Osmania University Syllabus for M. Pharmacy (Pharmacology)

(w.e.f. academic year 2009-10)

FACULTY OF TECHNOLOGY
HYDERABAD

Scheme of Instruction and Evaluation for M. Pharmacy (Pharmacology)

I – Semester – Revised-2009

Subject Code	Subject / Paper	Theory / Practical	Instruction Hours per week		Evaluation	Duration of External Examination	
					Theory	Practical	Internal / External
M.PCOL.T.1.101	Pharmaceutical Analytical Techniques	Theory	4	---	30	70	3
M.PCOL.T.1.102	Drug Design and Molecular Pharmacology	Theory	4	---	30	70	3
M.PCOL.T.1.103	Bioassays and Screening Methods	Theory	4	---	30	70	3
M.PCOL.T.1.104	Principles of Toxicology	Theory	4	---	30	70	3
M.PCOL.P.1.105	Pharmaceutical Analytical Techniques	Practical	-	6	30	70	6
M.PCOL.P.1.106	Bioassays and Screening Methods	Practical	--	6	30	70	6
M.PCOL.T.1.107	Scientific and Technical Writing (SAIL)	Tutorial	2	-	A/B/C/D	-	-
M.PCOL.1.108	Seminar	Theory		8	50		
			18	20	230	420	

Scheme of Instruction and Evaluation for M. Pharmacy (Pharmacology)
II– Semester – Revised-2009

Subject Code	Subject / Paper	Theory / Practical	Instruction Hours per week		Evaluation	Duration of External Examination	
					Theory	Practical	Internal / External
M.PCOL.T.1.201	Intellectual property rights & Regulatory affairs	Theory	4	---	30	70	3
M.PCOL.T.1.202	Advances in Pharmacology	Theory	4	---	30	70	3
M.PCOL.T.1.203	Biopharmaceutics and Pharmacokinetics	Theory	4	---	30	70	3
M.PCOL.T.1.204	Pharmacology & Pharmaco therapeutics	Theory	4	---	30	70	3
M.PCOL.P.1.205	Advances in Pharmacology	Practical	--	6	30	70	6

	Practicals.						
M.PCOL.P.1.206	Biopharmaceutics and Pharmacokinetics	Practical	--	6	30	70	6
M.PCOL.T.1.207	Entrepreneurship Management (SAIL)	Tutorial	2	-	A/B/C/D	-	-
M.PCOL.1.208	Seminar	Theory		8	50		
			18	20	230	420	

SAIL: Self assess Instrumentation Learning

Scheme of Instruction and Evaluation for M. Pharmacy (Pharmacology)

Semester III and IV

DISSERTATION – Original research work carried out by the candidate under the guidance of regular teaching faculty/visiting faculty of the department should be submitted in a bound form.

Evaluation of the dissertation shall be done by external and internal examiners appointed by the university.

Dissertation viva-voce Grade A/B/C/D/F
Dissertation report Grade A/B/C/D/F

A. Excellent B. Very good C. Good D. Fair F. Fail

PHARMACEUTICAL ANALYTICAL TECHNIQUES

Subject Code: M.PCOL.T.1.101 Sessional : 30
Period / Week: 4 Examinations : 70
Nature of Exam: Theory Duration of Exam : 3 hrs

UNIT – I

a) UV-Visible Spectroscopy: Basic principles, interaction of electromagnetic radiation with matter and its effects (electronic transitions). Concept of chromophore and auxochrome, 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.

b) 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, instrumentation (components and their significance). Chemical shifts concept, spin- spin coupling, spin-spin decoupling, shielding and deshielding, solvents. signal multiplicity phenomena in high resolution PMR. Interpretation of PMR spectra.

Brief introduction about Carbon-13 NMR and 2D NMR Spectroscopy.

UNIT – III

Mass Spectrometry: Basic principles and instrumentation (components and their significance). Ionization techniques, mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.

UNIT – IV

Chromatographic Techniques: Classification of chromatographic methods based on mechanism of separation and their basic principles. **Gas chromatography**: Instrumentation, column efficiency parameters, derivatisation methods, applications in pharmaceutical analysis. **Liquid chromatography**: Comparison of GC and HPLC, instrumentation in HPLC, normal and reversed phase packing materials, column selection, mobile phase selection, efficiency parameters, applications in pharmaceutical analysis. Instrumentation and applications of HPTLC, ion exchange chromatography, gel permeation chromatography, chiral chromatography, flash chromatography, and supercritical fluid chromatography (SFC).

UNIT – V

Electrophoresis: Principles, instrumentation and applications of moving boundary electrophoresis, zone electrophoresis (ZE), isotachphoresis, isoelectric focusing (IEF), continuous electrophoresis (preparative) and capillary electrophoresis. SDS gel electrophoresis and blotting techniques.

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

Recommended books

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 Text book 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., Brookescole 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, New York, 1985.

11. Schirmer, RE. Modem methods of pharmaceutical analysis, Vol. I & II, 2nd ed., CRC Press, Florida, 2000.

12. Moffat, AC, Osselton, MC, Widdop, B. Clarke's analysis of drugs and poisons, Vol. I & II, 3rd ed., K.M. Varghese Company, Mumbai, 2004.

DRUG DESIGN AND MOLECULAR PHARMACOLOGY

Subject Code : **M.PCOL T.1.102**	Sessional :30
Periods/Week : 4	Examination : 70
Nature of Exam : Theory	Exam Duration : 3 Hrs

UNIT –I

Pharmacokinetics approach to New Drug Discovery

Basic concepts and Defination, importance of ADME parameters in disposition, therapeutics and development their implication on drug discovery.

UNIT-II

Overview on computer aided Drug design (CADD) including QSAR, Combinational Chemistry, High Throughout screening (RTS)

UNIT-III

Molecular Basis of Drugs Action: Cell signaling, communication between cells and their environment, ion-channels, organizations of signal transduction pathways, third messengers, biosensors.

Drug Latentiation :Basic concept, Prodrugs of functional groups, Bio-precurssor prodrugs, chemical delivery system.

UNIT – IV

Biotechnology in Drug Discovery: Cloning of DNA, Expression of cloned DNA, Manipulation of DNA sequence information, New Biological Targets for Drug Development Novel Drug Screening strategies, Novel Biological Agents, Antibodies, Antisense eligonucleotide therapy, Gene therapy.

UNIT – V

Herbal Neutracauticals as new source for medicines.
Study of Advanced drugs from natural sources of following groups:
Anticancer, Anti AIDS, Hepatoprotectives, Antidiabetics, Brain Toni cs, Anti urolithiates, Antifilarial, Antihyperlipidimics.
Modern phytochemical screening techniques and evaluation of herbal drugs and their extracts and formulations, Concept of Reverse Pharmacognosy.

Books recommended

1. Comprehensive Medicinal chemistry Vol-4 Ed.C. Hanseh, Pergamon Press, New York.
2. Comprehensive Biotechnology, Ed. Murray Moo-Young, Pergamon Press, New York.
3. Comprehensive Biotechnology information publications (www./nobi.nml.nih.gov)
4. Dewick Paul M. Medicinal Natural Products-A Biosynthetic Approach.
5. Chakravarty T.K. " Herbal Options".

BIOASSAYS AND SCREENING METHODS

Subject Code : **M.P COL T.1.103** Sessional : 30
Periods/Week : 4 Examination : 70
Nature of Exam : Theory Exam Duration: 3 Hrs

UNIT –I

Drug discovery process: Principles techniques and statergies used in new drug discovery. High throughout screening. Human genomies robotics and economics of drug discovery, Regulations, for laboratory animal care and ethical requirements.

Bioassays : Basic principles of bioassays official bioassays, experimental models and statistical designs employed in biological standardization. Biological standardization of vaccines and sera with certain examples with reference to IP. Development of new bio assay methods.

UNIT – II

Preclinical models employed in the screening of new drugs belonging to following categories.

Antifertility agents, sympathomimetics, parasympathomimetics, muscle relaxants (both central and peripheral). Sedatives, hypnotics, antiarrhythmic agents, cardiac stimulants, cardiotonic agents bronohodilators, antihistaminics, eicosanoids.

Antipsychotic agents, antianxiety agents nootropic drugs antidepressant drugs; antiparkinsonism agents, anticpileptics; analgesics and anti-inflammatory agents; antiulcer agents; infarction; antiatherosclerotic drugs; antidiabetics; models for status epilepticus drugs. cerebroventricular and other newer techniques of drug administration and development; transgenic animals and other genetically prone animal models.

UNIT – III

Alternatives to animal screening procedures, cell-line handling and maintenance and propagation of cell lines, patch-clamp technique, in-vitro cell line based assays diabetics and arthraitis models, molecular biology techniques.

UNIT – IV

Principles of toxicity evaluations, ED50, LD50 and TD values, International guidelines (ICH Ethics and animal experimentation recommendations).Guidelines and regulatory agencies – CPCSEA,OECD,FDA, FHSA,EPA,EEC,WHO etc,

UNIT – V

Introduction to biostatistics, parametric and non-parametric tests. Regression and correlation: Linear regressions, Method of least squares; correlation coefficients, rank correlation, multiple regression Tests of significance: testing hypotheses, tests of significance based on normal distribution. t-test; significance of correlation coefficient. F-test and Analysis of Variance: 1-Way, 2-Way and 3-way classification, Chi-

square test of (i) Variance of a normal population (ii) Goodness of fit, (iii) Independence in contingency tables. Non parametric tests, order statistics, sign test, run test, Median test.

Books recommended

1. Pre – Clinical Drug Development , Rogge
2. Basic and clinical Pharmacology, Katzung
3. Pharmacological screening methods, N.S. Parmer and Shivkumar
4. Pharmacological screening methods, N.S. Parmer 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.Vogel, Springer publications.

BASIC PRINCIPLES OF TOXICOLOGY

Subject Code : **M.PCOL T.1.104** Sessional : 30
Periods/Week : 4 Examination : 70
Nature of Exam : Theory Exam Duration : 3 Hrs

Unit – I

General principal of regulatory toxicology. Use of animals in preclinical toxicology studies, role of preclinical toxicology in drug discovery and development process. Experimental considerations for assessing possible human risk. Flow chart for development of preclinical testing. Dose conversion factors, clinical signs toxicity.

Unit – II

Single dose and repeat dose toxicity studies; Factors influencing such studies such as species, sex, size, route ,dose level; Data evaluation and regulatory requirements. Determination of Maximum Tolerated Dose (MTD) and LD 50 as per revised OECD guidelines. Allergenicity testing, dermal toxicity, immunotoxicology and in vitro methods of toxicology.

Unit – III

Reproductive toxicology assessment of male reproductive toxicity, spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity; alterations in reproductive endocrinology; Relationship between maternal and developmental toxicity.

Unit – IV

Mutagenicity; Mechanisms of mutagenesis, point mutations,; Individual chromosomes and complete genome mutations, germ cell mutations, somatic cell mutation; Tests systems in vitro, chromosome damage and chromosomal aberration test, gene mutation, in vivo micronucleus tests in rodents, metaphase analysis.

Unit – V

Preclinical toxicological requirements for biologicals and biotechnological products; safety analysis; problems specific to recombinant products, toxicokinetics, principles of GLP as per OECD guidelines for conducting preclinical toxicity studies

Books recommened

1. Drug safety Evaluation, Shayne C Gad, Wiley Interscience
2. The toxicologist's pocket handbook, Michael J derelanko 2nd Ed,2008,CRC press
3. Relevent OECD guidelines (Internet resources)
http://www.ingentaconnect.com /content/oecd/16073/2001/00000001/00000004

PHARMACEUTICAL ANALYTICAL TECHNIQUES (PRACTICAL)

Subject Code : M.PCOL.P.1.105 Sessional : 30
Period / Week: 6 Examination : 70
Nature of Exam: Practical Exam Duration : 6 Hrs

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 of drugs (2 experiments).
3. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations. (2 experiments).
4. Experiments based on the application of derivative spectroscopy. (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradient elution) 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.

BIOASSAYS AND SCREENING METHODS

Subject Code : M.PCOL P 1.106 Sessional : 30
Periods/week : 6 Examination : 70
Nature of Exam: Practicals Exam Duration: 6 Hrs

List of Experiments

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1. Biological standardization of drugs like acetylcholine/Histamine
2. Experiments on CNS. General screening methods of drugs on CNS
   CNS stimulants and depressants, anxiogenics and anxiolytics, amnestics and nootropics, anti convulsants, analgesics, safety pharmacology.
3. Drugs acting on Gastrointestinal tract
   General screening methods for the anti ulcer activity, intestinal motility, and anti-diarrhoeals.
4. Experiments on CVS

   General screening procedure of anti-arrhythmic agents, anti-hypertensives, anti-ischemics.
5. Experiments on Local anesthetics
   General methods for evaluating local anesthetic activity
6. Experiments on General Pharmacology
   Enzyme induction activity, drug dependence and withdrawl effects.
7. Experiments on Diueretics
   General screening methods for evaluating the diuretic activity.
8. Screening procedure for antidiabetic drugs.
9. Experiments on analgesic and anti-inflammatory agents
   General methods of screening for the evaluation of analgesics and anti inflammatory agents, [both acute and chronic models]
10. General methods for evaluating the antimicrobial activities of chemotherapeutic agents.
11. Estimation of biochemical and free radical scavengers.

Recommended books

1. Hand book of Experimental Pharmacology S.K.Kulkarni
2. Hand book of laboratory animal science, Animal models, Jann Hau, 2nd edition vol 2, 2002.
3. Hand book of Laboratory Animal Science: Selection and Handling of Animals in Biomedical research: v 1, Per Svendsen, Jann Hau, 1994

SCIENTIFIC AND TECHNICAL WRITING

Subject Code : M.PCOL T 1.107 Sessional : 50
Periods/week : 2 Examination : --
Nature of Exam : Tutorials Exam Duration: --

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.

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.

UNIT – II

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

Kinds of outline: topic outlines, conceptual outline, sentence outlines and combination of topic and sentence outlines

UNIT – III

DRAFTING TITLES, SUB TITLES, 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

UNIT – IV

PARTS OF DISSERTATION/RESEARCH REPORT/ARTICLE

Introduction, Review of Literature, Methodology, Results and Discussion
Ask questions related to: content, continuity, clarify, validity internal consistency and objectivity during writing each of the above parts.

UNIT – V

WRITING FOR GRANTS

Clearly state the question to be addressed; Rationale and importance of the question being address; Emperial and theoretical conceptualization; Presenting pilot study/data; Research proposal of method; Clarity, specificity of method; Clear organization; Outcome of study and its implications; Budgeting; Available infra-structure and recourses and Executive summary

References

1. APA (1984): Publication Manual of Americal 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.

INTELLECTUAL PROPERTY RIGHTS AND REGULATORY AFFAIRS

M PCH.T.1.201 **Period/Week: 4**
Examination: 70 **Nature of Exam: Theory**
Sessional: 30 **Duration of Exam: 3 hrs**

UNIT – I

Patents and Intellectual Property Rights (IPR): definition, scope, objectives, source of patient information, patent processing and application. Patents, copyrights, trademarks, silent features, trade related aspects (TRIPS), international and regional agreements.

UNIT – II

GATT and WTO: GATT – historical, prospectives, objectives, fundamental principles, impact on developing countries. WTO-objectives, scope, functions, structure, status, membership and withdrawal, dispute settlement, impact on globalization, India-tasks & challenges.

UNIT – III

Regulatory Affairs: Indian context – requirements and guidelines of GMP, understanding of drugs and cosmetics act 1940 and rules 1945 with reference to schedule M, U and Y.

UNIT – IV

Related Quality Systems: Objectives and guidelines of USFDA, WHO and ICH. Introduction to ISO series.

UNIT – V

Documentation: Documentation types related to pharmaceutical industry, protocols, harmonizing formulation development for global filings, NDA, ANDA, CTD, dealing with post-approval changes – SUPAC, handling and maintenance including electronic documentation.

Recommended Books:

1. Guarino RA. New drug approval process, 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. Katju SN. Laws and drugs. Law Publishers.
5. Original Laws published by Government of India.
6. Hussain. Law of drugs in India.
7. Websites: www.fda.org ; www.wipo.int , www.ich.org , www.cder.org .

ADVANCES IN PHARMACOLOGY

Subject Code : M.PCOL T 1.202 Sessional : 30
Periods/week : 6 Examination : 70
Nature of Exam: Theory Exam Duration: 3 Hrs

UNIT –I

Receptor Pharmacology

General aspects of receptor pharmacology,structural and functional aspects of receptor s, regulation of receptors,isolation,classification and characterization of receptors.

UNIT – II

Neurotransmission Pharmacology

General aspects and steps involoved in neurotransmission
Neurohumoral transimission in autonomic nervous system.
Neurohumoral transmission in central nervous system
Non-adrenergic non-cholinergic transmission [NANC].

UNIT – III

A detailed study of the mechanism of action, pharmacology of drugs used in ANS-Parasympathomimetics and lytics, sympathomimetics and lytics, agents acting at neuromuscular junction and ganglia.
CNS- General anaesthetics, sedatives, hypnotics. Drugs used to treat anxiety, depression, psychosis, mania,epilepsy, neurodegenerative deseases, drug dependence and addiction.
CVS- diuretics, anti ischemics, antihypertensives, antiarrythmics, drugs for heart failure and dyslipieiemia.

UNIT – IV

A detailed study of the mechanism of action, pharmacology of drugs used in Autocoid pharmacology- a study of the mechanisms involved in the formation, release, pharmacological actions and possible physiological role of histamine,serotinine,kinins,prostaglandins,opioidautocoids and cyclic 3' – 5' AMP. Systemic pharmacology of drugs acting as agonists and antagonists to the autocoids.
GIT Pharmacology – anti ulcer,prokinetics,antiemetics, antidiarrhoeal and drugs for constipation and irritable bowel syndrome.
Hormone and hormone antagonists.Anti biotics and chemotherapeutic agents. Analgesics and anti-inflammatory agents.

UNIT – V

FREE RADICAL AND IMMUNO PHARMACOLOGY

Generation of free radicals, role of free radicals in etiopathology 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 immunomodulators.

Recommemded books

1. Clinical Pharmacology by D.R.Lawrnce and P.N.Bennette
2. Pharmacology and Pharmacotherapeutics R.S. Satoskar and S.D. Bhandarkar.
3. The Pharmacology basis of therapeutics. 10th edition by Louis S.Goodman and Altred Gillman
4. Pharmacology by H.P. Rang and M.A. Dale
5. Biopharmaceutics and Pharmacokinetics and introduction by E. Notary
6. Drug Metabolism by Berhard Tests and Peter Jenner.
7. Principles of Drug action by Goldstein, Aranow and Kolman.
8. Pharmacokinetics : Regularory Industrial Academic Perspectives, Second Edition, edited by Peter G.Welling and Francis L.S.Tse
9. The Drug Development Process: Increasing Efficiency and cost Effectiveness, edited by Peter G.Welling, louis Lasagna and Umesh V. Banakar
10. Pharmaceutical Practice , Win field

BIOPHARMACEUTICS AND PHARMACOKINETICS

Subject Code : M.PCOL.T.1.203 Sessional : 30
Period / Week: 4 Examinations : 70
Nature of Exam: Theory Duration of Exam: 3 hrs

UNIT -1

Bioavailability and Bioquiovalence: Objectives, bioavailability & variations, measurements of bioavailability, enhancing bioavailability, concepts of equivalents, official bioequivalence protocols & therapeutic equivalence.

UNIT -2

Drug Absorption: General consideration, absorption / drug transport mechanisms, role factors affecting absorption, absorption of drug non-peroral routes, 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 -3

Pharmacokinetcs: 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.

UNIT - 4

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

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

UNIT – 5

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

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

Recommended books

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.

PHARMACOLOGY & PHARMACO THERAPEUTICS

Subject Code : M.PCOL T.1.204 Sessional : 30
Periods/Week : 4 Examination : 70
Nature of Exam : Theory Exam Duration : 3 Hrs

UNIT –I

Principles of Pharmacokinetics.

A. Revision of Basic concepts.
B. Clinical Pharmacokinetics.
1. Dose – response in man
2. Influence of renal and hepatic disease on Pharmacokinetics
3. Therapeutics drug monitoring
4. Population Pharmacokinetics.

UNIT – II

Basics in clinical pharmacology
Clinical trials of drugs,design of clinical trials
Therapeutic drug monitoring and critieria for TDM.
Adverse Drug Reactions, Drug Interactions and ADR monitoring.

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 infraction, TB, leprosy, leukemia, solid tumors, lymphomas, psoriasis, respiratory, urinary , g.i. tract infections, endocarditic, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.

UNIT – IV

Drug therapy and Pharmacokinetics in
a. Geriatrics
b. Pediatrics
c. Pregnancy & Lactation.

UNIT - V

Pharmacogenetics: Historical aspects of pharmacogenetics, biomarkers, inter-racial and individual variability in drugs metabolism., receptors .Role of drug transporters, interethnic differences, clinical view points and future perspectives, stem cell – a new therapeutic approach. Gene therapy, Pharmacovigilance concepts and its impact.

Recommended Books

1. Biopharmaceutics and Pharmacokinetics, Venkateshwarlu
2. Clinical Pharmacy and therapeutics , Herfindal
3. Drug Disposition and Pharmacokinetics , H.Curry
4. Pharmacokinetics ,Milo Gibaldi
5. Managing clinical Drug development , Cocchetto
6. Pharmacogenomics , Kalow
7. Durg discovery and development, Rang
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 Pharmacology by D.R.Lawrnce and P.N.Bennette

ADVANCES IN PHARMACOLOGY PRACTICALS

Subject Code : M.PCOL P.1.205 Sessional : 30
Periods/week : 6 Examination : 70
Nature of Exam: Practicals Exam Duration: 6 Hrs

List of Experiments.

Minimum 8 experiments shall be conducted.

1. Experiments for studying the effects of the more important biogenic agents like histamine, acetylcholine, 5HT, oxytocin and their effect in the presence of antagonist on suitable isolated tissue preparations.
2. Estimation of PA2 values of various antagonists under suitable isolated tissue preparations.
3. Experiments on CVS- effect of various drugs on isolated heart preparations on various animal models under normal arrhythmic and hypo dynamic conditions.
4. Drugs acting on Gastro intestinal tract. To study the drug activity on oesophagal motility.
5. Monitoring of drug concentrations in saliva/urine/blood.
6. Action of CNS stimulants and depressants using suitable experimental model.
7. Evaluation of antidepressant and anti anxiety drugs.
8. Drug absorption and elimination studies.
9. Any other experiment based on the topics mentioned in theory,
10. Virtual and stimulated experiments are permitted.

BIOPHARMACEUTICS AND PHARMACOKINETICS

Subject Code : M.PCOL.P.1.206 Sessional : 30

Period / Week: 6 Examinations : 70

Nature of Exam: Practicals Duration of Exam: 6 hrs

Suggested 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.

ENTREPRENEURSHIP MANAGEMENT

Subject Code : M.PCOL T 1.207 Sessional : 50
Periods/week : 2 Examination : --
Nature of Exam: Tutorials Exam Duration: --

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.
- 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

UNIT – II: THE ENTREPRENEUR

- Entrepreneurial motivation – dynamics of motivation.
- Entrepreneurial competency – Concepts.
- Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur'' role.

UNIT – III: 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.

UNIT – IV: 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

UNIT – V: PREPARING PROJECT PROPOSAL TO START ON NEW ENTERPRISE

- Project work – Feasibility report; Planning, resource mobilization and implementation.

Reference

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.