15CBPH61 Pharmaceutical Chemistry-VI (Medicinal Chemistry-II)

Course Objective:

The course is designed to impart the knowledge in the field of medicinalchemistry. In medicinal chemistry, the insight into the drug design processDescribe the drug design process from idea to market..Explain the development of a given drug. Describe qualitatively the structure - activity relations and discuss their significance to a specific drug development project.

Theory **3-0-0-3**

Unit I: Autocoids **12hrs**

Antihistamines and Eicosanoids.:Histamine, 5-hydroxy tryptamine and their antagonists and Prostaglandins, Thromboxanes and Leukotrienes.

Unit II: Cardiovascular system: **12 hrs**

(a) Antihypertensive drugs (b) Antianginal and vasodilator drugs (c) Antiarrhythmic drugs
(d) Antihyperlipidemic drugs (e) Diuretics

Unit III: Hemopoietic system & Endocrines **12 hrs**

Drugs used in hemopoieticsystem : Anticoagulant and anti platelet drugs.
Drugs used in endocrine disorders (a) Anti thyroid drugs (b) Oral hypoglycemic agents

Unit IV: Chemotherapeutic agents **12 hrs**

Drugs used in Protozoal, parasitic and other infections; (including sulphonamides) antibiotics, Anti- viral, Antineoplastic agents .Immunosuppressive agents and anti-HIV agents.

Unit V: Miscelllaneous group of compounds **12 hrs**

Drugs affecting uterine motility: Oxytocics, prostaglandins. Diagnostic agents

Total **60 hrs**

Course Outcomes

At the end of the course, the student will be able to

CO1: Illustrate about different eicosanoids, their biochemical functions and the synthesis, mode of action of the antagonists

CO2: Outline about different Cardiovascular diseases and explain about different classes of drugs acting on cardiovascular system, their mechanism of action, Structure activity relationship, synthesis and their uses

CO3: Explain about the hemopoietic system, endocrine disorders and classify on various drugs acting on hemopoietic system, thyroid dysfunctions and diabetes mellitus

CO4: Compare and contrast the different classes of Anti-microbial drugs, Antineoplastic agents & Immunosuppressive agents and demonstrate their role in treating various infectious and non-infectious diseases

CO5: Categorize on the Drugs acting on uterine motility and discuss about the role of different diagnostic agents

Practicals **0-0-3-2**

1. Synthesis of 7-hydroxy 4-methyl coumarin
2. Synthesis of phenothiazine
3. Synthesis of sulphacetamide
4. Synthesis of sulphanilic acid
5. Synthesis of fluorescein
6. Assay ofsulphacetamide
7. Assay of isoniazid
8. Assay of quinine sulphate
9. Assay of chloroquine phosphate
10. Assay of tolbutamide
11. Identification of Paracetamol by I R spectrum
12. Identification of Diclofenac by I R spectrum

Course Outcomes

At the end of the course, the student will be able to

CO1: Identify and develop synthetic schemes for some important structural moieties like coumarins

CO2: Make use of the synthetic schemes that are available for the preparation of various sulpha drugs

CO3: Select and utilize the synthetic protocols available for the preparation of important diagnostic agents like fluorescein

CO4: Determine the percentage purity of the important drugs using acid-base, oxidation-reduction, diazotisation and non-aqueous titrimetric methods

CO5: Interpret the structure of important drugs using IR spectrometry

Textbooks

1. Organic Pharmaceutical and Medicinal Chemistry,J S Qadry, Vlo 1 and 2 , 4th Edn,CBS,2012
2. Medicinal Chemistry,Vol 1 and 2 , K.Ilango and Valentina,Keerthi,2007

Reference books

1. Tb. Of Organic, Medicinal & Pharmaceutical Chemistry, Wilson & Gisvolds , Lippincott
2. Organic Chemistry Of Drug Synthesis, Vol. I - Vi., Lednicer, Daniel, John Wiely2005
3. Tb. Of Organic, Medicinal & Pharmaceutical Chemistry, Wilson & Gisvolds ,

Lippincott

4. Advanced Practical Medicinal Chemistry, Ashutoshkar, New Age,2009.
5. Burgers Medicinal Chemistry & Drug Discovery:Vol 1-5,Braham Donald J, Wiley,2003
6. Foye's Principles Of Medicinal Chemistry,Thomas Lemke L, 7th Edn,Lippincott,2013
7. Medicinal Chemistry, Ashutosh Kar,5thedn, Newage, 2010

15CBPH62 Biopharmaceutics & Pharmacokinetics

Course Objective:

The course is designed to impart the knowledge in the field of Pharmaceutics. The various topics like biopharmaceutics and pharmacokinetics their compartment models other important topics like clinical pharmacokinetics are enable the students to understand and involved in the determination of measurement of bioavailability. In addition to the theoretical aspects, the basic practical knowledge relevant to the bio pharmaceutics and pharmacokinetics is also imparted.

THEORY **3-0-0-3**

Unit I : Introduction **4hrs**

Introduction to Biopharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting.

Unit II : Biopharmaceutics: **12hrs**

1. Passage of drugs across biological barrier (passive diffusion, active transport, facilitated diffusion)
2. Factors influencing absorption - Physicochemical, Physiological and pharmaceutical
3. Drug distribution in the body, plasma protein binding.

Unit III : Pharmacokinetics: **12hrs**

1. Significance of plasma drug concentration measurement.
2. Compartment model: Definition and Scope
3. Pharmacokinetics of drug absorption zero order and first order absorption rate constant using Wagner - nelson method.
4. Volume of distribution

Unit IV : Compartment kinetics **16hrs**

1. One compartment and two compartment models. Determination of pharmacokinetic parameters from plasma and urine data after Drug administration by intra-vascular and extra vascular route.
2. Curve fitting (method of residuals) regression procedures.
3. Clearance concept, renal clearance, determination of renal clearance . .
4. Extraction ratio, hepatic clearance, biliary excretion Extrahepatic circulation
5. Non-linear pharmacokinetics with special reference to one compartment model after I.V drug administration, Michaelis Menten Equation, detection of non-linearity (Saturation mechanics).

Unit V : Clinical Pharmacokinetics: **16hrs**

1. Definition and scope
2. Dosage adjustment in patients with renal and hepatic failure
3. Design of single dose bio-equivalence study and relevant statistics
4. Pharmacokinetic drug interactions and their significance in combination therapy.
5. Measurement of bioavailability, Cmax and area under the curve (AUC).
6. Review of regulatory requirements for conduction of bioequivalent studies

Total hrs : **60hrs**

Course Outcomes

At the end of the course, the student will be able to

CO1: Define Bio pharmaceutics and Pharmacokinetics and their role in formulation development and clinical setting

CO2: Outline the mechanisms of Passage of drugs across biological barrier

CO3: Interpret plasma drug concentration measurement by the application of compartment model.

CO4: Analyse Drug administration by intra-vascular and extra vascular route by Curve fitting regression procedures.

CO5: Predict the clinical significance of drug bioavailability and bioequivalence as related to drug product safety

Practicals **0-0-3-2**

1. Determination of plasma concentrations of paracetamol and aspirin
2. Determination of Cmax and tmax.
3. Assessment of AUC by trapezoidal rule
4. Plotting of plasma concentration time profile on ordinary and semilog graph paper
5. Determination of t 1/2 and K from PC - time profile of IV infusion
6. Invitro evaluation - dissolution rate studies of marketed paracetamol preparations.
7. Disintegration test for marketed samples of capsules and tablets and their effect on absorption
8. Determination of: t 1/2 , K, V, and CL from PC - time data following oral administration, IV bolus
9. Determination of absorption rate constant by method of residuals

Course Outcomes

At the end of the course, the student will be able to

CO1: Interpret the plasma concentrations of different formulations

CO2: Assessment of AUC by trapezoidal rule and determine the plasma concentration time profile on ordinary and semilog graph paper

CO3: Analyse the dissolution rate studies of marketed paracetamol Preparations

CO4: Explain the test for different formulations and determine the Pharmacokinetic parameters following Oral and Iv administration.

CO5: Estimate the absorption rate constant by Method of residuals.

Textbooks

1. Biopharmaceutics and Pharmacokinetics, A Treatise, D.M.Brahmankar and Sunil B.Jaiswal Vallabh Publications / Prakashan2nd edition 2010
2. Handbook of clinical Pharmacokinetics, Milo Gibaldi and Laurie Prescott by ADIS Health, New York: ADIS Health Science Press, 4th edition 1983

References:

1. Biopharmaceutics and clinical Pharmacokinetics, Milo Gibaldi Lea & Febiger; 4 Sub edition ,, 1991
2. Remington's Pharmaceutical Sciences, Alfonso R. Gennaro ,Mack Publishing Company, Pennsylvania. 17th edition .2006.
3. Pharmacokinetics, Milo Gibaldi, Donald Perrier; Marcel Dekker,Inc Sciences Press , Binding: Hardback Publisher: CRC **Press,**2nd edition , 2015 .
4. Biopharmaceutics and Pharmacokinetics, Robert E.Notari M. Dekker; ,Enlarged 2nd edition ,1975
5. Clinical Pharmacokinetics, Concepts and Applications, Malcolm Rowland and Thomas N.Tozer, Lea and Febiger, Philadelphia, 3rd edition ,1995
6. Dissolution, Bioavailability and Bioequivalence, Abdou H.M., Mack Publishing Company, Pennsylvania,11th edition,1989.
7. Biopharmaceutics and Clinical Pharmacokinetics-An introduction ,Revised and expanded By Robert.E.Notari, Marcel Dekker Inc, New York ,B4th edition 1987

15CBPH63 Pharmacology-II

Theory: **3-0-0-3**

Unit I: Pharmacology of Cardiovascular System **12hrs**

Definition, classification, mechanism of action & pharmacokinetic, adverse effects, uses, dose and route of administration, precautions, contraindications and drug interaction of

a) Digitalis and cardiac glycosides
b) Antihypertensive drugs
c) Antianginal and vasodilator drugs, including calcium channel blockers
d) Antiarrhythmic drugs
e) Antihyper lipidemic drugs
f) Drugs used in the therapy of shock

Unit II: Drugs Acting on the Haemopoietic System: **12hrs**

Definition, classification, mechanism of action & pharmacokinetic, adverse effects, uses, dose and route of administration, precautions, contraindications and drug interaction of

a) Haematinics
b) Anticoagulants, Vitamin K and haemostatic agents
c) Fibrinolytic and anti-platelet drugs
d) Blood and plasma volume expanders.

Unit III: Drugs acting on urinary system: **12hrs**

Definition, classification, mechanism of action & pharmacokinetic, adverse effects, uses, dose and route of administration, precautions, contraindications and drug interaction of

a) Fluid and electrolyte balance
b) Diuretic & anti-diuretics

Unit IV: Autocoids: **12hrs**

Definition, classification, mechanism of action & pharmacokinetic, adverse effects, uses of

a) Histamine, 5-HT and their antagonists
b) Prostaglandins, thromboxanes and leukotrienes
c) Pentagastrin, Cholecystokinin, Angiotensin, Bradykinin and substance P.

Unit V: Drugs Acting on the Respiratory System: **12hrs**

Definition, classification, mechanism of action & pharmacokinetic, adverse effects, dose and therapeutic uses of

a) Anti-asthmatic drugs including bronchodilators
b) Anti-tussive and expectorants
c) Respiratory stimulants

Total **60 hours**

Course Outcomes

At the end of the course, the student will be able to

CO1: Compare & study about the definition, Classification, Mechanism of Action & Pharmacokinetics Adverse effects, Uses, Dose and route of administration, Precautions contraindications and drug interactions of Pharmacology of drugs acting on Cardiovascular System

CO2: Classify and distinguish the definition, Mechanism of Action & Pharmacokinetics Adverse effects, Uses, Dose and route of administration, Precautions contraindications and drug interactions of Pharmacology of various drugs acting on Haemopoietic System

CO3: Illustrate & Summarize the Definition, Classification, Mechanism of Action & Pharmacokinetics Adverse effects, Uses, Dose and route of administration, Precautions contraindications and drug interactions of Pharmacology of drugs acting in Urinary System

CO4: Define and list the Classification, Mechanism of Action, Pharmacokinetics, Adverse effects & Uses of Autocoids

CO5: Apply & make use of definition, Classification, Mechanism of Action & Pharmacokinetics Adverse effects, Uses, Dose, Route of administration, Precautions contraindications and drug interactions of Pharmacology of drugs acting on Respiratory System

Practicals **0-0-3-2**

1. Common laboratory animals in experimental pharmacology
2. Some common and standard techniques of blood collection, Separation of plasma and serum.
3. Procedures for rendering animal unconscious and chemical euthanasia.
4. Study of different routes of administration of drugs in mice/rats.
5. To study the Concentration response curve of acetylcholine using chicken/rat ileum by matching bioassay
6. To study the Concentration response curve of acetylcholine using chicken/rat ileum by Interpolation bioassay
7. Effect of neostigmine on the concentration-response curve of acetylcholine
8. Effect of atropine on the concentration-response curve of acetylcholine
9. To record the Concentration response curve of acetylcholine using rat colon
10. To record the CRC of histamine on guinea pig ileum/chicken ileum
11. To record the CRC of 5HT on rat fundus preparation
12. To study the inotropic and chronotropic effects of drugs on isolated frog heart

Course Outcomes

At the end of the course, the student will be able to

CO1: What is experimental Pharmacology and Name the laboratory animals in experimental pharmacology

CO2: Demonstrate Techniques involved blood collection, Euthanasia, Different routes of administration of drugs

CO3: Experiment with chicken ileum preparation and develop Concentration response curve of Acetyl Choline, Histamine & 5 HT

CO4: Examine the effect of drug Neostigmine & Atropine on concentration response curve of Acetyl Choline & Histamine

CO5: Analyse the ionotropic and chronotropic effect of drugs of isolated heart and Examine the Drug Tachyphylaxis, Tolerance, Resistance & Addiction with Standard graphs.

Text Books:

1. Essentials of medical pharmacology by Tripathi, K. D, 7th Edition, Publisher: Jaypee brothers medical publishers 2013.

2. Pharmacology and Pharmacotherapeutics by Satoskar, R.S. and Bhadarkar, S.D: 23rd edition

   Popular prakashan 2013.
3. Pharmacology, Rang, H.P. & Dale M.M. 8th edition. Published by Elsevier, 2015.
4. Hand book of Experimental Pharmacology. S. K. Kulkarni. Published by Vallabh prakashan, 2015.

Reference Books:

1. The Pharmacological basis of therapeutics. Goodman and Gillman. 12th edition. Published by McGraw-Hill Education, 2011
2. Modern Pharmacology by Charles R Craig, & Robert E. Stitzel, 5th edition. Publisher: Little Brown.Co
3. Modern Pharmacology by Charles R Craig, & Robert E. Stitzel, 6th edition. Philadelphia ; London : Lippincott Williams & Wilkins, c2004.
4. Basic and clinical pharmacology by Katzung, B.G. 12th edition. Publisher: McGraw-Hill
5. Essentials of Pharmacotherapeutics by F.S.K. Barar, 4th edition, S Chand & Co Ltd 2009.
6. Fundamentals of Experimental Pharmacology, Ghosh M. N, 6th edition, Hilton & company 2015.

15CBPH64 Pharmaceutical Jurisprudence & Ethics

Theory **2-0-0-2**

Unit I: Introduction: **9hrs**

a) Pharmaceutical Legislations - A brief review.
b) Drugs & Pharmaceutical Industry - A brief review
c) Pharmaceutical Education - A brief review**.**

Unit II:Drugs and Cosmetics Act: **9hrs**

Drugs and Cosmetics Act 1940 and Rules 1945

Unit III: An elaborate (practical oriented) study of: **9hrs**

a) Pharmaceutical Ethics
b) Pharmacy Act 1948
c) Drugs and Magic Remedies (Objectionable Advertisements) Act 1954
d) Medicinal & Toilet Preparations (Excise Duties) Act 1955
e) Narcotic Drugs & Psychotropic Substances Act 1985 & Rules
f) Drugs Price Control Order.

Unit IV: A brief study of the following with special reference to the main provisions **9hrs**

a) Provisions Act 1919
b) Medical Termination of Pregnancy Act 1970 & Rules 1975
c) Prevention of Cruelty to Animals Act 1960
d) States Shops & Establishments Act & Rules
e) Insecticides Act 1968
f) AICTE Act 1987
g) Factories Act 1948
h) Minimum Wages Act 1948
i) Patents Act.

Unit V: Prescription/Non-prescription Products **9hrs**

A brief study of the various Prescription/Non-prescription Products, Medical / Surgical accessories, Diagnostic aids appliances available in the market.

Total **45hrs**

Course Outcomes

At the end of the course, the student will be able to

CO1: Outline and summarize the salient features of Pharmaceutical legislations, Drugs and Pharmaceutical industry and Pharmaceutical education.

CO2: Explain Drug and Cosmetics act and Rules 1945.

CO3: Make use of objectives, essential features, offences and penalties in detail study of Medicinal and Toilet preparations act, Narcotic Drugs control order.
Apply the professional ethics in hospital and clinical pharmacy.
Make use of education regulation followed in Pharmacy act and Plan the registration of pharmacist in respective state Pharmacy council.

CO4: Explain the main provisions of Provisions act, Medicinal Termination of Pregnancy act, States and shops and establishments Act and rules, Insecticides act and rules, AICTE act, patents act and Minimum wages act. Support the prevention of cruelty to animals act

CO5: Elaborate the various prescription/non prescription products, medical appliances, surigical accessories, diagnostic appliances available in market

Textbooks

1. Textbook of Forensic Pharmacy,Mohanta.Published by CBS Publishers & Distributors Pvt. Ltd., New Delhi, 2013.
2. Forensic Pharmacy - Pharmaceutical Jurisprudence,Suresh.B. Publishe by Birla Publications Pvt Ltd.

Reference Books

1. Handbook of Drug Laws, M L Mehra. Year of Publication. Hard Bound English Universal Book Traders, Delhi. Yr. Of Pub.2002.
2. Drugs and Cosmetics Act, 1940, EBC. 3rd Edition, 2011. Publisher: Eastern Book Company
3. Forensic pharmacy and ethics, S. C. Mahajan J. B. K. Narang. New Delhi:Jaypee brothers,1989. Publication Data.
4. A manual of drugs & pharmacy laws in India, H K Bharati Publisher:Kachhi Mohall,Sadhana Mandir,1984.
5. Laws of drugs.Katju s.n, 5th edition,year of pb:2013

15CBPH65 Therapeutic Drug Monitoring And Bioavailability

Theory **2 0 0 2**

Unit I: Pharmacokinetic parameters of drugs and their determination **9 hrs**

Overview of the pharmacokinetic processes such as absorption, distribution, metabolism and excretion of a drug. Determination of pharmacokinetic parameters of a drug – Cmax, tmax, t1/2, Kel, clearance, volume of distribution and mean residence time.

Unit II: Pharmacokinetic Variability (body weight, size, obesity, age, sex, genetic factors) **9 hrs**

Changes in pharmacokinetics of a drug taking body weight, size and obesity as a covariate. Pharmacokinetic variability - age (neonates, infants, children and elderly) sex and genetic factors.

Unit III: Pharmacokinetic Variability – effect of disease states **9 hrs**

Creatinine clearance and glomerular filtration rate in renal impairment. Changes in drug pharmacokinetics in patients with renal disease, liver disease, cardiovascular disease, thyroid disease and burns.

Unit IV: Pharmacokinetic Variability – drug interactions **9 hrs**

Drug-drug interactions: Drug absorption – drug interactions, drug distribution – drug interactions. Drug metabolism – drug interactions: Enzyme induction and enzyme inhibition. Drug excretion – drug interaction.

Unit V: Individualization and optimization of drug dosage regimen **9 hrs**

Deciding the drug dosage regimen based on clinical data, clinical manifestations and TDM. Indications for TDM. Role of clinical pharmacist in individualization and optimization of drug dosage regimens.

Total **45 hrs**

Course Outcomes

At the end of the course, the student will be able to

CO1: Determine the primary pharmacokinetic parameters for the pharmacokinetic models.

CO2: Discuss the pharmacokinetic variability of digoxin/ aminoglycosides/ antiepileptics across different age groups.

CO3: Estimate creatinine clearance of renal impaired patients with given serum creatinine and discuss the pharmacokinetic variability of drugs for the given patient data.

CO4: Explain the pharmacokinetic drug interactions with suitable examples.

CO5: Elaborate on the role of pharmacist in the individualization and optimization of aminoglycosides/ antiepileptics/cardiovascular drug dosage regimen.

Practicals **0 3 0 2**

1. Determination of bioavailability of various dosage forms by in Vivo and in vitro methods (Tablets, capsules and injections)

2. Problems on dosage adjustment based on patient's body weight, age and renal function (Gentamycin, digoxin, cyclosporin)
3. Therapeutic drug monitoring (Gentamycin, digoxin, theophylline, lithium, phenobarbitone, diazepam, amitriptylline)

Course Outcomes

At the end of the course, the student will be able to

CO1:	Determine AUC (area under the curve) for the given plasma concentration – time data.
CO2:	Estimate the glomerular filtration rate for the given patient data.
CO3:	Design the drug dosage regimen of gentamicin for an anephric patient weighing 74 Kg and 55 year old female patient.
CO4:	Modify phenytoin dosage regimen for a patient who has been recently started on antitubercular drug therapy.
CO5:	Estimate the renal clearance of digoxin for the given patient data.

Textbooks

1. Biopharmaceutics and Clinical Pharmacokinetics, Milo Gibaldi et al, 4th edition, Lea & Febiger, 1991.
2. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, Malcolm Rowland et al, 4th revised edition, Lippincott Williams and Wilkins, 2007.
3. Biopharmaceutics and Pharmacokinetics- A Treatise, D.M.Brahmankar et al, 3rd edition, Vallabh Publications / Prakashan, 1995.

Reference Books

1. Handbook of clinical Pharmacokinetics, Milo Gibaldi et al, ADIS Health Sciences Press, 1983.
2. Basic skills in interpreting laboratory data, Mary Lee et al, 5th revised edition, American Society of Health System Pharmacists, 2013.
3. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills, Parthasarathi G et al, 2nd edition, Universities Press, 2012.
4. Biopharmaceutics and Clinical Pharmacokinetics-An introduction, Robert.E.Notari et al, 4th edition, CRC Press, 1986.