U.P. TECHNICAL UNIVERSITY LUCKNOW



Syllabus

M. Pharm. Pharmacology

U.P. TECHNICAL UNIVERSITY, LUCKNOW STUDY AND EVALUATION SCHEME

Course: M. Pharm. Pharmacology Semester-I

Course: M.Pharm. Pharmacology Semester-I											
S.No.	Course code	Subject	Per (hours		IA		IA		Е	SE	Total
		Theory	Т	P	Т	P	Т	P			
1	PHAR-511	Modern Analytical Techniques	4	-	30	-	70	-	100		
2	PHAR-512	Pharmaceutical Biostatistics & Computer Application	4	-	30	-	70	-	100		
3	PHAR-514	Drug Regulatory Affairs and& Intellectual Property Rights	4	-	30	-	70	-	100		
4	PHAR-520	Clinical Pharmacokinetics & Biopharmaceutics	4	-	30	-	70	-	100		
5	PHAR-521	Pharmacology & Toxicology	4	-	30	-	70	-	100		
Practical Day to							Day Eva	luation			
6	PHAR-511P	Modern Analytical Techniques	-	6	-	30	-	70	100		
7	PHAR-521P	Pharmacology & Toxicology	-	6	-	30	-	70	100		
								Total	700		

T- Theory, P-Practical IA- Internal Assessment ESE- End Sem. Examination Note: Duration of ESE – Theory exam is of 3hours and practical exam is 6 hours

U.P. TECHNICAL UNIVERSITY, LUCKNOW STUDY AND EVALUATION SCHEME

Course: M.Pharm. Pharmacology **Semester-II**

S.No.	Course code	Subject	Period (hours/week)		IA		ESE		Total
		Theory	T	P	Т	P	Т	Р	
1	PHAR-532	Screening Methods & Bioassays	4 - 3			-	70	-	100
2	PHAR-533	Advanced Pharmacology	4	4 -		-	70	-	100
3	PHAR- 534	Clinical Pharmacology	gy 4 -		30	-	70	-	100
4	PHAR-525	Synopsis of the proposed dissertation & Viva voce							
Practical Day to Day Evaluati									on
5	PHAR-532P	Screening Methods & Bioassays	-	6	-	30	-	70	100
6	PHAR-533P	Advanced Pharmacology	-	6	-	30	-	70	100
			1	1	1	1	1	Total	600

T- Theory, P-Practical IA- **Internal Assessment ESE- End Sem. Examination**Note: Duration of ESE – Theory exam is of 3hours and practical exam is 6 hours

U.P. TECHNICAL UNIVERSITY, LUCKNOW STUDY AND EVALUATION SCHEME

Course: M.Pharm. Pharmacology Semester-III & IV

S.No.	Course Code	Subject	ect Period I A E SE (hours/week)				SE	Subject Total	
		Theory	T	P	T	P	T	P	
1	PHAR 611	Dissertation							300
2	PHAR 612	Presentation &	Viva voc	e					200
	1	1						Total	500

M. Pharm (Pharmacology) (First Semester)

PHAR-511 Modern Analytical Techniques

Unit - 1

UV-Visible Spectroscopy: Principle of UV-Visible Spectroscopy, Chromophores and their interaction with UV-visible radiation and their utilization in structural, qualitative and quantitative analysis of drug molecules. Woodward-Fieser rule, use of shiff reagents for elucidation of structures. Fundamentals of Optical Rotatory Dispersion. Cotton effect curves, octant rule, circular dichronism.

Unit - 2

Infrared Spectroscopy: Infrared radiation and its interaction with organic molecules, vibrational mode of bonds, instrumentation and applications, effect of hydrogen bonding and conjugation on absorption bands, interpretation of IR spectra. FTIR and ATR, X-ray diffraction methods.

Unit - 3

Nuclear magnetic resonance spectroscopy: Magnetic properties of nuclei, field and precession, chemical shift concept, isotopic nuclei, reference standards and solvents. H NMR spectra, chemical shifts, multiplicity, coupling constants, integration of signals, interpretation of spectra, decoupling-double resonance and shift reagent methods.

Principles of FT-NMR with reference to C NMR, free induction decay, average time domain and frequency domain signals. Spin-spin and spin-lattice relaxation phenomenon. Protein noise decoupled spectra. Nuclear overhauser enhanced C NMR spectra, their interpretation and application. APT and DEPT techniques. Introduction of 2D NMR techniques, COSY, with application.

Unit - 4

Mass spectrometry: Basic principles and brief outline of instrumentation. Ion formation, molecular ion, metastable ion, fragmentation process in relation to molecular structure and functional groups. Relative abundance of isotopes, chemical ionization, FAB, ESI, Maldy, GC-MS and other recent advances in mass spectrometry.

Unit - 5

Chromatographic techniques: Principles of separation and application of Column, Paper, Thin layer and Gas chromatography, HPLC, HPTLC, Size exclusion chromatography, Affinity chromatography, Electrophoresis. Instrumentation of HPLC, Preparative and micropore columns, Reverse phase columns, Mobile phase selection and detectors in HPLC. Instrumentation and application of DCCC.

Biological standardization: Bioassay & Radioimmunoassay: ELISA, Radioimmunoassay of drugs like Digitalis & Insulin

(4)

PHAR-511 P Modern Analytical Techniques

Practicals based on theory syllabus.

Books Recommended:

- 1. Willard, H.H., Merrit, L.L., Dean, J.A., Settle P.A., Instrumental Methods of Analysis, Van Nostrand.
- 2. Skoog, D.A., Heller, F.J., Nieman, T.A., Principles of Instrumental Analysis, WB Saunders.
- 3. Hunson, J.W., ed. Pharmaceutical Analysis, Modern Methods, part A & B, Marcel Dekker.
- 4. Schirmer, R.E., ed. Modern Methods of Pharmaceutical Analysis, Vols 1, 2. Boca Raton F.L., CRC Press.
- 5. Mann, C.K., et al., Instrumental Analysis Harper & Row.
- 6. Jaffe, H.H., Orchin M., Theory & Applications of Ultraviolet Spectroscopy, Willy.
- 7. Silverstein, Spectrometric identification of Organic Compounds, Willy.
- 8. Bovey, F., Jelinski, L., Miran, P., Nuclear Magnetic Resonance Spectroscopy, Sau: Diego Academic.
- 9. Stothers, J.B., Carbon-13 NMR.Spectroscopy, Academic.
- 10. Gordy, W., Theory & Applications of Electron Spin Resonance, Willy.
- 11. Haswell, S.J., ed. Atomic Absorption Spectroscopy, Elsevier.
- 12. Ardrey, R.E., Pharmaceutical Mass Spectra, Pharmaceutical Press, London.
- 13. Budzikiewicz, et al., Interpretation of Mass Spectra of Organic Compounds, Holden-Day San Francisco.
- 14. Beckett and Stenlake, Practical Pharmaceutical Chemistry, CBS.
- 15. Stahl, E., Thin Layer Chromatography- A laboratory Handbook, Springer-Verlag
- 16. Giddings, J.C., Principles and Theory- Dynamics of Chromatography, Marcel Dekker.
- 17. Sethi, P.D., Quantitative Analysis of Pharmaceutical formulations, CBS Publishers, New Delhi.
- 18. Kemp William, Organic spectroscopy, Pal grave, New York.
- 19. Kalsi, P.S., Spectroscopy of organic compounds, New age publishers, New Delhi.
- 20. Gross Mass Spectrometry
- 21. WHO Quality Assurance of Pharmaceuticals, Vol. I, II.
- 22. Sethi, P.D., HPLC, Quantitative Analysis of Pharmaceutical Formulations, CBS Publishers, Delhi.
- 23. Sethi, P.D., HPTLC, Quantitative Analysis of Pharmaceutical Formulations, CBS Publishers, Delhi.
- 24. Haffmann, Chromatography.
- 25. Sethi and Charcgankar, Identification of Drugs in Pharmaceutical Formulations by TLC.
- 26. Robert D. Braun, Introduction to Instrumental Analysis.
- 27. Wilfried, M.A. Niessen- Liquid Chromatography-Mass Spectrometry.
- 28. Harry G. Brittain, Spectroscopy of Pharmaceutical Solids.
- 29. George, S., Steroid Analysis in Pharmaceutical Industry.
- 30. Higuchi, Pharmaceutical Analysis.
- 31. Bidingmeyer, Practical HPLC Methodology and Applications.
- 32. Hoffmann, Mass Spectrometry: Principle and Application.
- 33. Scott, Techniques and Practice of Chromatography.

- 34. Wilkins, Identification of Microorganism by Mass Spectrometry.
- 35. Wu, Handbook for Size Exclusion Chromatography and related Techniques.

PHAR-512 Pharmaceutical Biostatistics and Computer Applications

Unit - 1

Methods of collection of data, classifications and graphical representation of data. Binomial and normal probability distribution. Polygon, histogram, measure of central tendency. Significance of statistical methods, probability, degree of freedom, measures of variation - Standard deviation, Standard error.

Unit - 2

Sampling, sample size and power. Statistical inference and hypothesis. Tests for statistical significance: student t-test ,Chi-square test, confidence level, Null hypothesis.

Unit - 3

Linear regression and correlation. Analysis of Variance (one way and two way). Factorial designs (including fraction factorial design). Theory of probability, Permutation and Combination , Ratios, Percentage and Proportion. Two way ANOVA and Multiple comparison procedures.

Unit - 4

Non-parametric tests, Experimental design in clinical trials, Statistical quality control, Validation, Optimization techniques and Screening design. Correlation and regression, least square method, significance of coefficient of correlation, nonlinear regression.

Unit - 5

Bioassays-calculations of doses response relationships, LD_{50} , ED_{50} , probit analysis.

Applications of software for statistical calculation viz. SPSS, foxtron.

Application of computers in Pharmaceutical sciences.

Book Recommended:

- 1. Bolton, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.
- 2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.
- 3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.
- 4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.
- 5. Finney, D.J., Statistical Methods in Biological Assays, Hafner, New York.
- 6. Montgomery, D.C., Introduction to Statistical Quality Control, Willy.
- 7. Khan, Irfan A., Biostatistics for Pharmacy.
- 8. Khan, Irfan, A., Fundamentals of Biostatistics.
- 9. Gauthaman, Biostatistics for Pharmacy students.
- 10. Lipschutz, Introduction to Probability and Statistics.
- 11. Liwan Po, Statistics for Pharmacist.
- 12. William E. Fassett, Computer Application in Pharmacy.
- 13. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.
- 14. Nageswara Rao and Tiwari, Biostatistics and Computer Applications.

PHAR-514 Drug Regulatory Affairs and Intellectual Property Rights

IInit _ 1

Drug & Cosmetics Act with special reference to schedule Y and M, schedule of medical devices. **Unit - 2**

Concept of total quality management, requirements of GMP, GLP, GCP, Regulatory requirements of drugs and Pharmaceutical (USFD-NDA/ANDA)

Unit - 3

Documentation and Maintenance of records.

Unit - 4

Intellectual property rights patents, Trademarks, Copyrights, Patents Act.

Unit - 5

Environment protection Act, Pollution Control, Factories Act.

Books Recommended:

- 1. Willing, S.W., & Stoker, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker, New York.
- 2. Guarino, R.A., New Drug Approval Process, Marcel Dekker, New York.
- 3. Drug & Cosmetic Act.
- 4. Patents Act.
- 5. Consumer Protection Act.
- 6. Environmental Protection Act.
- 7. Federal Food, Drug & Cosmetic Act.
- 8. Bansol, IPR Guidelines for Pharm students and Researchers.
- 9. Pisano-FDA Regulatory Affairs.
- 10. Phillip W. Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology.

PHAR-520 Clinical Pharmacokinetics and Biopharmaceutics

Unit-1

- a. Introduction to Pharmacokinetics and basic concepts.
- b. Absorption and distribution

Biological half-life, Area under curve, apparent volume of distribution, concept of clearance, Drug Disposition.

c.Compartment models and their limitations- one compartment open model and multicompartment models. Kinetics of Intra-venous infusion and multiple dosage regimens. Protein binding of drugs.

Unit-2

a. Biotransformation of Drugs

Phase-I and Phase-II metabolic reactions. Microsomal and Non-microsomal biotransformation reactions. Factors influencing drug metabolism.

b. Elimination of drugs

Unit-3

Bioavailability – Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems. Study of different in-vitro and in-vivo / biological models for determination of absorption, distribution, metabolism and excertion and permeability of drug. Study of

physiological transporter systems and physiological barriers like BBB, blood testis barrier and blood placental barrier.

Unit-4

Nonlinear pharmacokinetics- Causes of non-linearity, detection of non-linearity, Michaelis Menten equation, Estimation of Km and Vmax, with respect to individualization of a drug.

Unit-5

Drug dissolution; in-vitro dissolution testing models. *In vitro* dissolution testing model factors affecting dissolution test design Types of dissolution apparatus, Dissolution methodology, *In Vitro – In vivo* approaches used IVIVC correlation levels & types

Book Recommended

- a. Golub E. "The Limits of Medicine: How Science shapes our hope for the cure".1997, Time Books, New York.
- b. Gennaro, A.R., "Remington: The Science & Practice of Pharmacy" 21st ed., 2009, Lippincott.
- c. Milo Gibaldi and Laurie Prescott, "Hand book of clinical Pharmacokinetics" 1983, Adis Health Science Press, New York.
- d. Larry Bauer and P.B. Bauer Larry, "Clinical Pharmacokinetics". Mc-Graw Hill.
- e. Michael E. Winter. "Basic Clinical Pharmacokinetics".2010, Lipincott Williams & Wilkins.
- f. Leon Shargel, Susanna Wu-Pong, and Andrew B.C. Yu, "Applied Biopharmaceutics & Pharmacokinetics" 2004, McGraw- Hill.
- g. Milo Gibaldi and Donald Perrier, "Pharmacokineties". 5th ed., Vol 15. Marcel Dekker. Inc.
- h. V. Venkateshwarlu, "Biopharmaceutics and Pharmacokinetics." 2008, Pharm Med Press.
- i. Milo Gibaldi, "Biopharmaceutics and Clinical Pharmacokinetics" 2008, Pharm Med Press.

PHAR-521 Pharmacology and Toxicology

Systemic Pharmacology-

Unit-1

A detailed study of the mechanism of action, pharmacology and toxicology of drugs used in

- a. ANS- Parasympathomimetics and lytics, sympathomimetics and lytics, agents acting at neuromuscular junction and ganglia.
- b. Local and general anesthetics.
- c. CNS General anesthetics, sedatives, hypnotics. Drugs used to treat anxiety, depression, psychosis, mania, epilepsy, neurodegenerative diseases, drug dependence and addiction.

Unit-2

- a. CVS- Diuretics, anti ischemics antihypertensives, antiarrythmics,drugs for heart failure and dyslipidiemia.
- b. Autocoid Pharmacology- A study of the mechanisms involved in the formation, release, pharmacological actions and possible physiological role of histamine, serotonin, kinins, prostaglandins, opioidautocoids and cyclic 3' –5' AMP. Systemic pharmacology of drugs acting as agonists and antagonist to the autocoids.
- c. Immunopharmacology- Cell and biochemical mediators involved in allergy, immunomodulation and inflammation. Classification of hypersentitivity reactions and diseases involved. Therapeutic agents for allergy, asthma, COPD and other immunological diseases with emphasis on immunomodulators.

Unit-3

- a. GIT pharmacology- Antiulcer, prokinetics, antiemetics, antidiarrhoeal and drugs for constipation and irritable bowel syndrome.
- b. Analgesics and anti-inflammatory agents.
- c. Hormone and hormone antagonists.
- d. Antibiotics & Chemotherapeutic agents.

Unit-4

Toxicology

- a. Principles of toxicology.
- b. Abnormal action of drugs such as tolerance, addiction, habituation, idiosyncracy, allergy, hypersensitivity, antagonism, synergism, potentiation, tachyphylaxis.
- c. Heavy metals poisoning.

Unit-5

Drug Interactions & Rationale for Drug Combinations

Its implications and possible means to avoid them. Drug – Drug interactions involving antibiotics, cardiovascular drugs, antihistaminic drugs and analgesic, anti-inflammatory agents. Various mechanisms of drug interaction, drug-food interaction and drug - drug interaction.

Books Recommended:

- 1. The Pharmacological basis of therapeutics, 11ed. Goodman and Gilman's., Mc Graw Hill
- 2. Pharmacotherapy; A pathophysiological Approach, Josef T. Dipiro & Robert L. Talbert ,7th. Ed.,2005, Mc Graw Hill
- 3. Pharmacology Katzung., 11ed., 2007
- 4. Fundamentals of experimental pharmacology by M.N.Ghosh., Hiltton Kolkata, 2007
- 5. Handbook of experimental pharmacology by S.K.Kulkarni., Vallabh Prakashan, New Delhi,
- 6. Text book of In vitro practical pharmacology by IanKitchen., Oxford: Blackwell, 1984
- 7. Pharmacological experiments on intact preparations by L. J. Mc Leod, University of Edinburgh, Churchill Livingstone.1970
- 8. Hand book of clinical pharmacokinetics- Gibaldi and Prescott.; Adis health science Press, New York, 1983
- 9. Principles of drug action. The Basis of Pharmacology by Avram Goldstein, Lewis Aronow, Harper and Row, New York, 1968.
- 10. Clinical pharmacology by Molmon and Morrelli.2009
- 11. Clinical Drug trials and tribulations by Allen E. Cato.2nd ed. Marcel Dekker, New York, 2002
- 12. Drug interactions by Ivan H. Stockley.6th ed., Pharmaceutical Press 2002

PRACTICAL Based on Theory

(Second Semester)

PHAR-532 Screening Methods & Bioassays Unit-1

Regulations for Laboratory Animals care and Ethical Requirements

Guidelines and regulatory agencies- CPCSEA, OECD, USFDA, ICH, FHSA, WHO

Unit-2

LABORATORY ANIMALS:

- a. Commonly used laboratory, transgenic and other genetically prone animal models (viz., nude mice, SH rats etc).
- b. Techniques of blood collection, anesthesia and euthanasia of experimental animals.
- c. Various routes of drug administration.
- d. Maintenance and breeding of Laboratory animals.

Unit-3

PRINCIPLES OF BIOLOGICAL STANDARDIZATION:

- a. Statistical treatment of model problems in evaluation of drugs.
- b. Methods of biological assay, principles of biological assays with certain examples.
- c. Development of new bioassay methods.

Unit-4

Organization of screening for the Pharmacological activity of new substances with emphasis on evaluation using *in vivo*, *in vitro*, *ex vivo*, *in situ*, *in silico* and other possible animal alternative models.

- a. General Principles and Safety Pharmacology Procedures
- b. Anti-hypertensives, anti-arrythmics, vasodilators and diuretics
- c. CNS pharmacology behavioural and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-epileptics and Nootropics
- d. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers, multiple sclerosis, etc

Unit-5

Screening for Pharmacological Activity

- a. Analgesics, anti-inflammatory and antipyretic agents.
- b. Gastrointestinal drugs Anti-ulcer, anti-emetic, anti-diarrhoeal and laxatives.
- c. Anti-cancer agents.

- d. Drugs for metabolic disorders like anti-diabetic, anti-hyperlipidemic ,anti-obesity, and hepatoprotective agents.
- e. Anti-oxidants and Anti-fertility agents

Books Recommended:

- 1. Biological standardization by J.H. Burn, D.J. Finney and L.G. Goodwin.2nd ed. Oxford Uni. Press, 1950
- 2. Indian Pharmacopoeia, Govt of India press2009.
- 3. Screening methods in Pharmacology by Robert A. Turner, .,1971, Academic Press, New York.
- 4. Evaluation of drugs activities by Laurence and Bachrach. 1971, Academic Press, New York.
- 5. Methods in Pharmacology by Arnold Schwartz., 1972, The Univ. Of Chicago Press.
- 6. Selected topics on the Experimental Pharmacology by Usha G. Kamat, Dadkar, N.K and Seth, U.K., 1972.
- 7. Fundamentals of experimental Pharmacology Ghosh, M.N., 2007, Hilton Company, Kolkata.
- 8. Pharmacological experiment on intact preparations by L. J. Mc Leod; Churchill Livingstone.1970
- 9. Drug Discovery and Evaluation by Vogel HG& Vogel WH, Maas J. Springer, 2010
- 10. Animal models in toxicology by Shayne Cox Gad and Christopher P. Chengelis.2006, Informa HealthCare.
- 11. The UFAW Handbook on the care and management of laboratory and other Research animals by UFAW. 8th ed.,2010, Wiley-Blackwell
- 12. Principles and methods of toxicology by Hayes. 4th ed., 2001, Taylor & Francis
- 13. CRC Handbook of toxicology by Derelanko and Hollinger.2nd ed., CRC Press 2001.

PRACTICALS-

Practical based on theory.

PHAR-533 Advanced Pharmacology

Unit-1

- a. Introduction to Molecular pharmacology and Drug Design.
- b. Molecular mechanism of drug action: Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and phosphatidyl inositol. Ionic channels and their modulators.
- c. **Endogenous bioactive molecules:** Cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiestrase enzyme and protein kinase C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators. Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.

Unit-2

Recent trends on different classes of receptors as follows and drugs acting on them-

- a) Angiotensin receptors
- b) Excitatory amino acid receptors
- c) Kinin receptors
- d) Adrenoceptors
- e) Low molecular weight heparins, hirudins and GP II/IIIa receptor antagonists
- f) Imidazole receptors
- g) Cholinergic receptors

Unit -3

Recent trends on different classes of receptors as follows and drugs acting on them-

- a) Dopamine receptors
- b) Serotonin receptors
- c) Hormone receptors
- d) GABA and Benzodiazepine receptors
- e) Opiod receptors
- f) Purinergic receptors
- g) Glutamate receptors

Unit-4

Ion channel and their modulators: calcium, potassium, sodium and chloride channels-

- a. Apoptosis: pharmacological and clinical implications
- b. Adhesion therapy and cardiac and vascular remodeling
- c. Basic Concepts of Chronopharmacology and their implications to Drug Therapy.
- d. Basic concepts of high throughput screening
- e. Immunopharmacology: antibody dependent and cellular cytotoxicity.

Unit-5

Concept of gene therapy and recent development in the treatment of various hereditary diseases. Transgenic mouse and its applications. Human genome mapping and its potential in drug research.

Books Recommended:

- Katzung, B.G; Basic and Clinical Pharmacology, 10th ed., 2007, Lange Medical Publisher, USA
- 2. Barar, F.S.K., Essentials of Pharmacotherapeutics, 2008, S. Chand and Company, New Delhi
- 3. Bowman, W.C. and Rand, M.J.; Textbook of Pharmacology, 1991, Blackwell, Oxford
- 4. Melmon, K.L., and Morelli; Clinical Pharmacology: Basic Principle of Therapeutics, 1992, Mc Millan, New York
- 5. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology with Clinical Applications,6th ed. Lippincott Williams & Wilkins, 2003.
- 6. Drill, V.A.; Pharmacology in Medicine, 4th ed. McGraw Hill, New York
- 7. Grollman Pharmacology and Therapeutics, 7th ed., 1970, Lea and Febiger, Philadelphia
- 8. Bacq Z.M., Cepek, Fundamentals of Biochemical Pharmacology
- 9. Avery, G.S., Drug Treatment, 1997, Adis Press, Sydney
- 10. Goodman and Gilman; Pharmacological Basis of Therapeutics, 11ed., 2006, Mc Graw Hill
- 11. Rang, H.P., Dale, M.N., Pharmacology, 5th ed., 2005, Churchill Livingston, UK.

PRACTICALS-

Practical based on theory.

PHAR-534 Clinical Pharmacology

UNIT-1 Basics of Clinical Pharmacology and clinical research.

- a. Introduction to clinical Pharmacology Terminology, basic components and scope.
- b. **New drug discovery process** Process of drug development, preclinical studies, types of clinical trials, choice of patients, exclusion criteria of patients.
- c. **Drugs in Pregnancy**-: Prescribing in pregnancy, harmful effects on fetus, pharmacokinetics in pregnancy.

Drugs in Infants and Children-: Practical aspects of prescribing, pharmacokinetic **Drugs in Elderly-**: Pharmacokinetics changes, pharmacodynamic changes.

d. Pharmacogenetics and its clinical significance

UNIT-2: Pharmacotherapeutics of following diseases: Management and clinical Practice Guidelines

- a. **Cardio-vascular** -: Hypertension(HTN) including hypertension in pregnancy, Angina pectoris(AP), Acute myocardial Infarction AMI), Congestive heart failure(CHF), Cardiac arrhythmia (CA), Atherosclerosis, Peripheral vascular disorders(PVD)
- b. **Renal Disease**-: Acute and chronic renal failure (ARF and CRF), End stage renal disease (ESRD), Renal dialysis (Heamodialysis and Peritoneal dialysis), Renal Transplantation, Clinical alerts associated with drug dose selection in renal impairment.
- c. **Hepatic Disorders**-: Hepatitis (A,B,C), jaundice, Fatty liver, Liver fibrosis, Liver cirrhosis, Alcohol and drug induced complications associated with hepatic impairment
- d. **Gastrointestinal Diseases**-: hyperacidity, nausea and vomiting, Peptic ulcer, Diarrhea and constipation, hemorrhoids (piles), colots.
- e. **Respiratory Diseases**-: Pneumonia, Flu (Influenza), Bronchitis, Chronic Obstructive pulmonary disease (COPD), Asthma.
- f. **Autoimmune and meatabolic disorder:-**Rheumatic fever, Pain management Rheumatoid arthritis, Osteoarthritis, gout and Hyperuricemia, Diabetes mellitus(DM).
- g. Neoplastic disorder:-Leukemia; General Principal of cancer chemotherapy.

UNIT 3: Immunopharmacology

- a. Basic of immunopharmocology and its clinical significance.
- b. **Current concept in theory and research of drugs for**(i)AIDS(ii)Vaccines and sera (iii)Drug allergy (iv)Tissue Transplantation (v) Immunomodulators, immunostimulantes,

immunosuppressant (vi)In vitro and in vivo tests significance in immunological investigation(Ex. ELISA)

UNIT 4:

- a. **Adverse drug reaction (ADR):-**Type of reaction (Type A&B), Yellow card system, anaphylactic reaction management and monitoring.
- b. **Therapeutic Drug Monitoring (TDM):-**Clinical significance and its need on patients associated with narrow therapeutic range of drugs Eg. digoxin, amino glycosides, Phenytoin.

UNIT 5:

- a. **Infectious Disease**:- Tuberculosis(TB),Chicken pox,Syphilis,Gonorrhea,Urinary tract infection(UTI).
- b. General guideline for rational use of antibiotic, Resistance to antibiotic.

Books Recommended:

- Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London 4th ed., 2007
- 2. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, Elsevier, 2005
- 3. Russell J. Greene and Norman D. Harris, Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, 3rd ed.; Chapman and Hall, New York
- 4. Herfindal, E.T. and Hirschman, J.L.; Clinical Pharmacy and Therapeutics, Lippincott,
- 5. Koda and Kimble; Applied Therapeutics: The Clinical Uses of Drugs 9th Ed., Lippincott
- 6. Relevant Reviews Articles from Medical and Pharmaceutical Literature
- 7. Scott, L.T; Basic skills in interpreting laboratory data, American Society of Health System Pharmacist ,1996
- 8. Harrison's Principles of Internal Medicine, Vol-I And II, 17th Edition, 2008, Mc Graw-Hill
- 9. Davidson's Principle And Practice Of Medicine, 20th Edition,2009, Churchill, Livingston, London
- 10. Chaudhari, S.K. Quintessence of Medical Pharmacology; Central Publishers, New Delhi
- 11. Kundu, A.K.; Bedside Clinics in Medicine, Academic Publishers, Part-I and II, 2009
- 12. Balakrishan, K.V., Komar's Manual of Medical Prescriptions, Paras Publications
- 13. Oxford Textbook of Medicine,5th ed., Edited by David A. Warrell, Timothy M. Cox and John D. Firth, Blackwell Science

- 14. Panda, U.N., Textbook of Medicine, 2000, CBS publisher, New Delhi
- 15. Jambur Ananth; Psychopharmacology Treatment of Psychiatric Disorders, Jaypee Brothers, New Delhi, 2007.
- 16. Misbahuddin, M, Chaudhari, M.A., Jalil, A; Community Pharmacology, Jaypee, New Delhi
- 17. Patten, J; Neurological Differential Diagnosis, 2 Edition, 2005, Springer
- 18. Bickley, L.S., Bates's Guide to Physical Examination and History Taking, 6th ed.,2009 Lippincott
- 19. Walton, J.; Boain's Diseases of Nervous System, Tenth Edition, Oxford Uni. Press.