# R19 COURSE STRUCTURE AND SYLLABUS Effective from Academic Year 2019-20 Admitted Batch

# I YEAR I Semester

Course Code	Course Title	L	T	Р	Credits
Professional	Pharmacotherapeutics – I	3	0	0	3
Core-I					
Professional	Clinical Pharmacy Practice	3	0	0	3
Core-II					
Professional	Clinical Toxicology	3	0	0	3
Elective-I	2. Hospital and Community Pharmacy				
	3. Clinical Research and Pharmacovigilance				
Professional	Molecular Biology	3	0	0	3
Elective-II	Advances in Preclinical Evaluation				
	Drug Regulatory Affairs				
MC	Research methodology and IPR	2	0	0	2
Laboratory-I	Pharmacotherapeutics – I Lab	0	0	4	2
Laboratory-II	Clinical Pharmacy Practice Lab	0	0	4	2
Audit	Audit Course - I	2	0	0	0
	TOTA	L 16	0	8	18

# I YEAR II Semester

Course Code	Course Title	L	Т	Р	Credits
Professional	Pharmacotherapeutics – II	3	0	0	3
Core-III					
Professional	Clinical Pharmacokinetics and Drug monitoring	3	0	0	3
Core-IV					
Professional	Biopharmaceutics and Pharmacokinetics	3	0	0	3
Elective-III	2. Clinical Research				
	3. Quality use of Medicines				
Professional	Principles of Drug Discovery	3	0	0	3
Elective-IV	Cellular and molecular pharmacology				
	3. Nutraceuticals				
Laboratory- III	Pharmacotherapeutics – II Lab	0	0	4	2
Laboratory- IV	Clinical Pharmacokinetics and Drug monitoring Lab	0	0	4	2
	Mini Project with Seminar	2	0	0	2
Audit	Audit Course- II	2	0	0	0
	Total	16	0	8	18

# Audit Courses 1 & 2

- 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

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY 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:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence-based medicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s). Etiopathogenesis and pharmacotherapy of diseases associated with following systems

#### 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

#### **REFERENCES:**

- 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

#### **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:

- Understand the elements of pharmaceutical care and provide comprehensive patient care services
- Interpret the laboratory results to aid the clinical diagnosis of various disorders
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

#### **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 & Poison 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. Poison Information Service: Definition, need, organization and functions of poison information centre.

#### **REFERENCES**

- 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. Relevant review articles from recent medical and pharmaceutical literature

### 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 handling the first aid, elimination enhancement and treatment of poisoning and supportive care in poisoning due to

- Pesticides
- Drug over usage
- Heavy metals
- Radiation
- Snakes and anthropod bites
- Food poisoning

The student also gains knowledge in substance abuse and treatment of drug dependence.

#### **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

# **REFERENCES:**

1. Matthew j ellenhorn. Ellenhorns medical toxicology – diagnosis and treatment of poisoning. Second edition. Williams and willkins publication, london b.

2. V V Pillay. Handbook of forensic medicine and toxicology. Thirteenth edition 2003 paras publication, Hyderabad

# **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:

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals □ Understand the community pharmacy management
- Know about value added services in community pharmacies

#### 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

# **REFERENCES**

- 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 MPP Ramesh Adepu, BSP Publishers, Hyderabad
- 5. Remington Pharmaceutical Sciences.
- 6. Relevant review articles from recent medical and pharmaceutical literature

#### 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;

- explain the regulatory requirements for conducting clinical trial
- Demonstrate the types of clinical trial designs
- Explain the responsibilities of key players involved in clinical trials
- · Execute safety monitoring, reporting and close-out activities
- Explain the principles of Pharmacovigilance
- Detect new adverse drug reactions and their assessment
- Perform the adverse drug reaction reporting systems and communication in 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 centres 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.

#### **REFERENCES:**

- 1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- 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

# **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, know about total molecular biology with structures, chromosomes arrangement, the processes occur in cell, synthesis and processing of prokaryotic and eukaryotic transcripts. Transport of RNA within eukaryotic cell. Regulatory elements of genes-promoters.

#### 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 5

**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.

### **REFERENCES:**

- 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.

# 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:

- Understand the care and handling experimental animals
- Understand drug rules and regulations for conducting animal studies
- Know about preclinical & clinical studies of different ANS drugs and their models.

#### 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, ED 50, LD50 and TD values, acute, sub-acute and chronictoxicity studies.

#### **REFERENCES**

- 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. Guta
- 10. Handbook of Experimental Pharmacology, S K. Kulkarni

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

#### **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:**

- Students will come to know the different competent regulatory authorities globally.
- Students be aware of technical aspects pertaining to the marketing authorization application (MAA)
- The regulatory guidelines and directions framed by the regulatory authorities will be helpful to place the drug products in market for marketing approvals.

#### **UNIT I**

# **Drug Regulatory Aspects (India)**

- 1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA)
- 2. Drugs and Cosmmetics 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 Management, Effluent etc.)
- 5. Quality Assurance and Qulaity Control Basic understanding for in-built quality.

#### **UNIT III**

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

# **UNIT IV**

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 Directorate DMF
- 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. Pharmaceutical Regulatory Affairs Selected Topics , CVS Subramanyam and J Thimmasetty, Vallabh Prakashan Delhi 2013

#### 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: At the end of this course, students will be able to

- Understand research problem formulation.
- Analyze research related information
- Follow research ethics
- Understand that today's world is controlled by Computer, Information Technology, but tomorrow world will be ruled by ideas, concept, and creativity.
- 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.
- 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"

#### **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

# PHARMACOTHERAPEUTICS- LAB - I (Laboratory -1)

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.

- 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.

# **REFERENCES:**

- 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

# **CLINICAL PHARMACY PRACTICE- LAB (Laboratory-2)**

# **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)

### **REFERENCES**

- 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

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

Prerequisite: None

Course objectives: Students will be able to:

- Understand that how to improve your writing skills and level of readability
- Learn about what to write in each section
- Understand the skills needed when writing a Title Ensure the good quality of paper at very first-time submission

#### 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

- 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

#### **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

# 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.

- 1. R. Nishith, Singh AK, "Disaster Management in India: Perspectives, issues and strategies "New Royal book Company.
- 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.

# 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: Students will be able to

- Understanding basic Sanskrit language
- Ancient Sanskrit literature about science & technology can be understood
- Being a logical language will help to develop logic in students

# 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

- 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.

# **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: Students will be able to

- · Knowledge of self-development
- Learn the importance of Human values
- Developing the overall personality

#### 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

#### **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: Students will be able to:

- Discuss the growth of the demand for civil rights in India for the bulk of Indians before the arrival of Gandhi in Indian politics.
- Discuss the intellectual origins of the framework of argument that informed the conceptualization of social reforms leading to revolution in India.
- Discuss the circumstances surrounding the foundation of the Congress Socialist Party [CSP]
  under the leadership of Jawaharlal Nehru and the eventual failure of the proposal of direct
  elections through adult suffrage in the Indian Constitution.
- Discuss the passage of the Hindu Code Bill of 1956.

#### 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.

- 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.

# 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: Students will be able to understand:

- What pedagogical practices are being used by teachers in formal and informal classrooms in developing countries?
- What is the evidence on the effectiveness of these pedagogical practices, in what conditions, and with what population of learners?
- How can teacher education (curriculum and practicum) and the school curriculum and guidance materials best support effective pedagogy?

#### 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.

- 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.

# 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: Students will be able to:

- Develop healthy mind in a healthy body thus improving social health also
- Improve efficiency

# 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

- 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

# 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: Students will be able to

- Study of Shrimad-Bhagwad-Geeta will help the student in developing his personality and achieve the highest goal in life
- The person who has studied Geeta will lead the nation and mankind to peace and prosperity
- Study of Neetishatakam will help in developing versatile personality of students

#### 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

- "Srimad Bhagavad Gita" by Swami Swarupananda Advaita Ashram (Publication Department), Kolkata.
- 2. Bhartrihari's Three Satakam (Niti-sringar-vairagya) by P.Gopinath, Rashtriya Sanskrit Sansthanam, New Delhi.