



# **SYLLABUS**

## **M.S. (Pharm.) Pharmacology & Toxicology**

**NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH  
GUWAHATI**

**SilaKatamur (Halugurisuk), P.O.: Changsari  
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## M.S. (Pharm.) Pharmacology & Toxicology

Course No.	Course Name	Credits
<b>Semester-I</b>		
<b>Core Subjects (All compulsory): 14</b>		
PC 510	Pathophysiology	1
PC 520	General Pharmacology	2
PC 530	Experimental & Molecular Pharmacology	2
PE 520	Biopharmaceutics and Pharmacokinetics	2
GE510	Biostatistics	2
GE 520	Fundamentals of Intellectual Property (IP) & Technology Management	1
GE 511	Seminar	1
LG510	General Laboratory Experience-15 hours/week	3
<b>Elective Subjects (any 2 credits)</b>		
EL501	Chemotherapy of Parasitic and Microbial Infections: Part 1	1
EL502	Pharmacogenomics and Transgenic biology	1
	Choose any core course of other department MC/PA/PE/MD)	1
<b>TOTAL CREDITS</b>		<b>16</b>
<b>Semester-II</b>		
<b>Core Subjects (All compulsory): 12</b>		
PC620	CNS and Respiratory Pharmacology	2
PC630	Autonomic, CVS, Blood, Renal and GI Pharmacology	2
PC640	Autacid and Endocrine Pharmacology	1
PC650	Clinical Pharmacology and Regulatory Toxicology	2
PC660	Pharmacological Screening and Assays	1
GE611	Seminar	1
LS610	General Laboratory Experience15hours/week	3
<b>Elective Subjects (any 2 credits)</b>		
EL/PC 601	Chemotherapy of Parasitic and Microbial Infections: Part 2	1
EL/PC6 02	Pharmacovigilance and Medical Writing	2
EL/PC6 03	Immunopharmacology	1
PC 610	Drug Metabolism	1
	Choose any core course of other department (MC/PA/PE/MD/BT)	1
<b>TOTAL CREDITS</b>		<b>14</b>
<b>Semester-III</b>		
<b>Project (22 weeks)</b>		
TH-598	Synopsis	5
TH-599	Presentation	3
<b>TOTAL CREDITS</b>		<b>8</b>
<b>Semester-IV</b>		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
<b>TOTAL CREDITS</b>		<b>12</b>
<b>GRAND TOTAL CREDITS (I to IV Semesters)</b>		<b>50</b>

**M.S. (Pharm.)**  
**Pharmacology & Toxicology**  
**Semester-I**

**PC-510 :- Pathophysiology (1 Credit)**

**Chapter 1:** Fundamentals and recent advances of understanding the disease pathogenesis

**Chapter 2:** Pathophysiology and molecular basis of cardiovascular disorders (Angina, hypertension, arrhythmia, congestive heart failure, hyperlipoproteinemias); gastrointestinal disorders (peptic ulcer, pancreatitis, inflammatory bowel disease), hepatic diseases, bronchial asthma, neurological diseases (depression, schizophrenia, epilepsy), neurodegenerative disorders (Alzheimer's disease, Parkinson's disease, Amyotrophic Lateral Sclerosis, Huntington Disease, Multiple Sclerosis), endocrine disorders (disorders of thyroid glands, adrenal glands, diabetes etc), rheumatoid arthritis, gout and anaemia.

**Recommended Books/Literature:**

**PC-520:- General Pharmacology (2 Credits)**

**Chapter 1:** Introduction to pharmacology: ADME and factors influencing disease conditions.

**Chapter 2:** Concept of receptors as a drug target, Receptor classifications, structure, drug receptor interaction, G-protein, receptor characterization, receptor theories, agonist, antagonist

**Chapter 3:** GPCR- Classification, Receptor regulation: GPCR desensitization, down regulation, up regulation, Regulators of Gprotein signaling

**Chapter 4:** Ion channels and Ion channels linked receptors and their regulation

**Chapter 5:** Nuclear receptors and

Transmembrane signaling mechanisms, Second messenger system

**Chapter 6:** Transcription factors with special emphasis to Nrf2 and NF-kB, Mechanism of transcription factors, pharmacological target and role in different diseases conditions

**Chapter 7:** Membrane Transporters and Drug Response

**Chapter 8:** Dose response relationship and different type of antagonism

**Chapter 9:** Efficacy and Toxicity evaluation using different experimental models, dose-response analysis, margin of safety in pre-clinical development.

**Chapter 10:** Drug discovery, the Pharmaceutical Industry and Regulation

**Recommended Books**

**PC-530:- Experimental and Molecular Pharmacology (2 Credits)****Chapter 1: In vivo Experiments**

a) **Laboratory animals:** Study of CPCSEA and OECD guidelines for maintenance, breeding and conduct of experiments on laboratory animals, Common lab animals: Description and applications of different species and strains of animals. 3 R's concept, alternatives to animal experimentations, Organs-on-chips. Popular transgenic and mutant animals.

Techniques for collection of blood and common routes of drug administration in laboratory animals, Techniques of blood collection including cannulation techniques and euthanasia

b) **Dose calculations and rational for animal species selection:** Dose selection, calculation and conversions, preparation of drug solution/suspensions, grouping of animals and importance of sham negative and positive control groups. Rationale for selection of animal species and sex for the study.

**Chapter 2: In vitro experiments**

a) **Cell free and Cell based assays** (Introduction to Primary and secondary culture). Applications of cell culture for drug screening. Cell viability studies.

b) **Experimental Molecular Techniques:** Western blotting, Northern and Southern Hybridisation, ELISA, RT PCR, Flowcytometer, Surface Plasmon Resonance, Tissue micro array etc., High Content screening.

c) Imaging techniques in pharmacological research

**Recommended Books/Literature****PE-520:- Biopharmaceutics and Pharmacokinetics (2 Credits)**

- 1. Introduction:** Definitions, ADME, concentration time profile, plotting the data, different fluid compartments and blood flow rate compartment models, biological half-life, elimination rate constant. Biopharmaceutics and pharmacokinetics in drug research.
- 2. GIT Absorption of drugs:** Mechanism, physico-chemical, biological and pharmaceutical factors affecting drug absorption through GIT. Techniques for the GIT absorption assessment .
- 3. Drug disposition:** Total body clearance, renal clearance, mechanism of clearance, clearance ratio, factors affecting renal clearance, hepatic clearance, volume of distribution and its significance.
- 4. Protein and tissue binding:** Factors affecting protein binding, kinetics of protein

binding, determination of rate constant and different plots (direct, scatchard and reciprocal), Implication of protein binding on pharmacokinetic parameters.

- 5. Bioavailability and Bioequivalence:** Definitions, federal requirements, methods of determination of bioavailability using blood and urinary excretion data. Protocol design for bioavailability assessment. Methods for bioequivalence determination.

Protocol design for bioavailability and bioequivalence assessment. Methods for bioequivalence determination. Regulatory perspective of design acceptance and BE determination - BCS based approach to avoid human PK study for BE determination.

- 6. Pharmacokinetic characterization of drugs:** Pharmacokinetics of drugs following one/two compartment open models with first order elimination kinetics as applied to rapid intravenous injection, Intravenous transfusion and oral administration. Determination of absorption rate constant using Wagner-Nelson, Loo Riegelman methods. Flip-flop models, method of residual. Urinary excretion data and its application in pharmacokinetic characterization of drugs. Pharmacokinetics of multiple dosing. Pharmacokinetics of modified/sustained release dosage forms.
- 7. Dosage regimen:** Dosage regimen adjustment in patients with renal and hepatic diseases. Drug dosage in elderly, children, and obese patients.
- 8. Non-Linear Pharmacokinetics:** Various causes of non-linearity, Michaelis-Menten kinetics, In-vivo estimation of  $K_m$  and  $V_m$ . Lineweaver Burk equation.
- 9. Physiologic pharmacokinetics models:** Mean Residence Time (MRT); Statistical moment theory; Mean absorption time (MAT); Mean dissolution time (MDT); Lagrange and spline method Application and limitations of physiologic pharmacokinetic models.
- 10. Miscellaneous Topics:** Chronopharmacokinetics, Drug toxicity and forensic pharmacokinetics, kinetics of maternal-fetal drug transfer, pharmacokinetics v/s pharmacological/ clinical response, metabolic kinetics

### Recommended Books

1. Applied biopharmaceutics pharmacokinetics. LEON SHARGEL AND ANDREW B.C. YU, 2016, 7<sup>th</sup> Edition.
2. Foundation of Pharmacokinetics. Rescigno, A. 2003.
3. Handbook of Bioequivalence Testing. Sarfaraz K. Niazi. 2007, 1<sup>st</sup> Edition.
4. Biopharmaceutics and Relevant Pharmacokinetics. Wagner, J. G. 1970.
5. Textbook of Biopharmaceutics and Clinical Pharmacokinetics. Niazi, S.K. 1980.
6. Modeling in Biopharmaceutics, Pharmacokinetics, and Pharmacodynamics: Homogeneous and Heterogeneous Approaches. Macheras, P. and A. Iliadis, 2016, 2<sup>nd</sup> Edition.
7. Comparative Pharmacokinetics: Principles, Techniques and Applications. Riviere, J.E., 2011, 2nd Edition.
8. Introduction to Biopharmaceutics. Gibaldi, M. 1971.
9. Biopharmaceutics and Pharmacokinetics: An Introduction. Notari, R. E.2008.
10. BA/BE guidance of US FDA and EMEA, BCS waiver guidance by USFDA

### GE-510 :- Biostatistics

(2 Credits)

1. **Statistics:** Introduction, its role and uses. Collection; Organization; Graphics and

pictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation.

2. **Probability:** Basic concepts; Common probability distributions and probability distributions related to normal distribution.
3. **Sampling:** Simple random and other sampling procedures. Distribution of sample mean and proportion.
4. **Estimation and Hypothesis testing:** Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student-t and Chi square tests. Sample size and power.
5. **Experimental design and analysis of variance:** Completely randomized, randomized blocks. Latin square and factorial designs. Post- hoc procedures.
6. **Correlation and regression:** Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.
7. **Non-parametric tests:** Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal wallis and Friedman two way anova tests. Spearman rank correlation.
8. **Statistical techniques in pharmaceuticals:** Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

#### Recommended Books:

1. Fundamentals of Biostatistics by Bernard Rosner.
2. Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon.
3. Statistical Misconceptions by Huck GE-520 Fundamentals of Intellectual Property (IP) and Technology

#### GE-520 :- Fundamentals of Intellectual Property (IP) and Technology Management (1 Credit)

1. **Intellectual property:** Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property- patents, copyrights, trademark; Factors effecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications.
2. **Trade related aspects of intellectual property rights:** Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trade in Services); Protection of plant and animal genetic resources; Biological materials; Gene patenting; Biotechnology / drug related IPR issues; Status in India and other developing countries; Case studies and examples; TRIPS issues on herbal drugs.
3. **Nuts and bolts of patenting, copyright and trademark protection criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS:** Filing of a patent application; Precautions before patenting- disclosures / non-disclosures, publication-article / thesis; Prior art search- published patents, internet search patent sites, specialized services- search requests, costs; Patent application- forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications- provisional, non provisional,

PCT and convention patent applications; International patenting-requirement procedures and costs; Financial assistance for patenting- introduction to schemes by NRDC and TIFAC; Publication of patents-gazette of India, status in Europe and US; Patent annuity; Patent attorneys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infringement- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists University / organisational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information-internet sites, brochures, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Berne convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringements.

- 4. Technology Development/transfer/commercialisation related aspects:** Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialisation and commercialisation-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personnel; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory licensing excess to medicine issues; DOHA declaration, POSTWTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalisation of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPs; Related registration and marketing issues; Case studies antiretroviral drugs and others.
- 5. Funding sources for commercialization of technology:** Preparation of a project report, financial appraisal, business models; GOI schemes and incentives; NRDC, TePP, HGT, TDB schemes. PATSER; Venture capitalists, banks. Incubator concept-Case studies with respect to IIT,CCMB, IMTECH, NIPER. Documentation and related aspects.
- 6. Ethics and values in IP:** IP and ethics-positive and negative aspects of IPP; Societal responsibility; Avoiding unethical practices; Echo-responsibility-economic, social and environmental benefits of modern biotechnology; Voluntary adoption of pollution control strategies. 49 60 Courses of Study 2015.

#### Recommended Books:

1. Law Relating to Intellectual Property by B.L.Wadhwa.
2. IPR Handbook for Pharma Students and Researchers by P.Bansal.
3. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012).
4. Patent Agent Examination by Sheetal Chopra and Akash Taneja.
5. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan.
6. Making Breakthrough Innovation Happen by Porus Munshi.
7. Innovation X- Why a Company's Toughest Problems are its Greatest Advantage by Adam Richardson.



8. Legal Drafting for the Layman by Nabhi Kumar Jain.
9. How to Write and Publish a Scientific Paper by Rober A Day.
10. Concise Law Dictionary-with Legal Maxims, Latin Terms and Words and Phrases by Justice Y.V.Chandrachud.
11. Biomedical Research- From Ideation to Publication by G.Jagadeesh and others.

**GE-511 :- Seminar****(1 Credit)**

1. Introduction, Information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and references.
4. Reading research papers.
5. Skills in oral presentation.

**Each student has to present a seminar before end of the semester.**

**LG-510 :- General Laboratory Experience****(3 Credits)**

1. **Analytical Techniques (75 hours):**
  - a) Spectral analysis workshop (45 hours).
  - b) Separation techniques (30 hours).
2. **Computer and application in pharmaceutical sciences (100 hours):** Introduction to computers, basic unit and functions, H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dbase, windows, statistical S/W programs and packages. Steps involved in S/W development, computer languages with emphasis to FORTRAN language and programming, hands on experience in pharmaceutical software systems. Use of computers in information retrieval systems.
3. **Pharmacology (25 hours):** Animal handling, route of administration of drugs, dose response relationship, acute toxicity testing of drugs, analgesic activity of a compound, estimation of protein and haematological parameters.
4. **Biotechnology in pharmaceutical sciences (20 hours):** Day -1: Preparation for plasmid miniprep. Day-2: Plasmid miniprep and restriction digestion. Day-3: Gel electrophoresis and molecular weight calculation. Day-4: Discussion of result and viva.
5. **Specialization (50 hours):**
  - a) To prepare granules by dry granulation using Roller compactor.
  - b) To optimize wet granulation process and perform scale up using Rapid Mixer Granulator (RMG)
  - c) Study the dissolution behaviour/ drug release pattern of various conventional, sustained release, enteric coated and nanoparticulate dosage form and establishment of dissolution kinetics. Study of various factors affecting dissolution / drug release
  - d) Study of drug protein binding and effect of competitive agent on binding kinetics
  - e) Plotting and interpretation of pharmacokinetics data and calculation of various pharmacokinetic parameter

**EL501/PC 540:Chemotherapy of Parasitic and Microbial Infections, Part 1****(Credit: 1)**



**Chapter 1:** Introduction to parasitic and infectious diseases.

**Chapter 2: Pathogenesis and molecular basis of pathogen and host interactions of following disease areas:**

- (a) Tuberculosis. Chemotherapeutic agents & their mechanism of action. Mechanism of drug-resistance in tuberculosis, multidrug resistance (MDR)& development of modern approaches for effective management.
- (b) Filarial infections. Mechanism of action of anti-filarial drugs. Targets of anti-filarial drug development.
- (c) HIV infection. Mechanism of action of anti-HIV drugs. Targets for antiHIV drug development.
- (d) Malaria. Mechanism of action of antimalarial drugs. Targets for antimalarial drug development. Mechanism of drug-resistance in malaria.
- (e) Amoebiasis. Mechanism of action of anti-amoebic drugs, recent drug targets Leishmaniasis. Mechanism of action of anti-leishmanial drugs. Targets for anti-leishmanial drug development, Drug-resistance in leishmaniasis, and recent drug targets. Leishmaniasis. Mechanism of action of anti-leishmanial drugs. Targets for anti-leishmanial drug development, Drug-resistance in leishmaniasis, and recent drug targets

#### **EL502: Pharmacogenomics and Transgenic Biology**

**(Credit: 1)**

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

# M.S. (Pharm.) Pharmaceutics

## Semester - II

### PC-620:- CNS AND RESPIRATORY PHARMACOLOGY

(2 Credits)

**Unit 1:** CNS drug discovery and challenges

**Unit 2:** Neurotransmitters, and their receptors (5-HT, excitatory amino acids, GABA, glycine, cannabinoids, melatonin), peptides as mediators (substance P, neuropeptide Y, somatostatin, cholecystinin, neurotensin, enkephalin, Orexin, CGRP, nerve growth factors, etc),

neuromodulators, neuromediators and transporters

**Unit 3: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of** antianxiety drugs, antidepressants, antipsychotic drugs, psychomotor stimulants

**Unit 4: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of** anti-epileptics

**Unit 5: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of** antimigraine drugs,

**Unit 6: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of** local anesthetics, general anesthetics, centrally acting muscle relaxants

**Unit 7: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of** narcotic analgesics

**Unit 8: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of** drugs used in Alzheimer's disease, Parkinson's disease, Huntington's disease, Multiple sclerosis

**Unit 9: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of** drugs used in Stroke

**Unit 10:** Gene therapy and cell-based therapy for CNS disorders

**Unit 11: Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of** drugs used in asthma, COPD and cough.

#### Recommended Books/Literature:

### PC-630 :- AUTONOMIC, CVS, BLOOD, RENAL AND GI PHARMACOLOGY, CREDITS

(2 Credits)

**Chapter 1:** Introduction to Autonomic Pharmacology:

Neurotransmission: The Autonomic and Somatic Motor Nervous Systems, pharmacology of Muscarinic Receptor Agonists and Antagonists, Anticholinesterase Agents, Pharmacology of Ganglionic stimulants and blocking agents, neuromuscular blocking agents, Pharmacology of adrenergic agonists and antagonists

**Chapter 2:** Introduction to CVS Pharmacology: CVS drug discovery and challenges,

Antihypertensive drugs and newer targets for hypertension, Antianginal drugs and newer targets for myocardial infarction, Drugs for Heart failure and antiarrhythmic drugs, Pharmacology of Lipid lowering and anti-obesity agents, CVS disease models and evaluation of effect of NCEs

**Chapter 3:** Factors necessary for erythropoiesis: Homopoietic growth factors. Mechanism of blood clotting, hematopoietic agents, Oral anticoagulants: Factors increase/decrease the efficacy of oral anticoagulants, Heparin, Platelet adhesion and activation: Antiplatelet agents, thrombolytic agents and antifibrinolytic agents and hemostatic agents, integrins as therapeutic agents

**Chapter 4:** Renal Pharmacology: Diuretics, vasopressin

**Chapter 5:** Pharmacology of GI drugs: Drugs for peptic ulcer, emetics, antiemetics, drug regulating GI motility, GI disease models for evaluation of effects of NCEs

**Recommended Books/Literature:**

**PC-640:- AUTACOIDS AND ENDOCRINE PHARMACOLOGY (1 Credit)**

1. Introduction to autocooids
2. Pharmacology of histamine & bradykinin: receptors, agonists and antagonists
3. Pharmacology of eicosanoids: COX inhibitors. Pain and inflammatory models for screening
4. Adenohypophyseal hormones and related substances.
5. Thyroid and antithyroid drugs.
6. Insulin and oral hypoglycaemic agents, Endocrine pancreas.
7. Adrenocortical hormones: adrenocortical steroids and inhibitors of the synthesis.
8. Agents affecting the calcification estrogen, progesterone and androgens: their antagonists, Oral contraceptives

**Recommended Books/Literature:**

**PC-650 :- CLINICAL PHARMACOLOGY AND REGULATORY TOXICOLOGY (2 Credits)**

**Chapter 1:** Introduction to clinical pharmacology: Investigational new drug (IND) application, clinical trials (Phase I to Phase IV), new drug application (NDA) requirements, Regulatory agencies

**Chapter 2:** Pharmacovigilance, GCP Guidelines and GLP Guidelines, Individualization of drug therapy: Personalized medicine

**Chapter 3:** Preclinical testing strategy; Vis- -vis envisaged clinical studies; Experimental clarification of possible human risk; Technical details of experiments; Flow chart for development of preclinical testing

**Chapter 4:** Single dose and repeat dose toxicity studies: Factors influencing such studies such as species, sex, route, dose level; Data evaluation and regulatory requirements.

**Chapter 5:** Reproductive toxicology assessment of male reproductive toxicity: Spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity

**Chapter 6:** Mutagenicity:

Mechanisms of mutagenesis, germ cell mutations, somatic cell mutation; Tests systems in vitro, test for gene mutation in bacteria, chromosome damage, in vivo micronucleus tests in rodent, metaphase analysis.

**Chapter 7:** Carcinogenicity: Principles of carcinogenicity, dosesetting for arcinogenesis bio-assay, transplacental carcinogenesis; Cocarcinogenesis/tumor promotion.

**Chapter 8:** Toxicokinetics, animals and dose groups: Exposure measurement; determination of metabolites complicating factors in exposure interpretation, analytical method, good laboratory practices; Stereoisomerism vis- -vis regulatory requirements; Single enantiomers; Racemate enantiomer switch; Regulatory requirements.

**Chapter 9:** Preclinical toxicological requirements for biological and biotechnological products: Safety analysis; problems specific to recombinant products secondary pharmacology

**Chapter 10:** Safety Pharmacology - ICH S7 and S7B guidelines: Safety pharmacological studies for pharmaceuticals, Safety pharmacological studies for biological products

**Recommended Books/Literature:**

**PC-660 (Previously PC-611):- PHARMACOLOGICAL SCREENING AND ASSAYS (1 Credit)**

**Recommended Books/Literature:**

1. **Role of Pharmacology in drug discovery and approaches for target identification & Validation**
2. **Preclinical screening models:** a) for CNS activity- analgesic, antipyretic, antidepressant, antiepileptic, antiparkinsonism, alzheimer's disease **b)** for CVS activity- antihypertensives, antiarrhythmic, antidyslipidemic, and anticoagulants **c)** for other important drugs like antiulcer, antidiabetic, antiinflammatory, and anticancer
3. **Drug Metabolism Studies:** Metabolic stability studies, CYP enzyme inhibition studies and CaCo-2 cell permeability assay.
4. **Zebrafish model to screen pharmaceutical molecules**
5. Correlations between various animal models and human situations.

6. Correlation between *in-vitro* and *invivo* screenings

**GE-611:- Seminar****(1 Credit)**

Students are required to submit a written record and present details of the project to be pursued in semester-III & IV. This should include the purpose and basis of the project, stating aims, objectives and probable outcomes, be able to supplement these with necessary information, literature review towards it and process for the project itself.

**LS-610:- GENERAL LABORATOR EXPERIENCE****(3 Credits)**

03 Credits ...15 hrs/week

1. Demonstration of preclinical screening of following models a) Carrageenan induced paw edema model b) STZ induced diabetes c) PTZ/MES induced convulsant activity d) analgesic activity by Hot & Cold plate d) muscle relaxant activity by rota rod e) antidepressant activity by forced swim test or tail suspension test f) demonstration of blood pressure recording and ECG g) locomotor activity by actophotometer h) antianxiety in elevated plus maze.
2. Isolation of PBMC cells, *In vitro* drug screening for antiinflammatory, antidiabetic, organoprotective
3. Biochemical assays: SOD, catalase, GSH, ROS, lipid peroxidation, NO
4. Demonstration of flow cytometer, RTPCR, confocal microscope and western blotting

Demonstration of various imaging modalities like ultrasound, optical imaging and microCT.

**EL/PC-601:- CHEMOTHERAPY OF PARASITIC AND MICROBIAL INFECTIONS, PART 2****(1 Credit)**

1. **Chapter 1:** Introduction & general considerations of antimicrobial agents.
2. **Chapter 2:** Spectrum of activity, mechanism of action, ADME and therapeutic aspects of following Quinolones, sulphonamides, penicillins, cephalosporins, clavulanic acid, aminoglycosides, broad spectrum antibiotics.
3. **Chapter 3:** Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antifungal agents.
4. **Chapter 4:** Spectrum of activity, mechanism of action, ADME and therapeutic aspects of antiprotozoal agents.
5. **Chapter 5:** Spectrum of activity, mechanism of action, ADME and therapeutic aspects of antineoplastic agents. Modern non-invasive approaches in the diagnosis/management of cancer: Photodynamic/Photothermal therapies etc.,

**6. Chapter 6:** Physiology, Diagnosis techniques and management of viral infections diseases a) Dengue virus b) Chikun-Gunia virus C) Corona viruses

**Recommended Books/Literature:****EL/PC-602:- PHARMACOVIGILLANCE AND MEDICAL WRITING****(2 Credits)**

1. Pharmacovigilance History, Introduction, definition, Importance, objectives
2. Pharmacoepidemiology Definition, methods, interest and clinical applications  
Pharmacovigilance laws and Guidelines USFDA - MedWatch, European Union drug regulating authorities Pharmacovigilance, UKMedicines and healthcare products regulatory agency and yellow card system, India - CDSCO (National Pharmacovigilance program)
3. Post Marketing surveillance  
Importance, Off label prescription and off label marketing
4. Signal Detection and Management Definition, Sources, Validation, Assessment, Scope
5. 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
7. Basic of clinical Research Declaration of Helsinki, Single blind, double blind studies, Randomization rules, Special cases (Pregnant women, pediatrics population and others)
8. ICH Guidelines [ICH M3 (R2), ICH S6 (R1), ICH S4, ICH E6(R2), GCP (Indian perspective) CTD Investigator's Brochure, Clinical Study Protocol, Clinical Study Reports, Case Report Form
9. GPP guidelines GPP3 guideline
10. Software and tools
11. Ethical consideration for medical writing  
How to be an effective medical writer

**Recommended Books/Literature:**

**EL/PC-603:- IMMUNOPHARMACOLOGY****(1 Credit)**

1. Introduction to Immunopharmacology, Overview of the Immune Response, Hematopoiesis Including Lymphocyte Development and Maturation, T and B Cell Mediated Immunity, Cytokines, Innate and Acquired Immunity
2. Role of Cytokines, Interferons Colony Stimulating Factors like G-CSF, GM-CSF, TNF-alpha etc
3. Types of hypersensitivity reactions and molecular mechanism for auto immune diseases.
4. Immunosuppressive Drugs : Mechanism of Action, Absorption, Distribution and Excretion, Side Effects of I. Glucocorticoids II. Cytotoxic Agents - Methotrexate, Cyclophosphamide, Azathioprine III. Other molecular target agents : Cyclosporine, Tacrolimus, Sirolimus, Everolimus, Mycophenolate Mofetil, Fingolimod
5. Immunostimulants: Isoprinosine, Bacterial Extracts, Vaccines
6. Immunotargets and therapy against cancer, RA etc.,
7. Overview on production of monoclonal antibodies
8. Basics on neuroimmunology

**Recommended Books/Literature:****PC-610:- Drug Metabolism****(1 Credit)**

1. Biotransformation of drugs.
2. Enzymes responsible for biotransformations: microsomal and non-microsomal mechanisms.
3. Factors influencing enzyme induction and inhibition.
4. Factors affecting drug metabolism.
5. Drug metabolism in fetus and new born.
6. Models to study drug metabolism.
7. Dose effect relationships.
8. Excretion of drugs, biliary and fecal excretion.
9. Adverse drug reactions and drug interactions; Toxic reactions, allergic reactions, idiosyncrasy.
10. Acute poisoning and its treatment

**Recommended Books/Literature:**



