

**PHARMACOLOGY AND TOXICOLOGY**  
**M. S. (Pharm.)**

Course no.	Course Name	Credit hrs
<b>Semester I</b>		
<b>CORE SUBJECTS (ALL COMPULSORY)</b>		
PC-510	Pathophysiology	1
PC-520	General Pharmacology	2
PC-530	Experimental Pharmacology	1
PC-540	Drug Metabolism	1
PE-520	Biopharmaceutics and Pharmacokinetics	2
GE-510	Biostatistics	2
GE-511	Seminar	0.5
LG-510	General Laboratory Experience	2.5
	<b>Total</b>	<b>12</b>
<b>ELECTIVE SUBJECTS (4 CREDITS)</b>		
EL-501	Biochemical Engineering Fundamentals	2
EL-502	Biotechnology in Pharmaceutical Sciences	1
EL-503	Microbiology	1
EL-504	Industrial safety and green chemistry	1
EL-505	Computer Application in Biomedical Engineering	1
EL-506	Biological System Analysis and Control	1
EL-507	Productivity in management and reengineering (Neha	1
EL-508	Biosynthesis of Natural Products	1
EL-509	Chemotherapy of Parasitic and Microbial Infections	1
	Choose any core courses of other department (BT/MC/MD/NP/PA/PE)	
	<b>Total Credits</b>	<b>16</b>
<b>Semester II</b>		
<b>CORE SUBJECTS (ALL COMPULSORY)</b>		
PC-610	Pharmacological Screening and Assays	1
PC-620	CNS and Respiratory Pharmacology	2
PC-630	Autonomic, CVS, Blood, Renal and GI Pharmacology	2
PC-640	Autacoid and Endocrine Pharmacology	1
PC-650	Clinical Pharmacology and Regulatory Toxicology	2
PC-660	Pharmacogenomics and Transgenic biology	1
GE-511	Seminar	0.5
LS-610	General Lab Experience in the Area of Specialization	2.5
	<b>Total</b>	<b>12</b>
<b>ELECTIVE SUBJECTS (4 CREDITS)</b>		
EL-601	Biomechanics	2
EL-602	Mathematical Methods in Biomedical Engineering	1
EL-603	Logistics & distribution	1

EL-604	Total quality control	1
EL-605	Lean system, 6 sigma	1
EL-606	Introduction to Ayurveda and Polyherbal Formulations	1
EL-607	Chemotherapy and Immunopharmacology	2
EL-608	Pharmacovigilance and Medical Writing	2
	Choose any core courses of other department (BT/MC/MD/NP/PA/PE)	
	<b>Total Credits</b>	<b>16</b>
<b>Semester III</b>		
TH- 598	Synopsis, Presentation	9
<b>Semester IV</b>		
TH-698	Thesis Writing and Thesis Defense	9
	<b>TOTAL CREDITS (I TO IV SEMESTERS)</b>	<b>50</b>

## Semester I

<b>PC510 Pathophysiology (1 Credit)</b>	hrs
Factors influencing the disease conditions such as sex, age, nutritional status, genetic makeup etc.	5
Pathogenesis, symptoms and signs, laboratory findings and complications of respiratory, urinary tract, venereal and meningeal infections, congestive heart failure, hypertension, cardiac arrhythmias, ulcer, pancreatitis, hepatitis and cholecystitis, bronchial asthma, depression, schizophrenia, epilepsy, parkinsonism and Alzheimer disease; Amyotrophic Lateral Sclerosis, Huntington's Disease, Tay Sachs Disease, hypo and hyper thyroidism, diabetes mellitus and other endocrine diseases; rheumatoid arthritis, gout and anemia.	15

### READING MATERIAL

1. Essentials of Pathophysiology: Concepts of Altered Health States ,Author: Carol M. Porth, Glenn Matfin, Publisher: Lippincott Williams & Wilkins
2. Handbook of Pathophysiology ,Author: Elizabeth J. Corwin, Publisher: Lippincott Williams & Wilkins
3. Pathophysiology: The Biologic Basis for Disease in Adults and Children , Author: Sue E, RN Huether, Kathryn L.,RN McCance, Valentina L. Brashers, Publisher: Mosby Inc

### Course outcomes:

**After the successful completion of the course, students should be able to:**

- a) Have the basic understanding and pathophysiological mechanisms of various diseases.
- b) Will understand the mechanism of progression of the disease pathology and strategies for intervention.
- c) Will have an idea of worldwide epidemiology of the diseases.

<b>PC 520 - General Pharmacology (2 Credits)</b>	<b>hrs</b>
Drug receptor interaction theories, occupation theory, rate theory	4
Receptor occupation and response relationship, spare receptors, silent receptors, orphan receptors, presynaptic and postsynaptic receptors.	5
Receptor subtypes, IUPHAR nomenclature, clinical significance of receptor subclassification, receptor characterization methods (pharmacological characterization, radioligand methods and monoclonal antibodies).	5
Receptor down regulation and upregulation	4
Structure activity relationships, pharmacodynamic and pharmacokinetic aspects of chiral drugs, allosteric binding and thermodynamics of drug interactions with the receptors.	4
Transmembrane signal mechanisms, second messengers, viz., cAMP, cGMP, calcium.	4
Dose response relationship and different types of antagonisms.	4
Desensitization and tachyphylaxis.	3
Drug dependence and withdrawal responses.	3
Non-therapeutic uses of drugs	4

### **READING MATERIAL**

1. Essentials of Medical Pharmacology-Background for Drug Design, Author: Andrejus Korolkovas, Wiley-Interscience
2. Essentials of Medical Pharmacology, K.D. Tripathi, Jaypee publications
3. Goodman & Gilman's The pharmacological Basis of Therapeutics, Publisher: Mc-Graw Hills

### **Course outcomes:**

**After the successful completion of the course, students should be able to:**

- a) Understand the different aspects of receptors and their involvement in drug action.
- b) Understand the cellular signaling mechanisms elicited due to a drug.
- c) Demonstrate the importance of pharmacological characterization of receptors.

<b>PC-530 - Experimental Pharmacology (1 Credit)</b>	<b>hrs</b>
Common laboratory animals and their physiological parameters, breeding types, inbred strains, F1 hybrids; Random breeding, selective breeding, breeding methods, factors affecting the nature and degree of pharmacological responses; Handling and care of different animals; bleeding and different routes of administration and chemicaleuthanasia.	3
<b>In vitro experimentation:</b> Advantages and disadvantages; Physiological salt solutions, recording transducers, resting tensions, equilibrium, dose cycles; methods of stimulation, stimulating devices, operation of recording devices, superfusion, cascade superfusion, perfusion, some commonly used isolated preparations	3
<b>In vivo experimentation:</b> Advantages and disadvantages; anesthesia used in laboratory animals, common agents, dose calculations, cannulation methodology, ventilation rate, recording of arterial blood pressure, intestinal motility etc.	2
Conscious animal experimentation precautions to be taken in behavioral experiments.	1
<b>Animal cell-culture techniques:</b> Aseptic handling, cell counting and cell viability assays.	1
<b>Protein and DNA gel electrophoresis:</b> Western, northern, southern blot hybridization and PCR techniques.	2
<b>Ultra, differential and analytical centrifugation:</b> Protein purification and identification by RF-HPLC, LCMS-MS, MALDI	2
<b>Radiochemical methods of analysis:</b> Principle of radiation and radioactivity, decay of radioactivity, units, isotopes detection, scintillation detector (crystal and liquid), quenching, radioimmunoassay.	2
<b>Drug solution preparations:</b> Storage, concentration expression, common solvents, stabilizing agents, storage conditions, reference standards, methods of procurement of reference standards	2
Data collection, data reduction, data representation, cumulative and noncumulative dose response curves, transformation of data logit, probit, pA scale, pD scale.	2

## READING MATERIAL

1. Handbook of Experimental Pharmacology, Editor-in-chief: Hofmann, Franz B. Series Editors: Ganten, D., Page, C.P., Rosenthal, W., Michel, M.C., Beavo, J. A., Busch, A., Karlsson, J. A., Publisher: Springer.
2. Practical Pharmacology and Clinical Pharmacy, Author: S K Kulkarni , Publisher: Vallabh Prakashan
3. Current Protocols in Molecular Biology, Author: Frederick M. Ausubel, Roger Brent, Robert E. Kingston, David D. Moore, J.G. Seidman, John A. Smith, Kevin Struhl, Publisher: John Wiley & Sons, Inc.
4. Practical Biochemistry: Principles and Techniques, Fifth Edition – 2005, A. K. Wilson and J. Walker
5. Experimental Biochemistry, Third Edition – 1999, R. L. Switzer and L. F. Garriety, W. H. Freeman and Company

## Course outcomes:

After the successful completion of the course, students should be able to:

- a) Students will know the different proteomic and genomic techniques used in pre-clinical investigation and drug development.
- b) They will be able to propose the experimental approaches to test and analyse the drugs.
- c) They will know the basics of radioactivity and their functional applications in imaging.

d) Students will know the dose calculations, dose conversion in pre-clinical settings.

<b>PC 540 - Drug Metabolism (1 Credit)</b>	<b>hrs</b>
Biotransformation of drugs.	2
Enzymes responsible for bio-transformations: microsomal and non-microsomal mechanisms.	2
Factors influencing enzyme induction and inhibition.	2
Factors affecting drug metabolism.	2
Drug metabolism in fetus and new born.	2
Models to study drug metabolism.	2
Dose effect relationships.	1
Excretion of drugs, biliary and fecal excretion.	2
Adverse drug reactions and drug interactions; Toxic reactions, allergic reactions, idiosyncrasy.	3
Acute poisoning and its treatment	2

### **READING MATERIAL**

1. Biopharmaceutics and Pharmacokinetics – A Treatise, 1995, D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan
2. Drug Interactions, 1989, Philip D. Hansten, Lea and Febiger, Philadelphia

### **Course outcomes:**

**After the successful completion of the course, students should be able to:**

- a) The student's will have the knowledge of drug metabolism and its importance in drug pharmacokinetics and toxicity determination.
- b) The students will know the basics of drug metabolism studies in preclinical and clinical conditions.
- c) The course will help the students to perform the pharmacokinetics studies of novel drugs.

## Semester II

### PC-610

<b>Pharmacological Screening and Assays (1 Credit)</b>	<b>hrs</b>
General principles of screening, correlations between various animal models and human situations, animal ethics	6
Pharmacological screening models for therapeutic areas such as Hypertension, Cerebrallschaemia, Pain, Epilepsy, Depression, Parkinson's disease, Alzheimer's disease, Diabetes, Leishmaniasis	6
Correlation between <i>in-vitro</i> and <i>in-vivo</i> screens; Special emphasis on cell-based assay, biochemical assay, radioligand binding assay, high through put screening, high through put pharmacokinetic analysis, specific use of reference drugs and interpretation of results	8

#### READING MATERIAL

1. Drug discovery and evaluation pharmacological assays Hans Gerhard Vogel, Springer.
2. CPCSEA Guidelines

#### Course outcomes:

**After the successful completion of the course, students should be able to:**

- a) The students will learn rational behind selection of animal species or strain for pre-clinical studies.
- b) They will learn the basics of screening of drugs pre-clinically and their comparison with standard drugs.
- c) They will also have the knowledge of rationale behind development of animal models of different diseases.

## PC-620

<b>CNS and Respiratory Pharmacology (2 Credits)</b>	<b>hrs</b>
<b>Chemical transmission and drug action in the central nervous system: CNS drug discovery and challenges.</b>	4
<b>Neurotransmitters:</b> Dopamine, 5-HT, excitatory amino acids, GABA, glycine peptides as mediators.	4
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of: Benzodiazepines and its antagonists. Barbiturates, local anesthetics.	3
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of: 5-HT agonists and antagonists, tricyclic antidepressants, MAOI, atypical antidepressants, lithium.	3
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of anti-epileptics.	3
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in the treatment of Parkinsonism.	4
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of centrally acting muscle relaxants	4
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of narcotic analgesics.	4
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of psychomotor stimulants and psychotomimetic drugs, antipsychotic drugs.	4
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in Alzheimer's disease.	3
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of: respiratory stimulants, bronchodilators and anti-inflammatory agents used in asthma, cough suppressants.	4

### READING MATERIAL

1. Essentials of Medical Pharmacology, K.D. Tripathi, Jaypee publications
2. Goodman & Gilman's The pharmacological Basis of Therapeutics, Publisher: Mc-Graw Hills
3. Lipincott's Illustrated reviews: Pharmacology.

### Course outcomes:

**After the successful completion of the course, students should be able to:**

- a) Understand the action of drugs used in CNS, and Respiratory system.
- b) Students will gain knowledge of the pharmacodynamic and pharmacokinetics aspects of the drugs used for CNS, and Respiratory system.
- c) Students will also have an understanding of the therapeutic and toxicological facets of different drugs targeting CNS, and Respiratory system.



### PC-630

<b>Autonomic, CVS, Blood, Renal, and GI Pharmacology (2 Credits)</b>	<b>hrs</b>
Chemical transmission of the autonomic nervous system	4
<b>Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of the following</b>	
Muscarinic cholinergic receptor agonists and antagonists, Ganglionic stimulants and blocking agents, neuromuscular blocking agents, drugs acting on adrenoreceptors.	5
<b>Drugs acting on Cardiovascular system:</b> Cardiac glycosides and other cardiotonic agents, Anti dysrhythmic drugs, antianginal drugs, Anti-hypertensives (Calcium channel antagonists, ACE inhibitors, endothelium derived relaxing factors, lipid lowering agents)	8
<b>Drugs acting on Renal system:</b> Diuretics (drug altering the pH of urine, excretion of organic molecules)	3
<b>Oral anticoagulants:</b> Factors increase/decrease the efficacy of oral anticoagulants, heparin.	4
<b>Platelet adhesion and activation:</b> Antiplatelet agents, thrombolytic agents and antifibrinolytic agents and hemostatic agents.	4
<b>Factors necessary for erythropoiesis:</b> Hemopoietic growth factors.	4
<b>Drugs acting on the GI system:</b> H <sub>2</sub> receptor antagonists, proton pump inhibitors, antacids, emetics, antiemetics, and purgatives, Chologogues and drugs used in cholelithiasis.	8

#### READING MATERIAL

1. Essentials of Medical Pharmacology, K.D. Tripathi, Jaypee publications
2. Goodman & Gilman's The pharmacological Basis of Therapeutics, Publisher: Mc-Graw Hills
3. Lipincott's Illustrated reviews: Pharmacology

#### Course outcomes:

**After the successful completion of the course, students should be able to:**

- a) Understand the action of drugs used in CVS, ANS, Renal and GI system.
- b) Students will gain knowledge of the pharmacodynamic and pharmacokinetics aspects of the drugs targeting CVS, ANS, Renal and GI system
- c) Students will learn in detail about the toxicological profiles of different drugs.

### PC-640

<b>Autacoids and Endocrine Pharmacology (1 Credit)</b>	<b>hrs</b>
Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of the following: Histamine and bradykinin agonist and antagonists.	2
Drugs acting through eicosanoids and platelet activating factor.	2
Adrenocortical hormones: Adrenocortical steroids and inhibitors of the synthesis.	2

Agents affecting the calcification, estrogens and progesterone and their antagonists.	2
Adenohypophyseal hormones and related substances.	2
Thyroid and antithyroid drugs.	2
Insulin and oral hypoglycemic agents.	2
Endocrine pancreas	2
Oral contraceptive.	2
Androgens.	2

### **READING MATERIAL**

1. Essentials of Medical Pharmacology, K.D. Tripathi, Jaypee publications
2. Goodman & Gilman's The pharmacological Basis of Therapeutics, Publisher: Mc-Graw Hills
3. Lipincott's Illustrated reviews: Pharmacology

### **Course outcomes:**

**After the successful completion of the course, students should be able to:**

- a) Understanding the role of autocooids in maintain physiological and pathological functions.
- b) Students will gain knowledge of the pharmacodynamic and pharmacokinetics aspects of the drugs targeting modulating endocrine system.
- c) Student will be able to co-relate and extrapolate the response cause by autocooids.

**PC-650**

<b>Clinical Pharmacology and Regulatory Toxicology (2 Credits)</b>	<b>hrs</b>
<b>Introduction to clinical pharmacology:</b> Importance of clinical pharmacokinetics, therapeutic monitoring of important drugs.	2
<b>Drug-drug interactions:</b> Drug-food interactions; Drug-pollutant interaction.	2
Investigational new drug application, new drug application requirements; FDA requirements.	2
Preclinical testing strategy; Vis a-vis envisaged clinical studies; Experimental clarification of possible human risk; Technical details of experiments; Flow chart for development of preclinical testing.	4
Design and organization of phase-I to phase-IV clinical studies.	2
<b>Single dose and repeat dose toxicity studies:</b> Factors influencing such studies such as species, sex, size, route, dose level; Data evaluation and regulatory requirements.	4
<b>Reproductive toxicology assessment:</b> Spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity; Alterations in reproductive endocrinology; Relationship between maternal and developmental toxicity.	4
<b>Mutagenicity:</b> Mechanisms of mutagenesis, point mutations; Individual chromosomes and complete genome mutations, germ cell mutations, somatic cell mutation; Tests systems <i>in vitro</i> , test for gene mutation in bacteria, chromosome damage, gene mutation, <i>in vivo</i> micronucleus tests in rodent, metaphase analysis.	4
<b>Carcinogenicity:</b> Principles of carcinogenicity, prechronic studies for dose setting, chronic study, transplacental carcinogenesis; Cocarcinogenesis/tumor promotion, estimation of carcinogenicity of complex mixtures.	4
<b>Toxicokinetics, animals and dose groups:</b> Exposure measurement; determination of metabolites complicating factors in exposure interpretation, analytical method, good laboratory practices; Stereiosomerism vis-a-vis regulatory requirements; Single enantiomers; Racemate enantiomer switch; Regulatory requirements.	4
<b>Toxicokinetic methods validation:</b> Assay development Assay validation, study	4
<b>Preclinical toxicological requirements for biologicals and biotechnological products:</b> safety analysis; problems specific to recombinant products-secondary pharmacology, antibodies, transmission of viral infections, residual DNA, etc.	4

**READING MATERIAL**

1. Basic & Clinical Pharmacology, Bertram G. Katzung, Publisher: LANGE Basic Science
2. Regulatory Toxicology, Shayne C Gad, Publisher: Taylor & Francis Inc
3. Regulatory Toxicology, Second Edition, Christopher P Changelis, Shayne Cox Gad, Joseph F Holson, Publisher: Informa Healthcare.

**Course outcomes:**

**After the successful completion of the course, students should be able to:**

- a) The students will know about different toxicity studies (Acute, chronic, carcinogenicity and reproductive toxicity) required to perform before the application of INDA or NDA application.
- b) The students will know about the toxicokinetics of the drugs.
- c) Students will learn different aspects of drug discovery process starting from drug design, preclinical studies, clinical studies, registration of the drug to different regulatory authorities to clinical trials.

<b>PC 660 Pharmacogenomics and Transgenic Biology (1 Credit)</b>	<b>hrs</b>
Pharmacogenomics in personalized medicine	2
Interactions between drugs (small molecules) and genes (proteins)	2
Methods for pharmacogenomic discovery	1
Applications of pharmacogenomics in clinical settings	1
Early mouse development, Isolation of zygotes, Isolation of blastocysts, Cryopreservation	2
Derivation of ES cells from blastocysts, Preparation of ES cells for blastocyst injection, Preparing ES cells for aggregation chimeras	2
Pronuclear injection, 2 cell injection, blastocyst injection, electroporation of zygotes and embryonic stem cell culture including transfection, selection, cloning and analysis of embryonic stem cell clones	2
Mutations and Types, genetic modifications, Potential and application of murine embryonic stem cells, Chimerism	2
CRISPR-gRNA Design, CRISPR/CAS9 system, TALEN	4
Methods for CRISPR Delivery, CRISPR Gene Editing Therapy and Screening	2

## **READING MATERIAL**

### **Text Books :**

1. Culture of animal cells, 5th edition, By Ian Freshney
2. Molecular cell Biology By Harvey Lodish
3. Molecular biology of gene By James D Watson

### **Recommended References :**

1. Cell and Molecular Biology by E.D.P Robertis.
2. Molecular Biotechnology: Principles and applications 3rd edition, By R Bernad Glick.

### **Course outcomes:**

**After the successful completion of the course, students should be able to:**

- a) Embrace the latest technology of gene editing to develop transgenic animal model for mimicking an actual disease pathology.
- b) Students will think to avoid duplication of existing animal lines.

- c) Students will learn to improve the reproducibility of studies and avoid unnecessary harm to experimental animals by conducting a comprehensive review of existing data, available models and alternative experimental approaches.

### EL-607

<b>Immunopharmacology and Chemotherapy (2 Credits)</b>	<b>hrs</b>
Introduction to immunopharmacology, immunomodulators, immunostimulants and immunosuppressants.	4
General considerations of antimicrobial agents.	4
Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the following: Quinolones, sulphonamides, penicillins, cephalosporins, clavulanic acid, aminoglycosides, broad spectrum antibiotics.	5
Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antiprotozoal agents.	5
Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antineoplastic agents.	4
Pathophysiology and Management of Dengue	4
Pathophysiology and management of Chicken Gunia	4
Pathophysiology and management of COVID 19	5
Pathophysiology and management of SARS, MERS	5

#### READING MATERIAL

1. Immunopharmacology, Khan, Manzoor M., Publisher: springer
2. Immunopharmacology, By Steven C. Gilman, Thomas J. Rogers, Publisher: the telford press INC.
3. Essentials of Medical Pharmacology, K.D. Tripathi, Jaypee publications
4. Goodman & Gilman's The pharmacological Basis of Therapeutics, Publisher: Mc-G

#### Course outcomes:

**After the successful completion of the course, students should be able to:**

- a) Students will gain the knowledge about new epidemics.
- b) Students will learn the mechanism of entry, initiation of infection and different targets required for development of the drugs.
- c) Students will learn in detail about the pharmacology of different antibiotics used for their treatment.

**EL-608**

<b>Pharmacovigilance and Medical Writing (2 Credit)</b>	<b>hrs</b>
Pharmacovigilance History, Introduction, definition, Importance, objectives	2
Pharmacoepidemiology Definition, methods, interest and clinical applications	2
Pharmacovigilance laws and Guidelines USFDA - MedWatch, European Union drug regulating authorities Pharmacovigilance, UK-Medicines and healthcare products regulatory agency and yellow card system, India - CDSCO (National Pharmacovigilance program)	4
Post Marketing surveillance Importance, Off label prescription and off label marketing	4
Signal Detection and Management Definition, Sources, Validation, Assessment, Scope	2
Individual Case Safety Reports (ICSRs)- Definition, Types, Contents, Structure, Validity and assessment of ICSRs reports, Role ICSRs in Pharmacovigilance	6
Drug Development Process Discovery process, IND and its type, Regulatory bodies, Phase 0 – Phase III studies, NDA and approval	4
Basic of clinical Research Declaration of Helsinki, Single blind, double blind studies, Randomization rules, Special cases (Pregnant women, pediatrics population and others)	3
ICH Guidelines [ICH M3 (R2), ICH S6 (R1), ICH S4, ICH E6(R2), GCP (Indian perspective)	3
CTD Investigator's Brochure, Clinical Study Protocol, Clinical Study Reports, Case Report Form	2
GPP guidelines GPP3 guideline	2
Software and tools	2
Ethical consideration for medical writing	2
How to be an effective medical writer	2

**Reading Material:**

1. Talbot J, Aronson JK (eds.) Stephen's detection and evaluation of adverse drug Reactions
2. Andrews E, Moore N (eds.) Mann's Pharmacovigilance
3. Van Boxtel CJ, Santoso B, Edwards IR (eds.) Drug benefits and risks

4. Rawlins MD Therapeutics, evidence and decision-making
5. Aronson JK (ed.) Meyler's side effects of drugs
6. Sweetman SC (ed.) Martindale - the complete drug reference
7. World Health Organization WHO model formulary
8. Textbook of Pharmacovigilance by S.K. Gupta Published by Jaypee Brothers Medical Publishers (P) Ltd., 2011
9. Good Publication Practice 3 Guidelines
10. Robert B Taylor What Every Medical Writer Needs to Know
11. Stuart, Mark C. Complete guide to Medical Writing
12. ICH Guideline [ICH M3 (R2), ICH S6 (R1), ICH S4, ICH E6(R2)]
13. William F. Rosenberger, John M. Lachin, Randomization in Clinical Trials: Theory and Practice

**Course outcomes:**

**After the successful completion of the course, students should be able to:**

- a) Students will be able to classify the adverse drug reactions based on their severity.
- b) Student will learn how to report the adverse drug reactions to regulatory authorities.
- c) Students will learn help to create product dossier for regulatory submission.
- d) The course will open new avenues for the current pharmacovigilance industrial demands.
- e) Students will be able to write medical case reports/articles
- f) Extract data from statistical analysis reports and presenting it in a readable and understandable format.
- g) Develop promotional materials and package inserts for products available in the market
- h) Create product dossier for regulatory submission

**EL-508**

<b>Chemotherapy of Parasitic and Microbial Infections (1 Credit)</b>	<b>hrs</b>
Introduction to parasitic and infectious diseases.	1
Biology of tuberculosis.	1
Mechanism of action of antituberculosis drugs.	1
Targets for anti-tuberculosis drug development.	1
Mechanism of drug-resistance in tuberculosis.	1
Biology of human amoebiasis.	1
Mechanism of action anti-amoebic drugs.	1
Biology of filarial infections.	1
Mechanism of action of anti-filarial drugs.	1
Targets of anti-filarial drug development.	1
Biology of viral infection.	1
Mechanism of action of anti-HIV drugs.	1
Targets for anti-HIV drug development.	1
Biology of malaria.	1

Mechanism of action of anti-malarial drugs.	1
Targets for anti-malarial drug development	1
Mechanism of drug-resistance in malaria.	1
Biology of leishmaniasis.	1
Mechanism of action of anti-leishmanial drugs.	1
Targets for anti-leishmanial drug development.	1
Drug-resistance in leishmaniasis	1

### **READING MATERIAL**

1. Burger's Medicinal Chemistry and Drug, Six Edition- 2007 , Discovery, Vol. 5,Wiley & Sons Inc
2. Hamson's Principles of internal medicine, Seventeenth Edition-2007, McGraw Hill.
3. The leishmaniasis in biology and medicine, (Vol. I & II), Peters W, Killick-Kendrick R, Academic Press, London
4. Lymphatic filariasis ,T.B. Nutman London: ImperialCollege Press.
5. Handbook of drugs for tropical parasitic infection, Second Edition1996 , Taylor& Francis, Basingstoke, Abdi Y.A., Gustafsson L.L., , Ericsson Ö., HellgrenU.

### **Course outcomes:**

**After the successful completion of the course, students should be able to:**

- a) The students will learn the basic pathology of the parasitic and microbial infections.
- b) The students will understand mechanism of resistance development to anti-parasitic and anti-microbial drugs.
- c) Students will learn how to identify the different targets of drug development and use of them in development of novel drugs.