

Third Year

3.1 PHARMACOLOGY – II (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This subject will provide an opportunity for the student to learn about the drug with regard to classification, pharmacodynamic and pharmacokinetic aspects, adverse effects, uses, dose, route of administration, precautions, contraindications and interaction with other drugs. In this subject, drugs acting on autacoids, respiratory system, GIT, immune system and hormones, and pharmacology of autacoids and hormones will be concentrated. In addition, pharmacology of chemotherapeutic agents, vitamins, essential minerals and principles of toxicology are also taught. In addition to theoretical knowledge, the basic practical knowledge relevant to therapeutics will be imparted.
- 2. Objectives of the Subject Upon completion of the subject student shall be able to:**
 - a. understand the pharmacological aspects of drugs falling under the above mentioned chapters,
 - b. carry out the animal experiments confidently,
 - c. appreciate the importance of pharmacology subject as a basis of therapeutics, and
 - d. correlate and apply the knowledge therapeutically.

Text books (Theory)

- a. Tripathi, K. D. Essentials of medical pharmacology. 4th edition, 1999. Publisher: Jaypee, Delhi.
- b. Satoskar, R.S. and Bhadarkar, S.D. Pharmacology and pharmacotherapeutics. 16th edition (single volume), 1999. Publisher: Popular, Dubai.
- c. Rang, H.P. and Dale, M.M. Pharmacology. 4th edition, 1999. Publisher: Churchill Living stone.

Reference books (Theory)

- a. Goodman Gilman, A., Rall, T.W., Nies, A.I.S. and Taylor, P. Goodman and Gilman's The pharmacological Basis of therapeutics. 9th edition, 1996. Publisher: Mc Graw Hill, Pergamon press.
- b. Craig, C.R. and Stitzel, R.E. Modern Pharmacology. Latest edition. Publisher: Little Brown and company.
- c. Katzung, B.G. Basic and clinical pharmacology. Latest edition. Publisher: Prentice Hall, International.
- d. Gupta, P.K. and Salunkhe, D.K. Modern Toxicology. Volume I, II and III. Latest edition. Publisher: B.V. Gupta, Metropolitan Book Co. (p) Ltd, New Delhi.

Text books (Practical)

Kulkarni, S. K. and Dandia, P. C. Hand book of experimental pharmacology. Latest edition, Publisher: Vallab, Delhi.

Reference books (Practical) :

- a. Macleod, L.J. Pharmacological experiments on intact preparations. Latest edition, Publisher: Churchill livingstone.
- b. Macleod, L.J. Pharmacological experiments on isolated preparations. Latest edition, Publisher: Churchill livingstone.
- c. Ghosh, M.N. Fundamentals of experimental pharmacology. Latest edition, Publisher: Scientific book agency, Kolkata.
- d. Ian Kitchen. Textbook of in vitro practical pharmacology. Latest edition, Publisher: Black well Scientific.

3. Detailed syllabus and lecture wise schedule:**Title of the topic**

1. **Pharmacology of Drugs acting on Blood and blood forming agents**
 - a) Anticoagulants
 - b) Thrombolytics and antiplatelet agents
 - c) Haemopoietics and plasma expanders
2. **Pharmacology of drugs acting on Renal System**
 - a) Diuretics
 - b) Antidiuretics
3. **Chemotherapy**
 - a) Introduction
 - b) Sulfonamides and co-trimoxazole
 - c) Penicillins and Cephalosporins
 - d) Tetracyclins and Chloramphenicol
 - e) Macrolides, Aminoglycosides, Polyene & Polypeptide antibiotics
 - f) Quinolines and Fluroquinolines
 - g) Antifungal antibiotics
 - h) Antiviral agents
 - i) Chemotherapy of tuberculosis and leprosy
 - j) Chemotherapy of Malaria
 - k) Chemotherapy of protozoal infections (amoebiasis, Giardiasis)
 - l) Pharmacology of Anthelmintic drugs
 - m) Chemotherapy of cancer (Neoplasms)
4. **Immunopharmacology**
Pharmacology of immunosuppressants and stimulants
5. **Principles of Animal toxicology**
Acute, sub acute and chronic toxicity

6. The dynamic cell: The structures and functions of the components of the cell

- a) Cell and macromolecules: Cellular classification, subcellular organelles, macromolecules, large macromolecular assemblies
- b) Chromosome structure: Pro and eukaryotic chromosome structures, chromatin structure, genome complexity, the flow of genetic information.
- c) DNA replication: General, bacterial and eukaryotic DNA replication.
- d) The cell cycle: Restriction point, cell cycle regulators and modifiers.
- e) Cell signaling: Communication between cells and their environment, ion-channels, signal transduction pathways (MAP kinase, P38 kinase, JNK, Ras and PI3-kinase pathways, biosensors.

The Gene: Genome structure and function:

- a) Gene structure: Organization and elucidation of genetic code.
- b) Gene expression: Expression systems (pro and eukaryotic), genetic elements that control gene expression (nucleosomes, histones, acetylation, HDACS, DNA binding protein families.
- c) Transcription and Transcription factors: Basic principles of transcription in pro and eukaryotes. Transcription factors that regulate transcription in pro and eukaryotes.

RNA processing: rRNA, tRNA and mRNA processing.

Protein synthesis: Mechanisms of protein synthesis, initiation in eukaryotes, translation control and post-translation events

Altered gene functions: Mutations, deletions, amplifications, LOH, traslocations, trinucleotide repeats and other genetic abnormalities.

Oncogenes and tumor suppressor genes.

The gene sequencing, mapping and cloning of human disease genes.

Introduction to gene therapy and targeting.

Recombinant DNA technology: principles. Processes (gene transfer technology) and applications

Books:

- 1 Molecular Biology of the Cell by Alberts B., Bray, D., Lewis, J., Raff M., Roberts, K and Watson, JD, 3rd edition.
- 2 Molecular Cell Biology By Lodish, H., Baltimore, D., Berk, A et al., 5th edition.
- 3 Molecular Biology by Turner, PC., McLennan, AG., Bates, AD and White MRH 2nd edition.
- 4 Genes VIII by Lewin, B., (2004)
- 5 Pharmaceutical Biotechnology, by Crommelin, DJA and Sindelar RD (1997)
- 6 Recombinant DNA by Watson, JD., Gilman, M., et al., (1996)
- 7 Biopharmaceutical: Biochemistry and Biotechnology by Walsh, G., (1998)

3.1 PHARMACOLOGY – II (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Study of laboratory animals and their handling (a. Frogs, b. Mice, c. Rats, d. Guinea pigs, e. Rabbits).
2. Study of physiological salt solutions used in experimental pharmacology.
3. Study of laboratory appliances used in experimental pharmacology.
4. Study of use of anesthetics in laboratory animals.
5. To record the dose response curve of Ach using isolated ileum/rectus abdominis muscle preparation.
6. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by interpolation method.
7. To carry out bioassay of Ach using isolated ileum/rectus abdominis muscle preparation by three point method.
8. To record the dose response curve of Histamine using isolated guinea-pig ileum preparation.
9. Study of agonistic and antagonistic effects of drugs using isolated guinea-pig ileum preparation.
10. To carry out bioassay of Histamine using isolated guinea-pig ileum preparation by interpolation method.
11. To carry out bioassay of Histamine using guinea-pig ileum preparation by three point method.
12. To study the routes of administration of drugs in animals (Rats, Mice, Rabbits).
13. Study of theory, principle, procedure involved and interpretation of given results for the following experiments:
 - a) Analgesic property of drug using analgesiometer.
 - b) Antiinflammatory effect of drugs using rat-paw edema method.
 - c) Anticonvulsant activity of drugs using maximal electroshock and pentylenetetrazole methods.
 - d) Antidepressant activity of drugs using pole climbing apparatus and pentobarbitone induced sleeping time methods.
 - e) Locomotor activity evaluation of drugs using actophotometer and rotarod.
 - f) Cardiotonic activity of drugs using isolated frog heart and mammalian heart preparations.

Scheme of Practical Examination:

	Sessionals	Annual
Identification	02	10
Synopsis	04	10
Major Experiment (Bioassay)	08	30
Minor Experiment (Interpretation of given Graph or simulated experiment)	04	10
Viva	02	10
Max Marks	20	70
Duration	3hrs	4hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.2 PHARMACEUTICAL ANALYSIS (THEORY)

Theory : 3 Hrs. /Week

1. Quality Assurance:

- a. Introduction, sources of quality variation, control of quality variation.
- b. Concept of statistical quality control.
- c. Validation methods- quality of equipment, validation of equipment and validation of analytical instruments and calibration.
- d. GLP, ISO 9000.
- e. Total quality management, quality review and documentation.
- f. ICH- international conference for harmonization-guidelines.
- g. Regulatory control.

2. Chromatography:

Introduction, history, classification, separation techniques, choice of methods. The following techniques be discussed with relevant examples of pharmaceutical products involving principles and techniques of separation of drugs from excipients.

- a. **Column Chromatography:** Adsorption column chromatography, Operational technique, frontal analysis and elution analysis. Factors affecting column efficiency, applications and partition chromatography.
- b. **TLC:** Introduction, principle, techniques, R_f value and applications.
- c. **PC:** Introduction, principle, types of paper chromatography, preparation techniques, development techniques, applications.
- d. **Ion-exchange chromatography:** Introduction, principles, types of ion exchange synthetic resins, physical properties, factors affecting ion exchange, methodology and applications.
- e. **HPLC:** Introduction, theory, instrumentation, and applications.
- f. **HPTLC:** Introduction, theory, instrumentation, and applications.
- g. **Gas Chromatography:** Introduction, theory, instrumentation-carrier gases, types of columns, stationary phases in GLC & GSC. Detectors- Flame ionization detectors, electron capture detector, thermal conductivity detector. Typical gas chromatogram, derivatisation techniques, programmed temperature gas chromatography, applications.
- h. **Electrophoresis:** Principles of separation, equipment for paper and gel electrophoresis, and application.
- i. **Gel filtration and affinity chromatography:** Introduction, technique, applications.

3. **Electrometric Methods:**

Theoretical aspects, instrumentation, interpretation of data/spectra and analytical applications be discussed on the following topics.

- a. **Potentiometry:** Electrical potential, electrochemical cell, reference electrodes, indicator electrodes, measurement of potential and pH, construction and working of electrodes, Potentiometric titrations, methods of detecting end point, Karl Fischer titration.
- b. **Conductometry:** Introduction, conductivity cell, conductometric titrations and applications.
- c. **Polarography:** Instrumentation, DME, residual current, diffusion current and limiting current, polarographic wave, Ilkovic's equation, Effect of oxygen on polarographic wave, Polarographic maxima and suppressors and applications.
- d. **Amperometric Titrations:** Introduction, types of electrodes used, reference and indicator electrode, instrumentation, titration procedure, advantages and disadvantages of Amperometry over potentiometry. Pharma applications.

4. **Spectroscopy:**

Theoretical aspects, instrumentation, elements of interpretation of data/spectra and application of analytical techniques be discussed on:

a. **Absorption Spectroscopy:**

- Theory of electronic, atomic and molecular spectra. Fundamental laws of photometry, Beer-Lambert's Law, application and its deviation, limitation of Beer law, application of the law to single and multiple component analysis, measurement of equilibrium constant and rate constant by spectroscopy. Spectra of isolated chromophores, auxochromes, batho-chromic shift, hypsochromic shift, hyperchromic and hypochromic effect, effect of solvent on absorption spectra, molecular structure and infrared spectra.

Instrumentation – Photometer, U.V.-Visible spectrophotometer – sources of U.V.-Visible radiations, collimating systems, monochromators, samples cells and following detectors-Photocell, Barrier layer cell, Phototube, Diode array, applications of U.V.-Visible spectroscopy in pharmacy and spectrophotometric titrations.

- **Infrared Spectroscopy:** Vibrational transitions, frequency – structure correlations, Infrared absorption bands, Instrumentation–IR spectrometer – sources of IR, Collimating systems, monochromators, sample cells, sample handling in IR spectroscopy and detectors–Thermocouple, Golay Cells, Thermistor, Bolometer, Pyroelectric detector, Applications of IR in pharmacy.

- **Fluorimetric Analysis:** Theory, luminescence, factors affecting fluorescence, quenching. Instrumentation, Applications, fluorescent indicators, study of pharmaceutically important compounds estimated by fluorimetry.
- b. **Flame Photometry:** Theory, nebulisation, flame and flame temperature, interferences, flame spectrometric techniques and instrumentation and pharmaceutical applications.
- c. **Atomic Absorption Spectrometry:** Introduction, Theory, types of electrodes, instrumentation and applications.
- d. **Atomic Emission Spectroscopy:** Spectroscopic sources, atomic emission spectrometers, photographic and photoelectric detection.
- e. **NMR & ESR (introduction only):** Introduction, theoretical aspects and applications.
- f. **Mass Spectroscopy: (Introduction only)** – Fragmentation, types of ions produced mass spectrum and applications.
- g. **Polarimetry: (Introduction only)** – Introduction to optical rotatory dispersion, circular dichroism, polarimeter.
- h. **X-RAY Diffraction: (Introduction only)** – Theory, reciprocal lattice concept, diffraction patterns and applications.
- i. **Thermal Analysis:** Introduction, instrumentation, applications, and DSC and DTA.

3.2 PHARMACEUTICAL ANALYSIS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments:

1. Separation and identification of Amino Acids by Paper Chromatography.
2. Separation and identification of Sulpha drugs by TLC technique.
3. Effect of pH and solvent on the UV spectrum of given compound.
4. Comparison of the UV spectrum of a compound with that of its derivatives.
5. Determination of dissociation constant of indicators using UV-Visible spectroscopy.
6. Conductometric titration of mixture of acids with a strong base.
7. Potentiometric titration of an acid with a strong base.
8. Estimation of drugs by Fluorimetric technique.
9. Study of quenching effect in fluorimetry.
10. Colourimetric estimation of Sulpha drugs using BMR reagent.

11. Simultaneous estimation of two drugs present in given formulation.
12. Assay of Salicylic Acid by colourimetry.
13. Determination of Chlorides and Sulphates in Calcium gluconate by Nepheloturbidimetric Method.
14. Determination of Na/K by Flame Photometry.
15. Determination of pKa using pH meter.
16. Determination of specific rotation.
17. Comparison of the IR spectrum of a compound with that of its derivatives.
18. Demonstration of HPLC.
19. Demonstration of HPTLC.
20. Demonstration of GC-MS.
21. Demonstration of DSC.
22. Interpretation of NMR spectra of any one compound.

Reference Books:

1. Text Book of Pharm. Analysis by Higuchi. T and Hasen. E. B., New York Inter Science Publishers.
2. Quantitative Pharma. Analysis by Jenkins, The Blakiston division, New York.
3. Quantitative Drug Analysis, by Garrot. D, Chapman & Hall Ltd., London.
4. Undergraduate Instrumental Analysis by James. E., CBS Publishers.
5. Instrumental Analysis by Willard and Merritt, EWP, East West Press Ltd., Delhi/Madras.
6. Pharm Analysis by Skoog and West, Sounders Manipal College Publishing.
7. Text Book of Chemical Analysis, by A.I.Vogel, ELBS with Macmillan press, Hampshire.
8. Textbook of Pharm. Analysis by K.A.Connors, John Wiley & Sons, New York, Brisbane, Singapore.
9. Textbook of Pharm. Analysis (Practical) by Beckett & Stenlake, CBS Publishers, Delhi.
10. Textbook of Drug Analysis by P.D. Sethi., CBS Publishers, Delhi.
11. Spectroscopy by Silverstein, John & Wiley & Sons. Inc., Canada & Singapore.
12. How to practise GMP-A Plan for total quality control by P.P. Sharma, Vandana Publications, Agra.
13. The Science & Practice of Pharmacy by Remington Vol-I & II, Mack Publishing Co. Pennsylvania.
14. TLC by Stahl, Spring Verlay.
15. Text Book of Pharm. Chemistry by Chatten, CBS Publications.
16. Spectroscopy by William Kemp, ELBS with Macmillan Press, Hampshire.
17. I.P.-1996, The Controller of Publications, New Delhi.
18. BPC- Dept. of Health, U.K. for HMSO.
19. USP - Mack Publishing Co., Easton, PA.
20. The Extra Pharmacopoeia – The Pharm. Press, London.

Practicals

Title of the Experiment:

- 1 Study of agonistic and antagonistic effects of drugs using Guinea-pig ileum preparation.**
- 2 To study the effects of drugs on intestinal motility using frog's esophagus model*
- 3 To study the effects of drugs using rat uterus preparation.**
- 4 To study the anticonvulsant property of drugs (any one model).*
- 5 To study antihistaminic property of drug using histamine induced anaphylactic reaction in guinea pigs.
- 6 To study the apomorphine-induced compulsive behaviour (stereotypy) in mice.*
- 7 To study the muscle relaxant property of diazepam in mice using rotarod apparatus.*
- 8 To study the antiinflammatory property of indomethacin against carrageenan-induced paw oedema.**
- 9 To study the anxiolytic effect of diazepam in mice using mirrored-chamber apparatus.**
- 10 To demonstrate the effect of various drugs on the blood pressure and respiration of anaesthetized dog.
- 11 To study the effect of anthelmintics on earthworms.
- 12 To study the taming effect of chlorpromazine.*
- 13 To study the effects of drugs on vas deferense of the male rat.**
- 14 To study the effect of drugs on pesticide toxicity using rats as model.
- 15 To study the effect of drugs on heavy metal toxicity.

** indicate major experiment & * indicate minor experiment

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.3 PHARMACOTHERAPEUTICS – II (THEORY)

Theory : 3 Hrs. /Week

- 1. Scope of the Subject:** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
- 2. Objectives of the Subject Upon completion of the subject student shall be able to –**
 - a. know the pathophysiology of selected disease states and the rationale for drug therapy
 - b. know the therapeutic approach to management of these diseases;
 - c. know the controversies in drug therapy;
 - d. know the importance of preparation of individualised therapeutic plans based on diagnosis; and
 - e. appreciate the needs to 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 effects).

Text books (Theory)

Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication

Reference books (Theory)

- a. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange
- b. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- c. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA]

3. Detailed syllabus and lecture wise schedule :

Etiopathogenesis and pharmacotherapy of diseases associated with following systems / diseases –

Title of the topic

- 1. Infectious disease:** Guidelines for the rational use of antibiotics and surgical Prophylaxis, Tuberculosis, Meningitis, Respiratory tract infections, Gastroenteritis, Endocarditis, Septicemia, Urinary tract infections, Protozoal infection- Malaria, HIV & Opportunistic infections, Fungal infections, Viral infections, Gonorrhoea and Syphilis
- 2 Musculoskeletal disorders**
Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
- 3 Renal system**
Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders

- 4 **Oncology:** Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis
- 5 **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo

3.3 PHARMACOTHERAPEUTICS – II (PRACTICAL)

Practical : 3 Hrs./Week

Practicals :

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation.

The student shall be trained to understand the principle and practice involved in selection of drug therapy including clinical discussion.

A minimum of 20 cases should be presented and recorded covering most common diseases.

Assignments :

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment :

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

3.4 PHARMACEUTICAL JURISPRUDENCE (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** (4-6 lines): This course exposes the student to several important legislations related to the profession of pharmacy in India. The Drugs and Cosmetics Act, along with its amendments are the core of this course. Other acts, which are covered, include the Pharmacy Act, dangerous drugs, medicinal and toilet preparation Act etc. Besides this the new drug policy, professional ethics, DPCO, patent and design Act will be discussed.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, and appreciate) –
 - a. practice the Professional ethics;
 - b. understand the various concepts of the pharmaceutical legislation in India;
 - c. know the various parameters in the Drug and Cosmetic Act and rules;
 - d. know the Drug policy, DPCO, Patent and design act;
 - e. understand the labeling requirements and packaging guidelines for drugs and cosmetics;
 - f. be able to understand the concepts of Dangerous Drugs Act, Pharmacy Act and Excise duties Act; and
 - g. other laws as prescribed by the Pharmacy Council of India from time to time including International Laws.

Text books (Theory)

Mithal , B M. Textbook of Forensic Pharmacy. Calcutta :National; 1988.

Reference books (Theory)

- a. Singh, KK, editor. Beotra's the Laws of Drugs, Medicines & cosmetics. Allahabad: Law Book House; 1984.
- b. Jain, NK. A Textbook of forensic pharmacy. Delhi: Vallabh prakashan ; 1995.
- c. Reports of the Pharmaceutical enquiry Committee
- d. I.D.M.A., Mumbai. DPCO 1995
- e. Various reports of Amendments.
- f. Deshapande, S.W. The drugs and magic remedies act 1954 and rules 1955. Mumbai: Susmit Publications; 1998.
- g. Eastern Book Company .The narcotic and psychotropic substances act 1985, Lucknow: Eastern; 1987.

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Pharmaceutical Legislations** – A brief review.
2. Principle and Significance of professional ethics. Critical study of the code of pharmaceutical ethics drafted by PCI.
3. **Drugs and Cosmetics Act, 1940, and its rules 1945.**
 Objectives, Legal definition, Study of Schedule's with reference to Schedule B, C&C1, D, E1, F&F1, F2, F3, FF, G, H, J, K, M, N, P, R, V, W, X, Y.
 Sales, Import, labeling and packaging of Drugs And Cosmetics
 Provisions Relating to Indigenous Systems.
 Constitution and Functions of DTAB, DCC, CDL.
 Qualification and duties –Govt. analyst and Drugs Inspector.

4. **Pharmacy Act –1948.**
Objectives Legal Definitions, General Study, Constitution and Functions of State & Central Council, Registration & Procedure, ER.
5. **Medicinal and Toilet Preparation Act –1955.**
Objectives, Legal Definitions, Licensing, Bonded and Non Bonded Laboratory, Ware Housing, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations.
6. **Narcotic Drugs and Psychotropic substances Act-1985 and Rules.** Objectives, Legal Definitions, General Study, Constitution and Functions of narcotic & Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and regulations, Schedules to the Act.
7. **Study of Salient Features of Drugs and magic remedies Act and its rules.**
8. **Study of essential Commodities Act Relevant to drugs price control Order.**
9. **Drug Price control Order & National Drug Policy (Current).**
10. **Prevention Of Cruelty to animals Act-1960.**
11. **Patents & design Act-1970.**
12. **Brief study of prescription and Non-prescription Products.**

4. Assignments:

Format of the assignment

1. Minimum & Maximum number of pages
2. It shall be a computer draft copy
3. Reference(s) shall be included at the end.
4. Name and signature of the student
5. Assignment can be a combined presentation at the end of the academic year.
6. Time allocated for presentation may be 8+2 Min

Case studies relating to

1. Drugs and Cosmetics Act and rules along with its amendments, Dangerous Drugs Act, Medicinal and Toilet preparation Act, New Drug Policy, Professional Ethics, Drugs (Price control) Order, Patent and Design Act.
2. Various prescription and non-prescription products.
3. Medical and surgical accessories.
4. Diagnostic aids and appliances available in the market.

3.5 MEDICINAL CHEMISTRY (THEORY)

Theory : 3 Hrs. /Week

1. Modern concept of rational drug design: A brief introduction to Quantitative Structure Activity Relationship (QSAR), prodrug, combinatorial chemistry and computer aided drug design (CADD) and concept of antisense molecules.

A study of the development of the following classes of drugs including SAR, mechanism of action, synthesis of important compounds, chemical nomenclature, brand names of important marketed products and their side effects.

2. Anti-infective agents
 - a) Local anti-infective agents
 - b) Preservatives
 - c) Antifungal agents
 - d) Urinary tract anti-infectives
 - e) Antitubercular agents
 - f) Antiviral agents and Anti AIDS agents
 - g) Antiprotozoal agents
 - h) Anthelmintics
 - i) Antiscabies and Antipedicular agents
3. Sulphonamides and sulphones
4. Antimalarials
5. Antibiotics
6. Antineoplastic agents
7. Cardiovascular agents
 - a) Antihypertensive agents
 - b) Antianginal agents and vasodilators
 - c) Antiarrhythmic agents
 - d) Antihyperlipidemic agents
 - e) Coagulants and Anticoagulants
 - f) Endocrine
8. Hypoglycemic agents
9. Thyroid and Antithyroid agents
10. Diuretics
11. Diagnostic agents
12. Steroidal Hormones and Adrenocorticoids

3.5 MEDICINAL CHEMISTRY (PRACTICAL)

Practical : 3 Hrs./Week

1. Assays of important drugs from the course content.
2. Preparation of medicinally important compounds or intermediates required for synthesis of drugs.
3. Monograph analysis of important drugs.
4. Determination of partition coefficients, dissociation constants and molar refractivity of compounds for QSAR analysis.

Reference Books:

- a. Wilson and Gisvold's Text book of Organic, Medicinal and Pharmaceutical Chemistry, Lippincott-Raven Publishers-New York, Philadelphia.
- b. William.O.Foye, Principles of Medicinal Chemistry, B.I. Waverly Pvt. Ltd., New Delhi.
- c. Burgers, Medicinal Chemistry, M.E., Welly Med.Chemistry M.E. Walffed Johnwiley and Sons, Wiley-interscience Publication, New York, Toranto.
- d. A Text Book of Medicinal Chemistry Vol. I and II by Surendra N. Pandeya, S.G. Publisher, 6, Dildayal Nagar, Varanasi -10.
- e. Indian Pharmacopoeia 1985 and 1996. The Controller of Publications, Civil Lines, Delhi - 54.
- f. Current Index of Medical Specialities (CIMS) and MIMS India, MIMS, A.E. Morgan Publications (I) Pvt. Ltd, New Delhi-19.
- g. Organic Drug Synthesis-Ledniser Mitzsher Vol. I and II.
- h. Pharmaceutical Chemistry drug Synthesis Vol. I and II by H. J. Roth and A. Kleemann.
- i. The Science and Practice of Pharmacy Vol. 1 and 2, Remington, MACK Publishing Company, Easton, Pennsylvania.

3.6 PHARMACEUTICAL FORMULATIONS (THEORY)

Theory : 2 Hrs. /Week

1. **Scope of the Subject:** Scope and objectives of the course: Subject deals with the formulation and evaluation of various pharmaceutical dosage forms.
2. **Objectives of the Subject:** Upon completion of the subject student shall be able to (Know, do, appreciate) –
 - a. understand the principle involved in formulation of various pharmaceutical dosage forms;
 - b. prepare various pharmaceutical formulation;
 - c. perform evaluation of pharmaceutical dosage forms; and
 - d. understand and appreciate the concept of bioavailability and bioequivalence, their role in clinical situations.

Text books (Theory)

- a. Pharmaceutical dosage forms, Vol, I,II and III by lachman
- b. Rowlings Text book of Pharmaceutics
- c. Tutorial Pharmacy – Cooper & Gun

Reference books (Theory)

- a. Remington's Pharmaceutical Sciences
- b. USP/BP/IP

3. Detailed syllabus and lecture wise schedule:

Title of the topic

1. Pharmaceutical dosage form- concept and classification
2. **Tablets:** Formulation of different types of tablets, tablet excipients, granulation techniques quality control and evaluation of tablets. Tablet coating, Type of coating, quality control tests for coated tablet.
3. **Capsules;** Production and filling of hard gelatin capsules, Raw material for shell, finishing, quality control tests for capsules. Production and filling of soft gelatin capsules, quality control tests for soft gelatin capsules.
4. **Liquid orals:** Formulation and evaluation of suspensions, emulsions and solutions. Stability of these preparations
5. **Parenterals** Introduction Containers used for Parenterals (including official tests) Formulation of large and small volume Parenterals Sterilization
6. **Ophthalmic preparations (Semi – Solids):** Introduction and classification Factors affecting absorption and anatomy of skin Packaging storage and labeling, Ointments Types of Ointment Base Preparation of ointment, Jellies Types of jellies Formulation of jellies Suppositories, Method of preparation, Types Packaging
7. Definition and concept of **Controlled and novel Drug delivery systems** with available examples, viz. parenteral, trans dermal, buccal, rectal, nasal, implants, ocular

3.6 PHARMACEUTICAL FORMULATIONS (PRACTICAL)

Practical : 3 Hrs./Week

List of Experiments :

- 1. Manufacture of Tablets**
 - a. Ordinary compressed tablet-wet granulation
 - b. Tablets prepared by direct compression.
 - c. Soluble tablet.
 - d. Chewable tablet.
- 2. Formulation and filling of hard gelatin capsules**
- 3. Manufacture of parenterals**
 - a. Ascorbic acid injection
 - b. Calcium gluconate injection
 - c. Sodium chloride infusion.
 - d. Dextrose and Sodium chloride injection/ infusion.
- 4. Evaluation of Pharmaceutical formulations (QC tests)**
 - a. Tablets
 - b. Capsules
 - c. Injections
- 5. Formulation of two liquid oral preparations and evaluation by assay**
 - a. Solution: Paracetamol Syrup
 - b. Antacid suspensions- Aluminum hydroxide gel
- 6. Formulation of semisolids and evaluation by assay**
 - a. Salicylic acid and benzoic acid ointment
 - b. Gel formulation Diclofenac gel
- 7. Cosmetic preparations**
 - a. Lipsticks
 - b. Cold cream and vanishing cream
 - c. Clear liquid shampoo
 - d. Tooth paste and tooth powders.
- 8. Tablet coating (demonstration)**

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

Fourth Year

4.1 PHARMACOTHERAPEUTICS – III (THEORY)

Theory : 3 Hrs. /Week

1. **Scope :** This course is designed to impart knowledge and skills necessary for contribution to quality use of medicines. Chapters dealt cover briefly pathophysiology and mostly therapeutics of various diseases. This will enable the student to understand the pathophysiology of common diseases and their management.
2. **Objectives:** At completion of this subject it is expected that students will be able to understand –
 - a. the pathophysiology of selected disease states and the rationale for drug therapy;
 - b. the therapeutic approach to management of these diseases;
 - c. the controversies in drug therapy;
 - d. the importance of preparation of individualised therapeutic plans based on diagnosis;
 - e. needs to 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 effects);
 - f. describe the pathophysiology of selected disease states and explain the rationale for drug therapy;
 - g. to summarize the therapeutic approach to management of these diseases including reference to the latest available evidence;
 - h. to discuss the controversies in drug therapy;
 - i. to discuss the preparation of individualised therapeutic plans based on diagnosis; and
 - j. 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 effects).

Text Books

- a. Clinical Pharmacy and Therapeutics - Roger and Walker, Churchill Livingstone publication
- b. Pharmacotherapy: A Pathophysiologic approach - Joseph T. Dipiro et al. Appleton & Lange

Reference Books

- a. Pathologic basis of disease - Robins SL, W.B.Saunders publication
- b. Pathology and therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice - Green and Harris, Chapman and Hall publication
- c. Clinical Pharmacy and Therapeutics - Eric T. Herfindal, Williams and Wilkins Publication
- d. Applied Therapeutics: The clinical Use of Drugs. Lloyd Young and Koda-Kimble MA
- e. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.
- f. Relevant review articles from recent medical and pharmaceutical literature.

4.1 PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical : 3 Hrs./Week

Practicals:

Hospital postings for a period of at least 50 hours is required to understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy. Students are required to maintain a record of 15 cases observed in the ward and the same should be submitted at the end of the course for evaluation. Each student should present at least two medical cases they have observed and followed in the wards.

Etiopathogenesis and pharmacotherapy of diseases associated with following systems/ diseases:

Title of the topic

- 1 **Gastrointestinal system:** Peptic ulcer disease, Gastro Esophageal Reflux Disease, Inflammatory bowel disease, Liver disorders - Alcoholic liver disease, Viral hepatitis including jaundice, and Drug induced liver disorders.
- 2 **Haematological system:** Anaemias, Venous thromboembolism, Drug induced blood disorders.
- 3 **Nervous system:** Epilepsy, Parkinsonism, Stroke, Alzheimer's disease,
- 4 **Psychiatry disorders:** Schizophrenia, Affective disorders, Anxiety disorders, Sleep disorders, Obsessive Compulsive disorders
- 5 Pain management including Pain pathways, neuralgias, headaches.
- 6 Evidence Based Medicine

Assignments:

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Format of the assignment:

1. Minimum & Maximum number of pages
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year
4. It shall be computer draft copy
5. Name and signature of the student
6. Time allocated for presentation may be 8+2 Min.

Scheme of Practical Examination :

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.2 HOSPITAL PHARMACY (THEORY)

Theory : 2 Hrs. /Week

1. **Scope:** In the changing scenario of pharmacy practice in India, for successful practice of Hospital Pharmacy, the students are required to learn various skills like drug distribution, drug dispensing, manufacturing of parenteral preparations, drug information, patient counselling, and therapeutic drug monitoring for improved patient care.
2. **Objectives:** Upon completion of the course, the student shall be able to –
 - a. know various drug distribution methods;
 - b. know the professional practice management skills in hospital pharmacies;
 - c. provide unbiased drug information to the doctors;
 - d. know the manufacturing practices of various formulations in hospital set up;
 - e. appreciate the practice based research methods; and
 - f. appreciate the stores management and inventory control.

Text books: (latest editions)

- a. Hospital pharmacy by William .E. Hassan
- b. A text book of Hospital Pharmacy by S.H.Merchant & Dr. J.S. Qadry. Revised by R.K.Goyal & R.K. Parikh

References:

- a. WHO consultative group report.
- b. R.P.S. Vol.2. Part –B; Pharmacy Practice section.
- c. Handbook of pharmacy – health care. Edt. Robin J Harman. The Pharmaceutical press.

3. Lecture wise programme :

Topics

- 1 **Hospital - its Organisation and functions**
- 2 **Hospital pharmacy-Organisation and management**
 - a) Organizational structure-Staff, Infrastructure & work load statistics
 - b) Management of materials and finance
 - c) Roles & responsibilities of hospital pharmacist
- 3 **The Budget – Preparation and implementation**
- 4 **Hospital drug policy**
 - a) Pharmacy and Therapeutic committee (PTC)
 - b) Hospital formulary
 - c) Hospital committees
 - Infection committee
 - Research and ethical committee
 - d) developing therapeutic guidelines
 - e) Hospital pharmacy communication - Newsletter

5 Hospital pharmacy services

- a) Procurement & warehousing of drugs and Pharmaceuticals
- b) Inventory control
Definition, various methods of Inventory Control
ABC, VED, EOQ, Lead time, safety stock
- c) Drug distribution in the hospital
 - i) Individual prescription method
 - ii) Floor stock method
 - iii) Unit dose drug distribution method
- d) Distribution of Narcotic and other controlled substances
- e) Central sterile supply services – Role of pharmacist

6 Manufacture of Pharmaceutical preparations

- a) Sterile formulations – large and small volume parenterals
- b) Manufacture of Ointments, Liquids, and creams
- c) Manufacturing of Tablets, granules, capsules, and powders
- d) Total parenteral nutrition

7 Continuing professional development programs

Education and training

8 Radio Pharmaceuticals – Handling and packaging**9 Professional Relations and practices of hospital pharmacist****4.2 HOSPITAL PHARMACY (PRACTICAL)****Practical : 3 Hrs./Week**

1. Assessment of drug interactions in the given prescriptions
2. Manufacture of parenteral formulations, powders.
3. Drug information queries.
4. Inventory control

List of Assignments:

1. Design and Management of Hospital pharmacy department for a 300 bedded hospital.
2. Pharmacy and Therapeutics committee – Organization, functions, and limitations.
3. Development of a hospital formulary for 300 bedded teaching hospital
4. Preparation of ABC analysis of drugs sold in one month from the pharmacy.
5. Different phases of clinical trials with elements to be evaluated.
6. Various sources of drug information and systematic approach to provide unbiased drug information.
7. Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

Special requirements:

1. Each college should sign MoU with nearby local hospital having minimum 150 beds for providing necessary training to the students' on hospital pharmacy activities.
2. Well equipped with various resources of drug information.

Scheme of Practical Examination:

	Sessionals	Annual
Synopsis	05	15
Major Experiment	10	25
Minor Experiment	03	15
Viva	02	15
Max Marks	20	70
Duration	03hrs	04hrs

Note : Total sessional marks is 30 (20 for practical sessional plus 10 marks for regularity, promptness, viva-voce and record maintenance).

4.3 CLINICAL PHARMACY (THEORY)

Theory : 3 Hrs. /Week

1. Objectives of the Subject :

Upon completion of the subject student shall be able to (Know, do, appreciate) –

- a. monitor drug therapy of patient through medication chart review and clinical review;
- b. obtain medication history interview and counsel the patients;
- c. identify and resolve drug related problems;
- d. detect, assess and monitor adverse drug reaction;
- e. interpret selected laboratory results (as monitoring parameters in therapeutics) of specific disease states; and
- f. retrieve, analyse, interpret and formulate drug or medicine information.

Text books (Theory)

- a. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia.
- b. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc.
- c. Biopharmaceutics and Applied Pharmacokinetics - Leon Shargel, Prentice Hall publication.
- d. A text book of Clinical Pharmacy Practice; Essential concepts and skills, Dr.G.Parthasarathi et al, Orient Orient Langram Pvt.Ltd. ISSN8125026

References

- a. Australian drug information -Procedure manual. The Society of Hospital Pharmacists of Australia.
- b. Clinical Pharmacokinetics - Rowland and Tozer, Williams and Wilkins Publication.
- c. Pharmaceutical statistics. Practical and clinical applications. Sanford Bolton, Marcel Dekker, Inc.

2. Detailed syllabus and lecture wise schedule:

Title of the topic

1. **Definitions, development and scope of clinical pharmacy**
2. **Introduction to daily activities of a clinical pharmacist**
 - a. Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
 - b. Ward round participation
 - c. Adverse drug reaction management
 - d. Drug information and poisons information
 - e. Medication history
 - f. Patient counseling
 - g. Drug utilisation evaluation (DUE) and review (DUR)
 - h. Quality assurance of clinical pharmacy services

3. **Patient data analysis**
The patient's case history, its structure and use in evaluation of drug therapy & Understanding common medical abbreviations and terminologies used in clinical practices.
4. **Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results**
 - a. Haematological, Liver function, Renal function, thyroid function tests
 - b. Tests associated with cardiac disorders
 - c. Fluid and electrolyte balance
 - d. Microbiological culture sensitivity tests
 - e. Pulmonary Function Tests
5. **Drug & Poison information**
 - a. Introduction to drug information resources available
 - b. Systematic approach in answering DI queries
 - c. Critical evaluation of drug information and literature
 - d. Preparation of written and verbal reports
 - e. Establishing a Drug Information Centre
 - f. Poisons information- organization & information resources
6. **Pharmacovigilance**
 - a. Scope, definition and aims of pharmacovigilance
 - b. Adverse drug reactions - Classification, mechanism, predisposing factors, causality assessment [different scales used]
 - c. Reporting, evaluation, monitoring, preventing & management of ADRs
 - d. Role of pharmacist in management of ADR.
7. Communication skills, including patient counselling techniques, medication history interview, presentation of cases.
8. Pharmaceutical care concepts
9. Critical evaluation of biomedical literature
10. Medication errors

4.3 CLINICAL PHARMACY (PRACTICAL)

Practical : 3 Hrs./Week

Students are expected to perform 15 practicals in the following areas covering the topics dealt in theory class.

- a. Answering drug information questions (4 Nos)
- b. Patient medication counselling (4 Nos)
- c. Case studies related to laboratory investigations (4 Nos)
- d. Patient medication history interview (3 Nos)

Assignment:

Students are expected to submit THREE written assignments (1500 – 2000 words) on the topics given to them covering the following areas dealt in theory class.

Drug information, Patient medication history interview, Patient medication counselling, Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.

Format of the assignment:

1. Minimum & Maximum number of pages.
2. Reference(s) shall be included at the end.
3. Assignment can be a combined presentation at the end of the academic year.
4. It shall be computer draft copy.
5. Name and signature of the student.
6. Time allocated for presentation may be 8+2 Min.

4.4 BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. Detailed syllabus and lecture wise schedule

1 Research Methodology

- a) Types of clinical study designs:
Case studies, observational studies, interventional studies,
- b) Designing the methodology
- c) Sample size determination and Power of a study
Determination of sample size for simple comparative experiments, determination of sample size to obtain a confidence interval of specified width, power of a study
- d) Report writing and presentation of data

2 Biostatistics

2.1 a) Introduction

- b) Types of data distribution
- c) Measures describing the central tendency distributions- average, median, mode
- d) Measurement of the spread of data-range, variation of mean, standard deviation, variance, coefficient of variation, standard error of mean.

2.2 Data graphics

Construction and labeling of graphs, histogram, piecharts, scatter plots, semilogarithmic plots

2.3 Basics of testing hypothesis

- a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals.
- b) Level of significance (Parametric data)- students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way)
- c) Level of significance (Non-parametric data)- Sign test, Wilcoxon's signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA)
- d) Linear regression and correlation- Introduction, Pearson's and Spearman's correlation and correlation coefficient.
- e) Introduction to statistical software: SPSS, Epi Info, SAS.

2.4 Statistical methods in epidemiology

Incidence and prevalence, relative risk, attributable risk

3. Computer applications in pharmacy

Computer System in Hospital Pharmacy: Patterns of Computer use in Hospital Pharmacy – Patient record database management, Medication order entry – Drug labels and list – Intravenous solution and admixture, patient medication profiles, Inventory control, Management report & Statistics.

Computer In Community Pharmacy

Computerizing the Prescription Dispensing process

Use of Computers for Pharmaceutical Care in community pharmacy

Accounting and General ledger system

Drug Information Retrieval & Storage :

Introduction – Advantages of Computerized Literature Retrieval

Use of Computerized Retrieval

Reference books:

- a. Pharmaceutical statistics- practical and clinical applications, Sanford Bolton 3rd edition, publisher Marcel Dekker Inc. NewYork.
- b. Drug Information- A Guide for Pharmacists, Patrick M Malone, Karen L Kier, John E Stanovich , 3rd edition, McGraw Hill Publications 2006

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (THEORY)

Theory : 3 Hrs. /Week

1. Biopharmaceutics

1. Introduction to Biopharmaceutics
 - a. Absorption of drugs from gastrointestinal tract.
 - b. Drug Distribution.
 - c. Drug Elimination.

2. Pharmacokinetics

2. Introduction to Pharmacokinetics.
 - a. Mathematical model
 - b. Drug levels in blood.
 - c. Pharmacokinetic model
 - d. Compartment models
 - e. Pharmacokinetic study.
3. One compartment open model.
 - a. Intravenous Injection (Bolus)
 - b. Intravenous infusion.
4. Multicompartment models.
 - a. Two compartment open model.
 - b. IV bolus, IV infusion and oral administration
5. Multiple – Dosage Regimens.
 - a. Repetitive Intravenous injections – One Compartment Open Model
 - b. Repetitive Extravascular dosing – One Compartment Open model
 - c. Multiple Dose Regimen – Two Compartment Open Model
6. Nonlinear Pharmacokinetics.
 - a. Introduction
 - b. Factors causing Non-linearity.
 - c. Michaelis-menton method of estimating parameters.
7. Noncompartmental Pharmacokinetics.
 - a. Statistical Moment Theory.
 - b. MRT for various compartment models.
 - c. Physiological Pharmacokinetic model.
8. Bioavailability and Bioequivalence.
 - a. Introduction.
 - b. Bioavailability study protocol.
 - c. Methods of Assessment of Bioavailability

4.5 BIOPHARMACEUTICS AND PHARMACOKINETICS (PRACTICAL)

Practical : 3 Hrs./Week

1. Improvement of dissolution characteristics of slightly soluble drugs by some methods.
2. Comparison of dissolution studies of two different marketed products of same drug.
3. Influence of polymorphism on solubility and dissolution.
4. Protein binding studies of a highly protein bound drug and poorly protein bound drug.
5. Extent of plasma-protein binding studies on the same drug (i.e. highly and poorly protein bound drug) at different concentrations in respect of constant time.
6. Bioavailability studies of some commonly used drugs on animal/human model.
7. Calculation of K_a , K_e , $t_{1/2}$, C_{max} , AUC, AUMC, MRT etc. from blood profile data.
8. Calculation of bioavailability from urinary excretion data for two drugs.
9. Calculation of AUC and bioequivalence from the given data for two drugs.
10. In vitro absorption studies.
11. Bioequivalency studies on the different drugs marketed.(eg) Tetracycline, Sulphamethoxazole, Trimethoprim, Aspirin etc., on animals and human volunteers.
12. Absorption studies in animal inverted intestine using various drugs.
13. Effect on contact time on the plasma protein binding of drugs.
14. Studying metabolic pathways for different drugs based on elimination kinetics data.
15. Calculation of elimination half-life for different drugs by using urinary elimination data and blood level data.
16. Determination of renal clearance.

References:

- a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi
- b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvania.
- c. Pharmacokinetics: By Milo Gibaldi Donald, R. Merckel Dekker Inc.
- d. Hand Book of Clinical Pharmacokinetics, By Milo Gibaldi and Laurie Prescott by ADIS Health Science Press.
- e. Biopharmaceutics and Pharmacokinetics; By Robert F Notari
- f. Biopharmaceutics; By Swarbrick
- g. Bio pharmaceutics and Pharmacokinetics-A Treatise, By D. M. Brahmanekar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi
- h. Clinical Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febiger, Philadelphia, 1995.
- i. Dissolution, Bioavailability and Bioequivalence, By Abdou H.M, Mack, Publishing Company, Pennsylvania 1989.
- j. Biopharmaceutics and Clinical Pharmacokinetics-An introduction 4th edition Revised and expanded by Robert F Notari Marcel Dekker Inc, New York and Basel, 1987.
- k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

4.6 CLINICAL TOXICOLOGY (THEORY)

Theory : 2 Hrs. /Week

1. General principles involved in the management of poisoning
2. Antidotes and the clinical applications.
3. Supportive care in clinical Toxicology.
4. Gut Decontamination.
5. Elimination Enhancement.
6. Toxicokinetics.
7. Clinical symptoms and management of acute poisoning with the following agents –
 - a) Pesticide poisoning: organophosphorous compounds, carbamates, organochlorines, pyrethroids.
 - b) Opiates overdose.
 - c) Antidepressants
 - d) Barbiturates and benzodiazepines.
 - e) Alcohol: ethanol, methanol.
 - f) Paracetamol and salicylates.
 - g) Non-steroidal anti-inflammatory drugs.
 - h) Hydrocarbons: Petroleum products and PEG.
 - i) Caustics: inorganic acids and alkali.
 - j) Radiation poisoning
8. Clinical symptoms and management of chronic poisoning with the following agents –
Heavy metals: Arsenic, lead, mercury, iron, copper
9. Venomous snake bites: Families of venomous snakes, clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries.
10. Plants poisoning. Mushrooms, Mycotoxins.
11. Food poisonings
12. Envenomations – Arthropod bites and stings.

Substance abuse:

Signs and symptoms of substance abuse and treatment of dependence

- a) CNS stimulants :amphetamine
- b) Opioids
- c) CNS depressants
- d) Hallucinogens: LSD
- e) Cannabis group
- f) Tobacco

References:

- a. Matthew J Ellenhorn. ELLENHORNS MEDICAL TOXICOLOGY – DIAGNOSIS AND TREATMENT OF POISONING. Second edition. Williams and Willkins publication, London
- b. V V Pillay. HANDBOOK OF FORENSIC MEDICINE AND TOXICOLOGY. Thirteenth edition 2003 Paras Publication, Hyderabad

Fifth year

5.1 CLINICAL RESEARCH (THEORY)

Theory : 3 Hrs. /Week

1. Drug development process:

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

2. Clinical development of drug:

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
 - a. Sponsor
 - b. Investigators
 - c. Clinical research associate
 - d. Auditors
 - e. Contract research coordinators
 - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

References :

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

5.2 PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory : 3 Hrs. /Week

1. **Pharmacoepidemiology :**

Definition and scope:

Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

Measurement of outcomes in pharmacoepidemiology

Outcome measure and drug use measures

Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement

Concept of risk in pharmacoepidemiology

Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Pharmacoepidemiological methods

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods

Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system.

Sources of data for pharmacoepidemiological studies

Ad Hoc data sources and automated data systems.

Selected special applications of pharmacoepidemiology

Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

2. **Pharmacoeconomics:**

Definition, history, needs of pharmacoeconomic evaluations

Role in formulary management decisions

Pharmacoeconomic evaluation

Outcome assessment and types of evaluation

Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods:

Cost – minimization, cost- benefit, cost – effectiveness, cost utility

3. **Applications of Pharmacoeconomics**

Software and case studies

5.3 CLINICAL PHARMACOKINETICS AND PHARMACOTHERAPEUTIC DRUG MONITORING (THEORY)

Theory : 2 Hrs. /Week

- 1. Introduction to Clinical pharmacokinetics.**
- 2. Design of dosage regimens:**
Nomograms and Tabulations in designing dosage regimen, Conversion from intravenous to oral dosing, Determination of dose and dosing intervals, Drug dosing in the elderly and pediatrics and obese patients.
- 3. Pharmacokinetics of Drug Interaction:**
 - a. Pharmacokinetic drug interactions
 - b. Inhibition and Induction of Drug metabolism
 - c. Inhibition of Biliary Excretion.
- 4. Therapeutic Drug monitoring:**
 - a. Introduction
 - b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight, disease, Interacting drugs).
 - c. Indications for TDM. Protocol for TDM.
 - d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
 - e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.
- 5. Dosage adjustment in Renal and hepatic Disease.**
 - a. Renal impairment
 - b. Pharmacokinetic considerations
 - c. General approach for dosage adjustment in Renal disease.
 - d. Measurement of Glomerular Filtration rate and creatinine clearance.
 - e. Dosage adjustment for uremic patients.
 - f. Extracorporeal removal of drugs.
 - g. Effect of Hepatic disease on pharmacokinetics.
- 6. Population Pharmacokinetics.**
 - a. Introduction to Bayesian Theory.
 - b. Adaptive method or Dosing with feed back.
 - c. Analysis of Population pharmacokinetic Data.
- 7. Pharmacogenetics**
 - a. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.
 - b. Genetic Polymorphism in Drug Transport and Drug Targets.
 - c. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations