateDMF
c. Europe
    1) European Medicines Agency (EMEA/ National Authorities) EDMF

2) European Directorate for Quality of Medicines CEP/COS & Health Care Products.

3) MHRA – Medicines and Health Care Products Regulatory Agency

d. Product Filing
e. Responding Regulatory Deficiencies
f. Final Approval Procedure

Preparation, review and submission of Drug Master Files to Regulatory Authorities as per their specific requirements.

TEXT AND REFERENCE BOOKS:

1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.
5. Text Book of Forensic Pharmacy by CK Kokate
6. Pharmaceutical Regulatory Affairs - Selected Topics, CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi - 2013

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (PHARMACY PRACTICE)

RESEARCH METHODOLOGY AND IPR

Course Objectives:

- To understand the research problem
- To know the literature studies, plagiarism and ethics
- To get the knowledge about technical writing
- To analyze the nature of intellectual property rights and new developments
- To know the patent rights

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Understand research problem formulation.
CO 2. Analyze research related information. Follow research ethics.
CO 3. Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
CO 4. Understanding that when IPR would take such important place in growth of individuals & nation, it is needless to emphasis the need of information about Intellectual Property Right to be promoted among students in general & engineering in particular.
CO 5. Understand that IPR protection provides an incentive to inventors for further research work and investment in R & D, which leads to creation of new and better products, and in turn brings about, economic growth and social benefits.

UNIT - I

Meaning of research problem, Sources of research problem, Criteria Characteristics of a good research problem, Errors in selecting a research problem, Scope and objectives of research problem. Approaches of investigation of solutions for research problem, data collection, analysis, interpretation, Necessary instrumentations

UNIT - II

Effective literature studies approaches, analysis, Plagiarism, Research ethics

UNIT - III

Effective technical writing, how to write report, Paper Developing a Research Proposal, Format of research proposal, a presentation and assessment by a review committee

UNIT - IV

Nature of Intellectual Property: Patents, Designs, Trade and Copyright. Process of Patenting and Development: technological research, innovation, patenting, development. International Scenario: International cooperation on Intellectual Property. Procedure for grants of patents, Patenting under PCT.

UNIT - V

Patent Rights: Scope of Patent Rights. Licensing and transfer of technology. Patent information and databases. Geographical Indications. New Developments in IPR: Administration of Patent System. New developments in IPR; IPR of Biological Systems, Computer Software etc. Traditional knowledge Case Studies, IPR and IITs.

TEXT BOOKS:

1. Stuart Melville and Wayne Goddard, “Research methodology: an introduction for science & engineering students’”
2. Wayne Goddard and Stuart Melville, “Research Methodology: An Introduction”
3. Pharmaceutical Research Methodology and BioStatistics, B Subba Rao, Pharmamed Press
4. Intellectual Property Rights in Pharmaceutical Industry, B Subba Rao, Pharmamed Press

REFERENCES:

1. Ranjit Kumar, 2nd Edition, “Research Methodology: A Step by Step Guide for beginners”
2. Halbert, “Resisting Intellectual Property”, Taylor & Francis Ltd ,2007.
3. Mayall, “Industrial Design”, McGraw Hill, 1992.
4. Niebel, “Product Design”, McGraw Hill, 1974.
5. Asimov, “Introduction to Design”, Prentice Hall, 1962.
6. Robert P. Merges, Peter S. Menell, Mark A. Lemley, “Intellectual Property in New
7. Technological Age”, 2016.
8. T. Ramappa, “Intellectual Property Rights Under WTO”, S. Chand, 2008

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (PHARMACY PRACTICE)

PHARMACOTHERAPEUTICS LAB - I (Laboratory - I)

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

Course Outcomes: Upon completion of the course a learner shall be able to:

CO1 Perform case-based analysis and develop therapeutic plans for common diseases.
CO2 Interpret patient charts, lab values, and prescriptions.
CO3 Identify adverse drug reactions and formulate management plans.
CO4 Demonstrate patient counseling and therapeutic monitoring skills.
CO5 Collaborate effectively in clinical decision-making and documentation.

a) The cases may be selected from the following Wards:
   - Gastroenterology
   - Cardiology
   - Pulmonology
   - Orthopedics
   - Endocrinology
   - Dermatology

b) Rational use of medicines in special population admitted in above wards (three)

c) Calculation of Bioavailability and Bioequivalence from the given data (two)

d) Interpretation of Therapeutic Drug Monitoring reports of a given patient of any of the above wards (three)

e) Calculation of various Pharmacoeconomic outcome analysis for the given data from the above (two) Assignments The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

REFERENCE BOOKS:

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year I Sem (PHARMACY PRACTICE)

CLINICAL PHARMACY PRACTICE LAB (Laboratory - II)

Course Outcomes: Upon completion of the course a learner shall be able to:

CO1 Collect and evaluate patient data for therapeutic decision support.
CO2 Provide drug and poison information services to healthcare teams.
CO3 Prepare case reports and documentation using standard formats.
CO4 Demonstrate effective communication with patients and professionals.
CO5 Apply ethical principles and good clinical practice in daily activities.

List of Experiments:

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

REFERENCE BOOKS

1. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
2. Thomas J Johnson, Critical Care Pharmacotherapeutics
3. Collen D L, Sneha B S, Fundamental Skills for Patient Care in MPP
4. Patient Assessment in Pharmacy, by Yolanda M H
5. Relevant review articles from recent medical and pharmaceutical literature

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (PHARMACY PRACTICE)

PHARMACOTHERAPEUTICS - II (Professional Core - III)

Course Objective: This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence-based medicines.

Course Outcome: Upon completion of this course it is expected that students shall be able to: -

CO 1. Explain the therapeutic rationale, etiology, and management of neurological, psychiatric, renal, infectious, and o
CO 2. Develop individualized treatment plans considering comorbidities and patient-specific factors.
CO 3. Evaluate adverse drug reactions and therapeutic failures in clinical practice.
CO 4. Integrate pharmacotherapy with diagnostic findings and clinical parameters.
CO 5. Apply evidence-based guidelines to ensure rational use of medicines.

UNIT - I
Nervous System: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer's disease, Neuralgias and Pain pathways and Pain management.

UNIT - II
Psychiatric Disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders
Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease

UNIT - III
Infectious Diseases I: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.

UNIT - IV
Infectious Diseases II: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections. Gynecological disorders: Dysmenorrhea, Hormone replacement therapy.

UNIT - V
Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care

REFERENCE BOOKS:

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W. B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm - Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (PHARMACY PRACTICE)

CLINICAL PHARMACOKINETICS AND DRUG MONITORING (Professional Core - IV)

Course Objective: This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of in kinetic data.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

CO 1. Explain pharmacokinetic principles and their clinical relevance in dose individualization.
CO 2. Calculate and interpret pharmacokinetic parameters from patient data.
CO 3. Design and modify dosage regimens for special populations (renal, hepatic, pediatric, geriatric).
CO 4. Evaluate drug interactions using therapeutic drug monitoring data.
CO 5. Apply pharmacogenomic and PK/PD principles to optimize drug therapy.

UNIT - I

Introduction to Clinical Pharmacokinetics: Compartmental and Non-compartmental models, Renal and non-renal clearance, Organ extraction and models of hepatic clearance, Estimation and determinants of bioavailability, Multiple dosing, Calculation of loading and maintenance doses.
Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

UNIT - II

Pharmacokinetics of Drug Interactions: Pharmacokinetic drug interactions, Inhibition and Induction of Drug metabolism, Inhibition of Biliary Excretion.
Pharmacogenetics: Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, Pharmacogenetics and Pharmacokinetic/ Pharmacodynamic considerations.
Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive method or Dosing with feedback, Analysis of Population pharmacokinetic Data.

UNIT - III

Non-Linear Mixed Effects Modelling: The Structural or Base Model, Modeling Random Effects, Modeling Covariate Relationships, Mixture Model, Estimation Methods, Model Building Techniques, Covariate Screening Methods, Testing the model assumptions, Precision of the parameter estimates and confidence intervals, Model misspecification and violation of the model assumptions, Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometrics software.

UNIT - IV

Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the pediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy and lactation, Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in the in hepatic failure.

UNIT - V

Therapeutic Drug Monitoring: Introduction, Individualization of drug dosage regimen (Variability – Genetic, age, weight, disease and Interacting drugs), Indications for TDM, Protocol for TDM, Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.

TDM of drugs used in the following conditions:

Cardiovascular disease: Digoxin, Lidocaine, Amiodarone;
Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate;
Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline;
Organ transplantations: Cyclosporine;
Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin;
Antibiotics: Vancomycin, Gentamicin, Meropenem.

REFERENCE BOOKS:

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: McGraw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A. Blouin and Jane M. Pruemer Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams &Wilkins, USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams &Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.
12. John E. Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health-System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (PHARMACY PRACTICE)

BIOPHARMACEUTICS AND PHARMACOKINETICS (Professional Elective - III)

Course Objective: This course is designed to impart basic knowledge about biopharmaceutics, drug ADME process, kinetic modeling and distribution of drug. T

Course Outcome: Upon completion of this course it is expected that students shall be able to:

CO 1. Explain the principles of drug absorption, distribution, metabolism, and excretion.
CO 2. Describe bioavailability, bioequivalence, and their impact on therapeutic efficacy.
CO 3. Evaluate pharmacokinetic models and predict plasma concentration-time profiles.
CO 4. Apply pharmacokinetic data to dosage form design and optimization.
CO 5. Analyze bioequivalence studies and their regulatory importance.

UNIT - I

Introduction to Biopharmaceutics

I. Absorption of drugs from gastrointestinal tract.
II. Drug Distribution.
III. Drug Elimination.

UNIT - II

Introduction to Pharmacokinetics.

a. Mathematical model
b. Drug levels in blood.
c. Pharmacokinetic model
d. Compartment models
e. Pharmacokinetic study.

UNIT-III

One compartment and Multicompartment models.

a. Intravenous Injection (Bolus)
b. Intravenous infusion.
c. Two compartment open model.
d. IV bolus, IV infusion and oral administration

UNIT-IV

Nonlinear Pharmacokinetics.

a. Introduction
b. Factors causing Non-linearity.
c. Michaelis-menton method of estimating parameters.

UNIT-V

Bioavailability and Bioequivalence.

a. Introduction.
b. Bioavailability study protocol.
c. Methods of Assessment of Bioavailability

TEXT BOOKS:

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
2. Learn Shargel and ABC yu, Applied Biopharmacokinetics and
3. Biopharmaceutics and Pharmacokinetics by C.V.S. Subrahmanyam, Vallabh Prakashan.2010.

4. Basic biopharmaceutics, Sulnil S. Jambhekar and Philip J Brean.
5. Text book of Biopharmaceutics and Clinical Pharmacokinetics by Niazi Sarfaraz
6. Bio-Pharmaceutics and Pharmacokinetics by V. Venkateshwarlu.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (PHARMACY PRACTICE)
CLINICAL RESEARCH (Professional Elective - III)

Course Objective: This subject will provide different approaches to drug discovery, pharmacological, toxicological and new drug applications. It will also impart knowledge about clinical trials, ICH guidelines and their implementation, rules and regulations of GCP, CDSCO and different protocols.

Course Outcome: Upon completion of the course, the student shall be able to,

CO 1. Describe the design, conduct, and management of clinical trials.
CO 2. Discuss ethical and regulatory aspects of clinical investigations.
CO 3. Interpret statistical data and outcomes from clinical research.
CO 4. Evaluate safety and efficacy data for drug approval processes.
CO 5. Apply GCP principles to ensure high-quality clinical research.

UNIT - I

Drug development process: Introduction, Various Approaches to drug discovery, Pharmacological, Toxicological, IND Application, Drug characterization & Dosage form

UNIT - II

Clinical development of drug: a. Introduction to Clinical trials b. Various phases of clinical trial. c. Methods of post marketing surveillance d. Abbreviated New Drug Application submission.

UNIT - III

Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines, Challenges in the implementation of guidelines

UNIT - IV

Ethical guidelines in Clinical Research, Composition, responsibilities, procedures of IRB / IEC

UNIT - V

Role and responsibilities of clinical trial personnel as per ICH GCP a. Sponsor b. Investigators c. Clinical research associate d. Auditors e. Contract research coordinators f. Regulatory authority

a. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
b. Informed consent Process
c. Safety monitoring in clinical trials.

REFERENCE BOOKS:

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
2. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
7. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.
8. Clinical Research: Principles, Practices, Perspectives, Bikash Medhi, Pharmamed Press

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (PHARMACY PRACTICE)

QUALITY USE OF MEDICINES (Professional Elective - III)

Course objectives: This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Course Outcomes: Upon completion of this course itis expected that students shall be able to:

CO 1. Explain the concept and principles of quality use of medicines (QUM).
CO 2. Identify medication-related problems and propose corrective actions.
CO 3. Promote rational and cost-effective use of medicines in healthcare.
CO 4. Develop strategies to minimize medication errors and improve patient outcomes.
CO 5. Evaluate health policies and guidelines that influence medication safety.

UNIT - I

Introduction to Quality use of Medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.

UNIT - II

Concepts in QUM Evidence based medicine: Definition, concept of evidence-based medicine, Approach and practice of evidence-based medicine inclinical settings Essential drugs: Definition, need, concept of essential drug, National essential drug policy and list Rational drug use: Definition, concept and need for rational drug use, Rational drug prescribing, Role of pharmacist in rational drug use.

UNIT - III

QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. QUM in special population: Pediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.

UNIT - IV

Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.

UNIT - V

Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.

REFERENCE BOOKS:

1. A Textbook of Clinical Pharmacy Practice– Essential concepts and skills– Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata

2. Andrews E B, Moore N. Mann's Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen M R. Medication Errors

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (PHARMACY PRACTICE)

PRINCIPLES OF DRUG DISCOVERY (Professional Elective- IV)

Course Objective: The subject imparts basic knowledge of drug discovery process. This information will make the student competent in drug discovery process

Course Outcome: Upon completion of the course, the student shall be able to,

CO 1. Explain drug discovery processes, target identification, and validation techniques.
CO 2. Describe lead identification, optimization, and structure-activity relationships.
CO 3. Evaluate screening methods used in preclinical and clinical research.
CO 4. Discuss translational approaches linking basic research to clinical application.
CO 5. Apply innovative discovery strategies for novel drug targets.

UNIT - I

An overview of modern drug discovery process: Target identification, target validation, lead identification and lead Optimization. Economics of drug discovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role of Nucleic acid microarrays, Protein microarrays, Antisense technologies, siRNAs, antisense oligonucleotides, Zinc finger proteins. Role of transgenic animals in target validation.

UNIT - II

Lead Identification- combinatorial chemistry & high throughput screening, in silico lead discovery techniques, Assay development for hit identification.

Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure. Computational prediction of protein structure: Threading and homology modeling methods. Application of NMR and X-ray crystallography in protein structure prediction

UNIT - III

Rational Drug Design Traditional vs rational drug design, Methods followed in traditional drug design, High throughput screening, Concepts of Rational Drug Design,

Rational Drug Design Methods: Structure and Pharmacophore based approaches

Virtual Screening techniques: Drug likeness screening, Concept of pharmacophore mapping and pharmacophore-based Screening

UNIT - IV

Molecular docking: Rigid docking, flexible docking, manual docking; Docking based screening. De novo drug design.

Quantitative analysis of Structure Activity Relationship History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hansch analysis, Fee Wilson analysis and relationship between them.

UNIT - V

QSAR Statistical methods – regression analysis, partial least square analysis (PLS) and other multivariate statistical methods.

3D-QSAR approaches like COMFA and COMSIA

Prodrug design-Basic concept, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design

REFERENCE BOOKS:

1. Mouldy Sioud. Target Discovery and Validation Reviews and Protocols: Volume 2 Emerging Molecular Targets and Treatment Options. 2007 Humana Press Inc.
2. Darryl León. Scott MarkelIn. Silico Technologies in Drug Target Identification and Validation. 2006 by Taylor and Francis Group, LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. Springer New York Dordrecht Heidelberg London.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods and Principles in Medicinal Chemistry. Publisher Wiley-VCH
6. Abby L. Parrill. M. Rami Reddy. Rational Drug Design. Novel Methodology and Practical Applications. ACS Symposium Series; American Chemical Society: Washington, DC, 1999.
7. J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons, Inc., New Jersey.
8. Current Concepts in Drug Design, T Durai Ananda Kumar, Pharma Med Press

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M. Pharm I Year II Sem (PHARMACY PRACTICE)

CELLULAR AND MOLECULAR PHARMACOLOGY (Professional Elective - IV)

Course Objectives: The subject imparts a fundamental knowledge on the structure and functions of cellular components and help to understand the interaction of these components with drugs. This information will further help the student to apply the knowledge in drug discovery process.

Course Outcomes: Upon completion of the course, the student shall be able to:

CO 1. Describe molecular and cellular mechanisms underlying drug action.
CO 2. Explain signaling pathways and their pharmacological modulation.
CO 3. Evaluate molecular targets for drug development and therapy.
CO 4. Interpret molecular techniques applied in pharmacological research.
CO 5. Apply cellular assays and omics technologies in drug discovery.

UNIT - I

Cell biology Structure and functions of cell and its organelles Genome organization. Gene expression and its regulation, importance of siRNA and micro RNA, gene mapping and gene sequencing Cell cycles and its regulation. Cell death– events, regulators, intrinsic and extrinsic pathways of apoptosis. Necrosis and autophagy.

UNIT- II

Cell signaling Intercellular and intracellular signaling pathways. Classification of receptor family and molecular structure ligand gated ion channels; G-protein coupled receptors, tyrosine kinase receptors and nuclear receptors. Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate, (IP3), NO, and diacylglycerol. Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway, mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer and activator of transcription (STAT) signaling pathway.

UNIT- III

Principles and applications of genomic and proteomic tools DNA electrophoresis, PCR (reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISA and western blotting, Recombinant DNA technology and gene therapy Basic principles of recombinant DNA technology-Restriction enzymes, various types of vectors. Applications of recombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinical applications and recent advances in gene therapy.

UNIT- IV

Pharmacogenomics Gene mapping and cloning of disease gene. Genetic variation and its role in health/ pharmacology Polymorphisms affecting drug metabolism Genetic variation in drug transporters Genetic variation in G protein coupled receptors Applications of proteomics science: Genomics, proteomics, metabolomics, functionomics, nutrigenomics Immunotherapeutics Types of immunotherapeutics, humanisation antibody therapy, Immunotherapeutics in clinical practice

UNIT- V

Cell culture techniques Basic equipment used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures; isolation of cells, subculture, cryopreservation, characterization of cells and their application. Principles and applications of cell viability assays, glucose uptake assay, Calcium influx assays Principles and applications of flow cytometry b. Biosimilars

REFERENCE BOOKS:

1. The Cell, A Molecular Approach. Geoffrey M Cooper.

2. Cellular and Molecular Pharmacology by Amteshwar Singh Jaggi, Pharmamed Press
3. Pharmacogenomics: The Search for Individualized Therapies. Edited by J. Licinio and M -L. Wong
4. Handbook of Cell Signaling (Second Edition) Edited by Ralph A. et.al
5. Molecular Pharmacology: From DNA to Drug Discovery. John Dickenson et.al
6. Basic Cell Culture protocols by Cheril D. Helgason and Cindy L. Miller
7. Basic Cell Culture (Practical Approach) by J. M. Davis (Editor)
8. Animal Cell Culture: A Practical Approach by John R. Masters (Editor)
9. Current protocols in molecular biology vol I to VI edited by Frederick M. Ausuvel et la.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year II Sem (PHARMACY PRACTICE)

NUTRACEUTICALS (Professional Elective - IV)

Course Objectives: The students will expose to characteristic features of various phytochemicals as nutraceuticals in various diseased conditions and also know the role of antioxidant in free radical induced disease conditions and will expose to various food laws and regulations.

Course Outcomes: Upon completion of the course, the student shall be able to:

CO 1. Explain the classification, sources, and health benefits of nutraceuticals.
CO 2. Describe mechanisms of action and pharmacological properties of functional foods.
CO 3. Discuss the safety, regulation, and quality control of nutraceutical products.
CO 4. Evaluate the role of nutraceuticals in disease prevention and management.
CO 5. Apply evidence-based knowledge to recommend nutraceutical use in patient care.

UNIT - I

a. Definitions of Functional foods, Nutraceuticals and Dietary supplements. Classification of Nutraceuticals, Health problems and diseases that can be prevented or cured by Nutraceuticals i.e. weight control, diabetes, cancer etc.
b. Source, Name of marker compounds and their chemical nature, Medicinal uses and health benefits of following used as nutraceuticals/functional foods:
Spirulina, Soyabean, Ginseng, Garlic, Broccoli, Gingko, Flaxseeds

UNIT - II

Phytochemicals as nutraceuticals: Occurrence and characteristic features (chemical nature medicinal benefits) of following

a) Carotenoids- α and β-Carotene, Lycopene, Xanthophylls, lutein
b) Sulfides: Diallylsulfides, Allyltrisulfide.
c) Polyphenolics: Reservetrol
d) Flavonoids- Rutin , Naringin, Quercitin, Anthocyanidins, catechins, Flavones
e) Prebiotates / Probiotics.: Fructo oligosaccharides, Lactobacillum
f) Phytoestrogens: Isoflavones, daidzein, Geebustin, lignans
g) Tocopherols

UNIT - III

a. Introduction to free radicals: Free radicals, reactive oxygen species, production of free radicals in cells, damaging reactions of free radicals on lipids, proteins, Carbohydrates, nucleic acids.
b. Measurement of free radicals: Lipid peroxidation products, lipid hydroperoxide, malondialdehyde.

UNIT - IV

a. Free radicals in Diabetes mellitus, Inflammation, Ischemic reperfusion injury, Cancer, Atherosclerosis, Free radicals in brain metabolism and pathology, kidney damage, muscle damage. Free radicals involvement in other disorders. Free radicals theory of ageing.
b. Antioxidants: Endogenous antioxidants – enzymatic and nonenzymatic antioxidant defence, Superoxide dismutase, catalase, Glutathione peroxidase, Glutathione Vitamin C, Vitamin E, α- Lipoic acid, melatonin
Synthetic antioxidants: Butylatedhydroxy Toluene, Butylatedhydroxy Anisole.

UNIT - V

Food Laws and Regulations; FDA, FPO, MPO, AGMARK. HACCP and GMPs on Food Safety. Adulteration of foods.

Regulations and Claims – Current Products: Label Claims, Nutrient Content Claims, Health Claims, Dietary Supplements Claims

REFERENCE BOOKS:

1. Dietetics by Sri Lakshmi
2. Role of dietary fibres and nutraceuticals in preventing diseases by K. T. Agusti and P. Faizal: BS Publication.
3. Advanced Nutritional Therapies by Cooper. K.A., (1996).
4. The Food Pharmacy by Jean Carper, Simon & Schuster, UK Ltd., (1988).
5. Prescription for Nutritional Healing by James F.Balch and Phyllis A. Balch 2nd Edn., Avery Publishing Group, NY (1997).
6. G. Gibson and C. Williams Editors *2000 Functional foods* Woodhead Publ. Co. London.
7. Goldberg, I. *Functional Foods*. 1994. Chapman and Hall, New York.
8. Labuza, T.P. 2000 Functional Foods and Dietary Supplements: Safety, Good Manufacturing Practice (GMPs) and Shelf Life Testing in *Essentials of Functional Foods* M. K. Sachmidl and T.P. Labuza eds. Aspen Press.
9. Handbook of Nutraceuticals and Functional Foods, Third Edition (Modern Nutrition)
10. Shils, ME, Olson, JA, Shike, M. 1994 *Modern Nutrition in Health and Disease*. Eighth edition. Lea and Febiger

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year II Sem (PHARMACY PRACTICE)

PHARMACOTHERAPEUTICS - II LAB (Laboratory - III)

Course Outcomes: Upon completion of the course, the student shall be able to:

CO1 Analyze patient cases for neurological, infectious, and oncological diseases.

CO2 Design individualized treatment plans for clinical scenarios.

CO3 Identify and report ADRs and medication errors.

CO4 Demonstrate effective interprofessional communication during ward rounds.

CO5 Apply clinical reasoning and evidence-based guidelines to patient care.

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format.

I. The cases may be selected from the following diseases: 7. Neurology & Psychiatry 8. Oncology 9. Infectious Diseases & Immunology 10. Dermatology
II. Rational use of medicines in special population admitted in above wards (three)
III. Calculation of Bioavailability and Bioequivalence from the given data (two)
IV. Interpretation of Therapeutic Drug Monitoring reports of a given patient of any of the above wards (three)
V. Calculation of various Pharmacoeconomic outcome analysis for the given data from the above (two)

ASSIGNMENTS: The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

REFERENCE BOOKS:

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach-Appleton & Lange
3. Robins SL. Pathologic basis of disease -W. B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Clinical Pharmacy and Pharmacotherapeutics by Ravi Shankar, Pharma med Press
7. Chisholm - Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm I Year II Sem (PHARMACY PRACTICE)

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING LAB
(Laboratory - IV)

Course Outcomes: Upon completion of the course, the student shall be able to:

CO1 Perform pharmacokinetic calculations using plasma concentration data.

CO2 Design individualized dosage regimens and evaluate therapeutic responses.

CO3 Interpret laboratory data to assess drug safety and efficacy.

CO4 Demonstrate methods for drug concentration measurement and validation.

CO5 Apply PK/PD and TDM principles for optimizing pharmacotherapy.

List of Experiments:

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Manufacture of parenteral formulations, powders.
4. Drug information queries.
5. Inventory control
6. Study of Design and Management of Hospital pharmacy department of a hospital.
7. Composition of Pharmacy and Therapeutics committee – Organization, functions, and limitations.
8. Development of a hospital formulary for a teaching hospital
9. Various sources of drug information and systematic approach to provide unbiased drug information.
10. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management

REFERENCE BOOKS:

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: McGraw Hill.
2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A.Blouin and Jane M. Pruemer Concepts in Clinical Pharmacokinetics. AmericanSociety of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer. Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm II Year I Sem (PHARMACY PRACTICE)

BIOSTATISTICS (Professional Elective - V)

Course Objectives: The student shall know the introduction, scope of biostatistics and Research work, calculation and present of the data.

Course Outcomes: Upon completion of the course, the student shall be able to:

CO 1. Explain fundamental concepts of biostatistics and their role in clinical and pharmaceutical research.
CO 2. Apply statistical tools for data analysis, interpretation, and presentation in research studies.
CO 3. Evaluate sampling methods, hypothesis testing, and probability distributions.
CO 4. Perform correlation, regression, and ANOVA analyses using real datasets.
CO 5. Use statistical software to manage and interpret pharmacological or clinical data.

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UNIT - I

Introduction and scope of biostatistics: Use of statistics in Pharmacy. Population and Sample collection. Stages of research, types of data and methods of data collections. Data arrangement and presentation, formation of table and charts.

UNIT - II

Measures of central tendency: computation of means, median and mode from grouped and ungrouped data.
Measure of dispersion: computation of variance, standard deviation, standard error and their coefficients.

UNIT - III

Measures of Correlation and Regression
Probability rules: Binomial, Poison and Normal distribution.

UNIT - IV

Experimental designing, planning of an experiment, replication and randomization.
Analysis of Variance (ANOVA): 1-way, 2- Way

UNIT - V

Hypothesis testing: Student 't' test, Chi square test,
Non- Parametric Tests: Sign Test, Sign Rank Test, Wilcoxon Sign Rank Test

REFERENCE BOOKS:

1. Statistics for business and economics 3rd edition by Vikas books publications
2. Biostatistics & Computer applications by GN Rao and NK Tiwari
3. A Textbook of Research Methodologies and Biostatistics for Pharmacy Students,KPR Chowdary, Pharmamed Press
4. Sokal, R.R. and Rohlf, F.J. 1987. An Introduction to Biostatistics. W.H. Freeman and Company.
5. Bailey, N.T.J. 1981. Statistical Methods in Biology. English University Press.
6. Mitchell, K. and Glover, T. 2001. Introduction to Biostatistics. McGraw Hill, Publishing Co.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm II Year I Sem (PHARMACY PRACTICE)

PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (Professional Elective - V)

Course Objective: This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

Course Outcome: Upon completion of this course it is expected that students shall be able to:

CO 1. Explain the principles, scope, and applications of pharmacoepidemiology.
CO 2. Describe study designs and methodologies used in drug utilization and safety studies.
CO 3. Apply pharmacoeconomic evaluation methods such as cost-minimization, cost-effectiveness, and cost-utility an
CO 4. Evaluate drug policy decisions using pharmacoepidemiological and pharmacoeconomic data.
CO 5. Integrate health outcomes, safety, and cost data for rational decision-making in clinical practice.

UNIT - I

Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications; Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements. Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

UNIT - II

Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta-analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

UNIT - III

Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs. Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio, Average Cost-Effective Ratio. Person Time, Willingness to Pay, Time Trade Off and Discounting.

UNIT - IV

Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA).

UNIT - V

Definition, Steps involved, Applications, Advantages and disadvantages of the following:

Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures. Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modeling, Software used in Pharmacoeconomic analysis, Applications of Pharmacoeconomics.

REFERENCE BOOKS:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwe rLippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modeling for Health Economic Evaluation, Oxford University Press, London.
4. K G Revikumar, Pharmacoepidemiology and Pharmacoeconomics Concepts and Practices.
5. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programs Oxford University Press, London.
6. George E Mackinnon III. Understanding health outcomes and Pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes.
8. Walley, Pharmacoeconomics.
9. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
10. Relevant review articles from recent medical and pharmaceutical literature
11. Guru Prasad Mohanta and P K Manna, Textbook of Pharmacovigilance Concepts and Practice

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm II Year I Sem (PHARMACY PRACTICE)

PHYTOPHARMACEUTICALS (Professional Elective - V)

Course Objective: This subject will provide the knowledge about the sourse, phytochemistry, physiological activities of anticancer, CVS &Nervous systems and anti-inflammatory drugs from natural sources. This also gives information about isolation and characterization of phytoconstituents.

Course Outcome: Upon completion of the course, the student shall be able to,

CO 1. Describe the principles, sources, and therapeutic applications of phytopharmaceuticals.
CO 2. Explain methods for extraction, isolation, and characterization of plant-based active compounds.
CO 3. Discuss quality control, standardization, and regulatory aspects of herbal products.
CO 4. Evaluate pharmacological and toxicological data of phytochemicals.
CO 5. Apply scientific knowledge for formulation and clinical use of phytopharmaceuticals.

Source, phytochemistry (isolation, identification, chemical nature), and physiological activities of following phytopharmaceuticals.

UNIT - I

1) Anticancer: Taxol, other taxanes, Camptothecin, vinblastine, Genistein, Etoposide

UNIT - II

2) Nervous system activities: Hypericin, Valepotriates, Gingkolides
3) CVS activities: Colenol, Streptokinase

UNIT - III

4) Anti-inflammatory: Curcuminoids, Guggulipids, Boswellic acid, Serratiopeptidase.

UNIT - IV

5) Miscellaneous: Silymarin, Artemisinin, Omega-3 fatty acids. Charantin and momordicosides, Resveretrol, Protamine sulphate, prostaglandins.

UNIT - V

Occurrence, isolation and characteristic features (Chemical nature, uses in pharmacy, medicinal and health benefits) of following.

a) Carotenoids – i) α and β - Carotene ii) Xanthophyll (Lutein)
b) Limonoids – i) d-Limonene ii) α – Terpineol
c) Saponins – i) Shatavarins
d) Flavonoids – i) Resveratrol ii) Rutin iii) Hesperidin iv) Naringin v) Quercetin
e) Phenolic acids- Ellagic acid
f) Tocotrienols and Tocopherols

TEXT BOOKS:

1. Pharmacognosy: Trease and Evans, Bailliere & Tindall, 14th edth.
2. Pharmacognosy: Kokate, Purohit, Gokhale, Nirali Prakashan, Pune, 15th edtn.
3. Biochemistry: Delvin
4. Alkaloids Edited by J.R.F. Manske
5. Various Research Journals on Natural products and therapeutics.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (PHARMACY PRACTICE)

ENGLISH FOR RESEARCH PAPER WRITING (Audit Course - I & II)

Prerequisite: None

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Plan and structure sentences and paragraphs, write concisely, and avoid ambiguity, redundancy, and vague expressions.
CO 2. Understand how to clearly present findings, paraphrase correctly, avoid plagiarism, and effectively write abstracts and introductions.
CO 3. Organize and write all sections of a research paper, including literature review, methods, results, discussion, and conclusions.
CO 4. Gain key skills for writing strong titles, abstracts, introductions, and literature reviews
CO 5. Develop skills to write methods, results, discussions, and conclusions effectively, using useful phrases and strategies for successful first-time submissions.

UNIT-I:
Planning and Preparation, Word Order, Breaking up long sentences, Structuring Paragraphs and Sentences, Being Concise and Removing Redundancy, Avoiding Ambiguity and Vagueness

UNIT-II:
Clarifying Who Did What, Highlighting Your Findings, Hedging and Criticizing, Paraphrasing and Plagiarism, Sections of a Paper, Abstracts. Introduction

UNIT-III:
Review of the Literature, Methods, Results, Discussion, Conclusions, The Final Check.

UNIT-IV:
key skills are needed when writing a Title, key skills are needed when writing an Abstract, key skills are needed when writing an Introduction, skills needed when writing a Review of the Literature,

UNIT-V:
skills are needed when writing the Methods, skills needed when writing the Results, skills are needed when writing the Discussion, skills are needed when writing the Conclusions. useful phrases, how to ensure paper is as good as it could possibly be the first- time submission

TEXT BOOKS/ REFERENCES:

1. Goldbort R (2006) Writing for Science, Yale University Press (available on Google Books)
2. Day R (2006) How to Write and Publish a Scientific Paper, Cambridge University Press
3. Highman N (1998), Handbook of Writing for the Mathematical Sciences, SIAM. Highman's book.
4. Adrian Wallwork, English for Writing Research Papers, Springer New York Dordrecht Heidelberg London, 2011
5. Academic Writing,Ajay Semalty, Pharmamed Press

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (PHARMACY PRACTICE)

DISASTER MANAGEMENT (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- learn to demonstrate a critical understanding of key concepts in disaster risk reduction and humanitarian response.
- critically evaluate disaster risk reduction and humanitarian response policy and practice from multiple perspectives.
- develop an understanding of standards of humanitarian response and practical relevance in specific types of disasters and conflict situations.
- critically understand the strengths and weaknesses of disaster management approaches,
- planning and programming in different countries, particularly their home country or the countries they work in

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the concepts, types, and impact of natural and man-made disasters.
CO 2. Describe the economic, environmental, and social repercussions of various disasters.
CO 3. Discuss disaster preparedness, monitoring, and community participation methods.
CO 4. Evaluate disaster risk assessment techniques and strategies for risk reduction.
CO 5. Summarize mitigation strategies and programs implemented for disaster management in India.

UNIT-I:

Introduction:

Disaster: Definition, Factors and Significance; Difference Between Hazard and Disaster; Natural and Manmade Disasters: Difference, Nature, Types and Magnitude.

Disaster Prone Areas in India:

Study of Seismic Zones; Areas Prone to Floods and Droughts, Landslides and Avalanches; Areas Prone to Cyclonic and Coastal Hazards with Special Reference to Tsunami; Post-Disaster Diseases and Epidemics

UNIT-II:

Repercussions of Disasters and Hazards:

Economic Damage, Loss of Human and Animal Life, Destruction of Ecosystem. Natural Disasters: Earthquakes, Volcanisms, Cyclones, Tsunamis, Floods, Droughts and Famines, Landslides and Avalanches, Man-made disaster: Nuclear Reactor Meltdown, Industrial Accidents, Oil Slicks and Spills, Outbreaks of Disease and Epidemics, War and Conflicts.

UNIT-III:

Disaster Preparedness and Management:

Preparedness: Monitoring of Phenomena Triggering A Disaster or Hazard; Evaluation of Risk: Application of Remote Sensing, Data from Meteorological and Other Agencies, Media Reports: Governmental and Community Preparedness.

UNIT-IV:

Risk Assessment Disaster Risk:

Concept and Elements, Disaster Risk Reduction, Global and National Disaster Risk Situation. Techniques of Risk Assessment, Global Co-Operation in Risk Assessment and Warning, People's Participation in Risk Assessment. Strategies for Survival.

UNIT-V:

Disaster Mitigation:

Meaning, Concept and Strategies of Disaster Mitigation, Emerging Trends In Mitigation. Structural Mitigation and Non-Structural Mitigation, Programs of Disaster Mitigation in India.

TEXT BOOKS/ REFERENCES:

1. Disaster Management: Hazard and Risk Awareness – A Comprehensive Approach, N. V. S. Raju,BS Publications
2. Sahni, Pardeep Et. Al. (Eds.)," Disaster Mitigation Experiences and Reflections", Prentice Hall of India, New Delhi.
3. Goel S. L., Disaster Administration and Management Text and Case Studies", Deep &Deep Publication Pvt. Ltd., New Delhi.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (PHARMACY PRACTICE)

SANSKRIT FOR TECHNICAL KNOWLEDGE (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To get a working knowledge in illustrious Sanskrit, the scientific language in the world
- Learning of Sanskrit to improve brain functioning
- Learning of Sanskrit to develop the logic in mathematics, science & other subjects enhancing the memory power
- The engineering scholars equipped with Sanskrit will be able to explore the huge knowledge from ancient literature

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Recognize and pronounce Sanskrit alphabets correctly.
CO 2. Form simple sentences using basic tenses in Sanskrit.
CO 3. Understand the roots and grammatical order in Sanskrit.
CO 4. Identify technical information in Sanskrit literature.
CO 5. Relate Sanskrit concepts to modern engineering and scientific fields.

UNIT-I:
Alphabets in Sanskrit,

UNIT-II:
Past/Present/Future Tense, Simple Sentences

UNIT-III:
Order, Introduction of roots,

UNIT-IV:
Technical information about Sanskrit Literature

UNIT-V:
Technical concepts of Engineering-Electrical, Mechanical, Architecture, Mathematics

TEXT BOOKS/ REFERENCES:

1. “Abhyaspustakam” – Dr. Vishwas, Samskrita-Bharti Publication, New Delhi
2. “Teach Yourself Sanskrit” Prathama Deeksha-Vempati Kutumbshastri, Rashtriya Sanskrit Sansthanam, New Delhi Publication
3. “India’s Glorious Scientific Tradition” Suresh Soni, Ocean books (P) Ltd., New Delhi.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (PHARMACY PRACTICE)

VALUE EDUCATION (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to

- Understand value of education and self- development
- Imbibe good values in students
- Let the should know about the importance of character

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the role of values and ethics in self and social development.
CO 2. Demonstrate the importance of cultivating moral and human values.
CO 3. Develop positive thinking and integrity for personal growth.
CO 4. Practice tolerance, cooperation, and love for nature.
CO 5. Apply principles of self-management, honesty, and good health for character building.

UNIT-I:
Values and self-development –Social values and individual attitudes. Work ethics, Indian vision of humanism. Moral and non- moral valuation. Standards and principles. Value judgements

UNIT-II:
Importance of cultivation of values. Sense of duty. Devotion, Self-reliance. Confidence, Concentration. Truthfulness, Cleanliness. Honesty, Humanity. Power of faith, National Unity. Patriotism. Love for nature, Discipline

UNIT-III:
Personality and Behavior Development - Soul and Scientific attitude. Positive Thinking. Integrity and discipline, Punctuality, Love and Kindness.

UNIT-IV:
Avoid fault Thinking. Free from anger, Dignity of labour. Universal brotherhood and religious tolerance. True friendship. Happiness Vs suffering, love for truth. Aware of self-destructive habits. Association and Cooperation. Doing best for saving nature

UNIT-V:
Character and Competence –Holy books vs Blind faith. Self-management and Good health. Science of reincarnation, Equality, Nonviolence, Humility, Role of Women. All religions and same message. Mind your Mind, Self-control. Honesty, Studying effectively

TEXT BOOKS/ REFERENCES:

1. Chakroborty, S.K. “Values and Ethics for organizations Theory and practice”, Oxford University Press, New Delhi
2. Indian Culture Values and Professional Ethics, P. S. R. Murty,BS Publications

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (PHARMACY PRACTICE)

CONSTITUTION OF INDIA (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Understand the premises informing the twin themes of liberty and freedom from a civil rights perspective.
- To address the growth of Indian opinion regarding modern Indian intellectuals' constitutional role and entitlement to civil and economic rights as well as the emergence of nationhood in the early years of Indian nationalism.
- To address the role of socialism in India after the commencement of the Bolshevik Revolution in 1917 and its impact on the initial drafting of the Indian Constitution.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Describe the history, philosophy, and salient features of the Indian Constitution.
CO 2. Explain the fundamental rights, duties, and directive principles of state policy.
CO 3. Discuss the structure and functions of various organs of governance.
CO 4. Analyze the role of local administration and importance of grassroot democracy.
CO 5. Summarize the role and functioning of the Election Commission and welfare bodies.

UNIT-I:
History of Making of the Indian Constitution: History Drafting Committee, (Composition & Working), **Philosophy of the Indian Constitution:** Preamble**,** Salient Features.

UNIT-II:
Contours of Constitutional Rights & Duties: Fundamental Rights Right to Equality**,** Right to Freedom**,** Right against Exploitation**,** Right to Freedom of Religion**,** Cultural and Educational Rights**,** Right to Constitutional Remedies, Directive Principles of State Policy**,** Fundamental Duties.

UNIT-III:
Organs of Governance: Parliament**,** Composition**,** Qualifications and Disqualifications**,** Powers and Functions**,** Executive**,** President**,** Governor**,** Council of Ministers, Judiciary, Appointment and Transfer of Judges, Qualification, Powers and Functions.

UNIT-IV:
Local Administration: District's Administration head: Role and Importance, Municipalities: Introduction, Mayor and role of Elected Representative, CEO of Municipal Corporation. Pachayati raj: Introduction, PRI: Zila Pachayat. Elected officials and their roles, CEO Zila Pachayat: Position and role. Block level: Organizational Hierarchy (Different departments), Village level: Role of Elected and Appointed officials, Importance of grass root democracy.

UNIT-V:
Election Commission: Election Commission: Role and Functioning. Chief Election Commissioner and Election Commissioners. State Election Commission: Role and Functioning. Institute and Bodies for the welfare of SC/ST/OBC and women.

TEXT BOOKS/ REFERENCES:

1. The Constitution of India, 1950 (Bare Act), Government Publication.
2. Dr. S. N. Busi, Dr. B. R. Ambedkar framing of Indian Constitution, 1st Edition, 2015.
3. M. P. Jain, Indian Constitution Law, 7th Edn., Lexis Nexis, 2014.
4. D.D. Basu, Introduction to the Constitution of India, Lexis Nexis, 2015.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (PHARMACY PRACTICE)

PEDAGOGY STUDIES (Audit Course - I & II)

Prerequisite: None

Course Objectives: Students will be able to:

- Review existing evidence on the review topic to inform programme design and policy making undertaken by the DfID, other agencies and researchers.
- Identify critical evidence gaps to guide the development.

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Understand the theories of learning and research methodologies in pedagogy.
CO 2. Describe pedagogical practices used in formal and informal learning environments.
CO 3. Evaluate the effectiveness of teaching methods and teacher education programs.
CO 4. Explain the importance of professional development and support systems for teachers.
CO 5. Identify research gaps and future directions in pedagogy and education systems.

UNIT-I:

Introduction and Methodology: Aims and rationale, Policy background, Conceptual framework and terminology Theories of learning, Curriculum, Teacher education. Conceptual framework, Research questions**.** Overview of methodology and Searching.

UNIT-II:

Thematic overview: Pedagogical practices are being used by teachers in formal and informal classrooms in developing countries. Curriculum, Teacher education.

UNIT-III:

Evidence on the effectiveness of pedagogical practices, Methodology for the indepth stage: quality assessment of included studies. How can teacher education (curriculum and practicum) and the scho curriculum and guidance materials best support effective pedagogy? Theory of change. Strength and nature of the body of evidence for effective pedagogical practices. Pedagogic theory and pedagogical approaches. Teachers' attitudes and beliefs and Pedagogic strategies.

UNIT-IV:

Professional development: alignment with classroom practices and follow-up support, Peer support, Support from the head teacher and the community. Curriculum and assessment, Barriers to learning: limited resources and large class sizes

UNIT-V:

Research gaps and future directions: Research design**,** Contexts**,** Pedagogy**,** Teacher education**,** Curriculum and assessment**,** Dissemination and research impact.

TEXT BOOKS/ REFERENCES:

1. Ackers J, Hardman F (2001) Classroom interaction in Kenyan primary schools, Compare, 31 (2): 245-261.
2. Agrawal M (2004) Curricular reform in schools: The importance of evaluation, Journal of Curriculum Studies, 36 (3): 361-379.
3. Akyeampong K (2003) Teacher training in Ghana - does it count? Multi-site teacher education research project (MUSTER) country report 1. London: DFID.

4. Akyeampong K, Lussier K, Pryor J, Westbrook J (2013) Improving teaching and learning of basic maths and reading in Africa: Does teacher preparation count? International Journal Educational Development, 33 (3): 272–282.
5. Alexander RJ (2001) Culture and pedagogy: International comparisons in primary education. Oxford and Boston: Blackwell.
6. Chavan M (2003) Read India: A mass scale, rapid, 'learning to read' campaign.
7. www.pratham.org/images/resource%20working%20paper%202.pdf.

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (PHARMACY PRACTICE)

STRESS MANAGEMENT BY YOGA (Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To achieve overall health of body and mind
- To overcome stress

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Explain the eight components (Ashtanga) of yoga and their significance.
CO 2. Describe the principles of Yam and Niyam in daily life.
CO 3. Apply ethical and moral disciplines (Do's and Don'ts) for mental well-being.
CO 4. Demonstrate various Asanas and Pranayama techniques.
CO 5. Analyze the benefits of yoga poses and breathing practices on mind and body.

UNIT-I:
Definitions of Eight parts of yog. (Ashtanga)

UNIT-II:
Yam and Niyam.

UNIT-III:
Do`s and Don't's in life.
i) Ahinsa, satya, astheya, bramhacharya and aparigraha
ii) Shaucha, santosh, tapa, swadhyay, ishwarpranidhan

UNIT-IV:
Asan and Pranayam

UNIT-V:
i) Various yog poses and their benefits for mind & body
ii) Regularization of breathing techniques and its effects-Types of pranayam

TEXT BOOKS/ REFERENCES:

1. 'Yogic Asanas for Group Tarining-Part-I": Janardan Swami Yogabhyasi Mandal, Nagpur
2."Rajayoga or conquering the Internal Nature" by Swami Vivekananda, Advaita Ashrama (Publication Department), Kolkata

SULTAN-UL-ULOOM COLLEGE OF PHARMACY HYDERABAD
M.Pharm (PHARMACY PRACTICE)

PERSONALITY DEVELOPMENT THROUGH LIFE ENLIGHTENMENT SKILLS
(Audit Course - I & II)

Prerequisite: None

Course Objectives:

- To learn to achieve the highest goal happily
- To become a person with stable mind, pleasing personality and determination
- To awaken wisdom in students

Course Outcomes: Upon completion of the course a learner shall be able to

CO 1. Interpret Neetishatakam verses for wisdom, virtue, and personality development.
CO 2. Apply moral guidance from Neetishatakam to everyday conduct.
CO 3. Understand the teachings of Bhagavad Gita for performing duties with discipline.
CO 4. Relate basic philosophical knowledge from Gita to self-awareness and attitude.
CO 5. Develop enlightened personality traits based on spiritual and ethical values.

UNIT-I:

Neetisatakam-Holistic development of personality

- Verses- 19,20,21,22 (wisdom)
- Verses- 29,31,32 (pride & heroism)
- Verses- 26,28,63,65 (virtue)

UNIT-II:

Neetisatakam-Holistic development of personality

- Verses- 52,53,59 (dont's)
- Verses- 71,73,75,78 (do's)

UNIT-III:

Approach to day to day work and duties.

- Shrimad Bhagwad Geeta: Chapter 2-Verses 41, 47,48,
- Chapter 3-Verses 13, 21, 27, 35, Chapter 6-Verses 5,13,17, 23, 35,
- Chapter 18-Verses 45, 46, 48.

UNIT-IV:

Statements of basic knowledge.

- Shrimad Bhagwad Geeta: Chapter2-Verses 56, 62, 68
- Chapter 12 -Verses 13, 14, 15, 16,17, 18
- Personality of Role model. Shrimad Bhagwad Geeta:

UNIT-V:

- Chapter2-Verses 17, Chapter 3-Verses 36,37,42,
- Chapter 4-Verses 18, 38,39
- Chapter18 – Verses 37,38,63

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