Dr. Kajiram Adhikari

M Pharm in Clinical Pharmacy

(Revised Syllabus)

Purbanchal University

College of Medical and Allied Sciences, PUCMAS, Gothgaun

Morang, Koshi Anchal

पूर्वाञ्चल विश्वविद्यालय

Poush 2073

(January 2017)

Pharmacy Subject Committee, Purbanchal University			
1.	Dr. Dharma Prasad Khanal M Pharm, PhD.	Chairman	
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5.	Dr Sachit Kumar Neupane M Pharm, Pharm D	Member	
6.	Mr. Kshit Gartoulla M Pharm	Member	

Content

1. Mission Statement

Purbanchal University mission is to contribute to the nation for providing graduate trained pharmaceutical manpower through prescribed training program of M.Pharm, with Professional Pharmaceutical education and effective competency to undertake the national task of meeting social and pharmaceutical needs in clinical Pharmacy, Industrial Pharmacy, Patient Care, Pharmaceutical Education and Research.

2. Aim and Objective

To produce a competent pharmacist professionals Research pharmacists with background knowledge of various specializations of Pharmaceutical Science.

Master of Pharmacy in Clinical Pharmacy

Upon completion of the course, the candidate shall have Knowledge and understanding of the practice of Clinical & Hospital Pharmacy to provide the pharmaceutical services to the patient and community.

3. Admission

1. All the applicants for the Master of Pharmacy course must have passed the Bachelor of pharmacy degree from a recognized university and with minimum of CGPA/ SGPA 2.5 or 50 % in aggregate with **one year of Pharmacy practice experience ((for example work experience in hospital or, community or industry, analytical lab, academia etc.)** and must pass the entrance examination. The candidates will be admitted strictly in accordance with the merit secured at the Entrance examination.
2. No admission/ readmission/ promotions to be made after two weeks of the commencement of the classes in the semester.
4. A candidate admitted into Master of Pharmacy Post-Graduate Degree course in Purbanchal University, shall submit the prescribed application form for registration duly filled along with prescribed tuition fee.

The course structure and code numbers are revised as following table no. 3.3.

3.3.: Branch – C: Master of Pharmacy in Clinical Pharmacy						
	Credits	Marks Allocated				Total
		Theory		**Practical**		
First Semester		Internal	Final	Internal	Final	
MPHAR 614 - Biopharmaceutics and Pharmacokinetics	3 +1= 4	20	80	25	25	150
MPHAR 616 : Pathophysiology	3 +1= 4	20	80	25	25	150
MPHAR 617: Principles of Pharmacology and Toxicology	3	50	100	----	----	150
MPHAR 618: Clinical Pharmacy I	3 +1= 4	20	80	25	25	150
MPHAR-619: Hospital Pharmacy	3 +1= 4	20	80	25	25	150
	19 Credits					
Seminar as part of MPHAR 617/618/619 practical						**750**
Second Semester						
MPHAR 620: Novel Drug Delivery System and Pharmaceutical products	2	10	40	25	25	100
MPHAR 621: Pharmacotherapeutics - I	3 +1= 4	20	80	25	25	150
MPHAR 622: Biostatistics and Clinical Research	3	20	80	25	25	150
MPHAR 623: Clinical Pharmacy II	3 +1= 4	20	80	25	25	150
MPHAR 624 : Hospital and Community Pharmacy	3+1= 4	20	80	100	25	150
MPHAR 625: Pharmaceutical Jurisprudence	2	10	40			50
Seminar as part of MPHAR 621/623/624 practical						**750**
	19 Credits					
Clinical clerkship (practical for MPHAR 621/623/624 (3 credits)						
Third Semester						
MPHAR 630: Pharmacotherapeutics - II	3 +1= 4	20	80	25	25	150
MPHAR 631: Clinical Pharmacy III	3 +1= 4	20	80	25	25	150
MPHAR 632- Dissertation Synopsis	2	-	-	50	50	100
MPHR: 633: Pharmacoepidemiology and Pharmacoeconomics	2	10	40	--	--	50
	12 Credits					500
Clinical clerkship (practical for MPHAR 630, MPHAR 631) (2 credits)						
Fourth semester						
MPHAR 640A : Project Dissertation	8	-	-	300	-	300
MPHAR 640B : Article writing	2	-	-		50	50
MPHAR 640C: Defense (Viva-voice)	2	-	-	-	50	50
	12 Credits					400
Total Credits hours	**62 credits**					2350

4. Seminars

The candidate for Master of Pharmacy course will have to give seminar in each semester.

- First Semester: Seminar topics to be selected from the papers of specialization (Clinical Pharmacy, Pharmacotherapeutics) as 25 % practical examination.
- Second Semester: Seminar topics to be selected from the papers of specialization (Clinical Pharmacy, Pharmacotherapeutics) as 25% practical examination. .
- Third Semester: Seminar on the introduction of dissertation (Thesis Synopsis 2 credits).
- Fourth Semester: Seminar will be on entire work of dissertation.

The candidate will have to give seminar with the help of audio visual aids. In case of first and second semester's seminar, 25 % of the internal practical marks will be allocated for seminar. The evaluation of seminar will be based 50% on scientific content and 50% on presentation skill.

1. Nature, Duration and Structure of the Courses

The normal duration of the course is 2 years (4 semesters). In each of the first two semesters, there shall be course work comprising minimum of 15 weeks of instruction and examination preparation leave of one week. The part of the third semester will be allocated for instruction & fourth semester shall be exclusively dedicated for dissertation. The maximum duration of the course shall be double the normal duration i.e. 4 years in special circumstances.

Each academic year consists of two semesters as mentioned above. Each specialization of the Master of Pharmacy program will have a curriculum and course content (syllabi) for the subjects recommended by the subject committee and approved by the Academic Council of the Purbanchal University as mentioned in the scheme of instruction below. The course content of the individual subjects, theory and practical, is expressed in terms of a specified number of credits. The number of credits assigned to a subject depends on the number of contact hours (lectures) per week. In general, credits are assigned to the subjects based on the contact hours per week per semester. One credit of theory is equivalent to fifteen lecture hours. One credit of practical or hospital internship is equivalent to minimum of 45 hours. The medium of instruction (including examinations and project reports) shall be English. The assessment of the student's performance in each course will be based on continuous internal evaluation and semester-end examinations. The allocation of marks for each of the component of assessment is indicated in Table: 3.3.

5. Writing a Review Paper

The candidate for M. Pharm. course will have to write a review paper (in each semester (First, second and Third)) related to the core course (as per below table) during first and second semester. Students have to review the papers published in reputed international Journals using "HINARI" or other data base. The papers will be evaluated by subject teacher as 25 % of end semester practical examination of the respective subjects.

Semester	M Pharm in Clinical Pharmacy
First Semester	MPHAR 617 or MPHAR 618 or MPHAR 619
Second Semester	MPHAR 621 or MPHAR 623 or MPHAR 624

6. Attendance, Assessment and Final Examination

The students must attend every lecture, seminar and practical classes. However, to accommodate for sickness and other contingencies, the attendance requirement shall be a minimum of 75% of the classes in any particular subject, otherwise s/he shall not be allowed to take the final examination in that subject. In addition, to be eligible for final examinations, student must compulsorily pass the internal assessments. Internal tests include the MCQs as well as long answer and short answer questions. University conducts final examination at the end of each semester. The procedure of final examination conduction will be as per the examination rules of the university. The end-semester question model is in accordance with the model attached in annex: I.

7. Dissertation

The topics for the dissertation shall be assigned by the Supervisor, a recognized Post-graduate Teacher and/or visiting faculty, **within two weeks of the beginning of third semester.** Every candidate presenting himself/herself for the M. Pharm. fourth semester examination is required to submit two type written copies of the dissertation duly certified by the Supervisor. The dissertation shall be sent to external examiner for evaluation. The candidate defense the dissertation and he suggested corrections and suggestions of external examiner's have to be incorporated and final four copies has to be submitted to the University/college not later than seven days of defense. The dissertation also needs to be certified by the Principal of the college or HOD of Department of Pharmacy. The dissertation is to be submitted not before 23 months from the date of commencement of first semester of M. Pharm Course. If candidate fails to submit his/her dissertation within 27 months, he/she will have to submit dissertation in subsequent semester. In case of affiliated colleges, the Principal of the concerned College/Institute will forward the dissertation to the PUCMAS office.

- So every candidate pursuing M. Pharm course is required to carry out work on a selected research project under the guidance of a recognized postgraduate teacher and/or visiting faculty. The results of such a work shall be submitted in the form of a dissertation. The dissertation is aimed to train a postgraduate student in research methods and techniques. It includes identification of the problem, formulation of a hypothesis, review of literature, getting acquainted with recent advances, designing of a research study, experimental work and/or collection of data, critical analysis, and comparison of results and drawing conclusions.

The dissertation should be written under the following headings:

1. Introduction 2. Aims or Objectives of study 3. Review of literature 4. Material and Methods 5. Results 6. Discussion 7. Conclusion 8. Recommendation 9. References 10. Tables 11. Annexure.

The written text of dissertation shall be not less than 50 pages and shall not exceed 150 pages excluding references, tables, questionnaires and other annexure. It should be neatly typed with double line spacing on one side of the white paper (A4 size, 8.27" x 11.69") and bound properly with black color cover. Spiral binding should be avoided. The dissertation shall be certified by the supervisor and co-supervisor if any, Head of the Department and Head of the Institution. The dissertation shall be submitted at least one month before the end of fourth semester.

Three copies of the dissertation duly recommended by the Guide supervisor, to the Head of the Department for evaluation by the external examiner nominated by Purbanchal University, one month before the final defense notified.
The evaluation scheme will be as shown in tablet 6 and evaluation sheet is attached in Annex-IV.

8. Viva-voce Examination

The Viva-Voce examination shall aim at assessing the depth of knowledge, logical reasoning, confidence and oral communication skills. The Viva-Voce examination shall be held immediately after the defense of the dissertation. If any candidate fails to submit the dissertation on or before the date prescribed, his/her Viva-Voce shall be conducted during the subsequent examination, which shall not be earlier than six months from the date fixed in the first instance.

9. Examiners

There shall be at least two examiners, out of them one shall be external examiner and the other one shall be the internal examiner. The internal examiner ordinarily is the supervisor.

10. Award of Class

निर्णय नं.१०. पूर्वाञ्चल विश्वविद्यालय प्राज्ञिक परिषद्को मिति २०८७।०४।२१ गते शुक्रवार बसेको बैठक०

Grading System

Percent of marks value	Letter grades	Grade
90 and above	A+	4.00
80 and Below 90	A	3.75
70 and Below 80	B+	3.50
60 and Below 70	B	3.00
50 and Below 60	C	2.50
40 and Below 50	D	1.75
Below 40	F	

CGPA (Cumulative Grade Point Average) at the end of the degree defines the division which will be one of the followings: CGPA definitions

CGPA	Division
3.75-4.00	Excellence
3.50-Below 3.75	Distinctions
3.00- Below 3.50	First Divisions
2.5-Below 3.00	Second Division
2.0-Below 2.5	Pass

The CGPA of student must remain 2 or above throughout the duration of studies. A student who has not obtained the minimum CGPA by the completion of all semester exams shall be allowed to take betterment examination having lowest grade i.e. 'C' grade according to proposed grading system to improve grade to make up the minimum CGPA.
The student will be allowed to sit for betterment exam after completion of all semester exams, according to
The betterment examination application submitted by student and approval from the office of examination management. The maximum duration for completion of the undergraduate program for a student shall be three years more for three or four years
Course and two years more for two year course plus the duration of concerned academic program. It shall be
counted from the last date of completing final exam of final semester/yearly exam. The student must clear
all the course requirements including all the provisions of evaluation scheme within this period.

प्राज्ञिक परिषदको मिति २०८२।०८।०८ गतेका दिन बसेको बैठकका निर्णयहरु

१) पूर्वाञ्चल विश्वविद्यालयद्वारा Thesis वा Dissertation विषय समावेश हुने विभिन्न संकाय अन्तर्गतका शैक्षिक कार्यक्रमहरुमा अन्तिम परीक्षाफल प्रकाशित भएको मितिले ३ (तीन) महिना भित्र Thesis वा Dissertation सम्बन्धी कार्य सम्पन्न गरी नियमानुसार विश्वविद्यालयमा प्राप्त हुन आएमा नियमितरुपमा उत्तिर्ण गरेको मानिने र सर्वोत्तम विद्यार्थी घोषणा गर्दा उक्त समायवधि भित्र Thesis वा Dissertation को कार्य सम्पन्न गर्ने विद्यार्थी मध्येबाट मात्र घोषणा गर्ने साथै उक्त समयावधि भन्दा पश्चात् Thesis वा Dissertation बुझाउने विद्यार्थीलाई आंशिक विद्यार्थी मान्ने ।

२) पूर्वाञ्चल विश्वविद्यालयका विभिन्न संकाय अन्तर्गतका विभिन्न शैक्षिक कार्यक्रमहरुमा विद्यार्थीहरुले अनिवार्यरुपमा बुझाउनु पर्ने Thesis/Dissertation or Project Works जस्ता विषयहरु छिलो गरि बुझाउने गरेकाले अब उपरान्त शैक्षिक शत्र २०७२/०७३ देखि लागु हुने गरि Thesis/Dissertation or Project Works विषयको Viva Date राखेर Viva भएकै वर्षलाई Year of Completion मानेर Passed Year उल्लेख गरि प्रमाण पत्र उपलब्ध गराउने ।

First Semester		Internal	Final	Internal	Final	
MPHAR 616: Pathophysiology	3 +1= 4	20	80	25	25	150
MPHAR 617:Basic Principles of Pharmacology and Toxicology	4	50	100	-	-	150
MPHAR 614 - Biopharmaceutics and Pharmacokinetics	3 +1= 4	20	80	25	25	150
MPHAR 618: Clinical Pharmacy I	3 +1= 4	20	80	25	25	150
MPHAR-619: Hospital Pharmacy I	3 +1= 4	20	80	25	25	150
	20 Credits					**750**
Seminar as part of MPHAR 617/618/619 practical						

MPHAR 616T: Pathophysiology [45 hrs]

Scope

This course is designed to impart knowledge on the area of Pathophysiology.

Objectives

Upon completion of the course student shall be able to

- Understand the basic pathophysiology of different systems.
- Understand the causes and mechanisms of disease of different diseases.
- Understand the basic diagnostic tests.

Unit-1: Membrane Physiology, Nerve and Muscle **(4 hrs)**

Physicochemical properties of cell membrane, permeability & transport. Genesis of resting membrane potential. Action potential. Contraction of skeletal and smooth muscles.

Unit-2: CNS and ANS **(3 hrs)**

General Introduction to neurophysiology. Neurohumoral transmission in CNS and ANS. Pathophysiology of depression and Parkinsonism.

Unit-3: Blood **(8 hrs)**

Principles of hemopoiesis. Erythropoiesis. Fate of RBC"s. Regulation of WBC production. Functions of WBC. Immune system. Blood groups. Hemostasis and blood coagulation. Pathophysiology of Jaundice and Anemia.

Unit-4: Cardiovascular System **(7 hrs)**

Properties of cardiac muscle. Action potential and spread of impulse in the heart. ECG. Cardiac cycle. Neural regulation of cardiac activity. Cardiac output: measurement and regulation. Neural control of circulation. Pathophysiology of Hypertension, Arrhythmia, Angina pectoris and Cardiac failure.

Unit-5: Respiratory System **(5 hrs)**

Lung volumes and capacities. Mechanics of respiration. Exchange of gases in the lungs. O_2 CO_2 carriage, dissociation curve. Neural regulation of respiration. Chemical regulation of respiration. Pathophysiology of Pneumonia, Asthma, Hypoxia, Cyanosis and Dyspnoea.

Unit-6: Gastrointestinal System **(8 hrs)**

General Organization of G.I. tract. Motility, Nervous Control and Blood Circulation. Gastric secretion, Biliary and pancreatic secretions. Digestion and Absorption. Pathophysiology of Peptic Ulcer, Constipation and Diarrhea.

Unit-7: Endocrine System **(4 hrs)**

Various endocrine glands and their related disorders (Diabetes, Pituitary disorders, Thyroid and parathyroid disorders, Adrenocorticotropic disorders).

Unit-8: Reproduction **(4 hrs)**

Male reproductive physiology. Female reproductive physiology. Hypothalamic – pituitary – gonadal axis. Puberty. Pregnancy. Parturition and lactation.

Unit-9: Etiology and diagnosis of neoplastic diseases: **(2 hrs)**

Classification of tumors, Etiologic factors, Diagnosis of tumors and Treatment modalities.

MPHAR 616P: Pathophysiology practical

1. Demonstration of pathological slides of different diseases discussed in theory.
2. Discuss the common laboratory and diagnostic tests of above systems discussed in Theory
3. Obtain a basic understanding of the need for various laboratory and diagnostic tests in the diagnosis and treatment of disease.

References:

4. Robbins and Cotran Pathologic Basis of Disease –Kumar, Abbas, Fausto W.B. Saunders, 8th ed., 2010.
5. Harrison's Principles of Internal Medicine, McGraw-Hill, latest Edition.
6. Textbook of Medical Physiology by A.C. Guyton, Saundersco. Londo
7. Text Book of Pathology by Harsh Mohan. Jaypee Brothers, New Delhi
8. Text Book of pathology. BN Dutta. Jaypee Brothers, New Delhi
9. Gould, B. E. Pathophysiology for the Health Professions 3rd ed., Philadelphia, PA, Saunders Publishers, 2006.

MPHAR 617T: Basic Principles of Pharmacology and Toxicology [60 hrs]

Scope

This course is designed to impart knowledge on the area of Basic Pharmacology and Toxicology.

Objectives

Upon completion of the course student shall be able to

- Understand ADME.
- Understand the theories of Drug action.
- Understand the basic principles of Toxicology.

Unit-1: Drug Absorption (8 hrs)

Drug absorption: Gastrointestinal, Percutaneous and rectal kinetics and factors affecting drug absorption from GIT, skin permeation and bioavailability

Unit-2: Drug distribution (4 hrs)

Plasma protein binding, Factors affecting plasma protein binding, Tissue binding, transfer of drugs through biological barriers and their therapeutic implication in drug action.

Unit-3: Biotransformation (12 hrs)

Biotransformation of drugs, phase I and phase II metabolic reactions. Microsomal and non-microsomal (enzymes). Example reactions.

Drug metabolism in liver, kidney, intestine and placenta. Drug metabolism in fetus and new born. In-vitro and In-vivo studies in drug metabolism. Factors influencing drug metabolism: Stereo-chemical and physico-chemical factors; Physiological factors (species difference, stain difference, sex, age and environmental factors); Pathological states; Genetic factors.

Unit-4: Excretion of drugs (6 hrs)

Various organs for drug excretion, Mechanism of drug excretion from kidney, Factors affecting renal excretion of drug. Elimination of drugs: Concept of hepatic and renal clearance of drugs, biological half-life.

Unit-5: Pharmacodynamics (20 hrs)

Theories of Drug action: Principles of drug action, ion channels, enzymes, Drug receptor theory: Types of receptors: G-Proteins, Second messengers and gene therapy, Principle of drug design, structure activity relationship of selected groups like opioid drugs, catecolamines, penicillin, barbiturates, benzodiazepines.

Unit-6: General principles of toxicology (10 hrs)

History and scope of toxicology, Definition of poison, Mechanisms of toxicology, Risk Assessment, Management of poisoning with particular reference to barbiturates, opioids, organ phosphorous and atropine poisoning, heavy metals and heavy metal antagonists.

Reference

1. Biological standardization by J.H. Burn D.J. Finney and I.G. Goodwin
2. Indian Pharmacopeia and other Pharmacopeias
3. Screening methods in Pharmacology by Robert Turner. A
4. Evaluation of drugs activities by Laurence and Bachrach
5. Methods in Pharmacology by Arnold Schwartz.
6. Selected topics on the experimental pharmacology by Usha G.Karnal Dadkar, N.K and Seth, U.K
7. Fundamentals of experimental Pharmacology by M.N.Ghosh

8. Pharmacological experiment on intact preparations by Churchill Livingstone
9. Drug discovery and Evaluation by Vogel H.G.
10. Animal models in toxicology by Shyane Cox Gad and Christopher .P Chengellis.
11. The UFAW hand book on the care and management of laboratory animals by UFAW.
12. Principles and methods of toxicology by Hayes.
13. CRC Hand book of toxicology by Derelanko and Holinger.
14. Intellectual Property rights, The WTO Intellectual property Rights and their Knowledge Economy by Keith. E. Maskus.

Journals

1. Indian Journal of Pharmacology.
2. Indian Journal of Physiology and Pharmacology
3. Indian Journal of Experimental Biology.
4. Pharmacological research.

MPHAR 614 T- Biopharmaceutics and Pharmacokinetics [45 hours]

Scope

This course is designed to impart knowledge on the area of stability of drug products.

Objectives

Upon completion of the course student shall be able to:

- Understand the Bioavailability and Bioequivalence of Drug products.
- Understand the method development, validation and procedure to conduct the BA/BE study.
- Understand the techniques of Interpretation of the BA/BE Data

Unit-1: Introduction (8 hrs).

Definition of Bioavailability, bioequivalence, generic drugs, types of BA, methods to determine BA, Hatch max-man act 1971. Formulation factors affecting bioavailability of drugs in dosage forms of tablets, capsules, parenterals, liquid orals and topical dosage forms. DDA Regulations about BA/BE.

Unit-2: Application of Biopharmaceutics in BA/BE (15 hrs).

Biopharmaceutical aspects of absorption, distribution, metabolism and elimination, factors influencing bioavailability of dosage forms, methods to determine BA/BE. Bioavailability of highly variable drugs, narrow therapeutic index drugs and poorly soluble drugs. Methods for enhancement of BA. Drug product selection, concept of orange book, need of BE studies, generic drug product selection, study submission and drug review process

3. Ethical Issues involved in BA/BE studies Designing of protocol, rationale of the research, selection of subjects. Construction, role and responsibilities of IRB/IEC. Helsinki declaration.

Unit-3: Conduct of Study (5 hrs)

Design of the study, inclusion and exclusion criteria, sampling point, sampling volume, treatment groups, Approaches to determine bioequivalence (21 CFR 320.24)

Unit-4: Interpretation of the Data (7 hrs)

Statistical methods used for the treatment of the data, Statistical software to treat the data obtained from analysis, presentation of results and determination of conclusions.

Unit-5: Bioanalytical method development and validation for BA/BA studies. (10 hrs)

Introduction, sample preparation, column, method validation with ICH guidelines, upgraded technologies like GC-MS, LC-MS. Application of RIA.

MPHAR 614P - Advanced Biopharmaceutics and Pharmacokinetics Practical

1. Dissolution studies of 3 marketed formulations (immediate, sustain release) determination of drug release kinetics.
2. Measurement of bioavailability based on urinary data of commonly used 3 drugs in clinic.
3. Practical's based on biopharmaceutical aspects of drug formulations (pharmacotechnical variables)
4. Preparation of model study protocol for BA/BE
5. Determination of similarity and dissimilarity factor Development of bioanalytical method and validation of the same.

Reference

1. Milo Gibaldi & Donald Perrier. Pharmacokinetics, 1992, Marcel Dekker, New York.
2. D.M. Brahmankar, S.B. Jaiswal. 1997, Biopharmaceutics & Pharmacokinetics - A treatise. CBS Publications, New Delhi.
3. P.L. Madan. Biopharmaceutics & Pharmacokinetics, 2000, Jaypee publications, New Delhi.
4. Gibaldi & Pancot. Handbook of clinical pharmacokinetics. 1992, Marcel Dekker.
5. Swarbrik. Biopharmaceutics. 1987, Lea & Febiger book publication. U. K
6. Dr. Tapan Kumar Pal, M. Ganeshan. Bioavailability and Bioequivalence in Pharmaceutical Technology. CBS Publishers and Distributors.
7. Llyod r. Snyder, J. J. Kirkland, J. L. Glajch. Practical HPLC method development. John Wiley & Sons
8. Peter G. Welling, Francis L. S. Tse, Shrikant V. Dighe. Pharmaceutical Bioequivalence. Marcel Dekker Inc.
9. Jerry L. Hamelink, Peter F. Landrum, Harold L. Bergman, William H. Benson. Bioavailability. Physical, chemical, and biological interactions. Lewis publishers.
10. DDA Regulations, MOHP, Government of Nepal.
11. Helsinki Declaration. World Medical Association.
12. The Analysis of Drugs in Biological Fluids, Joseph Chamberlain, CRC Press.
13. EMEA for Bioanalytical method validation.
14. Industrial guidelines for Bioanalytical method validation.
15. BA-BE guidelines for BA-BE studies as per USFDA (CFR).
16. Milo Gibaldi & Donald Perrier. Pharmacokinetics, 1992, Marcel Dekker, New York.
17. D.M. Brahmankar, S.B. Jaiswal. 1997, Biopharmaceutics & Pharmacokinetics - A treatise. CBS Publications, New Delhi.
18. Yadav A.V, Yadav V.B, Shete A.S, Experimental biopharmaceutics and pharmacokinetics
19. www.fda.gov/cder/guidance/3618 , 8www.fda.gov/cder/guidance/2070DFT
20. www.iuphar.org/pdf/hum_55.pdf
21. www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-Id/bio/bio-a_c

MPHAR 618T: Clinical Pharmacy I **[45 hours]**

Scope

This course is designed to impart knowledge on the area of Clinical Pharmacy.

Objectives

Upon completion of the course student shall be able to:

- Understand the Clinical Pharmacokinetics.
- Understand the Clinical Evaluation of New Drugs
- Understand the use of Clinical Laboratory Tests.
- Understand the Clinical Evaluation of New Drugs
- Understand the contrast media used in diagnostic purpose.
- Understand the Drugs in Special Patient groups.
- Understand the techniques of Drug Therapy Monitoring and Patient Data Analysis.
- Understand the principles involved in the management of poisoning by different agents.
- Critically apprize the clinical biomedical literature

Unit-1: Introduction **(1 hr)**

Definition, development and scope of Clinical Pharmacy

Unit-2: Clinical Pharmacokinetics and Pharmacodynamics **(7 hrs)**

Volume of distribution, Clearance, Plasma protein binding, concentration dependent clearance, flow dependent clearance, multi compartment models, physiologic model, pharmacodynamic models, time course of drug action, cumulative effects of drugs, steep concentration effect curves.

1. Hysteresis 2. Prosteresis, 3. Target Concentration Strategy. 4. Variability and control strategies in quantitative therapeutics Bioavailability, Drug Biotransformation,

1. Pharmacokinetic variability; Body weight & size, obesity, age. Drug metabolism, Plasma protein binding and renal excretion in newborn & children. Sex, pregnancy and genetic factors. Polymorphic acetylation and oxidation

2. Effect of disease states on drug disposition, therapeutic drug monitoring and dosage prediction of digoxin, gentamycin and anticonvulsants. Hypothesis of individualization & optimization of drug therapy.

Unit-3: Clinical Evaluation of New Drugs **(3 hrs)**

Clinical trials, various phases of clinical trials, design and execution of trials in different clinical settings.

Unit-4: Clinical Laboratory Tests (6 hrs)

Used in the evaluation of disease states, and interpretation of test results. Hematological, liver function, renal function tests, tests associated with cardiac disorders, fluid and electrolyte balance, common tests in urine, sputum, feces. Sensitivity screening for common pathogenic micro-organisms, its significance, resistance in disease states and selection of appropriate anti-microbial regimens.

Unit-5: Studies of Imaging Pharmaceuticals (contrast media) - (5 hrs)

Introduction, parenteral injection methods, types of contrast media, characteristics of iodinated contrast media, pharmacodynamics, and pharmacokinetics of contrast media and clinical applications), preventive care and emergency, response to contrast media, patient education and assessment. Patient preparations, pre-medication, types of contrast medium reactions.

Unit-6: Drugs in Special Patient Groups (Pregnancy and Nursing, Neonates and Children, Elderly). (2 hrs)

Unit-7: Clinical Importance of Genetics in Drugs effects. (1 hr)

Unit-8: Drug Therapy Monitoring (6 hrs)

Medication chart view, clinical review, TDM Pharmacist interventions, and therapeutic drug monitoring and dosage prediction of digoxin, gentamycin and anticonvulsants. Hypothesis of individualization & optimization of drug therapy. Ward round participation. Adverse drug reaction management. Medication history and patient counseling. Drug utilization evaluation (DUE) and review (DUR), quality assurances of clinical pharmacy services. Patient data analysis. Introduction of information sources available.

Unit-9: Patient Data Analysis (3 hrs)

The patient's case history. its structure and use in evaluation of drug therapy. Patient medication history review, presentation of cases, teaching skills. Understanding common medical abbreviations and terminology used in clinical practices.

Unit- 10: Clinical Toxicology (7 hrs)

General principles involved in the management of poisoning. Antidotes and their clinical applications. Supportive care in clinical toxicology. Gut decontamination. Elimination enhancement. Toxicokinetics. Clinical symptoms and management of acute poisoning with the following agents: Pesticide poisoning: organophosphorus compounds, carbamates, organochlorines, pyrethroids Opiate overdose, Antidepressants, Barbiturates and benzodiazepines, Alcohol: ethanol, methanol, Paracetamol and salicylates, Non steroidal anti-inflammatory drugs, Radiation poisoning.

5 Clinical symptoms and management of chronic poisoning with the following agents: Heavy metals: Arsenic, lead, mercury, iron, copper. Food Poisoning.

Unit- 11: Clinical Literature Evaluation (4 hrs)

Objective, primary, secondary and tertiary literature, Evaluation Techniques and steps. Study design, Statistical tests and Bias. Introduction to systematic review and meta analysis.

Use HINARI or other Data Bases

Examples: Fowkes, F. G. R., & Fulton, P. M. (1991). Critical appraisal of published research: Introductory guidelines. *BMJ*, 302, 1136-1140. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1669795/

Kissling, L. S., & Davis, J.M. (2009). How to read and understand and use systematic reviews and meta-analyses. *Acta Psychiatrica Scandinavica*, 119, 443-450. doi:10.1111/j.1600-0447.2009.01388.x [PMID: 19469725]

Young, J. M., & Solomon, M. J. (2009). How to critically appraise an article. *Nature Clinical Practice Gastroenterology & Hepatology*, 6(2), 82-91. doi:10.1038/ncpgasthep1331 [PMID: