

Co	urse 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
*	NP-510	Separation Techniques	1
**	PE-520	Biopharmaceutics and Pharmacokinetics	2
**	BT-510	Biotechnology in Pharmaceutical Sciences	1
*	GE-510	Biostatistics	2
**	GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
	GE-511	Seminar	1
	LG-510	General Laboratory Experience	3
		Total Credits	16
Se	mester - 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
Se	mester – III		
Pro	ojects (22 weeks))	
	TH-598	Synopsis	5
	TH-599	Presentation	3
		Total Credits	8
Se	mester – IV		
	TH-698	Thesis	9
	TH-699	Defence of Thesis	3
		Total Credits	12
		Grand Credits (I to IV Semesters)	50



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. Drug receptor interaction theories, occupation theory, rate theory.
- 2. Receptor occupation and response relationship, spare receptors, silent receptors, orphan receptors, presynaptic and postsynaptic receptors.
- 3. Receptor characterization methods: Pharmacological characterization, radioligand methods, monoclonal anti-bodies, receptor subtypes, IUPHAR nomenclature, clinical significance of receptor subclassification.
- 4. Receptor down regulation and upregulation.
- 5. Structure activity relationships, pharmacodynamic and pharmacokinetic aspects of chiral drugs, allosteric binding, thermodynamics of drug interactions with the receptors.
- 6. Transmembrane signal mechanisms, second messengers, viz., cAMP, cGMP, calcium.
- 7. Dose response relationship and different types of antagonisms.
- 8. Desensitization and tachyphylaxis.
- 9. Drug dependence and withdrawal responses.
- 10. Non therapeutic uses of drugs.

- 1. The Pharmacological Basis of Therapeutics by Goodman & Gilman
- 2. Casarett & Doull's Essentials of Toxicology, edited by CD Klassen and JB Watkins

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PC-530: Experimental Pharmacology (1 credit)

- 1. 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 chemical euthanasia.
- In vitro experimentation: 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. **In vivo 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.
- 4. Conscious animal experimentation precautions to be taken in behavioural experiments.
- 5. **Animal cell-culture techniques**: Aseptic handling, cell counting and cell viability assays.
- 6. **Protein and DNA gel electrophoresis:** Western, northern, southern blot hybridization and PCR techniques.
- 7. **Ultra, differential and analytical centrifugation:** Protein purification and identification by RF-HPLC, LCMS-MS, MALDI.
- 8. **Radiochemical methods of analysis:** Principle of radiation and radioactivity, decay of radioactivity, units, isotopes detection, scintillation detector (crystal and liquid), quenching, radioimmunoassay.
- 9. **Drug solution preparations:** Storage, concentration expression, common solvents, stabilizing agents, storage conditions, reference standards, methods of procurement of reference standards.
- 10. **Data collection:** Data reduction, data representation, cumulative and noncumulative dose response curves, transformation of data logit, probit, pA scale, pD scale.

Recommended Books:

- 1. Pharmacology by Lippincott
- 2. Drug Discovery and Evaluation: Pharmacological Assays by Vogel

***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
- 8. Biology of filarial infections
- 9. Mechanism of action of anti-filarial drugs
- 10. Targets of anti-filarial drug development.
- 11. Biology of HIV infection.
- 12. Mechanism of action of anti-HIV drugs
- 13. Targets for anti-HIV drug development.

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- 14. Biology of malaria
- 15. Mechanism of action of anti-malarial drugs.
- 16. Targets for anti-malarial drug development
- 17. Mechanism of drug-resistance in malaria.
- 18. Biology of leishmaniasis.
- 19. Mechanism of action of anti-leishmanial drugs
- 20. Targets for anti-leishmanial drug development.
- 21. 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

* NP-510 : 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.

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- 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: Biopharmaceutics and Pharmacokinetics (2 Credit)

- 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.

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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, by Rowland, M. and T. N. Tozer

**BT-510: Biotechnology in Pharmaceutical Sciences (1 credit)

- 1. **Biotechnology in pharmaceutical Sciences perspective:** Biology in drug discovery; Traditional drug discovery vs rational drug discovery; rational drug discovery pipeline; concept of target based drug design and target discovery; role of plant biotechnology in edible vaccine development.
- 2. **Genomics in target discovery:** Concept of genome, genes and gene expression; genome sequencing and sequence comparison methods (microarray); comparative genomics and expression genomics for target discovery of communicable disease and lifestyle disease.
- 3. **Systems and methods of molecular biology:** Isolation and validation of targets; PCR, RT-PCR nucleic acid isolation; cloning vectors (some examples), enzymes used in molecular cloning methods (some examples); cloning and characterization of biopharmaceuticals.
- 4. **Protein expression systems:** Gene expression in bacteria, yeast, insect and mammalian cells.
- 5. **Enzyme purification and assay:** Various protein purification methods; enzyme based assay for small molecule screening.
- 6. **Bioprocess technology:** *Upstream process:* Introduction to microbial growth, media formulation; sterilization, inoculum preparation.
- 7. **Bioprocess technology:** Fermentation: Fermentation process design, operation and characteristics of fermentation processes; batch, fed-batch and continuous culture systems, instrumentation and bioprocess control.
- 8. **Downstream process:** Introduction to various downstream process operations in biopharmaceutical manufacturing such as centrifugation, filtration, tangential flow filtration, cell disintegration, solvent-solvent extraction, supercritical fluid extraction etc.
- 9. **Biotechnology in pharmaceutical industry:** Major areas of biotechnology in the pharmaceutical industry such as antibiotics, vaccines, diagnostics, antibodies, biopharmaceuticals (insulin, interferon, GSF, CSF and therapeutic proteins etc.); commercial aspects, priorities for future biotechnological research.
- 10. **Industrial enzymes in drug development:** Penicillin amidase, lipase, oxidoreductase, nitrilase, protease etc.; use of all these enzymes for enantioselective synthesis of pharmaceutically important drugs/drug intermediates, future directions.

- 1. Analysis of Genes and Genomes by Richard J Reece. John Wiley & Sons
- 2. Molecular Biotechnology by Principles and Applications of Recombinant DNA by Bernard R. Glick, Jack J. Pasternak and Cheryl L. Patten, ASM Press

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- 3. Principles of Fermentation Technology by P F Stanbury, A. Whitaker, S. J. Hall. Butterworth-Heinemann.
- 4. Bioprocess Engineering Principles by Pauline M. Doran, Academic Press
- 5. Pharmaceutical Biotechnology by Concepts and Applications by Gary Walsh, John Wiley & Sons

*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 (1credit)

- 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 gentic 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 searchpublished 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; 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 infringments.

- 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 personnal; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsary 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, 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.

- 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

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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-15 hours/week (3 credits)

- 1. Analytical Techniques (30 hours): Separation techniques.
- 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 languageand 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, analgesic activity of a compound, estimation of protein and haematological parameters.
- 4. Biotechnology in pharmaceutical sciences (20 hours):
 - Day -1: Preparation for plasmid minirep.
 - Day-2: Plasmid minirep and restriction digestion.
 - Day-3: Gel electrophoresis and molecular weight calculation.
 - Day-4: Discussion of result and viva.
- 5. **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

Note: * Common in all disciplines

- ** Common between Pharmaceutics and Pharmacology & Toxicology
- *** Common between Medicinal Chemistry and Pharmacology & Toxicology

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SEMESTER - II

*PC-610: Drug Metabolism (1 credit)

- 1. Biotransformation of drugs.
- 2. Enzymes responsible for bio-transformations, microsomal and non-microsomal mechanisms.
- 3. Factors influencing enzyme induction and inhibition.
- 4. Factors effecting 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, idiosyncracy.
- 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. General principles of screening, correlations between various animal models and human situations, animal ethics.
- 2. Pharmacological screening models for therapeutic areas such as hypertension,' cerebral ischaemia, pain, epilepsy, depression, Parkinson's disease, Alzheimer's disease, diabetic, leishmania etc.
- 3. Correlation between *in-vitro* and *in-vivo* 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.

Recommended Books:

- 1. Drug Discovery and Evaluation: Pharmacological Assays by Vogel
- CPCSEA guidelines.

PC-620: CNS and Respiratory Pharmacology (2 credits)

- 1. Chemical transmission and drug action in the central nervous system: CNS drug discovery and challenges.
- 2. Neurotransmitters: Dopamine, 5-HT, excitatory amino acids, GABA, glycine peptides as mediators.
- 3. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of: Benzodaizepines and its antagonists. Barbiturates, local anesthetics.
- 4. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of 5-HT agonist and

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- antagonists, tricyclic antidepressants, MAOI, atypical antidepressants, lithium.
- 5. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of antiepileptics.
- 6. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in the treatment of Parkinsonism.
- 7. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of centrally acting muscle relaxants
- 8. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of narcotic analgesics.
- 9. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of psychomotor stimulants and psychotomimetic drugs, antipsychotic drugs.
- 10. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of drugs used in Alzheimer's disease,
- 11. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of: respiratory stimulants, bronchodilators and antiflammatory agents used in asthma, cough suppressants.

Recommended Books:

- 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. 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) Pharmacology by Lippincott.

PC-630: Autonomic, CVS, Blood, Renal, and GI Pharmacology (2 credits)

- 1. Chemical transmission of the autonomic nervous system.
- 2. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of the followings: Muscarinic cholinergic receptor agonists and antagonists. Ganglionic stimulants and blocking agents, neuromuscular blocking agents, drugs acting and adrenoceptors.
- 3. Cardiac glycosides and other cardiotonic agents: Anti dysrhythmic drugs, antianginal drugs.
- 4. **Antihypertensives:** Calcium channel antagonists, ACE inhibitors, endothelium derives relaxing factors, lipid lowering agents.
- 5. **Diuretics:** Drug altering the pH of urine, excretion of organic molecules.
- 6. Oral anticoagulants: Factors increase/decrease the efficacy of oral anticoagulants, heparin.
- 7. Platelet adhesion and activation: Antiplatelet agents, thrombolytic agents and antifibrinolytic agents and hemostatic agents.
- 8. **Factors necessary for erythropoiesis:** Homopoietic growth factors.
- 9. H2 receptor antagonists: Proton pump inhibitors, antacids, emetics, antiemetics and cancer chemotherapy, purgatives,

- 1. The Pharmacological Basis of Therapeutics by Goodman and Gilman's
- 2. 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).

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PC-640: Autacoids and Endocrine Pharmacology (1 credit)

- 1. Pharmacodynamic, pharmacokinetic, therapeutic and toxicological facets of the following Histamine and brady kinin agonist and antagonists.
- 2. Drugs acting through eicosanoids and platelet activating factor.
- 3. Adenohypophyseal hormones and related substances.
- 4. Thyroid and antithyroid drugs.
- 5. Insulin and oral hypoglycemic agents.
- 6. Endocrine pancreas.
- 7. Adrenocortical hormones: adrenocortical steroids and inhibitors of the synthesis.
- 8. Agents affecting the clacification, estrogens and progesterone and their antagonists.
- 9. Oral contraceptive.
- 10. Androgens.

Recommended Books:

- 1. The Pharmacological Basis of Therapeutics by Goodman and Gilman's
- 2. Pharmacology by Rang and Dale
- 3. Basic and Clinical Pharmacology by Katzung

PC-650: Clinical Pharmacology and Regulatory Toxicology (2 credits)

- Introduction to clinical pharmacology: Importance of clinical pharmacokinetics, therapeutic monitoring of important drugs.
- 2. **Drug-drug interactions:** Drug-food interactions; Drug-pollutant interaction.
- 3. Investigational new drug application, new drug application requirements; FDA requirements.
- 4. 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.
- 5. Design and organisation of phase-I to phase-IV clinical studies.
- 6. **Single dose and repeat dose toxicity studies:** Factors influencing such studies such as species, sex, size, route, dose level; Data evaluation and regulatory requirements.
- 7. **Reproductive toxicology assessment of male reproductive toxicity:** Spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity; alterations in reproductive endocrionology; relationship between maternal and developmental toxicity.
- 8. **Mutagenicity:** Mechanisms of mutagenesis, point mutations; Individual chromosomes and complete genome mutations, germ cell mutations, somatic cell mutation; Tests systems in vitro, test for gene mutation in bacteria, chromosome damage, gene mutation, in vivo micronucleus tests in rodent, metaphase analysis.
- Carcinogenicity: Principles of carcinogenicity, prechronic studies for dose-setting, chronic study, transplacental carcinogenesis; Cocarcinogenisis/tumor promotion, estimation of carcinogenicity of complex mixtures.
- 10. **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.
- 11. **Toxicokinetic methods validation:** Assay development; Assay validation, study monitoring, calibration of standards; validation report.

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12. **Preclinical toxicological requirements for biologicals and biotechnological products:** safety analysis; problems specific to recombinant productssecondary pharmacology, antibodies, transmission of viral infections, residual DNA, etc.

Recommended Books:

- 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: Immunopharmacology and Chemotherapy (2 credits)

- 1. Introduction to immunopharmacology, immunomodulators, immunostimulants and immunosuppressants.
- 2. General considerations of antimicrobial agents.
- 3. **Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the following:** Quinolones, sulphonamides, penicillins, cephalosporins, clavulanic acid aminoglycosides, broad spectrum antibiotics,
- 4. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the chemotherapeutic agents used in tuberculosis,
- 5. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antifungal agents,
- 6. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antiprotozoal agents,
- 7. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antimalarial agents, antiparasitic drugs
- 8. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of theantiviral drugs, drugs used in the treatment of AIDS
- 9. Spectrum of activity, mechanism of action, ADME and therapeutic aspects of the antineoplastic agents.

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. 8.
- 8. Walker and Peter F. Weller
- 9. Essentials of Tropical Infectious Disease by Richard L. Guerrant, David H. Walker, Peter F. Weller
- 10. History of Human Parasitology by F. E. G. Cox
- 11. Malaria Parasites and other Haemosporidia by P. C. C. Garnham
- 12. Diagnostic Microbiology by Bailey & Scott
- 13. Medical Microbiology by Samuel Baron
- 14. Textbook of Microbiology by P. C. Baveja
- 15. Human Parasitic Infections of Pharmaceutical and National Importance edited by Prati Pal Singh and V. P. Sharma
- 16. Quantitative Real-time PCR in Applied Microbiology edited by Martin Filion

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2014

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 in the area of Specialization-10 hours/week (2 credits)

Ed50 calculation, working of stereotoxy apparatus, effect of drug on locomotor activity, demonstration of blood pressure recording, SDS PAGE, western blotting experiment, DNA Gel Electorphoresis 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.

Note: * Common in all disciplines