THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY
CHENNAI-600 032

SYLLABUS – M.PHARMACY 2006-2007
BRANCH VII – PHARMACY PRACTICE

SYLLABUS FOR PHARMACY PRACTICE COURSE

BRANCH - VII

PHARMACY PRACTICE COURSE

General :-

After completing the post graduate pharmacy practice course, the student should be able to:

1. Understand the patho-physiology of specific diseases.

2. Recognise the signs, symptoms and laboratory testing, abnormalities associated with each of the disease state.

3. Able to suggest appropriate drug therapy with the knowledge of Bio-Pharmaceutics and pharmacokinetics.

4. Able to comment on drug interaction and adverse drug reaction.

5. Able to suggest alternative therapy in such cases and also when therapy fails.

6. Organise Pharmacy services at Hospitals.

7. Provide Health care system and patient counselling.

8. Provide drug information when needed, to the people of medical, para-medical professionals.

9. Prepare a competent Post-Graduate in Pharmacy practice who can teach confidently clinical pharmacy and pharmacology subjects at under-graduate and Diploma programmes in Pharmacy.

M. PHARMACY

I YEAR

SYLLABUS FOR PHARMACY PRACTICE – BRANCH VII

COMMON TO ALL BRANCHES - PAPER – I

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

THEORY **75 Hours(3 hrs./week)**

1. UV-VISIBLE SPECTROSCOPY : 6 Hours.

Brief review of electromagnetic spectrum and absorption of radiations. The chromophore concept, absorption law and limitations. Theory of electronic spectroscopy, absorption by organic molecules, choice of solvent and solvent effects, modern instrumentation – design and working principle. Applications of UV-Visible spectroscopy (qualitative and quantitative analysis), Woodward – Fischer rules for calculating absorption maximum, Photometric titrations and its applications.

2. FLAME EMISSION SPECTROSCOPY AND ATOMIC ABSORPTION SPECTROSCOPY : 3 Hours.

Principle, instrumentation, interferences and applications in Pharmacy.

3. SPECTROFLUORIMETRY : 3 Hours.

Theory, instrumentation, advantages, relationship of chemical structure to fluorescence spectra, solvent effect, effect of acids and bases on fluorescence spectra, concentration effects, factors affecting fluorescence intensity, comparison of fluorescence and UV-Visible absorption methods and applications in Pharmacy.

4. INFRARED SPECTROPHOTOMETRY : 6 Hours.

Introduction, basic principles, vibrational frequency and factors influencing vibrational frequency, instrumentation and sampling techniques, interpretation of spectra, applications in Pharmacy. FT-IR-theory and applications, Attenuated Total Reflectance (ATR).

5. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY : 8 Hours.

Fundamental Principles and Theory, Instrumentation, solvents, chemical shift, and factors affecting chemical shift, spin-spin coupling, coupling constant, and factors influencing the value of coupling constant, spin-spin decoupling, proton exchange reactions, FT-NMR, 2D -NMR, NMDR, NOE, NOESY, COSY and applications in Pharmacy, interpretation of spectra, C13 NMR-Introduction, Natural abundance, C13 NMR Spectra and its structural applications.

6. ELECTRON SPIN RESONANCE SPECTROSCOPY : 2 Hours.

Theory and Principle, Limitations of ESR, choice of solvent, g-values, hyperfine splitting, instrumentation, difference between ESR & NMR and applications.

7. MASS SPECTROSCOPY : 8 Hours.

Basic principles and instrumentation, ion formation and types, fragmentation processes and fragmentation pattern, Chemical ionization mass spectroscopy (CIMS), Field Ionization Mass Spectrometry (FIMS), Fast Atom Bombardment MS (FAB MS), Matrix Assisted laser desorption / ionization MS (MALDI-MS), GC-MS, interpretation of spectra and applications in Pharmacy.

8. X-RAY DIFFRACTION METHODS : 4 Hours.

Introduction, generation of X-rays, X-ray diffraction, Bragg's law, X-ray powder diffraction, interpretation of diffraction patterns and applications.

9. OPTICAL ROTARY DISPERSION : 4 Hours.

Principle, Plain curves, curves with cotton effect, octant rule and its applications with example, circular dichroism and its relation to ORD.

10. THERMAL METHODS OF ANALYSIS : 5 Hours.

Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).

11. CHROMATOGRAPHIC TECHNIQUES : 15 Hours.

a) Classification of chromatographic methods based on mechanism of separation: paper chromatography, thin layer chromatography, ion exchange chromatography, column chromatography and affinity chromatography – techniques and applications.

b) Gas Chromatography : Theory and principle, column operation, instrumentation, derivatisation methods and applications in Pharmacy.

c) High Performance Liquid Chromatography : Principle, instrumentation, solvents used, elution techniques, RP-HPLC, LC-MS and applications in Pharmacy.

d) HPTLC and Super Critical Fluid Chromatography (SFC) : Theory and Principle, instrumentation, elution techniques and pharmaceutical applications.

12. ELECTROPHORESIS : 3 Hours.

Theory and principles, classifications, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing (IEF) and applications.

13. RADIO IMMUNO ASSAY : 3 Hours.

Introduction, Principle, Theory and Methods in Radio Immuno Assay, Related Immuno Assay procedures and Applications of RIA Techniques.

14. STATISTICAL ANALYSIS : 5 Hours.

Introduction, significance of statistical methods, normal distribution, probability, degree of freedom, standard deviation, correlation, variance, accuracy, precision, classification of errors, reliability of results, confidence interval, Test for statistical significance – students T-test, F-test, Chi-square test, correlation and regression.

PRACTICALS

1. Use of colorimeter for analysis of Pharmacopoeial compounds and their formulations.
2. Use of Spectro photometer for analysis for Pharmacopoeial compounds and their formulations.
3. Simultaneous estimation of combination formulations (minimum of 4 experiments).
4. Effect of pH and solvent on UV Spectrum of certain drugs.
5. Use of fluorimeter for analysis of Pharmacopoieal compounds.
6. Experiments on Electrophoresis.
7. Experiments of Chromatography.
    (a) Thin Layer Chromatography.
    (b) Paper Chromatography.
        1) Ascending Technique.

2) Descending Technique.
3) Circular Technique.
4) Two dimensional Paper Chromatography and TLC.

8. Experiments based on HPLC & GC.
9. IR, NMR and Mass Spectroscopy – Interpretation of spectra & Structural elucidation (atleast for 4 compounds each).
10. Any other relevant exercises based on theory.

REFERENCES

1. Spectrometric identification of Organic Compounds, Robert. M. Silverstein et al, 7th Edition, 1981.
2. Fundamentals of Mathematical Statistics, S.C. Gupta and V.K. Kapoor.
3. Principles of Instrumental Analysis by Donglas A. Skoog, James, J. Leary, 4th Edition.
4. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson – 2001.
5. Vogel's Text Book of Quantitative Chemical Analysis, 6th Edition, 2004.
6. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
7. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th Edition.
8. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
9. Instrumental Methods of Analysis – Hobert H. Willard, 7th Edition.
10. Organic Spectroscopy – William Kemp, 3rd Edition.
11. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
12. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
13. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
14. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
15. Stereo Chemistry – Conformation and Mechanism by P. S. Kalsi, 2nd Edition.
16. Spectroscopy of Organic Compounds by P. S. Kalsi.
17. Organic Chemistry by I. L. Finar Vol. II – 5th Edition.

SYLLABUS FOR PHARMACY PRACTICE

BRANCH – VII

PAPER II

PHARMACO THERAPEUTICS

THEORY **75 Hours(3 hrs./week)**

Pathophysiology and applied therapeutics of diseases associated with following system/diseases with special reference to the drugs of choice.

1. Cardiovascular system **9 Hours.**

Hypertension, Congestive cardiac failure, Ischaemic heart disease (Angina, Myocardial infarction), Arrhythmias, Hyperlipidaemias, Endocarditis, Thrombo-embolic disorders, Cardiac arrest – resuscitation.

2. Respiratory system **5 Hours.**

Pulmonary function tests, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases. Hydrogen ion hemostasis and blood gases

3. Renal system **6 Hours.**

Diuretic therapy, Potassium depletion, Hyperkaelemia, Alkalosis, Acute renal failure, Chronic renal failure, Dialysis, Renal replacement therapy, End-stage renal disease, Drug induced renal diseases.

4. Haematological diseases **5 Hours.**

Blood and body fluids, Complications of blood transfusion and blood substitutes, Anaemia, Drug induced haematological disorders

5. Immunology **5 Hours.**

Immune disease – pathogenesis, mechanism of action of drugs, Glucocorticoids – anti-inflammatory, anti-allergic and immunosuppressive actions in tissue as well as organ transplantation, Vaccines – management of primary immunodeficiencies

6. Endocrine system **5 Hours.**

Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis.

7. Nervous system **4 Hours.**

Epilepsy, Parkinson's disease, Stroke and transient ischaemic attacks, Headache, Migraine.

8. Psychiatric disorders **4 Hours.**

Schizophrenia, Depression, Anxiety disorders, Sleep disorders.

9. Gastrointestinal system **4 Hours.**

Ulcer diseases, inflammatory bowel diseases, Hepatitis, Jaundice, Diarrhoea and constipation.

10. Bone and joint Disorders **4 Hours.**

Osteoporosis, rheumatoid arthritis, osteoarthritis, gout, Paget's disease of bones.

11. Infectious diseases **10 Hours.**

Meningitis, Respiratory tract infections, Gastroenteritis, Pneumonia, Bacterial endocarditis, Septicaemia, Otitis media, Urinary tract infections, Tuberculosis, Leprosy, Protozoal infections and helmenthiasis, HIV and opportunistic infections, Fungal infections.

12. Skin and sexually transmitted diseases **2 Hours.**

Psoriasis, Eczema and scabies, Syphilis and Gonorrhoea.

13. Oncology **5 Hours.**

Cell cycle, General principles of cancer chemotherapy, Commonly used cytotoxic drugs, Chemotherapy of lung cancer, breast cancer, head and neck cancer, prostate cancer, colorectal cancer, haematological malignancies.

14. Ophthalmology **1 Hour.**

Glaucoma, Eye infections

15. Pain management **4 hours.**

Pathophysiology of inflammation and repair, Pain pathways, Analgesics and NSAIDs, Opiates, Local anaesthetics, Neuralgia, muscle relaxants.

16. General Prescribing Guidelines for :- **2 Hours.**
Paediatric patients.
Geriatric patients.
Pregnancy & Breast feeding.

TEXT BOOKS

1. Clinical Pharmacy and therapeutics- Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy : A Patho-physiological approach- Joseph T. Dipiro et al. Appleton and Lange.

REFERENCE BOOKS

1. Pathologic basis of diseases-Robins SL, W.B.Saunders publication.
2. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice.
3. Green and Harris, Chapman and Hall Publication.
4. Clinical Pharmacy and therapeutics- Eric Herfindal, Williams and Wilkins Publication.
5. Applied Therapeutics: the clinical use of drugs. Lloyd Young and Koda-Kimble MA [ISBN 0-333-65881-7].
6. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.
7. Relevant review articles from recent medical and pharmaceutical literature.

PRACTICALS

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format. The cases may be selected from the following diseases:

1. Cardiology

a) Arrhythmias, b) Ischaemic heart disease, c) Congestive heart failure, d) Myocardial Infarction, e) Hypertension, f) Thrombo-embolic disease,
g) Endocarditis.

2. Gastroenterology

a) Diarrhoea, Constipation, b) Acid peptic disease, c) Hepatic diseases - Hepatitis, Cirrhosis & Drug induced hepatic disorders, d) Oesophageal reflux, e) Helicobacter pylori induced gastric disorders.

3. Rheumatology

a) Rheumatoid arthritis, b) Gout, c) Degenerative joint disease - Temporal arthritis, Polymyalgia rheumatica etc., d) Systemic lupus erythmatosis.

4. Respiratory medicine

a) Asthma, b) Congestive obstructive airways disease (COAD), c) Acute respiratory failure, d) respiratory tract infections, e) Interstitial lung disease f) Respiratory aids.

5. Surgery

a) Prophylactic Antibiotics, b) Anticoagulants - Heparin, Warfarin, c) Thrombolytics, d) Adjunctive therapy, e) Pre-operative medications, f)Analgesia.

6. Geriatric Medicine

a) Postural hypotension, b) Dementia & delirium, c) Compliance assessment.

7. Paediatrics

a) Acute otitis media, b) Tonsillitis, c) Paediatric asthma, d) Paediatric gastroenteritis, e) Colic, f) Immunisation, g) Attention deficit disorder, h) Febrile neutropaenia.

8. Oncology

a) Breast Cancer, b) Lung cancer - Small cell, Non small cell, c) Gastric cancer, d) Colon cancer, e) Genitourinary tract cancer - Bladder, Prostate, Testicular, f) Skin cancer, g) Radiation therapy h) Adjunctive therapy - Anti-emetics, Mouth care, Nutrition, Extravasations, Pain control, Blood products, i) Colony stimulating factors, j)Infectious disease in immuno-compromised patients, k) Hypercalcemia l) Cerebral oedema m) Malignant effusions.

9. Renal

a) Acute renal failure, b) Chronic renal failure, c) Drug induced renal disease.

10. Haematology

a) Leukaemias, b) Lymphomas - Hodgkin's, Non-Hodgkin's, c) Multiple myeloma, d) Anaemia, e) Bleeding disorders.

11. Infectious Disease

a) Respiratory tract infections b) Tuberculosis c) Urinary tract infections, d) Joint and borne infections, e) Skin and Soft tissue infections.

12. Critical Care

a) Haemodynamic monitoring , b) Parenteral & enter nutrition,
c) Pharmacotherapy of ventilated patients, d) Shock - Septic, Cardiogenic.

13. Endocrinology

a) Diabetes, b) Osteoporosis, c) Thyroid disorders, d) Syndrome of inappropriate anti-diuretic hormone secretion e) Adrenal disorders.

14. Dermatology

a) Psoriasis, b) Dermatitis, c) Drug induced skin disorders.

15. a) Convulsive disorder b) Parkinson ‘s disease, c) Neuro-degenerative disorders, d) Stroke, e) TIAs.

16. Psychiatry

a) Uni-polar and bipolar disorders, b) Anxiety, c) Psychosis, d) Alcohol abuse,
e) Drug abuse.

17. Ophthalmology

a) Ocular infections, b) Conjunctivitis, c) Glaucoma, d) Post-operative management.

Assignments:

The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

TEXT BOOKS

1. Clinical Pharmacy and therapeutics- Roger and Walker, Churchill Livingstone publication.
2. Pharmacotherapy: A Patho-physiological approach - Joseph T. Dipiro et al. Appleton and Lange.

REFERENCE BOOKS

1. Pathologic basis of diseases-Robins SL, W.B. Saunders publication.
2. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice.
   Green and Harris, Chapman and Hall Publication.
3. Clinical Pharmacy and therapeutics- Eric T. Herfindal, Williams and Wilkins Publication.

4. Applied Therapeutics: The clinical use of drugs. Lloyd Young and Koda-Kimble MA[ISBN 0-333- 65881 – 7].
5. Avery's drug treatment, 4th Edn, 1997, Adis international Limited.
6. Relevant review articles from recent medical and pharmaceutical literature.

JOURNALS

1. British Medical Journal.
2. New England Journal of Medicine.
3. Annals of Pharmacotherapy.
4. Lancet.

SYLLABUS FOR PHARMACY PRACTICE

BRANCH – VII

PAPER - III

HOSPITAL AND COMMUNITY PHARMACY

THEORY **75 Hours(3 hrs./week)**

I. COMMUNITY PHARMACY 18 hours.

1. Introduction to the concept of community pharmacy - its activities and professional responsibilities.
2. The role of the community pharmacy and its relationship to other local health care providers.
3. Prescribed medication order - interpretation and legal requirements.
4. Patient counselling in community pharmacy.
5. Over the counter (OTC) sales.
6. Health education and community pharmacy: Family planning, first aid, communicable disease prevention, smoking cessation, screening programs.
7. Services to Nursing homes/clinics.
8. Community Pharmacy management : Financial, material and staff management, infrastructure requirements, drug information resources, computers in community pharmacy.
9. Code of ethics for community pharmacists.
10. Polypharmacy and its implications.

II. COMMUNICATION SKILLS 3 Hours.

Principal and elements of communication skills, non verbal communication in pharmacy, barriers in communication, listening skills, questioning skills, explaining skills and ethics in communication.

III. HOSPITAL PHARMACY 22 Hours.

1. The role of hospital pharmacy department and its relationship to other hospital departments and staff.

2. Pharmacy and Therapeutics Committee:
   Selection of drugs, Hospital formulary development and management, Assessing drug efficacy, Assessing and managing drug safety, evaluating the cost of pharmaceuticals, identifying and addressing drug use problems including standard treatment guidelines. Other hospital committees such as infection control committee and research & ethics committee.

3. Hospital pharmacy management

Staff (professional and non-professional), Materials (drugs, non-drugs, consumables), Financial (drug budget, cost centres, sources of revenue, revenue collection), Policy and Planning, Infrastructure requirements (building, furniture and fittings, specialised equipment, maintenance and repairs), Workload statistics.

4. Hospital Pharmacy Services

Purchasing, storage, stability and safety of drugs, drug distribution, Radiopharmaceuticals, IV additive services and total parentral nutrition.

IV. PHARMACOEPIDEMIOLOGY 5 Hours.

- Definitions and scope.
- Methods [qualitative, quantitative and Meta-analysis models].
- System for monitoring drug effects.
- Advantages and disadvantages of pharmacoepidemiology.

V. PHARMACOECONOMICS 4 Hours.

Definitions and scope, types of economic evaluation, cost models and cost effectiveness analysis.

VI. PUBLIC HEALTH POLICY AND HEALTH CARE SYSTEM 2 Hours.

VII. CONCEPT OF RATIONAL USE OF DRUGS 5 Hours.

- Importance of rational drug use.
- Pharmacists role.
- Drug use indicators.
- Guidelines for rational prescribing.

VIII. EVIDENCE BASED MEDICINE 7 Hours.

- Formulating clinical questions.
- Searching for the best evidence.
- Critical appraisal of the evidence.
- Applying evidence to patients.
- Evaluation.

IX. EDUCATION AND TRAINING 4 Hours.

Training of technical staff, training and continuing education for pharmacists, pharmacy students, medical staff and students, nursing staff and students, formal and informal meetings and lecturers, drug and therapeutics newsletter Ethical issues in biomedical research – Principles of ethics in biomedical research, good clinical practice [ICH GCP guidelines], Ethical committee [institutional review board], its constitution and functions, ethics of publication.

X. MEDICATION ERROR AND MEDICATION ADHERENCE

5 Hours.

Categories and causes of medication error, tools to measure the performance of the medication use process, categories of medication non-adherence, role of pharmacist in medication error and medication adherence.

PRACTICALS

The student is expected to perform ABC and VED analysis on the given data on drugs used in the hospital, participate in activity session involving issues regarding pharmacy and therapeutic committee, prepare a model monograph for a drug formulary, critically analyse the given data on hospital pharmacy budget, work flow patterns etc., perform patient medication interview and counselling and present drug profiles one new drugs.

ASSIGNMENTS

The student is expected to perform the following and report.

- Comparison of prescription handling in two community pharmacies.
- Audit of OTC sales over a 24 hour period in a local community pharmacy].
- Role of community pharmacists in health education, family planning, first aid, smoking cessation screening programmes, immunisation, etc.
- Code of ethics for community pharmacies.
- Summary of the advice and recommendations which should be provided to the customers at a community pharmacy.
- Select a new drug, which has recently been marketed in India for the first time. Prepare a report for a hospital's Drug and Therapeutic Committee, and make a case either for or against the addition of this new drug on to the hospital's formulary. Issues, which you may need to cover, include the drug's pharmacology, its clinical use, the opinions of relevant hospital consultants and a cost comparison with existing therapies for the same condition for which the new drug is indicated.
- Examine and report on the drug distribution methods used in a local hospital .
- Examine and report on the purchase and inventory of drugs in a local hospital.

REFERENCES

1. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, 4th Edn, 1997, Adis international limited.
4. Evidence based medicine: How to practice and teach EBM. Sharon E Straus III Edition Churchill Livingston.

JOURNALS

1. Hospital Pharmacist, UK.
2. Indian Journal of Hospital Pharmacy.

SYLLABUS FOR PHARMACY PRACTICE

BRANCH – VII

PAPER – IV

CLINICAL PHARMACY

THEORY **75 Hours(3 hrs./week)**

INTRODUCTION TO CLINICAL PHARMACY

- Definition, development and scope **1 Hour.**

PATIENT DATA ANALYSIS **16 Hours.**

- The patient's case history, its structure and use in evaluation of drug therapy, presentation of cases.
- Communication skills including patient medication history interview, patient counselling, teaching skills.
- Understanding common medical abbreviations and terminologies used in clinical practices.
- Haematological, Liver function, Renal function, Tests associated with cardiac disorders.
- Fluid and electrolyte balance, Common tests in urine, sputum, faeces, CSF.
- Sensitivity screening for common pathogenic micro-organisms, its significance, resistance in disease states and selection of appropriate anti-microbial regimens.

DRUGS & POISONS INFORMATION **10 Hours.**

- Introduction to information resources available.
- Systematic approach in answering drug information queries.
- Critical evaluation of drug information and literature.
- Preparation of written and verbal reports.
- Establishing a Drug Information Centre.
- Poisons information-organisation and information resources.
- Poisons management in drug dependence and drug abuse (opiates, cocaine, amphetamines, alcohols, benzodiazepines, barbiturates, tobacco). Role of emetics, anti-emetics and respiratory stimulants.

DAILY ACTIVITIES OF CLINICAL PHARMACISTS **16 Hours.**

- Drug therapy monitoring (Medication chart view, clinical review, TDM, pharmacist interventions).

- Ward round participation.
- Adverse drug reaction - Epidemiology, Classification, Risk factors, Monitoring and detecting adverse drug reactions, Assessing causality, Reporting adverse drug reactions.
- Pharmaceutical care.
- Drug utilisation evaluation (DUE) and review (DUR).
- Quality assurance of clinical pharmacy services.

NUTRITION **3 Hours.**

- Malnutrition and deficiency states.
- Enteral and parentral nutrition.

RESEARCH DESIGN AND CONDUCT OF CLINICAL TRIALS **9 Hours.**

- Research support including planning and execution of clinical trials.
- Guidelines for good clinical research practice and ethical requirements.
- Various phases of clinical trials.
- Categories of Phase IV studies.
- Monitoring and auditing of clinical trials.
- Design and execution of trials in different clinical settings.

CLINICAL PHARMACOKINETICS **14 Hours.**

- Clinical pharmacokinetic models.
- Physiological determinants of drug clearance and volumes of distribution.
- Renal and non-renal clearance.
- Organ extraction and models of hepatic clearance.
- Estimation and determinants of bioavailability.
- Multiple dosing.
- Calculation of loading and maintenance doses.
- Dose adjustment in renal failure, hepatic dysfunction, geriatric and paediatric patients.
- Therapeutic drug monitoring.

CLINICAL APPLICATION OF STATISTICAL ANALYSIS **6 Hours.**

- Basic concepts of biomedical statistics.
- Descriptive and differential statistics.
- Statistical tests-Parametric and Non-parametric.
- Sample size calculation.
- Confidence intervals.
- Test of significance.

PRACTICALS

- The students should be trained in the following aspects of services provided at the hospital and should be assessed for their performance on the same. The students are required to submit a record of activities (1-5) performed, which includes the strategies used.
- Patient Medication Interviews (3).
- Answering Drug Information Queries (4).
- Patient Medication Counselling (3).
- Literature Evaluation (2).
- Therapeutic Drug Monitoring.
- Problem solving in Clinical Pharmacokinetics (2).
- Ward Round Participation.
- Medication order review (2).
- Detection and assessment of adverse drug reactions and their documentation (3).

Assignments:

The students are required to submit atleast three assignments selected from the topics given to them.

1. Drug information.
2. Patient medication history interview.
3. Patient medication counseling.
4. Problem solving in Clinical Pharmacokinetics.
5. Literature evaluation pertaining to Therapeutic drug monitoring.
6. Critical appraisal of recently published articles in the biomedical literature which deals with a drug or therapeutic issue.
7. Case studies related to laboratory investigations covering the topics dealt in theory class.

REFERENCES

1. Basic skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists, Inc., USA.
2. Practice Standards and Definitions – The Society of Hospital Pharmacists of Australia, 1997.
3. Clinical Pharmacokinetics – Rowland and Tozer, Williams and Wilkins Publication.
4. Biopharmaceutics and Applied Pharmacokinetics – Leon Shargel, Prentice Hall publication.
5. Relevant review articles from recent medical and pharmaceutical literature.

JOURNALS

1. Pharmaceutical Journal. Royal Pharmaceutical Society, London.
2. Therapeutic Drug Monitoring.
3. European Journal of Clinical Pharmacology.
4. Indian Journal of Medical Research.
5. Journal of Pharmacy Practice and Research, Society of Hospital Pharmacists of Australia.
6. International Journal of Pharmacy Practice, UK.
7. Hospital Pharmacist, UK.
8. Indian Journal of Hospital Pharmacy.