SCHEME OF INSTRUCTION, EXAMINATION AND EVALUATION

Program Code: 887 **M. Pharm. (Pharmacology)**

2015 – 16

SEMESTER - I

Course Code	Course Title	Hours /Week			Credits	Marks		Duration of Exam
		L	T	P		Internal	End Exa	
PY.09.884.11.T	Pharmaceutical Analytical Techniques	3	0	-	3	25	75	3
PY.09.887.12.T	Bioassays and Clinical Research	4	0	-	4	25	75	3
PY.09.887.13.T	Advanced Pharmacology	4	0	0	4	25	75	3
PY.09.887.14.T	Principles of Toxicology	4	0	0	4	25	75	3
PY.09.887.15.T	Molecular Pharmacology and Drug Design	3	0	0	3	25	75	3
PY.09.884.11.P	Pharmaceutical Analytical Techniques	-	0	4	2	25	75	6
PY.09.887.12.P	Bioassays and Clinical Research	-	0	4	2	25	75	6
					22	175	525	
PY.09.887.10.S	SAIL	1	2	0	2	Grade		
PY.09.887.11.S	Seminar	1	0	2	2	Grade		

SEMESTER - II

Course Code	Course Title	Hours /Week			Credit	Marks		Duration of Exam
		L	T	P		Internal	End Exam	
PY.09.885.21.T	Int. Property Rights & Regulatory Affairs	3	0	-	3	25	75	3
PY.09.887.22.T	Biopharmaceutics and Pharmacokinetics	4	0	-	4	25	75	3
PY.09.886.23.T	Screening Methods in Pharmacology	4	0	0	4	25	75	3
PY.09.887.24.T	Clin. P'Cology & Pharmaco Therapeutics	4	0	0	4	25	75	3
PY.09.88X.25.T	Elective *	3	0	0	3	25	75	3
PY.09.887.22.P	Biopharmaceutics and Pharmacokinetics	-	0	4	2	25	75	6
PY.09.886.23.P	Screening Methods in Pharmacology	-	0	4	2	25	75	6
					22	175	525	
PY.09.887.20.S	SAIL	1	2	0	2	Grade		
PY.09.887.21.S	Seminar	1	0	2	2	Grade		

* Discipline Centric – Hospital and Community Pharmacy;
Open – Clinical Research & Pharmacovigilance

SEMESTER – III

Course Code	Course Title	Hours /Week	Credits	Marks		Duration in Weeks
				Internal	External	
PY.10.887.31.P	Design Seminar	30	6	50	-	6
PY.10.887.32.P	Progressive Seminar	30	10	50	-	10
		480	16	100		16

SEMESTER – IV

Course Code	Course Title	Hours /Week	Credits	Marks		Duration in Weeks
				Internal	External	
PY.10.887.41.P	Pre-Submission Seminar	30	10		50	10
PY.10.887.42.P	Submission and Adjudication	30	12		200	6
PY.10.887.43.P	Final Viva-voce	30	2		50	1
		510	24		300	17

PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.884.11.T	Exam Duration	:	3 Hrs.

Course Objectives:

To familiarize students in conventional and modern techniques of analysis used in different areas of pharmacy.

To understand the experimental concepts, the procedures and safety considerations in a quality control laboratory.

To give training in use of the technique and its applications in day to day practice.

To build on the basics learned at UG level and give latest advances in the area.

Course Outcomes:

By pursuing this course students are prepared for:

- *Research and Development*
- *Food, Bio and Pharma Industries*
- *Clinical Research and Quality Control Administration*

Unit - I :

UV-Visible Spectroscopy: Basic principles, interaction of electromagnetic radiation with matter and its effects (electronic transitions). Concept of chromophore and Auxo-chrome, effect of conjugation, solvent and pH. Instrumentation (components and their significance). Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs including multicomponent analysis. Woodward-Fieser rules for calculating absorption maximum for unsaturated hydrocarbons. Difference and derivative spectra.

Infra-Red Spectroscopy: Interaction of infrared radiation with organic molecules and it's effects on bonds. Instrumentation- Dispersive IR spectrophotometers and Fourier transform spectrophotometers. Sample handling for IR spectroscopy. Interpretation of IR spectra. Brief note on ATR. (Attenuated Total Reflectance).

Unit - II :

Nuclear Magnetic Resonance Spectroscopy: Fundamental Principles of NMR, Chemical shifts concept, spin-spin coupling, spin-spin decoupling, shielding, de-shielding, shift reagents and solvents. Signal multiplicity phenomena in high resolution PMR. Interpretation of PMR spectra. Brief introduction about Carbon-13 NMR Spectroscopy.

Mass Spectrometry: Basic principles Mass Spectrometry. Ionization techniques (EI and CI), Mass spectrum and its characteristics, molecular ion, metastable ions, fragmentions; fragmentation processes, Nitrogen Rules, Relative abundances of isotopes and their contribution to characteristic peaks and molecular formula determination.

Unit - III :

Chromatographic Techniques: General Principles, Classification of Chromatographic Methods Thin Layer Chromatography, Paper Chromatography and Column Chromatography and Methods based on Mechanism .

Gas Chromatography: Instrumentation, Column efficiency parameters, derivatization methods, applications in pharmaceutical analysis.

Liquid Chromatography: Principles of HPLC, Instrumentation, Normal and Reversed Phase Packing Materials, Column Selection, Mobile Phase Selection, Efficiency Parameters, Applications in Pharmaceutical Analysis. Chiral Chromatography, Flash Chromatography, and Supercritical Fluid Chromatography (SFC).

Unit - IV :

Electrophoresis: Principles, Instrumentation and Applications of Moving Boundary Electrophoresis Zone Electrophoresis (ZE), Isoelectric Focusing (IEF), Continuous Electrophoresis (Preparative) and Capillary Electrophoresis. SDS Gel Electrophoresis and Blotting Techniques.

Radio immunoassay and ELISA: Principle, instrumentation, applications and limitations.

Unit - V :

X-Ray Diffraction: Origin of X-rays, basic aspects of crystals, X-ray crystallography, miller indices, rotating crystal technique, single crystal diffraction, powder diffraction, structural elucidation and applications.

Thermal Analytical Techniques: Principles, Theoryand Applicationof ThermalAnalysis (DSC, DTAand TGA)

Books and References:

1. Skoog, DA, Holler, FJ, Crouch, SR. Principles of Instrumental Analysis. 6th ed., Baba Barkha Nath Printers, Haryana, 2007.
2. Silverstein, RM, Webstar, FX. Spectrometric Identification of Organic Compounds. 6th Ed., John Wiley & Sons (Asia) Pvt. Ltd., Singapore, 2005.
3. William Kemp. Organic Spectroscopy, 3rd ed., Palgrave, New York, 2006.
4. Jag Mohan, Organic Spectroscopy: Principles and Applications, 2nd Ed., Narosa Publishing House Pvt. Ltd., New Delhi, 2005.
5. Conners KA. A Textbook of Pharmaceutical Analysis, 3rd Ed., John Wiley & Sons, Singapore, 2004.
6. Willard HH, Merritt LL, Dean JA, Settle FA. Instrumental Methods of Analysis, 7th Ed., CBS Publishers & Distributors, New Delhi, 1986.
7. Pavia DL, Lampman GM, Kriz GS, Vyvyan JA. Introduction to Spectroscopy. 4th Ed., Brookes Cole Publishers, California, 2008.
8. Sharma BK. Instrumental Methods of Chemical Analysis, 25th Ed., Goel Publishing house, Meerut, 2006.
9. Beckett, AH, Stenlake, JB. Practical Pharmaceutical Chemistry, Part I & II, 4th ed., CBS Publishers & Distributors, New Delhi, 2004.
10. Ewing, GW. Instrumental Methods of Chemical Analysis, 5th Ed., McGraw Hill Book Company, NY, 1985.
11. Schirmer, RE. Modem Methods of Pharmaceutical Analysis, Vol. I & II, 2nd Ed., CRC Press, Florida, 2000.

BIOASSAYS AND CLINICAL RESEARCH

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.887.12.T	Exam Duration	:	3 Hrs.

Course Objectives:

This subject will provide an opportunity for the student to learn significance of bioassays and clinical trials in drug discovery process.

Course Outcomes:

Upon completion of the subject student shall be able to –

- Acquire the knowledge about various methods of bioassays for quantification of pharmaceutical products.
- Understand the phases of clinical trials and various guidelines for GCP.
- Appreciate the importance of clinical trials during drug discovery process.

Unit - I :

Introduction to Bioassays: Principles of bioassays. Types of bioassays. Errors in bioassays; Application of bioassay methods. Official bioassays – Acetyl choline, adrenaline, digitalis, histamine, serotonin, heparin.

Unit - II :

Bioassay of Hormones:- Insulin, oxytocin, vasopressin, growth hormone, gonadotrophin, thyrotropin, androgen, estrogen, progesterone.

Unit - III :

Bioassay of Vaccines and Sera: Diphtheria and Anti-Toxin, Tetanus and Anti-Toxin, Hepatitis-B, Pertussis, BCG, Influenza, Measles, Rubella, Rota Virus and Rabies and Anti-Serum.

Unit - IV :

Drug Discovery: Preclinical and Clinical Development of Drugs.

Introductionto Clinicaltrials: Various Phases of Clinical trials, Methods of Post Marketing Surveillance, New Drug Application submission.

Unit - V :

Ethical Guidelines in Clinical Research: Composition, responsibilities and procedures of IRB / IEC. Declaration of Helsinki, Informed Consent Process. Ethics and clinical trials in spec ial population.

Role and Responsibilities of Clinical Trial Personnel: Sponsor; Investigators; Auditors; Site Manager; Monitoring Personnel; Contract Research Coordinator; Contract Research Associate; Contract Research Organization and Regulatory Authority

Books and References:

1. Essentials of Pharmacotherapeutics- F.S.K Barar S. Chand Publications
2. Pharmacology by H.P. Rang and M.A. Dale
3. Principles of Clinical Research edited by Giovanna and Haynes.
4. Drug discovery and clinical research by Dr.SK Gupta.ist edition 2011. ICRI.

5. Ethical Guidelines for Biomedical Research on Human Subjects 2006. Indian Council of Medical Research, New Delhi.
6. Textbook of Clinical Trials edited by David Machin, Simon Dayand Sylvan Green, March 2005 John Wiley and sons.
7. Clinical Data Management edited byR K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
8. A Practical Guide to Human Research and Clinical Trials byDr.MUR Naidu and Dr. P.UshaRani.Taylor and Francis group.

ADVANCED PHARMACOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.887.13.T	Exam Duration	:	3 Hrs.

Course Objectives:

The subject is designed to strengthen the basic knowledge in the field of pharmacology and to impart recent advances in the drugs used for the treatment of various diseases..

Course Outcomes:

Upon completion of the course the student shall be able to:

- *Explain the mechanism of drug actions at cellular and molecular level*
- *Discuss the pathophysiology and pharmacotherapy of certain diseases*
- *Understand the adverse effects, contraindications and clinical uses of drugs used in treatment of diseases*
- *Appreciate the role of antioxidants in the free radical mediated diseases*
- *Design a clinical trial for new drugs as per the guidelines*

Unit - I :

Neurotransmission Pharmacology- General aspects and steps involved in neurotransmission; Neuro-humoral transmission in autonomic nervous system;. Neuro humoral transmission in central nervous system; Non-adrenergic non-cholinergic transmission [NANC].

Unit - II :

A detailed study of the mechanism of action, pharmacology of drugs used in-: ANS-Para-sympathomimetics, Para-sympatholytics, Sympathomimetics; Sympatholytics, Agents acting at neuromuscular junction and ganglia. CNS- General anaesthetics, sedatives, hypnotics. Drugs used to treat anxiety, depression, psychosis, mania, epilepsy, neurodegenerative diseases; Opioid analgesics, Drug addiction and dependence.

Unit - III :

CVS- diuretics, ant- ischemics; anti-hypertensives; anti-arrythmics, drugs for heart failure and dyslipidemia. GIT Pharmacology– anti ulcer, pro-kinetics, anti-emetics; anti-diarrheal and drugs for constipation and irritable bowel syndrome; Hormone and hormone antagonists; Anti-diabetics

Unit - IV :

A detailed study of the mechanism of action, pharmacology of drugs used in: Autacoid pharmacology- a study of the mechanisms involved in the formation, release, pharmacological actions and possible physiological role of histamine, serotinin, kinins, prostaglandins,. Analgesics and anti-inflammatory agent

Chemotherapeutic Agents: Anti-biotics, Anti-Malarials, Anti-Tuberculosis, Anti-Virals, Anti-Fungals, Anti-helminthics and Anti-cancer Agents

Unit - V :

Free radical and Immuno-pharmacology: Generation of free radicals, role of free radicals in etio-pathology of various diseases, protective activity of certain important antioxidants. Cell and biochemical mediators involved in allergy, immunomodulation and inflammation. Classification of hypersensitivity reactions and diseases involved. Therapeutic agents for allergy, asthma, COPD and other immunological diseases with emphasis on immuno-modulators.

Books and References:

1. Clinical Pharmacologyby D.R.Lawrnce and P.N.Bennette
2. Pharmacologyand Pharmaco-Therapeutics R.S. Satoskar and S.D. Bhandarkar.
3. The PharmacologyBasis of T herapeutics. 10th edition by Louis S.Goodman and Altred Gillman
4. Pharmacologyby H.P. Rang and M.A. Dale
5. Drug Metabolism byBerhard Tests and Peter Jenner.
6. Principles of Drug action by Goldstein, Aranow and Kolman.
7. Pharmacokinetics : RegularoryIndustrial Academic Perspectives, Second Edition, edited by Peter G.Welling and Francis L.S.Tse
8. Davidson's Principles of Internal Medicine, Vol I & II, 14th Edition, Mc Graw-Hill
9. Harrison's Principle and Practice of Medicine, 18th Edition, Churchill, Livingston, London
10. Essentials of Pharmaco-therapeutics, Barar F.S.K; S.Chand & Company, New Delhi

PRINCIPLES OF TOXICOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.887.14.T	Exam Duration	:	3 Hrs.

Course Objectives:

This subject is designed to impart the knowledge regarding the preclinical drug evaluation techniques in the drug discovery and development. The subject content helps the student to understand the maintenance of laboratory animals as per the guidelines, basic knowledge of various in-vitro and in-vivo preclinical evaluation processes, the newer methods of toxicity testing, and various guidelines for conducting toxicity studies.

Course Outcomes:

Upon completion of the course the student shall be able to,

- Apprise the general principles of toxicology, regulations and ethical requirement for the usage of experimental animals.
- Describe the various poisons and scope of adverse .reactions and its reporting system

Unit - I :

General principles of toxicology. Preclinical toxicology studies, acute toxicity study- acute single dose, acute repeat dose, sub-chronic toxicity, and chronic toxicity. Factors influencing such studies such as species, sex, size, route, dose level; Role of preclinical toxicologyin drug discovery and developmentprocess. Experimental considerations for assessing possible human risk. Flow chart for development of preclinical testing. Dose conversion factors. Determination of Maximum Tolerated Dose (MTD) and LD 50 as per revised OECD guidelines. Toxicokinetics

Unit - II :

General principles of Regulatory Toxicology. Regulatory requirements& guidelines for the new drug safety assessments- ICH, OECD, USFDA, EMEA, Japan, MHW guidelines

Unit - III :

In-vitro and *In-vivo* toxicitystudies pertaining to genotoxicity, mutagenicity, carcinogenicity, reproductive toxicity, ocular toxicity, dermal toxicity, immunotoxicology and allergenicity testing

Unit - IV :

Classification of Poisons, Action of poisons, Factors affecting action of Poisons, fate of poisons in the body, types of poisoning & general principle of treatmentof poisoning. Signs and symptoms, treatment of acute and chronic poisoning- Insecticidal poisoning, Alcohol Poisoning, Opium Poisoning, Snake poisoning and Heavy Metal Poisoning (lead, mercury and arsenic), Food poisoning and Poisonous foods.

Unit - V :

Pharmacovigilance: Definition, Collection of Data, Reporting, Assessment, Periodic Safety Update Reports, and Risk- benefit Assessment and Management.

Current Reporting Methods: Adverse Drug Reaction (ADR), Adverse Events (AE), Serious Adverse Event (SAE), Serious Adverse Reaction (SAR), Suspected Unexpected Serious Adverse Reaction (SUSAR)

Books and References:

1. Drug Safety Evaluation, Shayne C Gad, Wiley Interscience

2. The toxicologist's pocket handbook, Michael J derelanko Second Ed,2008,CRC press
3. Relevant OECD guidelines (Internet resources) http://www.ingentaconnect.com/content/oecd/16073/2001/00000001/00000004
4. Parikh's Textbook Of Medical Jurisprudence, Forensic Medicine And Toxicology,Sixth Edition, CBS publishers and distributors
5. Elements of Pharmacovigilance byRaman Sehgal, Dr. Rajat Sethi and Dr. Shobha Rani Hiremath..Kong Posh Publications
6. Cobert's Manual of Drug safety and Pharmacovigilance. Barton Cobert. 2011 2nd edition. Jones and Bartlett Learning.

MOLECULAR PHARMACOLOGY AND DRUG DESIGN

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.887.15.T	Exam Duration	:	3 Hrs.

Course Objectives:

The subject imparts a fundamental knowledge on the structure and functions of receptors at their molecular level which are very much essential in Drug Design. The topic on molecular pharmacology helps the student to upgrade their knowledge as per need of drug discovery and development.

Course Outcomes:

Upon completion of the course the student shall be able to,

- *Describe the molecular level drug receptor interactions and their importance in drug development.*
- *Describe the various drug discovery and development programme*
- *Learn the applicability of molecular pharmacology in drug development process.*
- *Know the modern approaches for drug discovery such as proteomics and genomics. .*

Unit - I :

Molecular Basis of Drug Action:- Receptor occupancy and Cellular signaling systems such as G-Proteins, cyclic nucleotides, Calcium and Phosphatidyl ionositol. Ionic Channels and their modulators. Third messengers. Biosensors. Regulation, Isolation and Characterization of Receptors; GAP Junctions and Apoptosis Pathways.

Unit - II :

Bioactivity: Endogenous bioactive molecules- cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme, protein kinase-A and protein kinase- C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelins and their modulators and atrial peptides.

Unit - III :

Receptors: Recent trends on different classes of receptors- Angiotensin receptors, excitatory amino acid receptors, kinin receptors, adrenoceptors, cholinergic receptors, ion channel receptors, imidazole receptors, dopamine receptors, serotonin receptors, histamine receptors, hormone receptors, GABA and benzodiazepine receptors, opiod receptors, purinergic receptors and glutamate receptors

Unit - IV :

Herbal Drug Therapy: Anticancer, Anti AIDS, Hepato-protectives, Anti-diabetics, Anti-urolithiates, Anti-filarial and Anti-hyperlipidimics. Modern PhytochemicalScreening Techniques and Evaluation of Herbal Drug Extracts and Formulations, Concept of Reverse Pharmacognosy.

Unit - V :

Drug Design: Overview on Computer Aided Drug Design (CADD) including QSAR, Combinatorial Chemistry, High Throughput Screening (HTS). Drug Latentiation -Basic Concept, Prodrugs of Functional Groups, Bio-precursor Prodrugs, Chemical Delivery System.

Books and References:

1. Comprehensive Medicinal chemistryVol-4 Ed.C. Hanseh, Pergamon Press, New York.
2. Katzung B G; Basic and Clinical Pharmacology, Lange Medical publisher, USA

3. Melmon KL and Morelli; Clinical Pharmacology: Basic Principles of therapeutics, Mc Millan, New York
4. Goodman and Gilman; Pharmacological Basis of Therapeutics, Mc Graw Hill
5. Rang HP, Dale MN, Pharmacology, Churchill Livingston, UK
6. Dewick Paul M. Medicinal Natural Products-ABiosynthetic Approach.
7. Chakravarty T.K. " Herbal Options".

PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	2	Quiz	:	05
Instruction Mode	:	Practical	End Semester	:	75
Course Code	:	PY.09.884.11.P	Exam Duration	:	6 Hrs.

Course Objectives:

To make students familiar with the principles of modern analytical techniques and application of analytical instruments in pharmacy.

Course Outcomes:

At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product.

List of Experiments :

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
2. Effect of solvents and pH on UV spectrum ofdrugs (2 experiments).
3. Estimation of multicomponent formulation byUV- Spectrophotometer in formulations. (2 experiments).
4. Experiments based on the application of derivative spectroscopy. (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradientelution) techniques. (2 experiments).
6. Interpretation of drugs by IR spectra.
7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).
8. Separation of protein drug substances by electrophoresis.
9. Any other relevant experiments based on theory.

Books and References:

BIO-ASSAYS AND CLINICAL RESEARCH

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	2	Quiz	:	05
Instruction Mode	:	Practical	End Semester	:	75
Course Code	:	PY.09.887.12.P	Exam Duration	:	6 Hrs.

Course Objectives:

This course will provide an opportunity to the students to learn about bioassays of different classes of drugs acting on various systems of the body and also to establish the safety and efficacy of various drugs through clinical studies and research.

Course Outcomes:

To acquaint with the basics of protocols for Bioassays and Clinical Research

List of Experiments:

1. Biological standardization of drugs like acetylcholine/Histamine / oxytocin/adrenaline using suitable isolated tissue preparations.
2. To study DRC of acetylcholine/Histamine / oxytocin/adrenaline in the presence and absence of antagonist on suitable isolated tissue preparations.
3. Calculation of dose-ratio of antagonist in presence and absence of agonist using suitable tissue preparations.
4. Determination of pA2 values of antagonist using suitable tissue preparations.
5. Estimation of biochemical and free radical scavengers.

Note: A minimum of 8 different experiments are expected to be covered

Books and References:

1. Handbook of Experimental Pharmacology- S.K.Kulkarni, Vallabh Prakashan, New Delhi
2. Some topics in Preclinical Pharmacology-Mahalaxmi Mohan , Career Publications, Nashik
3. A Handbook of Experiments in Preclinical Pharmacology- S.B.Kasture, Career Publications
4. Fundamentals of Experimental Pharmacology, Ghosh MN, Scientific Book Agency, Calcutta
5. Pharmacological Experiments on Isolated Preparations, Perry WLM, E &S, Livingston, London
6. Selected topics in Experimental Pharmacology, Sheth UK, Dadkar NK; Kothari Book Depot, Mumbai

INTELLECTUAL PROPERTY RIGHTS & REGULATORY AFFAIRS

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.885.21.P	Exam Duration	:	3 Hrs.

Course Objectives:

To make students familiar with the fundamental principles of IPR and Drug Regulatory Affairs

Course Outcomes:

On completion of the course the student would understand the principle and importance of IPR and Drug Regulatory Affairs in the Competitive World.

Further to familiarize with Safety and Pollution Control Regulations in addition to Other Product Regulations and Sustainable Development Principles.

Unit - I :

Intellectual Property Rights (IPR): Objectives, types of IPR, Patents-advantages, types, criteria, inventions – patentable, Impact on Pharmaceutical Industry, copyrights-types rights, trademarks-functions, types, geographical indications-significance, types, industrial designs, and trade secrets.

India Patents Act, 1970, Amendments, 1999, 2002, 2005, stages of patenting, patent opposition (Post Grant), maintaining the patent rights – Conditions, patent information – search and sources

Unit - II :

International Patent Filing Procedures – Requirements for patenting, utility, novelty non-obviousness, patent specification & claims, patent infringement and doctrine of equivalents, federal circuit and patent system.

International Organizations and Agreements – IPR: General Agreement on Tariffs and Trade (GATT)-Historical perspectives, objectives and impact, World Trade Organization (WTO)- scope, functions, structure, withdrawal ofmembership, dispute settlement, World Intellectual PropertyOrganization (WIPO) - objectives and programs, Paris Convention – background, scope, impact, Berne Convention, TRIPS Agreement-scope general features, specific features, The Doha Declaration, Patent Cooperation Treaty (PCT), Madrid Protocol.

Unit - III :

ICH – Guidelines: Harmonization Efforts, Basic Principles (Quality, Safety and Efficacy), ICH Q11 (Quality Management Systems); Common Technical Document (CTD) and Generic Drug Products.

WHO – Guidelines: Sampling Operations

PICS Guidelines: Basic Requirements of Medicinal Products and API's

OECD Guidelines: Clinical Studies

US-FDA: Orange Book, FDA Guidelines on Investigational New Drugs (IND), New Drug Applications (NDA).

Unit - IV :

Regulatory Affairs: Indian Context - Drugs and Cosmetics Act 1940 and Rules 1945 with reference to Schedule M, U and Y. Drug Regulatory Controls and Authorities;

Important Regulations: Importand Export of Drugs; Preparation and Submission of Marketing Application of India, US and Europe; Approval and Appeals Present and Issues of Confidentiality.

Unit - V

Industrial Safety Regulations: Industrial Development & Regulation Act 1951, Industrial Hazards – Mechanical, Electrical, Chemical and Pharmaceutical (MSDS Preparation), Industrial Safety - Plant, Gas, Dust, Fire and Explosion, Safety Management. Monitoring & Prevention Systems,

Pollution Control Regulations: Pollution Control Act; Industrial Effluent Testing & Treatment. Control of Environmental Pollution, Water and Solid Waste in Formulation, Synthetic and Fermentation Plants.

Other Product Regulations: Prevention of Food Adulteration Act 1954; Consumer Protection Act

Sustainable Development: 10 Principles Bench Marked against leading International Standards;

Books and References:

1. Guarino RA. New Drug Approval Processes, 4th ed., Vol 139, Marcel Dekker Inc., New York, 2004.
2. Willing SH. Good Manufacturing Practices for Pharmaceuticals. 5th ed., vol 109, Marcel Dekker Inc., New York, 2001.
3. Das P, Das G. Protection of Industrial Property Rights.
4. Treece DJ. Managing Intellectual Capital: Organizational, Strategic and Policy Dimension. Oxford University Press, England. Latest Edition.
5. Wadedhra BL. Law Relating to Patents, Trademarks, Copyright Design and Geographical Indications. Universal Law Publishing, New Delhi. Latest Edition.
6. Bansal P. IPR Handbook for Pharma Students and Researchers, Pharma Book Syndicate, Hyderabad. Latest Edition.
7. Katju SN. Laws and Drugs. Law Publishers.
8. Original Laws Published by Government of India.
9. Hussain. Law of Drugs in India.
10. Regulatory Guidelines Related to GMP by
    a. Australian code of GMPfor medicinal products, 16th Aug. 2002.
    b. 21 Code of Federal Regulation, parts 210, 211 & 58. (US-FDA Guidelines)
    c. MHRA, UK Guidelines on GMP
    d. GMP Guidelines byMedicines Control Council of South Africa
    e. Schedule M of D & C Act
11. WHO Guidelines: QualityAssurance of Pharmaceuticals – A Compendium of Guidelines and Related Materials – Vol. 2; WHO 2007;
12. GMP Guidelines (Websites: www.fda.org; www.wipo.int, www.ich.org, www.cder.org)
13. PICS Guidelines (Website: http://www.picscheme.org/)
14. Information on Orange Book [website: www.fda.gov/cder/ob/default.html].
15. Relevant OECD Guidelines (Website: http://www.ingentaconnect.com/content/oecd/16073/2001/00000001 /00000004
16. Subrahmanyam CVS, Thimma Setty JPharmaceutical Regulatory Affairs, Vallabha Prakashan, Delhi 2012.

BIOPHARMACEUTICS AND PHARMACOKINETICS

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.886.22.T	Exam Duration	:	3 Hrs.

Course Objectives:

To make students familiar with the fundamental principles of drug absorption, distribution, metabolism and excretion of drugs.

To emphasize on bioavailability study and application of biopharmaceuticals.

Course Outcomes:

On completion of the course the student would understand the

- *Drug absorption, distribution, metabolism, and elimination.*
- *Basic mechanisms and concepts of absorption, distribution, metabolism, and elimination.*
- *How to predict the fate of drugs in the body given all the physiological, chemical and physical parameters of the drug and the patient*

Unit - I :

Bioavailability and Bioequivalence: Objectives, bioavailability & variations, measurements of bioavailability, enhancing bioavailability, concepts of equivalents, official bioequivalence protocols & therapeutic equivalence. Methods of determining absorption-*in-vitro*, *in-situ*, and *in-vivo* methods.

Drug Distribution: Factors affecting, protein & tissue binding, kinetics, determination of rate constants & different plots (direct, Scatchard, & reciprocal).

Unit - II :

Pharmacokinetics: Parameters & determination, pharmacokinetic models – one compartment, multi compartment in IV bolus, IV infusion & extra vascular, drug & metabolites levels in blood, urine and other biological fluids. Integration of kinetics; Application of pharmacokinetics in new drug development, design of dosage forms and novel drug delivery systems. Physiological basis for in-vitro modeling.

Unit - III :

Pharmacokinetics of Multiple Dosing: Various terminology, determination, adjustmentofdosage in renal & hepatic impairment, individualization of therapy, therapeutic drug monitoring.

Unit - IV :

Chemical Stability Kinetics: Complex Chemical Reactions – Kinetics, Factors Affecting Chemical Stability, Stability Testing in Pre-formulation;

Non-linear kinetics: Causes of non-linearity, estimation of various parameters, bioavailability of drugs that follow non-linear kinetics. Chronopharmacokinetics & pharmacokinetics of elderly and infants.

Unit - V :

Drug Disposition and Excretion: Biotransformation, factors affecting biotransformation, Phase I & Phase-II reactions.

Clearance: Concept, renal, non-renal clearance, mechanism, determination, % drug metabolized, different volume of distribution.

Books and References:

1. Biopharmaceutics and Clinical Pharmacokinetics, Mile Gibaldi, Lea and Febriger, Philadelphia.
2. Current concepts in Pharmaceutical Sciences, Swarbrick, Lea and Febriger, Philadelphia.
3. Theory & Practice of Industrial Pharmacy, L.Lachman, Varghese Publ, Bombay.
4. Clinical Pharmacokinetics, Rowland and Tozer, Lea and Febriger, Philadelphia.
5. Biopharmaceutics and Clinical Pharmacokinetics, Niazi, Prentice Hall, London.
6. Remingtons Pharmaceutical Sciences, Mack & Co.
7. Biopharmaceutics & Clinical Pharmacokinetics, DM Brahmankar, Vallabh, Delhi.
8. C.V.S.Subrahmanyam, Textbook of Biopharmaceutics and Pharmacokinetics, 2009, Vallabh Prakashan, Delhi.

SCREENING METHODS IN PHARMACOLOGY

Scheme of Instruction			Scheme of Examination		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.887.23.T	Exam Duration	:	3 Hrs.

Course Objectives:

This course offer practical advantages in fine-tuning the understanding of various drug evaluation techniques and screening methods by using various experimental animals.

Course Outcomes:

Upon completion of the course the student shall be able to,

- *Describe the various newer screening methods involved in the drug discovery process.*
- *Learn the applicability and importance of biostatistics in preclinical research.*
- *Appreciate and correlate the preclinical data to humans.*

Unit - I :

Regulations for laboratory animal care and ethical requirements. Knowledge of CPCSEA. Proforma for performing experiments on animals. Transgenic mouse and its applications;

Unit - II :

Organization of preclinical screening program; Preclinical models employed in the screening of new drugs belonging to following categories: Sympatho mimetics, para-sympathomimetics, musclerelaxants (both central and peripheral), sedatives, hypnotics, antipsychotic agents, antianxiety agents, nootropic agents, antidepressant drugs; anti-parkinsonism agents, anti-epileptics;

Unit - III :

Preclinical models employed in the screening ofnew drugs belonging to following categories:

Antiarrhythmic agents, cardiac stimulants, cardiotonic agents, anti-hypertensives, bronchodilators, anti-histaminics, analgesics and anti-inflammatory agents; antiulcer agents; anti-atherosclerotic drugs; anti-diabetics; anti-fertility agents, anticancer agents

Unit - IV :

Alternatives to animal screening procedures: Animal cell lines and their applications, cell-line handling and maintenance and propagation of cell lines, patch-clamp technique, in-vitro cell line based assays on diabetics and arthritis models

Unit - V :

Sampling Methods: Simple Random, Stratified, Systematic and Cluster Sampling Procedures.

Design of experiments: Principles of replications, completely randomized design, randomized block design and latin square design.

Distribution and Testing of hypothesis: Introduction to normal distribution, null hypothesis, alternative hypothesis and type-1 and 2 errors in hypothesis.

Statistical tests: t - test (paired and unpaired), one way and two way analysis of variance test (ANOVA), chi-square tests- i) variance of normal population, ii) goodness of fit and iii) independence of attributes. Nonparametric tests- sign test, median test, run test and rank test. Correlation and regression analysis- Method of least squares, linear and nonlinear regression analysis, correlation coefficients.

Books and References:

1. Pre – Clinical Drug Development, Rogge
2. Basic and clinical Pharmacology, Katzung
3. Pharmacological screening methods, N.S. Parmar and Shivkumar
4. Pharmacological screening methods, N.S. Parmar and Shivkumar
5. Calculations for Pharmaceutical Practice , Winfield
6. Pharmacoepidemiology, Storm
7. CPCSEA, OECD, FDA, WHO, ICH guidelines from respective website downloads.
8. Drug Discovery and Pharmacological Evaluations, G. H.Vogel& W.H.Vogel, Springer publications.
9. Evaluation of Drug Activities, Pharmacometrics, Lawrence DR & Bacharah AL. Academic Press.
10. Screening Methods in Pharmacology, Turner RA, Academic Press, London

CLINICAL PHARMACOLOGY & PHARMACO THERAPEUTICS

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	4	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.887.24.T	Exam Duration	:	3 Hrs.

Course Objectives:

To train the students in the drug therapy management of different diseases

To develop the skills in students to identify and resolve any drug related problems

To appreciate the quality use of medicines

Course Outcomes:

Upon completion of the course, it is expected that students will be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of these diseases including reference to the latest available evidence
- Discuss the controversies in drug therapy and evidence based medicine
- Discuss the preparation of individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoring therapy (including alternatives, time- course of clinical and laboratory indices of therapeutic response and adverse effect/s)

Unit - I :

Basics in Clinical Pharmacology; Overview of Clinical Trial startup, Trial Monitoring and Close-out Activities.

Clinical Data Management Systems and its Components, Coding Dictionaries, Data M igration and Archival.

Unit - II :

Population Pharmacokinetics: Introduction to Bayesian Theory; Adaptive method or Dosing with feedback; Analysis of Population pharmacokinetic Data.

Pharmacogenomics: Introduction; Genetic Polymorphism in Drug Metabolism, Interethnic differences, Inter-racial and individual variability in drugs metabolism, Drug Transport and Drug Targets;

Unit - III :

Pathophysiology and drug therapy of the following disorders.

Schizophrenia, anxiety, depression, epilepsy, Parkinson's & Alzheimer's diseases , migraine hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infarction, TB, leprosy, leukemia, solid tumors, lymphomas, psoriasis, respiratory, urinary , g.i. tract infections, endocarditis, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.

Unit - IV :

Drug therapy and Pharmacokinetics: Geriatrics, Pediatrics, Pregnancy& Lactation.

New therapeutic approach: Biomarkers, Stem cell therapy, and Gene therapy.

Unit - V :

Rational Drug Use: Definition, Concept, Need, Role of Pharmacists in Rational Drug Use, Drug Use Indicators, Guidelines for Rational Prescribing of Medications.

Books and References:

1. Biopharmaceutics and Pharmacokinetics, Venkateshwarlu
2. Clinical Pharmacyand therapeutics , Herfindal
3. Drug Disposition and Pharmacokinetics , H.Curry
4. Pharmacokinetics ,Milo Gibaldi
5. Managing clinical Drug development , Cocchetto
6. Pharmacogenomics , Kalow
7. Drug discovery and development, Rang & Dale
8. Basic Statistics and Pharmaceutical Statistical applications , Muth
9. Pharmacokinetics for the Pharmaceutical Scientist , Wagner
10. W.H.O Publications ,Technical Report Series.
11. Clinical Pharmacologyby D.R.Lawrnce and P.N.Bennette
12. Clinical Pharmacyand Therapeutics; Roger and Walker, Churchil, Livingston, London

ELECTIVE

HOSPITAL & COMMUNITY PHARMACY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.884.24.P	Exam Duration	:	3 Hrs.

Course Objectives:

To acquaint with the Drug Policies for Hospital and Community Pharmacy

Course Outcomes:

To understand the Drug Information, Distribution and Dispensing Techniques and Policies

Unit - I :

Hospital Organization: Pharmacyand Therapeutics Committee and role ofhospital pharmacist

Hospital Drugpolicy: Drug committee, Formularyand guide lines, other hospital committees such as infection control committee and research and ethics committee

Hospital Pharmacy Management: Staff (professional, non-professional) materials (drugs, non-drugs and consumables), financial (drug budget, costcenter, source of revenue, revenue collection), policyand planning, infrastructure requirements (building, furniture, specialized equipment, maintenance and repairs), Workload statistics and logistics.

Unit - II :

Drug Distribution: Purchasing, warehousing (storage condition, expiry date control recycling of drugs, stock tacking, drug recalls), Drug distributing methods (Ward stock, individual patient dispensing, unitdose), Specific requirements for in patient, out patients, casualty/Emergency. Operation theatres, ICU/CCU, Drugs of dependence, Hospital waste management.

Drug Information Resources and Services: Primary, Secondaryand TertiaryResources for Drug Information Request, Search Strategy from SecondarySource of Computer Database, Comprehensive Searchand Multiple Databases and Resources, Drug Monographs and Its Utility;

Unit - III :

Bio-Medical Ethics: Ethical issues in biomedical research – Principle of ethics in biomedical research, good clinical practice (ICH GCP guideline), ethical committee (institutional review board), its constitution and functions, Significance of Patient consent and Physician consent; Ethics of publication.

Unit - IV :

Community Pharmacy: CommunityPharmacy Role and its relationships to other local health care providers

Prescribed Mediation Order - Interpretation and legal requirements communications skills- communications with prescribes and patients.

Over The Counter (OTC) Sales

Primary Healthcare in Community Pharmacy: Familyplanning , first aid ,Participation in primaryhealth care programs, Smoking cessation , Screening programs

Community Pharmacy Management: Financial materials, staff infrastructure, requirements,

Code of ethics for Community Pharmacist

Unit - V :

Pharmaco-epidemiology: Definition and Scope, Methods (Sources of data, study design, drug utilization studies, meta-analysis); Social cultural, economic factor influencing drug use. System for monitoring drug effects; Advantages and disadvantages of Pharmaco-epidemiology

Pharmaco-economics: Definition and scope, Types of economic evaluation, cost models and cost effectiveness analysis.

Books and References:

1. Hospital Pharmacy- Hassan W E, Lec and Febiger Publications.
2. Textbook of Hospital pharmacy- Allwood MC and Blackwell
3. Avery's Drug Treatment, 4th Edition, 1997, Adis International Ltd.
4. Remington's Pharmaceutical Sciences.
5. Relevant review articles from recent medical and Pharmaceutical Journal

ELECTIVE

CLINICAL RESEARCH & PHARMACOVIGILANCE

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	3 Hrs.	Mid Semester	:	20
Credits	:	3	Quiz	:	05
Instruction Mode	:	Lecture	End Semester	:	75
Course Code	:	PY.09.884.24.P	Exam Duration	:	3 Hrs.

Course Objectives:

This paper will provide the students

- An opportunity to learn drug development process
- Knowledge about the requirement for conducting clinical trials
- Training in conceptualizing, designing, conducting, managing and reporting of clinical trials.

Course Outcomes:

At completion of this paper it is expected that students will be able to (know, do and appreciate):

Drug development process and different phases of clinical trials

Material and regulatory requirements for conducting clinical trials

Types of clinical trial designs and responsibilities of key players involved in clinical trials

Site initiation, monitoring and close-out activities

Safety monitoring and reporting in clinical trials.

Classification, Detection and Monitoring of Adverse Drug Reactions

Unit - I :

Drug Discovery: Introduction to various approaches to drug discovery -Pharmacological, Toxicological, Drug characterization, different dosage forms. Preclinical studies.

Drug Development Process: Introduction to Clinical trials. Clinical trial designs. Phases of clinical trials (Phase 0- Phase IV trials), Investigational new drug development (IND), New drug development (NDA), Abbreviated new drug development (ANDA) ,Methods of post marketing surveillance.

Unit - II :

Ethical guidelines in Clinical Research: Composition, responsibilities and procedures of IRB / IEC; Declaration of Helsinki, Informed Consent Process. Ethics and clinical trials in special population.

Role and responsibilities of clinical trial personnel: a. Sponsor b. Investigators c Auditors d. Regulatory authority e. Monitor f. Site manager; g. Contract research organizations

Unit - III :

Designing of Clinical Study Documents (Protocol, Investigator brochure, Case report forms, Informed consent document); Overview of clinical trial startup, trial monitoring and close-out activities; Safety monitoring and adverse event reporting in clinical trials, SUSARS; Clinical Data management Systems and its components, Coding dictionaries, Data migration; and archival.

Unit - IV :

Pharmacovigilance: Definition, aims and need for pharmacovigilance; Definitions of the following terms: Adverse Drug Reaction (ADR), Adverse Events (AE), Serious Adverse Event (SAE), Serious Adverse Reaction (SAR), Suspected Unexpected Serious Adverse Reaction (SUSAR);

Adverse Drug Reactions: Classification, mechanism, Predisposing factors, causality assessment (different scales used); Current methods of Pharmacovigilance, Signal detection in Pharmacovigilance; Detection, Reporting, Monitoring and Management of ADRs; Role of pharmacistin management of ADR; Setting up of a pharmacovigilance center.

Unit - V :

FDA rules and regulations for reporting ADRs for various classes of drugs; Common databases used in pharmacovigilance (eg: ARGUS , Vigibase); ADR reporting systems in various countries. Pharmacovigilance programme in India (PVPI), Haemovigilance program; The council for International Organizations of Medical Sciences (CIOMS)

Books and References:

1. Central Drugs Standard Control Organization (CDSCO), Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on HumanSubjects 2006. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited byDavid Machin, Simon Dayand Sylvan Green, March 2005 John Wiley and sons.
5. Principles of Clinical Research edited by Giovanna and Haynes.
6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
7. Drug discovery and clinical research by Dr.SK Gupta.ist edition 2011. ICRI.
8. A Practical Guide to Human Research and Clinical Trials by Dr.MUR Naidu and Dr. P.UshaRani .Taylor and Francis group.
9. Elements of Pharmacovigilance by Raman Sehgal, Dr. Rajat Sethi and Dr. Shobha Rani Hiremath. .Kong Posh publications
10. Cobert's manual of Drug safetyand Pharmacovigilance. Barton Cobert. 2011 2nd edition. Jones andBartlett Learning.

BIOPHARMACEUTICS AND PHARMACOKINETICS

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	2	Quiz	:	05
Instruction Mode	:	Practical	End Semester	:	75
Course Code	:	PY.09.886.22.P	Exam Duration	:	6 Hrs.

Course Objectives:

To make students familiar with the fundamental principles of drug absorption, distribution, metabolism and excretion of drugs.

Course Outcomes:

Understands the basic mechanisms and concepts of absorption, distribution, metabolism, and elimination.

List of Experiments:

1. Comparative dissolution studies on different dosage forms for drugs.
2. Effect of pH / particle size on dissolution studies.
3. Plasma protein binding studies on different drugs.
4. Estimation of pharmacokinetic parameters in urine / serum samples.
5. Estimation of creatinine clearance.
6. Estimation of pharmacokinetic parameters for the given urinary excretion data.
7. Estimation of pharmacokinetic parameters for the given oral absorption data.

Books and References:

SCREENING METHODS IN PHARMACOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	60 Hrs.	Max. Marks	:	100
Hours/Week	:	4 Hrs.	Mid Semester	:	20
Credits	:	2	Quiz	:	05
Instruction Mode	:	Practical	End Semester	:	75
Course Code	:	PY.09.884.24.P	Exam Duration	:	6 Hrs.

Course Objectives:

To know and understand the Screening Methods in Pharmacology

Course Outcomes:

To acquaint with the protocols and familiarize with organizing experiments

List of Experiments:

1. Experiments to evaluate CNS stimulant activity, antidepressants, anxiogenics and anxiolytics, amnestics and nootropics, anti convulsants, anti-parkinsonian activity in suitable animal species
2. Experiments to evaluate anti-ulcer activity, intestinal motility, and anti-diarrhoeals in suitable animal species.
3. Experiments to study general screening procedure of anti-arrhythmic agents, anti-hypertensives,
4. Experiments to study Local anesthetic activity in suitable animals
5. Experiments to evaluate diuretic activity on suitable animal species.
6. Experiments to study antidiabetic activity of drugs in suitable animal species.
7. Experiments to study analgesic and anti-inflammatory activity in suitable animal species.
8. Experiments on enzyme-induction activity, drug dependence and withdrawal effects.
9. Monitoring of drug concentrations in saliva/urine/blood.
10. Drug absorption and elimination studies.

Note: Minimum 8 experiments shall be conducted**.**
Any other experiment based on the topics mentioned in theory

Books and References:

1. Handbook of Experimental Pharmacology- S.K.Kulkarni, Vallabh Prakashan, New Delhi
2. A Handbook of Experiments in Preclinical Pharmacology- S.B.Kasture, Career Publications
3. Fundamentals of Experimental Pharmacology, Ghosh MN, Scientific Book Agency, Calcutta
4. Drug Discovery and Pharmacological Evaluations, G. H.Vogel& W.H.Vogel, Springer publications.
5. Screening Methods in Pharmacology, Turner RA, Academic Press, Londo
6. Some Topics in Preclinical Pharmacology-Mahalaxmi Mohan , Career Publications, Nashik

SAIL

SCIENTIFIC AND TECHNICAL WRITING

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X1.I	Exam Duration	:	1 Hr.

Course Objectives:

To be able to appreciate and understand importance of writing scientifically.

- *To develop competence in writing and abstracting skills.*
- *To write either a draft research proposal or a chapter of dissertation.*

Course Outcomes:

Able to prepare a document with systematic approach

Unit - I :

COLLECTION AND EVALUATION OF INFORMATION: Identification sources, searching information, classifying information under fact/opinion, tabulating information, summarizing a text and presenting sequence of topics in different forms.

WRITING AS A MEANS OF COMMUNICATION: Different forms of scientific and technical writing; Articles in journals, Research notes and reports, Review articles, Monographs, Dissertations, Bibliographies.
How to formulate outlines: The reasons for preparing outlines
(i) as a guide for plan of writing (ii) as skeleton for the manuscript
Outline of topic, concept, sentence and combination of topic and sentence outlines

Unit - II :

DRAFTING TITLES, SUBTITLES, TABLES, ILLUSTRATIONS

- Tables as systematic means of presenting data in rows and columns and lucid way of indicating relationships and results.
- Formatting Tables: Title, Body stab, Stab Column, Column Head, Spanner Head, Box Head
- Appendices: use and guidelines

The Writing process: Getting started, Use outline as a starting device, Drafting, Reflecting and Re-reading
Checking: Organization, Headings, Content, Clarity and Grammar
Brevity and Precision in writing - Drafting and Re-drafting based on critical evaluation

PARTS OF DISSERTATION/RESEARCH REPORT/ARTICLE
Introduction, Review of Literature, Methodology, Results and Discussion
Content, continuity, clarify, validity internal consistency and objectivity during writing each of the above parts.

References:

1. APA (1984): Publication Manual of American Psychological Association 3rd Ed, Washington.
2. Cooper, H.M. (1990): Integrating Research: A Guide for Literature Reviews (2nd Edition). California: Sage.
3. Dunn, F.V & Others. (Ed.) (1984): Disserninating Research: Changing Practice. NY: Sage.

SAIL

RESEARCH METHODOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X2.I	Exam Duration	:	1 Hr.

Course Objectives:

To give exposure on how to do literature survey for the project work.
To develop technical writing skills in the form of a research report.

Course Outcomes:

To able to organize the research in an effective fashion

Unit – I :

Basics of Research: Definition, objectives, motivation, types of research and approaches; Descriptive research, conceptual, theoretical, applied and experimental.

Formation of Research Problem: Research Process: To determine what type of research to be done, plan of research work; Selection of research area, prioritization of research; Literature review: importance and methods, sources; Objectives and scope of work, developing research plan and schedule; Scheduling constraints, steps, problems in scheduling, limitations.

Experimental Modeling: Definition of experimental design, examples, single factor experiments, blocking and Nuisance factors, guidelines for designing experiments; General model of process: Input factors/ variables, Output parameters / variables controllable / uncontrollable variables, dependent / independent variables, experimental validity; Introduction to Risk assessment, reliability, sustainability, and uncertainty.

Unit – II :

Analysis of Data: Types of data: parametric and nonparametric, descriptive and inferential data; Collection of data: normal distribution, calculation of co-relation coefficient; Data processing: analysis, error analysis, meaning, and different methods; analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity/nonlinearity of model, testing adequacy of model; Test to be used in data exploration and their choice; Introduction of software used in data analysis.

Research Deliverables: Various Forms of Publication: T hesis, paper, research proposal; Thesis Writing: Introduction, literature review/state-of-the-art, research approach (methodology), results / findings, discussions, conclusions, scope for future work, references, appendices; Presentation: Poster, thesis, proposal, and paper.

Ethical and Plagiarism issues in research: Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines/ herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments; Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, bibliography, end note.

References:

1. C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers.
2. D. Montgomary, 2000. "Design of Experiments". 5th Ed. Wiley Interscience.
3. K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd ed. Himalaya publishing, Mumbai.
4. Schank Fr, 2008. "Theories of Engineering Experiments". 2nd Ed. Tata McGraw Hill.
5. J.W. Best and J.V. Kahn, 2006. "Research in Education". 10th Ed. PHI publication.

SAIL

TEACHING METHODOLOGY

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X3.I	Exam Duration	:	1 Hr.

Course Objectives:

To acquaint with the basic tools of teaching to part of teaching profession

Course Outcomes:

Able to practice the teaching techniques for effective dissemination of knowledge

Unit - I :

Learning and Instruction: Principles of Instructional design and learning theory, Merrill's five principles and Gagne's condition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learning model of Kolb.

Curriculum Development: A six step approach- Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom's Taxonomy, three domains of educational objectives.

Unit - II :

Assessment: Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.

Teaching Methods: Activities conducted individually, in pairs and in groups like self-introduction, peer introduction, group poster making, grammar and vocabulary games, etc.
Discussions; Role playactivities; Short presentations; Listening and viewing activities with follow up activities like discussion, filling up worksheets, writing exercises (using language lab wherever necessary/possible) etc.

References:

1. B.D. John, A.L. Brown and R.R. Cocking, 1999."How People Learn: brain, mind, experience and school". Washington, DC: NationalAcademy Press.
2. K.E. David, 2009. Curriculum Development for Medical Education: *A Six-Step Approach,* 2nd Ed. The John Hopkins University Press. ISBN 0-8018-9367-4.

SAIL

ENREPRENEURSHIP DEVELOPMENT

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X4.I	Exam Duration	:	1 Hr.

Course Objectives:

To provide conceptual inputs regarding entrepreneurship management.

To sensitize and motivate the students towards entrepreneurship management.

To orient and impart knowledge towards identifying and implementing entrepreneurship opportunities.

Course Outcomes:

To develop management skills for entrepreneurship management

Unit - I :

CONCEPTUAL FRAME WORK: Concept need and process in entrepreneurship development; Role of enterprise in national and global economy; Types of enterprise – Merits and Demerits; Government policies and schemes for enterprise development; Institutional support in enterprise development and management;

THE ENTREPRENEUR: Dynamics of Entrepreneurial Motivation; Concepts; Developing Entrepreneurial Competencies; Requirements and understanding the process of entrepreneurship development; self-awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur'' role.

Unit - II :

LAUNCHING AND ORGANISING AN ENTERPRISE: Environment scanning – Information, sources, schemes of assistance, problems; Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis; Resource mobilization - finance, technology, raw material, site and manpower; Costing and marketing management and quality control; Feedback, monitoring and evaluation; Project work – Feasibility report; Planning, resource mobilization and implementation.

GROWTH STRATEGIES AND NETWORKING; Performance appraisal and assessment; Profitability and control measures, demands and challenges; Need for diversification; Future Growth – Techniques of expansion and diversification, vision strategies; Concept and dynamics; Methods, Joint venture, co-ordination and feasibility study;

References:

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C.(1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

SAIL

COMPUTATIONAL TECHNIQUES

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X5.I	Exam Duration	:	1 Hr.

Course Objectives:

Learn the organization of a digital computer.
Learn to think logically and write pseudo code or draw flow charts for problems.

Course Outcomes:

Be familiar with the use of Office software.
Be exposed to presentation and visualization tools.as well as problem solving techniques and flow charts.

Unit - I :

Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.

Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).

Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).

Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemicalstructure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).

Unit - II :

Web page design: Need, concept and use of HTML

Databases: Meaning, Need and creating table, record creating and maintenance.

Internet concept: History, creating internet connection, common problems & solutions.

Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.

References:

1. W. E. Fassett, 1986."Computer Applications in Pharmacy", Lea & Febiger Publisher.
2. C.N. Madu, 2003. "Statistics as easy with Microsoft Excel for Windows", 1st Ed.Chi Pub. Inc.
3. http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
4. www.Pubmed.com
5. www.Pubchem.com
6. www.mdl.com
7. http://www.vlifesciences.com
8. http://spdbv.vital-it.ch
9. http://www.winstat.com
10. www.uspto.gov
11. www.esp.gov

SAIL

Laboratory Design, Safety and Management

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X6.I	Exam Duration	:	1 Hr.

Course Objectives:

To expose them to existing national safety standards
To acquaint with Laboratory Design and Management

Course Outcomes:

On Completion of the course the student will be able to perform the Experiments as per cGLP norms.

Unit - I :

Lab Design Criteria; Codes, Standards and References; Architectural Considerations, Walls, Doors, Windows, Security, Ceiling, Flooring, Cleanability, Sinks, Storage, Exit Paths, Engineering Considerations – Electrical, Plumbing, Utilities – Air, Water, Steam and Gases, Heating, Ventilation, Air Conditioning and Fume Hoods;

Laboratory Furniture Design and Location; General Laboratory Safety Practices; Standard Operating Procedures (SOP's);

Unit - II :

Management of Analytical Laboratory: Organization of Laboratories based on their types, staffing, skill development and training, budgeting and financing, purchase of costly equipment, qualities of laboratory manager and management styles.

Laboratory Inspections: Internal inspection, external audit, concepts, preparing for inspections and audits.

Reference standards: Types, preparation, containers, labeling, storage and use.

Documentation-STPs: Certificate of Analysis (COA.), LaboratoryNote Books: Typical Documents used in a GLP Laboratory including Standard Test Protocols (STP's),

References:

1. Laboratory Design Guidelines – University of North Carolina, USA
2. Laboratory Design Hand Book
3. Designing and Planning of Laboratories (2009)
4. Laboratory Design and Construction Guidelines (2010) – Departmentof Environment, Health and Safety, University of South Carolina, USA
5. Laboratory Safety Design Guide,(2007) – Departmentof Environment, Health and Safety, University of California, USA
6. Laboratory Safety Guidance,(2011) – OSHA, USA
7. Safe Lab (2007) Web site at www.cpsc.gov

SAIL

Creativity and Innovation

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X7.I	Exam Duration	:	1 Hr.

Course Objectives:

To impart the knowledge of various aspects of Creativity and Innovation

Course Outcomes:

On Completion of the course the student will be able to understand the significance of Creativity and Innovation.

Unit - I :

The process of technological innovation - factors contributing to successful technological innovation - the need for creativity and innovation - creativity and problem solving – brain storming - different techniques.

Unit - II :

Patents - Patent search - Patent laws -International code for patents

References:

1. Twiss, Brian."Managing Technological Innovation", Pitman Publishing Ltd., 1992.
2. Nystrom, Harry "Creativity and Innovation", John Wiley & Sons, 1979.
3. Khandwalla, N.– "Fourth Eye (Excellence through Creativity) - Wheeler Publishing", 1992.
4. I.P.R. Bulletins, TIFAC, New Delhi, 1997.

SAIL

Employability Skills

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X8.I	Exam Duration	:	1 Hr.

Course Objectives:

To enhance the employability skills of learners with a special focus on presentation skills, group discussion and interview skills.
To enable them to improve their soft skills necessary for workplace contexts.
To equip them with effective communicative competence for a global reach.

Course Outcomes:

Participate in conversations both formal and informal, attend phone calls and interviews successfully.
Read different types of texts and Listen to, and understand foreign accents.

Unit - I :

SPEAKING SKILLS: Conversationalskills (formaland informal contexts) - telephonic communication, attending job interviews (responding to FAQs) - taking part in GDs - making presentations.

WRITING SKILLS: Job applications – cover letter – resume – applying online – writing proposals – e-Mails – letters – reports – memos – minutes – blogging – tweeting – writing recommendations and instructions – writing for publications.

READING SKILLS: Vocabularybuilding – speed reading (skimming – scanning) – reading different genres of texts from newspapers to philosophical treatises – criticalreading – effective reading strategies such as reading 'beyond the lines', summarizing, graphic organizers and distinguishing facts from opinions.

Unit - II :

LISTENING/VIEWING SKILLS: Speeches of different nationalities with focus on American and British accent (TED talks, podcasts) – listening to lyrics – lectures – instructions – dialogues – news casting – talk shows – interviews (Hard talk, Devil's Advocate)

SOFT SKILLS: Motivation - persuasive skills – negotiations – time management – emotional intelligence – stress management – creative and critical thinking.

References:

1. Barker, A. Improve Your Communication Skills. New Delhi: Kogan Page India Pvt. Ltd., 2006.
2. Craven, Miles. Listening Extra – A resource book of multi-level skills activities.Cambridge University Press, 2004.
3. Gammidge, Mick. Speaking Extra - A resource book of multi-level skills activities. Cambridge University Press, 2004.
4. Hartley, Peter. Group Communication. London: Routledge, 2004.
5. John Seely. The Oxford Guide to Writing and Speaking. New Delhi: Oxford University Press, 2004.
6. Naterop Jean & Rod Revell. Telephoning in English. Cambridge University Press,1987.
7. Ramesh, Gopalswamy and Mahadevan Ramesh. The ACE of Soft Skills. New Delhi: Pearson, 2010.

Web Sources:

1. www.humanresources.about.com
2. www.careerride.com

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INFORMATION SEARCH TECHNIQUES

Scheme of Instruction			**Scheme of Examination**		
Total Duration	:	30 Hrs.	Max. Marks	:	50
Hours/Week	:	2 Hrs.	Assignment	:	20
Credits	:	2	Attendance	:	05
Instruction Mode	:	Tutorial	Seminar	:	25
Course Code	:	PY.09.880.X9.I	Exam Duration	:	1 Hr.

Course Objectives:

To learn the types of information searches and know the importance of search preparation
To establish the formulation of search strategies and understand the types of search techniques and also to make use of the search techniques in information retrieval
To identify the search techniques to various search tools

Course Outcomes:

Able to distinguish between simple, advanced and meta searches
Plan for a search session and formulate search strategies
Select the appropriate search tool for the required information
Apply the use of search techniques to various search tools

Unit - I :

Types of Searches:- Simple searching, Advanced searching and Meta searching, Keywords, Search preparation.
Search Strategy: Steps in developing search strategy, advantages of a search strategy

Unit - II :

Search Techniques: Boolean Logic, Parenthesis, Phrase searching, Truncation, Wildcards and Field searching
Application of Search Techniques: Searching from deep web sources eg Medline/PubMed; Searching from directories and search engines; and Searching in subject portals eg: HINARI

References:

1. Eyers John E. Searching bibliographic databases effectively. Health Policyand Planning. 1998. 13(3): 339
2. Finding Information on the Internet: A Tutorial *UC Berkeley - Teaching Library Internet Workshop* (2010)
3. *Steve Lawrence and C. Lee Giles.* Searching the Web: General and Scientific Information Access, *NEC Research Institute.* IEEE Communications Magazine. January1999. 116-122p.

Web Sources:

1. HINARI: Health Internetwork for Access to Research Information. http://www.who.int/hinari/en/(May2010)
2. Indiana University Library: Basic Database Searching Techniques. http://www.libraries.iub.edu/index.php?pageId =1480 (March 2010)
3. National Library of Medicine. Medline/PubMed. PubMed Tutorial. http://www.ncbi.nlm.nih.gov/pubmed/ (2010)
4. Open University. Information skills for researchers. http://www.open.ac.uk/infoskillsresearchers/search-techniques.htm (2010) and http://www.lib.berkeley.edu/TeachingLib/Guides/Internet/FindInfo.html (2010)
5. Reitz, Joan M.(2004). *Online Dictionary for Library and Information Science*. URL:ODLIS - http://lu.com/odlis/
6. T he search manual - Cochrane Libraryhttp://www.thecochranelibrary.com/view/0/SearchManual.html (2010)
7. University Of West England. The Cochrane Library http://www.uwe.ac.uk/library/resources/hea/docs/cochrane.pdf (2010) and Meta searching. http://writing.colostate.edu/activities(2010)