NIPER
RAEBARELI

SYLLABUS

M.S. (Pharm.)

Pharmacology & Toxicology

M.S. (Pharm.) Pharmacology & Toxicology

Course No.	Course Name	Credits
Semester – I		
*** PC-511	Pathophysiology	1
*** PC-520	General Pharmacology	2
*** PC-530	Experimental Pharmacology	1
PC-540	Chemotherapy of Parasitic and Microbial Infections	1
∞ MC-530	Separation Techniques	1
¤ PE-520	Biopharmaceutics and Pharmacokinetics	2
© PE-540	Regulatory Consideration for Pharm Development II	1
* GE-510	Biostatistics	2
¶ GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Lab Experience	3
	Total Credits	**16**
Semester - II		
@ PC-610	Drug Metabolism	1
** PC-611	Pharmacological Screening and Assays	1
PC-620	CNS and Respiratory Pharmacology	2
PC-630	Autonomic, CVS, Blood, Renal and GI Pharmacology	2
PC-640	Autocoid and Endocrine Pharmacology	1
*** PC-650	Clinical Pharmacology and Regulatory Toxicology	2
PC-660	Chemotherapy and Immunopharmacology	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
	Total Credits	**14**
Semester – III		
Projects (22 weeks)		
TH-598	Synopsis	5
TH-599	Presentation	3
	Total Credits	**8**
Semester – IV		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
	Total Credits	**12**
	Grand Credits (I to IV Semesters)	**50**

Note:

*	Common in all disciplines
**	Common in PA, PE, RA, PC, RT
***	Common in PC, RT
∞	Common in MC, PA, PE, PC, BT
¤	Common in PE, PC, RT
©	Common in PE, RA, PC
@	Common in MC, PE, PC, RT
¶	Common in PA, PE, RA, PC, RT, MD

M.S. (Pharm.) Pharmacology & Toxicology
SEMESTER - I

PC 511 - Pathophysiology (1 Credit)

1. Factors influencing the disease conditions such as sex, age, nutritional status, genetic make up etc.
2. Pathogenesis, symptoms and signs, laboratory findings and complications of respiratory, urinary tract, venereal and meningial infections
3. Pathogenesis, symptoms and signs, laboratory findings and complications of Congestive heart failure, hypertension, cardiac arrhythmias
4. Pathogenesis, symptoms and signs, laboratory findings and complications of Ulcer, pancreatitis
5. Pathogenesis, symptoms and signs, laboratory findings and complications of hepatitis and cholecystitis
6. Pathogenesis, symptoms and signs, laboratory findings and complications of Bronchial asthma
7. Pathogenesis, symptoms and signs, laboratory findings and complications of depression, schizophrenia, epilepsy
8. Pathogenesis, symptoms and signs, laboratory findings and complications of Parkinsonism and Alzheimer disease.
9. Pathogenesis, symptoms and signs, laboratory findings and complications of Hypo and hyper thyroidism, diabetes mellitus and other endocrine diseases
10. Pathogenesis, symptoms and signs, laboratory findings and complications of Rheumatoid arthritis, gout and anemia

Recommended Books:

1. Pharmacotherapy: A Pathophysiologic Approach by Dipiro and others
2. The Pharmacological Basis of Therapeutics by Goodman and Gilman's

PC 520 - General Pharmacology (2 Credits)

1. Concept of receptors as a drug target
2. GPCR- Classification, structure, drug receptor interaction, G-protein, receptor characterization, receptor theories, agonist, antagonist
3. Receptor regulation: GPCR desensitization, down regulation, up regulation
4. Regulators of G-protein signaling
5. Ion channels and Ion channel linked receptors and their regulation
6. Nuclear receptors
7. Transmembrane signaling mechanisms
8. Second messenger system
9. Transcription factors: Nrf2 Mechanism of action, pharmacological target and role in different diseases conditions
10. Dose response relationship and different type of antagonism

11. Efficacy and Toxicity evaluation using different experimental models, dose-response analysis, margin of safety in pre-clinical development
12. Chronopharmacology

Recommended Books:

1. The Pharmacological Basis of Therapeutics by Goodman & Gilman
2. Casarett & Doull's Essentials of Toxicology, edited by CD Klassen and JB Watkins
3. Scientific journals in the area of pharmacology(Trends in Pharmacological Sciences, Annual Reviews of Pharmacology and Toxicology, British Journal of Pharmacology, European Journal of Pharmacology, Pharmacology and Therapeutics, Nature Review Drug Discovery, Nature Review Neuroscience, Brain Research)

PC 530 - Experimental Pharmacology (1 Credit)

1. Introduction to pharmacological research
2. Research ethics and publication ethics
3. Common laboratory animals and their physiological parameters, factors affecting the nature and degree of pharmacological responses; Handling and care of different animals; Bleeding and different routes of administration, anaesthetics used in animal research and chemical euthanasia.
4. Animal experimentation: Advantages and disadvantages; Anaesthesia used in laboratory animals, common agents, dose calculations, cannulation methodology, ventilation rate, recording of arterial blood pressure, intestinal motility etc.
5. Conscious animal experimentation, precautions to be taken in behavioural experiments
6. Humanized mouse
7. Imaging techniques in pharmacological research
8. Drug solution preparations: Storage, concentration expression, common solvents, stabilizing agents, storage conditions, reference standards, methods of procurement of reference standards. False positive and false negative response.
9. *In vitro* experimentation: Advantages and disadvantages
10. Animal cell-culture techniques: Aseptic handling, cell counting and cell viability assays. Tissue isolation, tissue fixation, common fixtatives, preparation of single cell suspension.
11. Protein and DNA gel electrophoresis: Western, northern, southern blot hybridization and PCR techniques.
12. Protein purification and identification by two dimensional gel electrophoresis, LCMS-MS, MALDI.

Recommended Books:

1. Drug Discovery and Evaluation: Pharmacological Assays by Vogel& Vogel
2. CPCSEA guidelines (http://cpcsea.nic.in)

PC 540 - Chemotherapy of Parasitic and Microbial Infections (1 Credit)

1. Introduction to parasitic and infectious diseases
2. Biology of tuberculosis.
3. Mechanism of action of anti-tuberculosis drugs.
4. Targets for anti-tuberculosis drug development.

5. Mechanism of drug-resistance in tuberculosis.
6. Biology of human amoebiasis
7. Mechanism of action of anti-amoebic drugs.
9. Biology of filarial infections
10. Mechanism of action of anti-filarial drugs
11. Targets of anti-filarial drug development
12. Biology of HIV infection
13. Mechanism of action of anti-HIV drugs
14. Targets for anti-HIV drug development
15. Biology of malaria
16. Mechanism of action of anti-malarial drugs
17. Targets for anti-malarial drug development
18. Mechanism of drug-resistance in malaria
19. Biology of leishmaniasis
20. Mechanism of action of anti-leishmanial drugs
21. Targets for anti-leishmanial drug development
22. Drug-resistance in leishmaniasis

Recommended Books:

1. Chemotherapy by Frank Hawking
2. Parasitic Protozoa by Julius P. Kreier and Ristic
3. Maraia by Julius P. Kreier
4. Chemotherapy and Drug Resistance in Malaria by Wallace Peter
5. Atlas of Tropical Medicine and Parasitology by Wallace Peter and Geoffrey Pasvol
6. Manson's Tropical Diseases: Expert Consult Basic by Gordon C. Cook
7. Tropical Infectious Diseases: Priciples, Pathogens and Practice by Richard L. Guerrant, David H. Walker and Peter F. Weller
8. Essentials of Tropical Infectious Disease by Richard L. Guerrant, David H. Walker, Peter F. Weller
9. History of Human Parasitology by F. E. G. Cox
10. Malaria Parasites and other Haemosporidia by P. C. C. Garnham
11. Diagnostic Microbiology by Bailey & Scott
12. Medical Microbiology by Samuel Baron
13. Textbook of Microbiology by P. C. Baveja
14. Human Parasitic Infections of Pharmaceutical & National Importance edited by Prati Pal Singh and V. P. Sharma
15. Quantitative Real-time PCR in Applied Microbiology edited by Martin Filion

MC 530 - Separation Techniques (1 Credit)

1. **Separation Techniques:** Need for learning separation techniques, separation techniques in natural product research and drug discovery, extraction techniques.
2. **Chromatography:** General principles, classification of chromatographic techniques, normal and reverse phase, bonded phase chromatography, stationary phases, activity of stationary phases, elutropic series, and separation mechanisms.
3. **Column Chromatography and Short Column Chromatography:** Column packing, sample loading, column development, detection
4. **Flash Chromatography and Vacuum Liquid Chromatography:** Objectives,

optimization studies, selecting column and stationary phases, selecting suitable mobile phases, automated flash chromatography, and reverse phase flash chromatography.

5. **High Performance Liquid Chromatography:** Principles, instrumentation, peak shapes, capacity factor, selectivity, plate number, plate height, resolution, band broadening, pumps, injector, detectors, columns, column problems, gradient HPLC, HPLC solvents, trouble shooting, sample preparation, method development.
6. **Planar Chromatography - TLC/HPTLC/OPLC:** Basic principles, sample application, development of plates, visualization of plates, 2D TLC, densitometry, Over pressure layer chromatography.
7. **Counter Current Chromatography:** Basic principles, droplet counter current chromatography, centrifugal partition chromatography, choice of solvents for SP and MP.
8. **Gas Chromatography:** Principles, instrumentation, split-splitless injector, head space sampling, columns for GC, detectors, quantification
9. **Biochromatography:** Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases
10. **Hyphenated Techniques:** Introduction to GC-MS and LC-MS techniques and their applications in natural products.

Recommended Books:

1. Methods in Biotechnology, Natural Product Isolation by Sarker, Latif, Gray
2. Methods in Biotechnology, Natural Product Isolation by Richard Canell
3. Various Reviews and Research Papers

PE 520 - Biopharmaceuticsand Pharmacokinetics (2 Credit)

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.
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
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 Km and Vm. Case studies.

9. **Physiologic pharmacokinetics models:** Mean Residence Time; Statistical Moment Theory; 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, by Shargel, L., S. Wu-Pong
2. Biopharmaceutics and Pharmacokinetics: An Introduction by Notari, R. E.
3. Introduction to Biopharmaceutics, by Gibaldi, M.
4. Biopharmaceutics and Relevant Pharmacokinetics, by Wagner, J. G.
5. Textbook of Biopharmaceutics and Clinical Pharmacokinetics by Niazi, S.K.
6. Handbook of Bioequivalence Testing, by Niazi, S. K.
7. Modeling in Biopharmaceutics, Pharmacokinetics, and Pharmacodynamics: Homogeneous and Heterogeneous Approaches, by Macheras, P. and A. Iliadis
8. Comparative Pharmacokinetics: Principles, Techniques and Applications, by Riviere, J. E
9. Foundations of Pharmacokinetics, by Rescigno, A.
10. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, byRowland, M. and T. N. Tozer

PE-540 - Regulatory Considerations for Pharmaceutical Development - II (1 Credit)

1. **International regulatory trends in the pharmaceutical industry**.

2. **Role of regulatory affairs department in pharmaceutical organization:** regulatory audits, interactions with various other departments, single point contact with regulatory agencies.

3. **Types of regulatory filings for pharmaceutical products:** goals of regulatory registration procedures, investigational new drug applications, introduction to various types of regulatory filings.

4. **New drug applications:** stages involved in NDA, different phases of clinical trials, purpose of IND, types, and categories of IND applications, and information to be given in IND applications.

5. **Chemistry, manufacturing, and control (CMC)information in NDA:** information related to the drug substance, like manufacturing process, specifications, and description of test methods. Information related to drug product: description of method of manufacturing, specifications, and acceptable limits. Information related to the placebo.

6. **Hybrid NDA:** a difference from NDA, historical background, literature-based hybrid NDAs, and other sources of information for NDA, examples of types of products considered under hybrid NDA.

7. **Abbreviated New Drug applications (ANDAs):** historical developments leading to creation of ANDA process, Hatch Waxman Act, patent term restoration, criteria for patent term extension, various types of Hatch Waxman Exclusivities, concept of therapeutic equivalence, ANDA review process.

8. **Paragraph IV certification ANDAs**: different ANDA patent certification options, Medicare Modernization Act, implications of this act on 30-month stay period and 180-day exclusivity, triggering and forfeiture of 180-day exclusivity, shared exclusivity.

9. **ANDA with suitability petition:** case studies of drug products considered appropriate for filing under suitability petition.

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 pharmaceutics:** 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 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; Penalities 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 attomeys technical aspects, criteria for selection, addresses, fee, rights and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infrigment- 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, brouchers, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Beme convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trademarks 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 personal; 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, POST WTO 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, and 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 benifits of modern biotechnology; Voluntary adoption of pollution control strategies

Recommended Books:

1. Law Relating to Intellectual Property by B.L.Wadhera
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. Skill in oral presentation

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

LG 510 - General Laboratory Experience -15 hours / week (3 Credits)

1. **Analytical techniques: (30 hours):** Separation Techniques
2. **Training on the specific software tools used in the area of specialization (100 hours)**
3. **Pharmacology (25 hours):** Animal handling, route of administration of drugs, dose response relationship, acute toxicity testing of drug, analgesic activity of a compound, estimation of protein and hematological parameters.
4. **Biotechnology for pharmaceutical sciences (20 hours):**

   Day-1: Preparation for plasmid miniprep

   Day-1: Plasmid miniprep and restriction digestion

   Day-3: Gel electrophoresis and molecular weight calculation

   Day-4: Discussion of result and viva

   Specialization (95 hours):

   Introduction to lab. experience and animal experimentation, blood glucose estimation, IC50 determination, demonstration of motor coordination, micro- scopic techniques, to study effect of drug on food and water intake, histopathological study, SDS PAGE demonstration, cell culture demonstration, cell viability assay.

M.S. (Pharm.) Pharmacology & Toxicology
SEMESTER - II

PC 610 - Drug Metabolism (1 Credit)

1. Biotransformation of drugs.
2. Enzymes responsible for bio-transformations, microsomal a non-microsomal mechanism
3. Factors influencing enzyme induction and inhibition.
4. Factors affecting drug metabolism.
5. Drug metabolism in fetus and newborn.
6. Models of 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, indiosyncracy.
10. Acute poisoning and its treatment

Recommended Books:

1. Introduction to Drug Metabolism, by G. Gordon Gibson and Paul Skett
2. Drug Metabolism Handbook Concepts and Applications Edited by Ala F. Nassar, Wiley

PC 611 - Pharmacological Screening and Assays (1 Credit)

1. Role of pharmacology in drug discovery, General principles of pharmacological screening.
2. Introduction to cell culture, Cell-based assay, Biochemical assays, CaCo-2 cell permeability assay. Gel electrophoresis assay.
3. Correlation between in vitro and in vivo screens.
4. Correlations between various animal models and human situations.
5. Pharmacological screening models. Transgenic animal model, Bioengineered models for drug screening.
6. Animal ethics, regulations for conducting animal experimentation. 3R's concept, Alternatives to animal experimentations, Organs-on-chips, Zebrafish model to screen pharmaceutical molecules.
7. Role of genomic and proteomic techniques in the process of target identification in drug discovery, MALDI-TOF, Microarray.
8. High-throughput screening and high-content screening.
9. Pharmacogenomics and Personal Medicine.
10. Network Pharmacology and Artificial Intelligence in Pharmacology and Drug Discovery.

Recommended Books/ Journals:

1. Drug Discovery and Evaluation: Pharmacological Assays by Vogel & Vogel
2. CPCSEA guidelines (http://cpcsea.nic.in)
3. Scientific journals in the area of pharmacology

PC 620 - CNS and Respiratory Pharmacology (2 Credits)

1. CNS drug discovery and challenges.
2. Neurotransmitters: dopamine, 5-HT, excitatory amino acids, GABA, glycine, cannabinoids, melatonin etc; Neurotransmitters receptors, their agonist and antagonists.
3. Neuromodulators, neuromediators and transporters.
4. Peptides as mediators: Substance P, neuropeptide Y, somatostatin, cholecystokinin, neurotensin, enkephalin, Orexin, CGRP etc.
5. Pharmacology of antianxiety drugs, antidepressants, antipsychotic drugs and psychomotor stimulants.
6. Pharmacology of antiepileptics.
7. Pharmacology of antimigraine drugs.
8. Pharmacology of local anaestheics, general anaesthetics, sedatives and hypnotics, centrally acting muscle relaxants.
9. Pharmacology of narcotic analgesics, Drug dependence and withdrawal responses
10. Pharmacology of drugs used in neurodegenerative disorders such as Parkinson's disease, Alzheimer's disease, Huntington's disease, Multiple sclerosis.
11. Drugs for stroke
10. Pharmacology of nerve growth factors
11. CNS disease models for evaluation of effects of NCEs
12. Gene therapy and cell-based therapy for CNS disorders
13. CNS disease models: Evaluation of the effect of NCEs
14. Respiratory pharmacology: Pharmacology of bronchodilators, pharmacology of anti-inflammatory agents used in asthma& COPD and cough suppressants
15. Asthma/COPD models for evaluation of effects of NCEs

Recommended Books/ Journals:

1. The Pharmacological Basis of Therapeutics by Goodman and Gilman's
2. Pharmacology by Rang and Dale
3. Pharmacotherapy: A Pathophysiologic Approach by Dipiro and others
4. Pharmacology by Lippincott
5. Drug Discovery and Evaluation: Pharmacological Assays by Vogel & Vogel
6. Scientific journals (Trends in Pharmacological Sciences, Annual Reviews of Pharmacology and Toxicology, British Journal of Pharmacology, European Journal of Pharmacology, Pharmacology and Therapeutics, Nature Review Drug Discovery, Nature Review Neuroscience, Brain Research)

PC 630 - Autonomic, CVS, Blood, Renal & GI Pharmacology (2 Credits)

1. Introduction to Autonomic Pharmacology: Chemical transmission of in the ANS (cholinergic and adrenergic)
2. Pharmacology of muscarinic cholinergic receptor agonists and antagonists. anticholiestrase agents
3. Pharmacology of sympathomimetic drugs.

4. Ganglionic stimulants and blocking agents, neuromuscular blocking agents
5. . Introduction to CVS Pharmacology: CVS drug discovery and challenges
6. Antihypertensives drugs and newer targets for hypertension
7. Antianginal drugs and newer targets for MI
8. Drugs for Heart failure and antiarrhythmic drugs.
9. . Pharmacology of Lipid lowering and antiobesity agents
10. . Factors necessary for erythropoiesis: Homopoietic growth factors. Mechanism of blood clotting, hematopoietic agents, Oral anticoagulants: Factors increase/decrease the efficacy of oral anticoagulants, Heparin
11. Platelet adhesion and activation: Antiplatelet agents, thrombolytic agents and antifibrinolytic agents and hemostatic agents, integrins as therapeutic agents
12. Renal Pharmacology: Diuretics, vasopressin
13. Gene therapy and cell based therapy for CVS disorders
14. CVS disease models: Evaluation of effect of NCEs
15. Pharmacology of GI drugs: Drugs for peptic ulcer, emetics, antiemetics, drug regulating GI motility
16. GI disease models for evaluation of effects of NCEs

Recommended Books/ Journals:

1. The Pharmacological Basis of Therapeutics by Goodman and Gilman's
2. Drug Discovery and Evaluation: Pharmacological Assays by Vogel & Vogel
3. Scientific journals (Trends in Pharmacological Sciences, Annual Reviews of Pharmacology and Toxicology, British Journal of Pharmacology, European Journal of Pharmacology, Pharmacology and Therapeutics, Cardiovascular journals, Nature Review Drug Discovery)

PC 640 - Autacoids and Endocrine Pharmacology (1 Credit)

1. Introduction to autacoids
2. Pharmacology of histamine: Histamine receptors, histamine agonists and antagonists
3. Pharmacology of bradykinin: Bradykinin receptors, bradykinin agonists and antagonists
4. Pharmacology of eicosanoids: COX inhibitors
5. Pain and inflammatory models for screening
6. Adenohypophyseal hormones and related substances.
7. Thyroid and antithyroid drugs.
8. Insulin and oral hypoglycemic agents, Endocrine pancreas.
9. Adrenocortical hormones: adrenocortical steroids and inhibitors of the synthesis.
10. Agents affecting the calcification,
11. Estrogens and progesterone and their antagonists, Oral contraceptive
12. Androgens

Recommended Books/ Journals:

1. The Pharmacological Basis of Therapeutics by Goodman and Gilman's
2. Pharmacology by Rang and Dale
3. Basic and Clinical Pharmacology by Katzung
4. Drug Discovery and Evaluation: Pharmacological Assays by Vogel & Vogel

PC 650 - Clinical Pharmacology and Regulatory Toxicology (2 Credits)

1. Introduction to clinical pharmacology
2. Investigational new drug (IND) application, clinical trials, new drug application (NDA) requirements; Regulatory agencies
3. Pharmacovigilance,
4. GCP Guidelines and GLP Guidelines
5. Individualization of drug therapy: Personalized medicine
6. Preclinical testing strategy; Vis-à-vis envisaged clinical studies; Experimental clarification of possible human risk; Technical details of experiments; Flow chart for development of preclinical testing.
7. Single dose and repeat dose toxicity studies: Factors influencing such studies such as species, sex, route, dose level; Data evaluation and regulatory requirements.
8. Reproductive toxicology assessment of male reproductive toxicity: Spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity.
9. 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.
10. Carcinogenicity: Principles of carcinogenicity, dose-setting for carcinogenesis bio assay, transplacental carcinogenesis; Cocarcinogenisis/tumor promotion.
11. Toxicokinetics, animals and dose groups: Exposure measurement; determination of metabolities complicating factors in exposure interpretation, analytical method, good laboratory practices; Stereiosomerism vis-à-vis regulatory requirements; Single enantiomers; Racemate enantiomer switch; Regulatory requirements.
12. Preclinical toxicological requirements for biological and biotechnological products: Safety analysis; problems specific to recombinant products secondary pharmacology.
13. Safety Pharmacology - ICH S7 and S7B guidelines
14. Safety pharmacological studies for pharmaceuticals
15. Safety pharmacological studies for biological products

Recommended Books/ Journals:

1. Clinical Pharmacology by Lawrence
2. Basic and Clinical Pharmacology by Katzung
3. ICH Guidelines
4. Schedule Y
5. OECD Guidelines
6. US FDA Guidelines

PC 660 - Chemotherapy and Immunopharmacology (2 Credits)

1. Introduction to immunopharmacology, immunomodulators, immunostimulants and immunosupperssants.
2. General considerations of antimicrobial agents.
3. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of following Quinolones, sulphonamides, penicillinscephalsoporins,clavulanic acid, aminoglycosides, broad spectrum antibiotics.
4. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of Quinolones, and aminoglycosides.
5. Chemotherapeutic agents used in tuberculosis.
6. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antifungal agents.
7. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of antiprotozoal agents.
8. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antimalarial agents, antiparasitic drugs.
9. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of antineoplastic agents

Recommended Books/ Journals:

1. Chemotherapy by Frank Hawking
2. Parasitic Protozoa by Julius P. Kreier and Ristic
3. Maraia by Julius P. Kreier
4. Chemotherapy and Drug Resistance in Malaria by Wallace Peter
5. Atlas of Tropical Medicine and Parasitology by Wallace Peter and Geoffrey Pasvol
6. Manson's Tropical Diseases: Expert Consult Basic by Gordon C. Cook
7. Tropical Infectious Diseases: Principles, Pathogens and Practice by Richard L. Guerrant, David H. Walker and Peter F. Weller
8. Essentials of Tropical Infectious Disease by Richard L. Guerrant, David H. Walker, Peter F. Weller
9. History of Human Parasitology by F.E.G. Cox
10. Malaria Parasites and other Haemosporidia by P.C.C. Garnham
11. Diagnostic Microbiology by Bailey & Scott
12. Medical Microbiology by Samuel Baron
13. Textbook of Microbiology by P.C.Baveja
14. Human Parasitic Infections of Pharmaceutical and National Importance edited by Prati Pal Singh and V.P. Sharma
15. Quantitative Real-time PCR in Applied Microbiology edited by Martin Filion

GE-611 : Seminar (1 credit)

Students are required to submit written record and present details of the project to be pursued in semester-III and 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 Laboratory Experience -10 hours/week (2 credits)

Ed50 calculation, working of stereotaxic apparatus, effect of drug on locomotor activity, demonstration of blood pressure recording, SDS PAGE, western blotting experiment, DNA Gel Electrophoresis experiment, MTT and LDH assay, effect of cyclophosphamide on neutrophil counts, Genotoxic effect of unknown drugs, histopathological evaluation with different target organ, microscopic techniques, blood cell counter.