Scheme and Syllabus

M. Pharmacy
Pharmacy Practice

Batch 2020 onwards

PTU

ਆਈ. ਕੇ. ਗੁਜਰਾਲ ਪੰਜਾਬ ਟੈਕਨੀਕਲ ਯੂਨੀਵਰਸਿਟੀ

By
Board of Studies Pharmacy
Department of Academics

First Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MPP 101T	Clinical Pharmacy Practice	4	-	25	75	100	4
MPP 102T	Pharmacotherapeutics-I	4	-	25	75	100	4
MPP 103T	Hospital & Community Pharmacy	4	-	25	75	100	4
MPP 104T	Clinical Research	4		25	75	100	4
MPP 105P	Pharmacy Practice Practical I	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	100	-	100	4
	Total	**16**	**19**	**250**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Second Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
MPP201T	Principles of Quality Use of Medicines	4	-	25	75	100	4
MPP202T	Pharmacotherapeutics II	4	-	25	75	100	4
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	-	25	75	100	4
MPP204T	Pharmacoepidemiology& Pharmacoeconomics	4		25	75	100	4
MPP205P	Pharmacy Practice Practical II	-	12	50	100	150	6
-	Seminar/Assignment#	-	7	100	-	100	4
	Total	**16**	**19**	**250**	**400**	**650**	**26**

- # Minimum five seminar/assignment each of 20 marks per semester

Third Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	**External**	**Total**	
MRM301T	Research Methodology & Biostatistics*	4	-	25	75	100	4
-	Journal Club	1	-	25	-	25	1
-	Discussion / Presentation (Proposal Presentation)	2	-	50	-	50	2
-	Research Work*	-	28	-	350	350	14
	Total	**7**	**28**	**100**	**425**	**525**	**21**

- *Non -University Exam

Fourth Semester

Course Code	Course Name	L	P	Marks			Credits
				Internal	External	Total	
-	Journal Club	1	-	25	-	25	1
-	Research Work	-	31	-	400	400	16
-	Discussion/Final Presentation	3	-	75	-	75	3
-	Co-curricular Activities	-	-	Satisfactory/Unsatisfactory			2*
Total		**4**	**31**	**100**	**400**	**500**	**22**

**Note: Required credit points 02 for satisfactory; Less than 02 credit points unsatisfactory*

***Credits not included towards calculation of CGPA**

Semester Wise Credits Distribution

Semester	Credit Points
I	26
II	26
III	21
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations & Other Scholarly Activities)	02*
Total Credit Points	**93 + 2* = 95**

- *Credit Points for Co-curricular Activities
- *Credits not included towards calculation of CGPA
- *The credit points assigned for extracurricular and or co-curricular activities shall be given by the Principals of the colleges and the same shall be submitted to the University

Guidelines for Awarding Credit Points for Co-curricular Activities

Name of the Activity	Maximum Credit Points
Participation in National Level Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student) OR Academic Award/Research Award from State Level/National Agencies	02
Participation in International Level Seminar/ Conference/ Workshop/ Symposium / Training Programs (related to the specialization of the student) #	02
Academic Award/Research Award from International Agencies	02
Research / Review Publication in National Journals (Indexed in Scopus / Web of Science) *	01
Research / Review Publication in International Journals (Indexed in Scopus / Web of Science) *$	02

- # International Conference held even in India will be considered for award of Credit Points.
- *Only those research / review publications will be considered which have been published during the tenure of M. Pharm. Course.
- $ International Journal: The Editorial Board outside India.

Academic Work

The department / teaching staff of respective courses shall maintain a regular record of attendance in Theory, Practical, Seminar, Assignment, Journal Club, and Discussion with the supervisor, Research work presentation and Dissertation.

Program Committee

1. M. Pharm. Programme shall have a Programme Committee constituted by the Head of the Institution in consultation with all the Heads of the departments.
2. The composition of the Programme Committee shall be as follows:
   a. A teacher at the cadre of Professor shall be the Chairperson
   b. One Teacher from each M. Pharm. Specialization
   c. Four student representatives (two from each academic year), nominated by the Head of the Institution
3. Duties of the Programme Committee:
   a. Periodically review the progress of the classes.
   b. Discuss the problems concerning curriculum, syllabus and the conduct of classes.
   c. Discussing with the course teachers on the nature and scope of assessment for the course and the same shall be announced to the students at the beginning of respective semesters.

Sessional Exams

- Two sessional exams shall be conducted for each theory/practical course
- The average marks of two sessional exams shall be computed for internal assessment
- Sessional exam shall be **conducted for 30 marks** for theory and shall be **computed for 15 marks**.
- Sessional exam for practical shall be **conducted for 40 marks** and shall be **computed for 30 marks**.

Question Paper Pattern for Theory Sessional Examinations

Multiple Choice Questions (MCQs) **OR** Objective Type Questions (5 x 2) (Answer all the questions)	10 x 1 = 10 **OR** 05 x 2 = 10
Short Answers (Answer 2 out of 3)	2 x 5 = 10
Long Answers (Answer 1 out of 2)	1 x 10 = 10
Total	**30 Marks**

Question Paper Pattern for Practical Sessional Examinations

Synopsis	10
Experiments	25
Viva voce	05
Total	**40 Marks**

Internal Assessment

- The internal assessment will have two components i.e. **Continuous Mode** and **Sessional Exams**

1. For Theory Courses having Internal of 25 Marks the scheme of internal award is:
    - Sessional Exams: 15 Marks
    - Continuous Mode: 10 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	08
Student – Teacher interaction	02
Total	**10**

2. For Practical Courses having Internal of 50 Marks the scheme of internal award is:
    - Sessional Exams: 30 Marks
    - Continuous Mode: 20 Marks

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	10
Based on Practical Records, Regular viva voce, etc.	10
Total	**20**

***Guidelines for the Allotment of Marks for Attendance**

Percentage of Attendance	Theory (Maximum Marks 08)	Practical (Maximum Marks 10)
95 – 100	08	10
90 – 94	06	7.5
85 – 89	04	5
80 – 84	02	2.5
Less than 80	0	0

1st SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPP101T	Clinical Pharmacy Practice	4	-	25	75	1	3	4

Scope: This course is designed to impart the basic knowledge and skills that are required to practice pharmacy including the provision of pharmaceutical care services to both healthcare professionals and patients in clinical settings.

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

1. Understand the elements of pharmaceutical care and provide comprehensive patient care services.
2. Interpret the laboratory results to aid the clinical diagnosis of various disorders.
3. Provide integrated, critically analysed medicine and poison information to enable healthcare professionals in the efficient patient management.

Module 01 **12 Hours**

Introduction to Clinical Pharmacy

- Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care

Module 02 **12 Hours**

Clinical Pharmacy Services

- Patient medication history interview
- Basic concept of medicine and poison information services
- Basic concept of pharmacovigilance, hemovigilance, materiovigilance and AEFI
- Patient medication counselling
- Drug utilisation evaluation
- Documentation of clinical pharmacy services
- Quality assurance of clinical pharmacy services

Module 03 **12 Hours**

Patient Data Analysis

- Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services
- Lab Data Interpretation: Hematological tests, Renal function tests, Liver function test

Module 04 **12Hours**

Lab Data Interpretation

- Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests

Module 05 **12Hours**

Medicines & Poison Information Services

- Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre.
- Poison Information Service: Definition, need, organization and functions of poison information centre

Recommended Books (Latest editions)

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata
2. Practice Standards and Definitions - The Society of Hospital Pharmacists of Australia
3. Basic skills in interpreting laboratory data - Scott LT, American Society of Health System Pharmacists Inc
4. Relevant review articles from recent medical and pharmaceutical literature.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPP102T	Pharmacotherapeutics-I	4	-	25	75	1	3	4

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, student shall be able to:

1. Describe and explain the rationale for drug therapy
2. Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence
3. Discuss the clinical controversies in drug therapy and evidence-based medicine
4. Prepare individualized therapeutic plans based on diagnosis
5. 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 effect/s)

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

Module 01 **12Hours**

Cardiovascular System

- Hypertension
- Congestive cardiac failure
- Acute coronary syndrome
- Arrhythmias
- Hyperlipidemias

Module 02 **12Hours**

Respiratory System

- Asthma
- Chronic obstructive airways disease
- Drug induced pulmonary diseases

Endocrine System

- Diabetes
- Thyroid diseases

Module 03 **16 Hours**

Gastrointestinal System

- Peptic ulcer diseases
- Reflux esophagitis
- Inflammatory bowel diseases
- Jaundice & hepatitis
- Cirrhosis
- Diarrhoea and constipation
- Drug-induced liver disease

Module 04 **12Hours**

Hematological Diseases

- Anemia
- Deep vein thrombosis
- Drug induced hematological disorders

Bone and joint disorders

- Rheumatoid arthritis
- Osteoarthritis
- Gout
- Osteoporosis

Module 05 **08Hours**

Dermatological Diseases

- Psoriasis
- Eczema and scabies
- Impetigo
- Drug induced skin disorders

Ophthalmology

- Conjunctivitis
- Glaucoma

Recommended Books (Latest editions)

1. Roger and Walker. Clinical Pharmacy and Therapeutics - Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange.
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication.
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication.

5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins.
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication.
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPP103T	Hospital & Community Pharmacy	4	-	25	75	1	3	4

Scope: This course is designed to impart basic knowledge and skills that are required to practice pharmacy in both hospital and community settings.

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

1. Understand the organizational structure of hospital pharmacy.
2. Understand drug policy and drug committees.
3. Know about procurement & drug distribution practices.
4. Know the admixtures of radiopharmaceuticals.
5. Understand the community pharmacy management.
6. Know about value added services in community pharmacies.

Module 01 **12 Hours**

Introduction to Hospitals

- Definition
- Classification
- Organizational structure

Hospital Pharmacy

- Definition
- Relationship of hospital pharmacy department with other departments
- Organizational structure
- Legal requirements
- Work load statistics
- Infrastructural requirements
- Hospital Pharmacy Budget
- Hospital Pharmacy management

Hospital Drug Policy

- Pharmacy & Therapeutics Committee
- Infection Control Committee
- Research & Ethics Committee
- Management of Medicines as per NABH

Module 02 **12 Hours**

- Hospital Formulary Guidelines and its development
- Developing Therapeutic guidelines
- Drug procurement process, and methods of Inventory control
- Methods of drug distribution

- Intravenous admixtures
- Hospital Waste Management

Module 03 **12Hours**

Education and training

- Training of technical staff
- Training and continuing education for pharmacists, pharmacy students, medical staff and students, nursing staff and students
- Formal and informal meetings and lectures
- Drug and therapeutics newsletter

Community Pharmacy Practice

- Definition
- Roles & responsibilities of community pharmacists, and their relationship with other health care providers

Community Pharmacy management

- Definition
- Roles & responsibilities of community pharmacists, and their relationship with other health care providers
- Community Pharmacy management
- Legal requirements to start community pharmacy
- Site selection, lay out & design, drug display, super drug store model, accounts and audits,
- Good dispensing practices
- Different software & databases used in community pharmacies
- Entrepreneurship in community pharmacy

Module 04 **12Hours**

Prescription

- Legal requirements & interpretation, prescription related problems

Responding to symptoms of minor ailments

- Head ache, pyrexia, menstrual pains, food and drug allergy
- OTC medication
- Rational use of over the counter medications
- Medication counselling and use of patient information leaflets
- Medication adherence – definition, factors influencing adherence behaviour, strategies to improve medication adherence
- Patient referrals to the doctors
- ADR monitoring in community pharmacies

Module 05 **12Hours**

Health Promotion

- Definition and health promotion activities, family planning
- Health screening services
- First aid
- Prevention of communicable and non-communicable diseases
- Smoking cessation
- Child & mother care

National Health Programs

- Role of community pharmacist in malaria and TB control programs

Home Medicines review program

- Definition, objectives, Guidelines, method and outcomes

Research in community pharmacy Practice

Recommended Books (Latest editions)

1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
2. Textbook of hospital pharmacy - Allwood MC and Blackwell.
3. Avery's Drug Treatment, Adis International Limited.
4. Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad.
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPP104T	Clinical Research	4	-	25	75	1	3	4

Scope: This course aims to provide the students an opportunity to learn drug development process especially the phases of clinical trials and also the ethical issues involved in the conduct of clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing, conducting and managing clinical trials.

Objectives: Upon completion of the course, it is expected that the students will be able to

1. Know the new drug development process.
2. Understand the regulatory and ethical requirements.
3. Appreciate and conduct the clinical trials activities.
4. Know safety monitoring and reporting in clinical trials.
5. Manage the trial coordination process.

Module 01 **12 Hours**

Drug development process

- Introduction, various approaches to drug discovery
- Investigational new drug application submission

Ethics in Biomedical Research

- Ethical Issues in Biomedical Research
- Principles of ethics in biomedical research
- Ethical committee [institutional review board] - its constitution and functions
- Challenges in implementation of ethical guidelines

ICH GCP guidelines
ICMR guidelines in conduct of Clinical trials
Drug Safety Reporting

Module 02 **12Hours**

Types and Designs used in Clinical Research

- Planning and execution of clinical trials
- Various Phases of clinical trials
- Bioavailability and Bioequivalence studies
- Randomization techniques (simple randomization, restricted randomization, blocking method and stratification)
- Types of research designs based on controlling method (experimental, quasi experimental, and observational methods)
- Time Sequences (prospective and retrospective)
- Sampling methods (cohort study, case control study and cross-sectional study)

- Health outcome measures (clinical & physiological, humanistic and economic)

Clinical Trial Study team

- Roles and responsibilities of: investigator, study coordinator, sponsor, monitor, contract research organization (CRO).

Module 03 **12Hours**

Clinical trial documents

- Guidelines to the preparation of following documents: protocols, investigator's brochure, informed consent form, case report forms, contracts and agreements, dairy cards

Clinical Trial Start up activities

- Site Feasibility Studies
- Site/Investigator selection
- Pre-study visit
- Investigator meeting
- Clinical trial agreement execution
- Ethics committee document preparation and submission

Module 04 **12Hours**

Investigational product

- Procurement and Storage of investigation product

Filing procedures

- Essential documents for clinical trial
- Trial master file preparation and maintenance
- Investigator site file
- Pharmacy file
- Site initiation visit
- Conduct, Report and follow up

Preparation and conduct of monitoring visit

- Review of source documents, CRF, ICF, IP storage
- Accountability and reconciliation
- Study Procedure
- EC communications
- Safety reporting
- Monitoring visit reporting and follow-up

Close-out visit

- Study related documents collection
- Archival requirement
- Investigational product reconciliation and destruction
- Close-Out visit report

Module 05 **12 Hours**

Quality Assurance and Quality Control in Clinical Trials

- Types of audits
- Audit criteria
- Audit process
- Responsibilities of stakeholders in audit process
- Audit follow-up and documentation
- Audit resolution and preparing for FDA inspections
- Fraud and misconduct management

Data Management Infrastructure and System Requirement for Data Management

- Electronic data capture systems
- Selection and implementation of new systems
- System validation and test procedures
- Coding dictionaries
- Data migration and archival

Clinical Trial Data Management

- Standard Operating Procedures
- Data management plan
- CRF & Data base design considerations
- Study set-up, Data entry, CRF tracking and corrections, Data cleaning
- Managing laboratory and ADR data
- Data transfer and database lock
- Quality Control and Quality Assurance in CDM
- Data mining and warehousing

Recommended Books (Latest editions)

1. Principles and practice of pharmaceutical medicine. Authors: Lionel. D. Edward, Aadrew. J. Flether Anthony W Fos , Peter D Sloaier Publisher: Wiley.
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone.
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.

8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs, Wiley Publications.
9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.
10. Relevant review articles from recent medical and pharmaceutical literature.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPP105P	Pharmacy Practice Practical – I	-	12	50	100	6	6	6

1. Treatment Chart Review (one)
2. Medication History Interview (one)
3. Patient Medication Counseling (two)
4. Drug Information Query (two)
5. Poison Information Query (one)
6. Lab Data Interpretation (two)
7. Presentation of clinical cases of various disease conditions adopting pharmaceutical care plan model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)

2nd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPP201T	Principles of Quality Use of Medicines	4	-	25	75	1	3	4

Scope: This course is designed to impart basic knowledge and skills that are required to practice quality use of medicines (QUM) in different healthcare settings and also to promote quality use of medicines, in clinical practice, through evidence-based medicine approach.

Objectives: Upon completion of this course students will be able to

1. Understand the principles of quality use of medicines.
2. Know the benefits and risks associated with use of medicines.
3. Understand regulatory aspects of quality use of medicines.
4. Identify and resolve medication related problems.
5. Promote quality use of medicines.
6. Practice evidence-based medicines.

Module 01 **12 Hours**

Introduction to Quality use of medicines (QUM)

- Definition and Principles of QUM
- Key partners and responsibilities of the partners
- Building blocks in QMC
- Evaluation process in QMC
- Communication in QUM
- Cost effective prescribing

Module 02 **12 Hours**

Evidence based medicine

- Definition, concept of evidence-based medicine
- Approach and practice of evidence-based medicine in clinical settings

Essential drugs

- Definition, need, concept of essential drug
- National essential drug policy and list

Rational drug use

- Definition, concept and need for rational drug use
- Rational drug prescribing, Role of pharmacist in rational drug use

Module 03 **12 Hours**

QUM in various settings

- Hospital settings, ambulatory care/residential care
- Role of health care professionals in promoting the QUM
- Strategies to promote the QUM
- Impact of QUM on E-health, integrative medicine and multidisciplinary care

QUM in special population

- Paediatric prescribing
- Geriatric prescribing
- Prescribing in pregnancy and lactation
- Prescribing in immune compromised and organ failure patients

Module 04 **12 Hours**

Regulatory aspects of QUM in India

- Regulation including scheduling
- Regulation of complementary medicines
- Regulation of OTC medicines
- Professional responsibility of pharmacist
- Role of industry in QUM in medicine development

Module 05 **12 Hours**

Medication errors

- Definition, categorization and causes of medication errors
- Detection and prevention of medication errors
- Role of pharmacist in monitoring and management of medication errors

Pharmacovigilance

- Definition, aims and need for pharmacovigilance
- Types, predisposing factors and mechanism of adverse drug reactions (ADRs)
- Detection, reporting and monitoring of ADRs
- Causality assessment of ADRs
- Management of ADRs
- Role of pharmacist in pharmacovigilance

Recommended Books (Latest editions)

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – Parthasarathi G, Karin Nyfort-Hansen and Milap Nahata.
2. Andrews EB, Moore N. Mann's Pharmacovigilance.
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach.

4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it.
5. Cohen MR. Medication Errors.
6. http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
7. http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
8. http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
9. Relevant review articles from recent medical and pharmaceutical literature

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPP202T	Pharmacotherapeutics II	4	-	25	75	1	3	4

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, student shall be able to

1. Describe and explain the rationale for drug therapy.
2. Summarize the therapeutic approach for management of various disease conditions including reference to the latest available evidence.
3. Discuss the clinical controversies in drug therapy and evidence-based medicine.
4. Prepare individualized therapeutic plans based on diagnosis.
5. 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 effect/s).

Module 01 **12 Hours**

Nervous system

- Epilepsy
- Parkinson's disease
- Stroke
- Headache
- Alzheimer’s disease
- Neuralgias and Pain pathways and Pain management

Module 02 **12 Hours**

Psychiatric disorders

- Schizophrenia
- Depression
- Anxiety disorders
- Sleep disorders
- Drug induced psychiatric disorders

Renal system

- Acute renal failure
- Chronic renal failure
- Renal dialysis
- Drug induced renal disease

Module 03 **12 Hours**

Infectious diseases

- General guidelines for the rational use of antibiotics and surgical prophylaxis
- Urinary tract infections
- Respiratory tract infections
- Gastroenteritis
- Tuberculosis
- Malaria
- Bacterial endocarditis
- Septicemia

Module 04 **12 Hours**

Infectious diseases

- Meningitis
- HIV and opportunistic infections
- Rheumatic fever
- Dengue fever
- H1N1
- Helmenthiasis
- Fungal infections

Gynecological disorders

- Dysmenorrhea
- Hormone replacement therapy

Module 05 **12 Hours**

Oncology

- General principles of cancer chemotherapy
- Pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies
- Management of nausea and vomiting
- Palliative care

Recommended Books (Latest editions)

1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication.
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange.
3. Robins SL. Pathologic basis of disease -W.B. Saunders publication.
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication.

5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins.
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-– McGraw Hill Publication.
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins.
8. Harrison's. Principles of Internal Medicine - McGraw Hill.
9. Relevant review articles from recent medical and pharmaceutical literature.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPP203T	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	-	25	75	1	3	4

Scope: This course is designed to enable students to understand the basics principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen. Also, it enables students to understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulation of pharmacokinetic data.

Objectives: Upon completion of this course, students will be able to

1. Design the drug dosage regimen for individual patients.
2. Interpret and correlate the plasma drug concentrations with patients' therapeutic outcomes.
3. Recommend dosage adjustment for patients with renal/ hepatic impairment.
4. Recommend dosage adjustment for paediatrics and geriatrics.
5. Manage pharmacokinetic drug interactions.
6. Apply pharmacokinetic parameters in clinical settings.
7. Interpret the impact of genetic polymorphisms of individuals on pharmacokinetics and or pharmacodynamics of drugs.
8. Do pharmacokinetic modelling for the given data using the principles of pharmacometrics.

Module 01 **12 Hours**

Introduction to Clinical pharmacokinetics

- Compartmental and Non compartmental models
- Renal and non-renal clearance
- Organ extraction and models of hepatic clearance
- Estimation and determinants of bioavailability
- Multiple dosing
- Calculation of loading and maintenance doses

Designing of dosage regimens

- Determination of dose and dosing intervals
- Conversion from intravenous to oral dosing
- Nomograms and Tabulations in designing dosage regimen

Module 02 **12 Hours**

Pharmacokinetics of Drug Interaction

- Pharmacokinetic drug interactions
- Inhibition and Induction of Drug metabolism
- Inhibition of Biliary Excretion

Pharmacogenetics: Genetic polymorphism in Drug metabolism

- Cytochrome P-450 Isoenzymes
- Genetic Polymorphism in Drug Transport and Drug Targets
- Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerations

Introduction to Pharmacometrics

- Introduction to Bayesian Theory
- Adaptive method or Dosing with feedback
- Analysis of Population pharmacokinetic Data

Module 03 **12 Hours**

Non-Linier Mixed Effects Modelling

- The Structural or Base Model
- Modeling Random Effects
- Modeling Covariate Relationships
- Mixture Model
- Estimation Methods
- Model Building Techniques
- Covariate Screening Methods
- Testing the model assumptions
- Precision of the parameter estimates and confidence intervals
- Model misspecification and violation of the model assumptions
- Model Validation
- Simulation of dosing regimens and dosing recommendations
- Pharmacometrics software

Module 04 **12 Hours**

Altered Pharmacokinetics

- Drug dosing in the elderly
- Drug dosing in the paediatrics
- Drug dosing in the obese patients
- Drug dosing in the pregnancy and lactation
- Drug dosing in the renal failure and extracorporeal removal of drugs
- Drug dosing in the in hepatic failure

Module 05 **12 Hours**

Therapeutic Drug monitoring

- Introduction
- Individualization of drug dosage regimen (variability – genetic, age, weight, disease and Interacting drugs)
- Indications for TDM
- Protocol for TDM
- Pharmacokinetic/Pharmacodynamic Correlation in drug therapy

TDM of drugs used in the following conditions

- Cardiovascular disease: Digoxin, Lidocaine, Amiodarone
- Seizure disorders: Phenytoin, Carbamazepine, Sodium Valproate
- Psychiatric conditions: Lithium, Fluoxetine, Amitriptyline
- Organ transplantations: Cyclosporine
- Cytotoxic Agents: Methotrexate, 5-FU, Cisplatin
- Antibiotics: Vancomycin, Gentamicin, Meropenem

Recommended Books (Latest editions)

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. Lippincott 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. 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.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists, USA.
9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams & Wilkins, USA.
10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. Pharma Book Syndicate, USA.
11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press, London.

12. John E. Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health- System Pharmacist, USA.
13. Relevant review articles from recent medical and pharmaceutical literature.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MPP204T	Pharmacoepidemiology & Pharmacoeconomics	4	-	25	75	1	3	4

Scope: This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

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

1. Understand the various epidemiological methods and their applications.
2. Understand the fundamental principles of Pharmacoeconomics.
3. Identify and determine relevant cost and consequences associated with pharmacy products and services.
4. Perform the key Pharmacoeconomics analysis methods.
5. Understand the Pharmacoeconomic decision analysis methods and its applications.
6. Describe current Pharmacoeconomic methods and issues.
7. Understand the applications of Pharmacoeconomics to various pharmacy settings.

Module 01 **12 Hours**

Introduction to Pharmacoepidemiology

- Definition, Scope, Need, Aims & Applications
- Outcome measurement: Outcome measures
- Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses
- Diagnosis and Therapy surveys
- Prevalence, Incidence rate
- Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements
- Concept of risk: Measurement of risk, Attributable risk and relative risk, Time- risk relationship and odds ratio

Module 02 **12 Hours**

Pharmacoepidemiological Methods

- Qualitative models: Drug Utilization Review
- Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds' ratio, Meta-analysis models
- Drug effects study in populations: Spontaneous reporting, Prescription event

Module 03 **12 Hours**

Introduction to Pharmacoeconomics

- Definition, history of Pharmacoeconomics
- Need of Pharmacoeconomic studies in Indian healthcare system

Cost categorization and resources for cost estimation

- Direct costs
- Indirect costs
- Intangible costs

Outcomes and Measurements of Pharmacoeconomics

- Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes
- Quality Adjusted Life Years, Disability Adjusted Life Years Incremental Cost-Effective Ratio
- Average Cost-Effective Ratio
- Person Time, Willingness to Pay, Time Trade Off and Discounting

Module 04 **12 Hours**

Pharmacoeconomic Evaluations

- Definition, Steps involved, Applications, Advantages and disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI), Cost Consequences Analysis (COA)

Module 05 **12 Hours**

Definition, Steps involved, Applications, Advantages and disadvantages of the following

- Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, Common HRQOL measures.
- Definition, Steps involved, Applications of the following: Decision Analysis and Decision tree, Sensitivity analysis, Markov Modelling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics

Recommended Books (Latest editions)

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
5. Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.

6. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.
7. Graker, Dennis. Pharmacoeconomics and outcomes. Walley, Pharmacoeconomics.
8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature.

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MIP205P	Pharmacy Practice Practical - II	-	12	50	100	6	6	6

Pharmacy Practice practical component includes experiments covering important topics of the courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

1. Causality assessment of adverse drug reactions (three)
2. Detection and management of medication errors (three)
3. Rational use of medicines in special population (three)
4. Presentation of clinical cases of various disease conditions adopting
5. Pharmaceutical Care Plan Model (eight)
6. Calculation of Bioavailability and Bioequivalence from the given data (two)
7. Interpretation of Therapeutic Drug Monitoring reports of a given patient (three)
8. Calculation of various Pharmacoeconomic outcome analysis for the given data (two)

3rd SEMESTER

Course Code	Course Title	Teaching Load		Marks		Exam (hrs)		Credits
		L	P	Int.	Ext.	Int.	Ext.	
MRM301T	Research Methodology & Biostatistics	4	-	25	75	1	3	4

Module 01 **12 Hours**

General Research Methodology

- Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques

Module 02 **12 Hours**

Biostatistics

- Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values

Module 03 **12 Hours**

Medical Research

- History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality

Module 04 **12 Hours**

CPCSEA Guidelines for Laboratory Animal Facility

- Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals

Module 05 **12 Hours**

Declaration of Helsinki

- History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care

Recommended Books (Latest editions)

1. Basic & Clinical Biostatistics, Beth Dawson and Robert G. Trapp. Lange Medical Books/McGraw-Hill Medical Publishing Division.
2. Research Methdology, R. Panneerselvam, PHI Learning Pvt. Limited, Delhi.
3. Methods in Biostatistics, B.K. Mahajan. JAYPEE Brothers Medical Publishers (P) Ltd.
4. CPCSEA Guidelines.
   A Handbook of Applied Statistics in Pharmacology, Katsumi Kobayashi and K. Sadasivan Pillai. CRC Press, Taylor & Francis Group.