SAVITRIBAI PHULE PUNE UNIVERSITY

FACULTY OF SCIENCE AND TECHNOLOGY

RULES & SYLLABUS

FIRST YEAR MASTER OF PHARMACY (M. Pharm.) COURSE

(EFFECTIVE FROM ACADEMIC YEAR 2020-2021)

Table - 1: Course of study for (**Clinical Practice- MCP**)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
Semester I					
MCP101T	Advanced Clinical Pharmacy	4	4	4	100
MCP102T	Pathophysiology and Applied Pharmacotherapeutics-I	4	4	4	100
MCP103T	Advanced Biostatistics and Research Methods	4	4	4	100
MCP 104T	Community Patient Care/Community Pharmacy	4	4	4	100
MCP105P	Clinical Practice Practical-I	12	6	12	150
-	Seminar & Assignment	7	4	7	100
Total		35	26	35	650
Semester II					
MCP201T	Clinical Research and Pharmacovigilance	4	4	4	100
MCP202T	Pathophysiology and Applied Pharmacotherapeutics-II	4	4	4	100
MCP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	4	4	100
MCP204T	Hospital Pharmacy	4	4	4	100
MCP205P	Clinical Practice Practical-II	12	6	12	150
-	Seminar & Assignment	7	4	7	100
	Total	35	26	35	650

Table 2: Scheme for internal assessments and end semester examinations
(**Clinical Practice - MCP**)

Course Code	Course	Internal assessments				End Semester Exams		Total marks
		Continuous Mode	Sessional Exams		Total			
			Marks	Duration				
Semester-I								
MCP101T	Advanced Clinical Pharmacy	10	15	1 Hr.	25	75	3 Hrs	100
MCP102T	Pathophysiology and Applied Pharmacotherapeutics-I	10	15	1 Hr	25	75	3 Hrs	100
MCP103T	Advanced Biostatistics and Research Methods	10	15	1 Hr	25	75	3 Hrs	100
MCP104T	Community Patient Care/ Community Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MCP105P	Clinical Practice Practical-I	20	30	6 Hr	50	100	6 Hrs	150
-	Seminar & Assignment	-	-	-	-	-		100
	Total							650
Semester-II								
MCP201T	Clinical Research and Pharmacovigilance	10	15	1 Hr	25	75	3 Hrs	100
MCP202T	Pathophysiology and Applied Pharmacotherapeutics-II	10	15	1 Hr	25	75	3 Hrs	100
MCP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	10	15	1 Hr	25	75	3 Hrs	100
MCP204T	Hospital Pharmacy	10	15	1 Hr	25	75	3 Hrs	100
MCP205P	Clinical Practice Practical-II	20	30	6 Hr	50	100	6 Hrs	150
-	Seminar & Assignment	-	-	-	-	-		100
								650

CLINICAL PRACTICE (MCP)

ADVANCED CLINICAL PHARMACY (MCP101T)

Scope

This course is designed to impart the basic knowledge and skills that are required to a clinical pharmacy professionals.

Objectives

Upon completion of the course the student shall be able to:

- Understand the various elements of pharmaceutical care and provide comprehensive patient careservices
- Interpret the laboratory data and to develop communication skill.
- Provide integrated, critically analyzed medicine and poison information to enable healthcare professionals in the efficient patient management.

THEORY **60 Hrs**

Unit-I	**Introduction to Clinical Pharmacy**	**12 Hrs**
	Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care	
	Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)	
Unit -II.	**Professional activities of a Clinical Pharmacist**	**12 Hrs**
	Ward Round Participation, Medication History Interview, Drug Therapy Monitoring (Medication Chart Review, Clinical Review, Therapeutic Drug Monitoring & Pharmacist Interventions), Adverse Drug Reaction Management, Drug Information & Poison Information, Patient Counseling, Drug Utilization evaluation (DUE) & Review (DUR), Quality Assurance of Clinical Pharmacy Services	
Unit-III	**Patient DataAnalysis**	**12 Hrs**
	The patient's case history, its structure & use in evaluation of drug therapy, presentation of cases. Communication skills, including patient counseling techniques, medication history interview, teaching skills. Understanding common medical abbreviations & terminologies used in clinical practices.	
	Clinical Laboratory Tests used in the evaluation of diseases states & interpretation of test results. Haemotological, Liver function, Renal function, Thyroid function tests. Medical imaging techniques Tests associated with cardiac disorders Fluid & Electrolyte balance Common tests in urine, sputum, faeces, CSF.	

Unit-IV	**Drug & Poison Information**	**12 Hrs**
	Introduction to Drug information, resources available, Systematic approach in answering drug information serve queries Critical evaluation of drug information and literature Preparation of written and verbal reports Establishing a drug information center Poisons information-organisation and information resources Poisons management in drug dependence and drug abuses (opiates, cocaine, amphetamines, alcohols, benzodiazepines, barbiturates, tobacco). Role of emetics, anti- emetics and respiratory stimulants.	
Unit-V	**Medication Error and Medication Adherence**	**12 Hrs**
	Categories and causes of medication error Performance indicators of the medication use process Categories of medication non-adherence Role of pharmacists at medication error and medication adherence **Evidence Based Medicine:** Formulating Clinical Questions, Searching for the best evidence, Critical Appraisal of the evidence, Applying evidence to patients, Evaluation.	

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- Hansen K N Parthasarath G (2004). A text book of clinical pharmacy practice – Essential concepts and skills. Orient longman Publications.
- Joseph Price Remington (1990). Remington Pharmaceutical sciences. 16th ed. Mack Pub. Co. Publications..
- Leon Shargel Alan H Mutnick Paul F Souney Larry N Swanson (2004).Comprehensive pharmacy review. 5th ed. Lippincott Williams & Wilkins publications.
- Leon Shargel Andrew Yu Susanna Wu-Pong (2012). Applied Biopharmaceutics & Pharmacokinetics. 6th ed. McGraw Hill Professional publications.
- Malcolm Rowland Thomas Tozer N (1995). Clinical Pharmacokinetics- concepts and applications. 3rd ed. Williams and Wilkins Publication.
- Relevant review articles from recent medical and pharmaceutical literature.
- Scott L Traub (1996). Basic skills in interpreting laboratory data. 2nd ed. American Society of Health System Pharmacists Inc publications.
- Sharon Straus E (2005). Evidence Based Medicine. 3rd ed. Churchill Livingtone publications.
- Society of Hospital Pharmacists of Australia (1997). Practice Standards and definitions – the Society of Hospital Pharmacists of Australia. The society publications.

PATHOPHYSIOLOGY AND APPLIED PHARMACOTHERAPEUTICS-I (MCP 102T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence–based medicines.

Objectives

Upon completion of the course the student shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis

THEORY **60 Hrs**

	Etiopathogenesis and pharmacotherapy of diseases associated with following systems	
Unit-I	**Cardiovascular system**	**12 Hrs**
	Acute Coronary Syndrome, Hypertension, Congestive Cardiac Failure, Ischaemic Heart Disease (Angina Pectoris, Myocardial Infarction) Arrythmias, Hyperlipidarmia, Cardiopulmonary Arrest Shock Cardiomyopathy	
Unit -II	**Respiratory System**	**12 Hrs**
	Introduction to pulmonary function tests, Asthma, Chronic Obstructive Pulmonary Disease, Drug Induced Pulmonary Diseases, Hydrogen Ion Hemostasis & Blood Gases (external and internal respiration).	
Unit-III	**Gastrointestinal system**	**12 Hrs**
	Gastro – Oesophageal Reflux Disease, Peptic Ulcer Disease, Inflammatory Bowel Disease, Hepatitis, Viral, Jaundice & Cirrhosis, Diarrhoea & Constipation, Drug Induced Liver Disease	
Unit-IV	**Gastrointestinal system:** Cirrhosis, Diarrhea & constipation, drug induce liver diseases.	**12 Hrs**
	Hematological disease: Anaemia's, Thalassemia, Drug Induced Haematological Diseases, Venous Thromboembolism, Acute Renal Failure / Chronic Renal Failure, Renal Dialysis and Transplantation, Drug Dosing In Renal Failure / Impairment, Drug Induced Renal Diseases, End-Stage Renal Disease, Diuretic Therapy, Potassium Depletion, Hyperkaelemia, Alakalosis.	
Unit-V	**Bone and joint disorders:** Gout & Hyperuricemia, Rheumatoid Arthritis, Osteoarthritis, Spondylitis, NAFLD	**12 Hrs**
	Dermatological Diseases: Acne Vulgaris, Psoriasis, Scabies,Eczema, Drug Induced Skin Disorders, Vetiligo.	
	Ophthalmology: Conjunctivitis, Glaucoma	

REFERENCES

1. JG Hardman, LE Limbard (2001). Goodman & Gilman's- The Pharmacological Basis of Therapeutics: McGraw-Hill publications.
2. Joseph DiPiro, Robert L, Talbert, Gary Yee, Gary Matzke, Barbara Well, Michael Posey L (2011). Pharmacotherapy: A Pathophysiologic approach. 8th ed: McGraw-Hill publications.
3. Roger Walker Clive Edwards (2003). Clinical pharmacy and therapeutics. 3rd ed.: Churchill Living stone publications.
4. Dennis Kasper L, Eugene Braunwald, Stephen Hauser, Dan Longo, Larry Jameson J, Anthony Fauci S (2005). Principles of Internal Medicine. 16th ed.: McGraw Hill Publications.
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6. Eric Herfindal T, Joseph Hirschman L (1984). Clinical Pharmacy and Therapeutics. 3rd ed.: Williams & Wilkins publications.
7. GK Mc Evoy (2004). American Hospital Formulary Services: American Society of Hospital Pharmacists.
8. Graeme S Avery (1980). Drug treatment- principles and practice of clinical pharmacology and therapeutics. 2nd ed.: Adis Press publications.
9. Mary Anne Koda-Kimble (2008). Applied Therapeutics. 9th ed.: Wolters Kluwer Health/Lippincott Williams & Wilkins publications.
10. Ramzi Cotran S, Vinay Kumar, Tucker Collins, Stanley Leonard Robbins (1999). Robbins pathologic basis of disease. 6th ed. : Saunders publications.
11. Relevant review articles from recent medical and pharmaHCPtical Journals.
12. Russell Greene J, Norman Harris D (2008). Pathology and Therapeutics for pharmacists - a basis for clinical pharmacy practice. 3rd ed.: Pharmaceutical Press Chapman and Hall Publications.
13. Sir Stanley Davidson, Christopher Haslett (2002). Davidson’s Principles and Practice of Medicine. 16th ed.: Churchill Living stone publications.
14. Society of Hospital Pharmacists of Australia (1997). Practice Standards and Definitions: The Society publications.

ADVANCED BIOSTATISTICS AND RESEARCH METHODS

(MCP 103T)

Scope

This course is designed to understand the importance of statistical applications to various clinical data.

Objectives

Upon completion of the course the student shall be able to:

- Understand the different approaches of data analysis.
- Understand the importance of statistic in experimental and non experimental research.

THEORY **60 Hrs**

Unit-I	Developing a research question, Resources for research question, Literature Review: Traditional Qualitative Review Meta-Analysis—A Quantitative Review, Preparation of Research Proposal	**12 Hrs**
	Variables—Definition of Variable, Types of variables—Dependent and Independent variables, Confounded variables, Measurement of variables, Types of measurement scales and their comparison. Reliability and Validity of Measurements.	
Unit -II	Validity, Types of validity—Internal validity, Construct validity, External validity, Threats to validity. Control: Subject as own control (Within Subject control), Statistical control.	**12 Hrs**
Unit-III	Non-experimental Research: Part 1—Observational, Archival and Case-Study Research: The Hermeneutic Approach.	**12 Hrs**
	Observational Research: Naturalistic Observation, Participant-Observer Research. Archival Research: Archival Data Collection and Compilation. Case Studies: Characteristic of Case Studies.	
	Non-experimental Research: Survey Research—Designing of Questionnaire, Methods of Administration, Response Rates. Types of Samples—Haphazard Samples, Purposive Samples, Convenience Samples and Probability Samples.	
Unit IV	True Experiments: Single-Factor Designs, Factors, Levels, Conditions, and Treatments. Within-Subject Designs.	**12 Hrs**
	True Experiments Part-2—Factorial Designs—Main Effects, Interactions, A Mixed Factorial Design.	
Unit V	Single-Subject Experiments: Advantages and Disadvantages. Quasi Experiments: The differences between Quasi and True Experiments. Design without Control Groups—Interrupted Time Series Designs and Repeated Treatment Designs.	**12 Hrs**

REFERENCE

1. Donald H. Mc Burney -Theresa L. White (2009). *Research Methods*. New Delhi: Cengage learning India Pvt. Ltd.
2. Hooda-R.P (2000). *Statistics for business and economics*. 3rd ed. New Delhi: MC. Millan Business books.
3. Tiwar N.K.,Rao G.N (2008). *Biostatistics & Computer applications*. Sultan Bazar, Hyderabad, AP: Pharma Med Press.
4. Lippincot Williams (2006). *Remingtons Pharmaceutical Sciences*. 21st ed. Noida, India: B.I. Publications.
5. Leon Lachman, Herbert A. Lieberman (2009):*The Theory and Practice of industrial Pharmacy* ,2 nd ed, New Delhi:CBS Publishers and Distributors.

COMMUNITY PATIENT CARE/COMMUNITY PHARMACY
(MCP 104T)

Scope

This course aims to provide the students an opportunity to learn details about community pharmacy and the role of clinical pharmacy in community pharmacy.

Objectives

Upon completion of this course it is expected that students shall be able to:

- Know the role, responsibility and working of community pharmacy.
- Understand the regulatory and ethical requirements.
- Know the importance of community pharmacy management.
- understand the role of community pharmacy in public health.

THEORY **60 Hrs**

Unit-I	**Introduction to the concept of community pharmacy – its activities and professional responsibilities**	**12 Hrs**
	a) The role of community pharmacy and its relationships to other local health care providers	
	b) Prescribed medication order- Interpretation and legal requirements	
	c) Over the counter (OTC) sales	
	d) OTC medication list and counseling, Rational use of common OTC medications (Vitamins and tonics, iron preparations, analgesics, NSAIDs, cough mixtures, anti-diarrial preparations)	
Unit -II	Health Education and Community Pharmacy: Family planning, first aid, communicable disease prevention, smoking cessation, screening programs.	**12 Hrs**
Unit-III	a) Services to nursing homes/clinics.	**12 Hrs**
	b) Community Pharmacy Management: Financial, material and staff management, infrastructure requirements, drug information resources, computers in community pharmacy.	
	c) Code of ethics for community pharmacy	
	d) Poly pharmacy and its implications	
Unit IV	A)Communication skills – Principles and elements of communication skills, non -verbal communication in pharmacy, barriers in communication, listening skills, questioning skills, explaining Skills. Patient counseling in community pharmacy	**12 Hrs**
	B) Education and training staff, training and continuing education for pharmacists, pharmacy students, Medical staff and students, nursing skills , explaining skills and ethics in communication	

Unit V	A) Public Health Policy and Health Care System – National & International	**12 Hrs**
	B) Concept of Rational Use of Drugs – Importance of rational drug use, pharmacists role, drug use indication, guidelines for rational prescribing.	
	C) Code of ethics for community pharmacists	

REFERENCE

1. William E Hassan (1986). Hospital Pharmacy. 5th ed. Lea & Febiger publications.
2. Allwood M C Fell J T (1980). Textbook of hospital pharmacy. John Wiley & Sons publications.
3. Graeme S Avery (1980). Drug treatment- principles and practice of clinical pharmacology and therapeutics. 2nd ed. india: Adis Press publications.
4. Joseph Price Remington (1990). Remington Pharmaceutical sciences. 16th ed. india: Mack Pub. Co. Publications.
5. Relevant review articles from recent medical and pharmaHCPtical literature
6. Sharon Straus E (2005). Evidence Based Medicine. 3rd ed. Churchill Livingtone publications.

CLINICAL PRACTICE PRACTICAL – I

(MCP 105P)

Patient medication history interview, answering drug information questions, patient medication counselling, participation in ward rounds. Case studies related to laboratory investigations covering the topics dealt in theory class.

List of Experiments (24)

1. Answering drug information questions (4)
2. (Queries related to Dosage, administration, contraindications, adverse drug reactions, drug use in pregnancy and lactation, drug profile, efficacy and safety)
3. Patient medication counselling – (3) Common diseases like Diabetes, Hypertension, Asthma, COPD, Acute Renal Failure, chronic Renal Failure.
4. Case studies related to laboratory investigations (4) – LFT, Hematology, Thyroid, Renal, Cardiac Enzymes.
5. Patient medication history interview (2)
6. Medication order review (2)
7. Detection and assessment of adverse drug reaction and their documentation (3)

Assignments

1. Drug information, Patient medication history interview
2. Patient medication counseling
3. Problem solving in clinical Pharmacokinetics
4. Literature evaluation pertaining to therapeutic range used in therapeutic monitoring of any two drugs frequently subjected for TDM.
5. Critical appraisal of two recently published articles in the biomedical literature, which deals with a drug or therapeutic issue.

CLINICAL RESEARCH AND PHARMACOVIGILANCE
(MCP 201T)

Scope:

This subject will provide a value addition and current requirement for the students in clinical research and pharmacovigilance. It will reach the students on conceptualizing, designing, conducting, managing and reporting of clinical trials. This subject also focuses on global scenario of Pharmacovigilance in different methods that can be used to generate safety data. It will teach the students in developing drug safety data in Pre-clinical, Clinical phases of Drug development and post market surveillance.

Objectives:

Upon completion of the course, the student shall be able to:

- Explain the regulatory requirements for conducting clinical trial.
- Demonstrate the types of clinical trial designs.
- Explain the responsibilities of key players involved in clinical trials.
- Execute safety monitoring, reporting and close-out activities.
- Explain the principles of Pharmacovigilance.
- Detect new adverse drug reaction and their assessment.
- Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance.

THEORY **60 Hrs**

Unit-I	**Regulatory Perspective of Clinical Trials:**	**12 Hrs**
	Origin and Principles of International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines. Ethical Committee: Institutional Review Board, Ethical guidelines for Biomedical Research and Human Participant Schedule Y, ICMR. Inform Consent Process: Structure and content of an Inform Consent Process Ethical principles governing informed consent process.	
Unit -II	**Clinical Trials: Types and Design**	**12 Hrs**
	Experimental Study- RCT and Non RCT Observation Study: Cohort , Case control, Cross sectional Clinical trial Study Team Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management.	
Unit-III	**Clinical Trial Documentation**	**12 Hrs**
	Guidelines to the preparation of documents, Preparation of protocol,Investigator Brochure, Case Report Forms, Clinical Study Report Clinical Trial Monitoring Safety monitoring in CT Adverse Drug Reactions: definition and types. Detection and reporting methods. Severity and seriousness assessment. Predictability and preventability assessment, Management of adverse drug reactions ; terminologies of ADR.	
Unit-IV	**Basic aspects, terminologies and establishment of Pharmacovigilance**	**12 Hrs**
	History and progress of Pharmacovigilance, Significant of safety monitoring,	

	pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centers in Hospitals, Industry and National programmes related to pharmacovigilance. Roles and responsibilities in Pharmacovigilance.	
Unit-V	**Methods, ADR reporting and tools used in Pharmacovigilance**	**12 Hrs**
	International classification of diseases, International Non-proprietary names for drugs, Passive and Active surveillance, Comparative observational studies, Targeted clinical investigations and Vaccine safety surveillance. Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting. Arugs, Aris G Pharmacovigilance, Vigiflow, Statistical methods for evaluating medication safety data. Introduction to pharmacoepidemiology and pharmacoeconomics.	

REFERENCES

1. Central Drugs Standard Control Organization– Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health;2001.
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical guidelines for Biomediical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical trials by David Machin, Simon Day and Sylvan Green. 2005. John Wiley and Sons.
5. Clinical Data management edited by R. K. Rondels, S A Varley, C F Webbs. Second edition, 2000. Wiley Publications.
6. Handbook of Clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
7. Principles of Clinical Research edited by Giovanna di lgnazio, di Giovanna and Haynes.

PATHOPHYSIOLOGY AND APPLIED PHARMACOTHERAPEUTICS – II
(MCP 202T)

Scope

This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skills in optimizing drug therapy of a patient by individualizing the treatment plan through evidence–based medicines.

Objectives

Upon completion of the course the student shall be able to:

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence based medicine
- Prepare individualized therapeutic plans based on diagnosis

THEORY **60 Hrs**

Unit-I	**Neurology & Psychiatry**	**12 Hrs**
	Epilepsy, Parkinson's Disease, Multiple sclerosis, Headache: Migrane & Tension Type, Pain Management, Stroke, Alzheimer's Disease, Anxiety Disorders, Bipolar Disorders, Depressive Disorde,r Schizophrenia, Psychosis Sleep Disorders, Substance – Related Disorders	
Unit -II	**Oncology (Blood cancer and Solid tumors)**	**12 Hrs**
	Basic Principles in Cancer Therapy, General Introduction To Cancer Chemotherapy Agents, Atiangiogenic agents, Chemotherapy of Brest Cancer, Chemotherapy of Lung Cancer, Chemotherapy of Head / Neck Cancer, Leukemia, Management of Chemotherapy – Nausea/ Vomiting, Pallative Care, Colorectal Cancer, Lyphomas, Prostate Cancer	
Unit-III	**Infectious Diseases**	**12 Hrs**
	Antimocrobial Regimen Selection, Central Nervous System Infections – Meningitis Endocarditis, Fungal Infections, Invasive, Gastrointestinal Infections, HIV/AIDS, Influenza, Intraabdominal Infections, Respiratory Tract Infections – Upper & Lower, Gastroeneritis, Sepsis & Septic Shock, STD's, Surgical Prophylasis, Tuberculosis, Urinary Tract Infections & Prostatitis	
Unit-IV	**Gynecologic & Obstetric Disorders / Ophthalmology/ Eye Disorders**	**12 Hrs**
	Menopause/ Hormone Replacement Therapy In Women, Pregnancy & Lactation : Therapeutic Considerations, Contraception, Conjunctivitis, Glaucoma Eye infections	
Unit-V	**Nutritional Disorder & Immunology**	**12 Hrs**
	Assessment & Nutritional Requirement, Enteral Nutritrion, Obesity, Total Parenteral Nutrition, Immune Disease – Pathogenesis, Mechanism of action of drugs, Orphan diseases(Sjogren's Syndrome, Paget Disease Extramammary, progeria)	

	Glucocorticoids – Anti inflammatory, Anti – allergic & Immunosuppressive actions in tissue as well as organ transplantation Vaccines, Toxiods and other immunobiologics	

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1. JG Hardman, LE Limbard, (2001). Goodman & Gilman's- The Pharmacological Basis of Therapeutics: 10th edition; McGraw-Hill publications.
2. Joseph DiPiro, Robert, L., Talbert, Gary Yee, Gary Matzke, Barbara Wells, Michael Posey, L., (2011). Pharmacotherapy: A Pathophysiologic approach: 8th edition; McGraw-Hill publications
3. Roger Walker, Clive Edwards, (2003). Clinical pharmacy and therapeutics: 3rd edition; Churchill Living stone publications
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5. Eric Herfindal, T., Joseph Hirschman, L., (1984). Clinical Pharmacy and Therapeutics: 3rd edition; Williams & Wilkins publications
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CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING (MPL203T)

Scope:

This course is designed to enable students to understand the application of pharmacokinetic principles to the safe and effective therapeutic management of drugs in an individual patient. Primary goals of clinical pharmacokinetics include enhancing efficacy and decreasing toxicity of a patient's drug therapy.

Objectives:

Upon completion of the course, the student shall be able to,

- Correlate the pharmacokinetic parameters with patient plasma profile of drug.
- Understand the application and significance of therapeutic drug monitoring.
- Dose adjustment in various disease conditions.

THEORY **60 Hrs**

Unit-I	**Introduction to Clinical pharmacokinetics.**	**12 Hrs**
	a. Primary pharmacokinetic parameters b. Interrelationship between primary pharmacokinetic parameters and their effect on plasma concentration-time profile c. Therapeutics Dosage regimens for special populations d. Physiologic variables Affecting drug clearance	
Unit -II	**Design of dosage regimens:**	**12 Hrs**
	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.	
Unit-III	**Pharmacokinetics of Drug Interaction:**	**12 Hrs**
	a. Pharmacokinetic drug interactions b. Inhibition and Induction of Drug metabolism c. Inhibition of Biliary Excretion.	
Unit-IV	**Therapeutic Drug monitoring:**	**12 Hrs**
	a. Introduction b. Individualization of drug dosage regimen (Variability – Genetic, Age and Weight , disease, Interacting drugs). c. Indications for TDM. Protocol for TDM. d. Pharmacokinetic/Pharmacodynamic Correlation in drug therapy. e. TDM of drugs used in the following disease conditions: cardiovascular disease, Seizure disorders, Psychiatric conditions, and Organ transplantations.	
Unit-V	**Dosage adjustment in Renal and hepatic Disease.**	**12 Hrs**
	Renal impairment b. Pharmacokinetic considerations in renal impairment	

	c. General approach for dosage adjustment in Renal disease. d. Measurement of Glomerular Filtration rate and creatinine clearance. e. Dosage adjustment for uremic patients. f. Extracorporeal removal of drugs. g. Genetic polymorphism in Drug metabolism: Cytochrome P-450 Isoenzymes. h. Effect of Hepatic disease on pharmacokinetics.	

REFERENCES

1. Alfonso Gennaro R (2000). Remington: The Science and Practice of Pharmacy. 16th ed.: Lippincott Williams & Willkins publications.
2. Brahmankar DM, Jaiswal SB (1998). Bio-pharmaceutics and Pharamcokinetics. 2nd ed.: Vallabh Prakashan publications.
3. Gilbaldi Milo (1991). Bio-Pharmaceutics and Clinical Pharmacokinetics. 4th ed.: Lea and Febiger publications.
4. Robert Notari E (1987). Bio-Pharmaceutics and Clinical Pharmacokinetics. 4th ed. : Marcel Dekker Inc publications.
5. John G Wagner (1971). Bio-Pharmaceutics and relevant Pharmacokinetics: Drug Intelligence Publications.
6. Leon Shargel, Andrew Yu, Susanna Wu-Pong (1993). Applied Biopharmaceutics & Pharmacokinetics. 6th ed.: McGraw-Hill publications.
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10. Shargel L, Yu AB (1993). Applied Bio-Pharmaceutics and Pharmacokinetics. 2nd ed.: Appleton & Lange publications .

HOSPITAL PHARMACY
(MCP204T)

Scope:
This course enables students to understand various aspects of hospital pharmacy.

Objectives:
Upon completion of the course, the student shall be able to:

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Understand the hospital drug policy and its significance.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

THEORY **60 Hrs**

Unit-I	**Introduction:**	**12 Hrs**
	The role of hospital pharmacy department and its relationship to other hospital departments and staff.	
Unit -II	**Hospital Drug Policy:**	**12 Hrs**
	a) Pharmacy and therapeutic committee (PTC) b) Hospital Formulary c) e-Medicine	
Unit-III	a)Hospital Committee - Infection committee - Research and ethical committee b) Developing therapeutic guidelines c) Hospital pharmacy communication - Newsletter	**12 Hrs**
Unit-IV	Definition & Scope – Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.	**12 Hrs**
	Measurement of outcomes in pharmacoepidemiology – outcome measure and drug use measures, prevalence, incidence and incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.	
	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 & Record Linkage system	
	Sources of data for pharmacoepidemiology 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	
Unit-V	**Pharmacoeconomics**	**12 Hrs**
	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: Case- minimization, Cost- benefit, Cost-effectiveness, Cost-Utility, Health Insurance - Medical Insurance.	
	Applications of Pharmacoeconomics – Software and case studies	

REFERENCES

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2. Brain Strom L Stephen Kimmel E Sean Hennessy (2011).Pharmacoepidemiology. 4th ed. Wiley Interscience publications.
3. William E Hassan (1986). Hospital Pharmacy. 5th ed. Lec and Febiger Publications.
4. Randy Vogenber F (2000). Introduction to Applied Pharmacoeconomics McGraw-Hill Publications.
5. Graeme S Avery (1980). Drug treatment- principles and practice of clinical pharmacology and therapeutics. 2nd ed. Adis Press publications.
6. Joseph Price Remington (1990). Remington Pharmaceutical sciences. 16th ed. Mack Pub. Co. Publications.
7. Sharon E Straus (2005). Evidence Based Medicine. 3rd ed. Elsevier/Churchill Livingstone Publication.

CLINICAL PRACTICE PRACTICAL- II
(MCP 205P)

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. Neurology& Psychiatry
2. Oncology
3. Infectious Diseases
4. Gynecologic & Obstetric Disorders/ Ophthalmology
5. Nutritional Disorder & Immunology
6. Cardiovascular disorders

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.