Pharm.D [Post Baccalaureate]

I Year

Course Code	Course	Theory Hrs/Week	Practical Hrs/Week	Tutorial Hrs/Week	Credit Point
17CPHDA4	Pharmacotherapeutics-III	3	3	1	6
17CPHDB4	Hospital Pharmacy	2	3	1	6
17CPHDC4	Clinical Pharmacy	3	3	1	6
17CPHDD4	Biostatistics & Research Methodology	2	-	1	6
17CPHDE4	Biopharmaceutics & Pharmacokinetics	3	3	1	3
17CPHDF4	Clinical Toxicology	2	-	1	3
17CPHDG4	Pharmacotherapeutics I & II	3	3	1	2
	TOTAL	18	15	06	32

II Year

Course Code	Course	Theory Hrs/Week	Practical Hrs/Week	Tutorial Hrs/Week	Credit Point
17CPHDA5	Clinical Research	3	-	1	4
17CPHDB5	Pharmacoepidemiology& Pharmacoeconomics	3	-	1	4
17CPHDC5	Clinical Pharmacokinetics & Therapeutic Drug Monitoring	2	-	1	4
17IPHDR5	Clerkship*	-	-	1	10
17RPHDR5	Project	-	20	-	8
	TOTAL	08	20	04	30

Attending ward rounds on daily basis.

** 30 marks – viva-voce (oral) 70 marks – Thesis work

III Year

Course Code	Course	Theory Hrs/Week	Practical Hrs/Week	Tutorial Hrs/Week	Credit Point
17IPHDI6	Internship/Residency training	-	20	-	-
17RPHDR6	Project	-	-	-	30
	TOTAL				30

Third Year:

- Internship or residency training including postings in specialty units. Student should independently provide the clinical pharmacy services to the allotted wards.
- Six months in General Medicine department, and Two months each in three other specialty departments

CORE SYLLABUS

PHARM.D

[DOCTOR OF PHARMACY]

POST BACCALAUREATE

I YEAR

17CPHDA4 - PHARMACOTHERAPEUTICS – III (THEORY)

Theory: 3 Hrs. /Week

Course 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).

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Understand the pathophysiology of selected disease states and the rationale for drug therapy of Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

CO2 Analyze the therapeutic approach to management of of Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

CO3 Importance of preparation of individualised therapeutic plans based on diagnosis of Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

CO4 Discuss the pathophysiology of selected disease states and the rationale for drug therapy o f Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

CO5 Identify the patient-specific parameters relevant in initiating drug therapy, and monitoring therapy of Gastrointestinal system, Haematological system, Nervous system, Psychiatry disorders& Pain.

REFERENCES

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.

17CPHDA4 - PHARMACOTHERAPEUTICS – III (PRACTICAL)

Practical: 3 Hrs/Week

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.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Analyze the principle and practice involved in selection of drug therapy including clinical discussion.

CO2 Understand the principles and practice involved in ward round participation and clinical discussion on selection of drug therapy

CO3 Importance of of case presentation and discussion of cases collected from hospital

CO4 Evaluation of prescriptions generated in hospital for drug interactions and find out the suitable management.

CO5 Prepare individualized therapeutic plans based on diagnosis

17CPHDB4 - HOSPITAL PHARMACY (THEORY)

Theory: 2 Hrs. /Week

Course 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.

2. 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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Able to know the professional activates of hospital pharmacy

CO2 Provide drug information query appropriately

CO3 Enable effective inventory procedures in the pharmacy

CO4 Know the manufacturing procedure for bulk drugs required in the hospital

CO5 Promote continuing medical education in hospitals

REFERENCES:

Text books: (latest editions)

a. Hospital pharmacy by William .E. Hassan

b. A text book of Hospital Pharmacyby 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.

17CPHDB4 - HOSPITAL PHARMACY (PRACTICAL)

Practical: 6 Hrs./Week

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Able to perform ABC Analysis to maintain inventory in hospital pharmacy

CO2 Provide drug information query appropriately to health care professionals and patients

CO3 Enable effective procurement of drugs in the pharmacy

CO4 Know the manufacturing procedure for large volume parenteral required in the hospital

CO5 Know to assess the prescription of individual patients

17CPHDC4 - CLINICAL PHARMACY (THEORY)

Theory: 3 Hrs. /Week

Course Objectives: 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.

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the elements of pharmaceutical care and provide comprehensive patient care services

CO2 Interpret the laboratory results to aid the clinical diagnosis of various disorders

CO3 Produce integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management

CO4 Prepare individualized therapeutic plans based on diagnosis

CO5 Analyze the practice involved in Clinical Pharmacy Services including clinical discussion.

REFERENCES:

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 etal, Orient Orient Langram Pvt.Ltd. ISSBN8125026

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.

17CPHDC4 - 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.

g. Answering drug information questions (4 Nos)
h. Patient medication counselling (4 Nos)
i. Case studies related to laboratory investigations (4 Nos)
j. Patient medication history interview (3 Nos)

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Monitor drug therapy of patient through medication chart review and clinical review
CO2 Obtain medication history interview and counsel the patients
CO3 Identify and resolve drug related problems
CO4 Detect, assess and monitor adverse drug reaction;
CO5 Retrieve, analyze, interpret and formulate drug or medicine information

17CPHDD4 - BIOSTATISTICS AND RESEARCH METHODOLOGY (THEORY)

Theory: 2 Hrs. /Week

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, scatterplots, semilogarthimic 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, Wilcoxan's signed rank test, Wilcoxan rank sum test, Mann Whitney U test, Kruskal-Wall is test (one way ANOVA)

d) Linear regression and correlation- Introduction, Pearsonn's

and Spearmann's correlation and correlation co-efficient.

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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain basic statistical concepts such as statistical collection, tabular and graphical representation of data

CO2 Demonstrate the concept of mean, median and mode, geometric mean, harmonic mean

CO3 Construct appropriate displays of data

CO4 Illustrate the common measures of dispersion from grouped and ungrouped data

CO5 Develop problem-solving techniques needed to accurately calculate probabilities and test values.

REFERENCES:

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, JohnE Stanovich , 3rd edition, McGraw Hill Publications 2006

17CPHDE4 - 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. Repititive Intravenous injections – One Compartment Open Model
   b. Repititive 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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain physiology of GIT, drug absorption, distribution and elimination process and factors affecting the ADME.

CO2 Describe various compartment models and their importance for the determination of pharmacokinetic parameters.

CO3 Discuss multi compartments, multiple dosage regimens and their importance.

CO4 Demonstrate non-linear pharmacokinetics, and non-compartment models and their importance to determine pharmacokinetic parameters.

CO5 Apply the knowledge to study the bioavailability and bioequivalence and discuss how to develop study protocol.

REFERENCES:

a. Biopharmaceutics and Clinical Pharmacokinetics by, Milo Gibaldi

b. Remington's Pharmaceutical Sciences, By Mack Publishing Company, Pennsylvnia.

c. Pharmacokinetics: By Milo Glbaldi Donald, R. Mercel 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. Brahmankar and Sunil B.Jaiswal, Vallabh Prakashan Pitampura, Delhi

h. Cilincal Pharmacokinetics, Concepts and Applications: By Malcolm Rowland and Thomas, N. Tozen, Lea and Febrger, 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 Rebort F Notari Marcel Dekker Inn, New York and Basel, 1987.
k. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James, C. Roylan, Marcel Dekker Inc, New York 1996.

17CPHDE4 - 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 Ka, Ke, $t_1/2$, Cmax, 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, Sulphamethoxzole, 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.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Discuss the improvement of dissolution characteristics and determination of dissolution behaviors with the model drug.

CO2 Explain the protein binding study of poorly and highly protein bound drug and extent of binding with one model drug.

CO3 Determine pharmacokinetic parameters of drug using biological fluids by considering one, two and non-compartment models

CO4 Describe bioavailability studies of different marketed drug utilizing experimental design.

CO5 Describe bioequivalence studies of different marketed drug utilizing experimental design.

17CPHDF4 - 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

COURSE OUTCOME

At the end of this course students will be able to,

CO1 To understand the principles and practice of clinical toxicology in order to prevent drug overdose/poisoning

CO2 To promote better care for the poisoned patient particularly through providing appropriate poisons information

CO3 Demonstrate an understanding of the health implications of toxic exposures and commonly involved chemicals for toxicity

CO4 Apply an understanding of the history, assessment, and therapy considerations associated with the management of a toxic exposure

CO5 Enable the pharmacist to function as contributing health care team member when faced with a toxic exposure experience, including emergencies

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.

17CPHDG4 PHARMACOTHERAPEUTICS I & II (THEORY)

Theory: 3Hrs/week

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

1. **Cardiovascular system:**
   Hypertension, Congestive cardiac failure, Angina Pectoris, Myocardial infarction, Hyperlipidaemias , Electrophysiology of heart and Arrhythmias.
2. **Respiratory system:**
   Introduction to Pulmonary function test, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases.
3. **Endocrine system :**
   Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis.
4. **General prescribing guidelines for**
   a. Paediatric patients
   b. Geriatric patients
   c. Pregnancy and breast feeding
5. **Ophthalmology:**
   Glaucoma, Conjunctivitis- viral & bacterial.
6. **Introduction to rational drug use**
   Definition, Role of pharmacist Essential drug concept Rational drug formulations.
7. **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, Gonarrhoea and Syphillis.
8. **Musculoskeletal disorders**
   Rheumatoid arthritis, Osteoarthritis, Gout, Spondylitis, Systemic lupus erythematosus.
9. **Renal system**
   Acute Renal Failure, Chronic Renal Failure, Renal Dialysis, Drug induced renal disorders.
10. **Oncology:**

Basic principles of Cancer therapy, General introduction to cancer chemotherapeutic agents, Chemotherapy of breast cancer, leukemia. Management of chemotherapy nausea and emesis.

11. **Dermatology:** Psoriasis, Scabies, Eczema, Impetigo.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Describe the pathophysiology and management of cardiovascular, respiratory and endocrine diseases

CO2 Describe the Patient case based Assessment Skills

CO3 describe the quality use of medicines issues surrounding the therapeutic agents in the treatment of these diseases

CO4 Demonstrate the clinical skills in the therapeutic management of these conditions

CO5 Apply the knowledge on communication skills to provide patient – centered care to diverse patients using the evidence based medicine

REFERENCES:

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]

17CPHDG4 - PHARMACOTHERAPEUTICS I & II (PRACTICAL)

Practical's: 3 Hrs. /Week

Practical's:

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.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the pathophysiology of selected disease states

CO2 Justify the diagnosis arrived based on investigations ordered

CO3 Develop individualized therapeutic plans based on diagnosis

CO4 Identify the patient-specific parameters relevant in initiating drug therapy and monitoring therapy by implementing SOAP / FARM notes

CO5 Able to provide appropriateness of the drug therapy

II Year

17CPHDA5 - 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.

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the new drug development process.

CO2 Describe the regulatory and ethical requirements.

CO3 Judge and justify the clinical trials activities

CO4 Illustrate the safety monitoring and reporting in clinical trials

CO5 Elaborate the trial coordination process

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.

17CPHDB5 - PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS (THEORY)

Theory: 3 Hrs. /Week

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.

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

Applications of Pharmacoeconomics

Software and case studies

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Explain the various epidemiological methods and their applications

CO2 Explain the fundamental principles of Pharmacoeconomics

CO3 Identify and determine relevant cost and consequences associated with pharmacy products and services.

CO4 Perform the key Pharmacoeconomics analysis methods

CO5 Analyze the Pharmacoeconomic decision analysis methods and its applications.

REFERENCES:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams & Wilkins, Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley & Sons, USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.
5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
6. Graker, Dennis. Pharmacoeconomics and outcomes.
7. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

17CPHDC5 - 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:**
   d. Introduction
   e. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs).
   f. Indications for TDM. Protocol for TDM.
   g. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy.
   h. 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.**
   i. Renal impairment
   j. Pharmacokinetic considerations
   k. General approach for dosage adjustment in Renal disease.
   l. Measurement of Glomerular Filtration rate and creatinine clearance.
   m. Dosage adjustment for uremic patients.
   n. Extracorporeal removal of drugs.
   o. Effect of Hepatic disease on pharmacokinetics.
6. **Population Pharmacokinetics.**
   p. Introduction to Bayesian Theory.
   q. Adaptive method or Dosing with feed back.
   r. Analysis of Population pharmacokinetic Data.
7. **Pharmacogenetics**
   s. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes.

t. Genetic Polymorphism in Drug Transport and Drug Targets.

u. Pharmacogenetics and Pharmacokinetics/Pharmacodynamic considerations

COURSE OUTCOME

At the end of this course students will be able to,

CO1 Design the drug dosage regimen for individual patients

CO2 Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes

CO3 Recommend dosage adjustment for patients with renal/ hepatic impairment

CO4 Manage pharmacokinetic drug interaction

CO5 Do pharmacokinetic modeling for the given data using the principles of pharmacometrics

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics. New York: Mc Graw Hill.
2. .Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling and Simulation. Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring. Iippincott Williams & Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug Monitoring and Toxicology. CRC Press, USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.
6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.Blouin and Jane M.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: concepts and applications. Iippincott Williams & Wilkins, USA.