# List of M Pharm( Pharmacy practice) courses relevant to Gender, Human Values, Environment and Sustainability and Professional Ethics

- Gender Issues
- Human Values
- Environment And Sustainability
- Professional Ethics

**1.3.1. QLM INSTITUTION INTEGRATES CROSSCUTTING ISSUES RELEVANT TO PROFESSIONAL ETHICS, GENDER, HUMAN VALUES, ENVIRONMENT AND SUSTAINABILITY IN TRANSACTING THE CURRICULUM.**

# KERALA UNIVERSITY OF HEALTH SCIENCES
## Thrissur - 680596

# SYLLABUS

## POST GRADUATE COURSE IN PHARMACY
### Master of Pharmacy (M.Pharm.)

| PHARMACY PRACTICE | MPP |
|---|---|
| KUHS Course Code | 281 |

(2019-20 Academic year onwards)

**2019**


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**Table – 2: Course of study for M.Pharm. I & II Semester**

| Course Code | Course | Credit Hours | Credit Points | Hrs./wk | Marks |
|---|---|---|---|---|---|
| **Semester I** | | | | | |
| MPP101T | Clinical Pharmacy Practice | 4 | 4 | 4 | 100 |
| MPP102T | Pharmacotherapeutics – I | 4 | 4 | 4 | 100 |
| MPP103T | Hospital & Community Pharmacy | 4 | 4 | 4 | 100 |
| MPP104T | Clinical Research | 4 | 4 | 4 | 100 |
| MPP105P | Pharmacy Practice Practical – I | 12 | 6 | 12 | 150 |
| - | Seminar /Assignment | 7 | 4 | 7 | 100 |
| **Total** | | **35** | **26** | **35** | **650** |
| **Semester II** | | | | | |
| MPP201T | Principles of Quality use of Medicines | 4 | 4 | 4 | 100 |
| MPP202T | Pharmacotherapeutics II | 4 | 4 | 4 | 100 |
| MPP203T | Clinical Pharmacokinetics and therapeutic Drug Monitoring | 4 | 4 | 4 | 100 |
| MPP204T | Pharmacoepidemiology& Pharmacoeconomics | 4 | 4 | 4 | 100 |
| MPP205P | Pharmacy Practice Practical II | 12 | 6 | 12 | 150 |
| - | Seminar /Assignment | 7 | 4 | 7 | 100 |
| **Total** | | **35** | **26** | **35** | **650** |

**Course of study for M. Pharm. III & IV Semester**

| Course Code | Course | Credit Hours | Credit Points | Marks |
|---|---|---|---|---|
| **Semester III** | | | | |
| MRM 301T | Research Methodology and Biostatistics | 4 | 4 | 100 |
| - | Journal Club | 1 | 1 | 25 |
| - | Discussion / Presentation(proposal presentation) | 2 | 2 | 25 |
| - | Research Work | 28 | 14 | 350 |
| **Total** | | **35** | **21** | **500** |
| **Semester IV** | | | | |
| - | Journal Club | 1 | 1 | 25 |
| - | Presubmission Discussion / Presentation | 3 | 3 | 75 |
| - | Research Work | 31 | 16 | 400 |
| **Total** | | **35** | **20** | **500** |

## CLINICAL PHARMACY PRACTICE (MPP 101T)

**Scope**

Thiscourseisdesignedtoimpartthebasicknowledgeandskillsthatarerequiredtopractice pharmacy including the provision of pharmaceutical care services to both healthcare professionalsandpatientsinclinicalsettings.

**Objectives**

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

- Understand the elements of pharmaceutical care and provide comprehensive patient careservices
- Interpretthelaboratoryresultstoaidtheclinicaldiagnosisofvariousdisorders
- Provideintegrated,criticallyanalyzedmedicineandpoisoninformationtoenable healthcareprofessionalsintheefficientpatientmanagement

**THEORY** **60Hrs**

1. IntroductiontoClinicalPharmacy:Definition,evolutionandscopeofclinical pharmacy, International and national scenario of clinical pharmacy practice, Pharmaceutical care 12Hrs
   Clinical Pharmacy Services: Ward round participation, Drug therapy review (Drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions)

2. ClinicalPharmacyServices:Patientmedicationhistoryinterview,Basicconcept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medicationcounselling,Drugutilisationevaluation,Documentationofclinical pharmacyservices,Qualityassuranceofclinicalpharmacyservices. 12Hrs

3. Patient Data Analysis: 12Hrs
   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 andnon-Verbal communications, its applications in patient care services.
   Lab Data Interpretation: Hematological tests, Renal function tests
   Liver function tests
4. Lab Data Interpretation: Tests associated with cardiac disorders, Pulmonary function tests, Thyroid function tests, Fluid and electrolyte balance, Microbiological culture sensitivity tests 12Hrs

5. Medicines & Poison Information ServicesMedicine 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. 12Hrs

PoisonInformationService:Definition,need,organizationandfunctionsof poison informationcentre.

**REFERENCES**


1. ATextbookofClinicalPharmacyPractice–Essentialconceptsandskills–Parthasarathi G,KarinNyfort-HansenandMilapNahata
2. PracticeStandardsandDefinitions-TheSocietyofHospitalPharmacistsofAustralia
3. Basicskillsininterpretinglaboratorydata-ScottLT,AmericanSocietyofHealth System PharmacistsInc
4. Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature.


## PHARMACOTHERAPEUTICS-I (MPP 102T)

**Scope**

Thiscourseaimstoenablethestudentstounderstandthedifferenttreatmentapproachesin managingvariousdiseaseconditions.Also,itimpartsknowledgeandskillsinoptimizingdrug therapyofapatientbyindividualizingthetreatmentplanthroughevidence-basedmedicines.

**Objectives**

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

- Describeandexplaintherationalefordrugtherapy
- Summarize the therapeutic approach for management of various disease conditions includingreferencetothelatestavailableevidence
- Discusstheclinicalcontroversiesindrugtherapyandevidencebasedmedicine
- Prepareindividualizedtherapeuticplansbasedondiagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoringtherapy(includingalternatives,time-courseofclinicalandlaboratory

indicesoftherapeuticresponseandadverseeffect/s)

**THEORY** **60Hrs**

Etiopathogenesis and pharmacotherapy of diseases associated with following systems

| | | |
|---|---|---|
| 1. | Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias. | 12Hrs |
| 2. | Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases<br>Endocrine system: Diabetes, Thyroid diseases | 12Hrs |
| 3. | Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis | 12Hrs |
| 4. | Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease<br>Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders | 12Hrs |
| 5. | Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis<br>Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders<br>Ophthalmology: Conjunctivitis, Glaucoma | 12Hrs |

**REFERENCES**


1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
2. Joseph T. Dipiro et al. Pharmacotherapy: A Pathophysiologic Approach- Appleton & Lange
3. RobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication
4. EricT.Herfindal.ClinicalPharmacyandTherapeutics-WilliamsandWilkinsPublication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs-LippincottWilliamsandWilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. PharmacotherapyPrinciplesandpractice-–McGrawHillPublication
7. CarolMattsonPorth.PrinciplesofPathophysiology-LippincottWilliamsandWilkins
8. Harrison's.PrinciplesofInternalMedicine-McGrawHill
9. Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

## HOSPITAL & COMMUNITY PHARMACY (MPP 103T)

**Scope**

Thiscourseisdesignedtoimpartbasicknowledgeandskillsthatarerequiredtopractice pharmacyinbothhospitalandcommunitysettings.

**Objectives**

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

- Understandtheorganizationalstructureofhospitalpharmacy
- Understanddrugpolicyanddrugcommittees
- Knowaboutprocurement&drugdistributionpractices
- Knowtheadmixturesofradiopharmaceuticals
- Understandthecommunitypharmacymanagement
- Knowaboutvalueaddedservicesincommunitypharmacies

**THEORY** **60Hrs**

1. Introduction to Hospitals – Definition, classification, organizational structure HospitalPharmacy:Definition,Relationshipofhospitalpharmacydepartment with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacymanagement — 12Hrs

   Hospital Drug Policy: Pharmacy & Therapeutics Committee, Infection Control committee, Research & Ethics Committee, Management of Medicines as per NABH

2. Hospital Formulary Guidelines and its development, Developing Therapeutic guidelines,Drugprocurementprocess,andmethodsofInventorycontrol, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management — 12Hrs

3. Educationandtraining:Trainingoftechnicalstaff,trainingandcontinuing education for pharmacists, Pharmacy students, Medical staff and students, Nursingstaffandstudents,Formalandinformalmeetingsandlectures,Drugand therapeuticsnewsletter. — 12Hrs

   CommunityPharmacyPractice:Definition,roles&responsibilitiesofcommunity

pharmacists, and their relationship with other health care providers.

Community Pharmacy management: Legal requirements to start community pharmacy,siteselection,layout&design,drugdisplay,superdrugstoremodel, accounts and audits, Good dispensing practices, Different softwares& databases usedincommunitypharmacies.Entrepreneurshipincommunitypharmacy.

4. Prescription – Legal requirements & interpretation, prescription related problems 12Hrs

Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy,
OTCmedication:RationaluseofoverthecountermedicationsMedication counselinganduseofpatientinformationleafletsMedicationadherence– Definition, factors influencing adherence behavior, strategies to improve medicationadherencePatientreferralstothedoctors

ADR monitoring in community pharmacies

5. HealthPromotion–Definitionandhealthpromotionactivities,familyplanning, Healthscreeningservices,firstaid,preventionofcommunicableandnon-communicablediseases,smokingcessation,Child&mothercare 12Hrs

NationalHealthPrograms-RoleofCommunityPharmacistinMalariaandTB controlprograms
Home Medicines review program – Definition, objectives, Guidelines, method and outcomes
Research in community pharmacy Practice

**REFERENCES**


1. HospitalPharmacy-HassanWE.LeaandFebigerpublication.
2. Textbookofhospitalpharmacy-AllwoodMCandBlackwell.
3. Avery'sDrugTreatment,AdisInternationalLimited.
4. CommunityPharmacyPractice–RameshAdepu,BSPPublishers,Hyderabad
5. Remington PharmaceuticalSciences.
6. Relevant review articles from recent medical and pharmaceuticalliterature

## CLINICAL RESEARCH (MPP 104T)

**Scope**

Thiscourseaimstoprovidethestudentsanopportunitytolearndrugdevelopmentprocess especiallythephasesofclinicaltrialsandalsotheethicalissuesinvolvedintheconductof clinical research. Also, it aims to imparts knowledge and develop skills on conceptualizing, designing,conductingandmanagingclinicaltrials.

**Objectives**

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

- Knowthenewdrugdevelopmentprocess.
- Understandtheregulatoryandethicalrequirements.
- Appreciateandconducttheclinicaltrialsactivities
- Knowsafetymonitoringandreportinginclinicaltrials
- Managethetrialcoordinationprocess

**THEORY** **60Hrs**

1. Drugdevelopmentprocess:Introduction,variousapproachestodrugdiscovery, 12Hrs InvestigationalnewdrugapplicationsubmissionEthicsinBiomedicalResearch: 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 and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.

2. TypesandDesignsusedinClinicalResearch:Planningandexecutionofclinical trials, 12Hrs 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)TimeSequences(ProspectiveandRetrospective),Samplingmethods (Cohortstudy,caseControlstudyandcrosssectionalstudy),Healthoutcome measures

   (Clinical & Physiological, Humanistic and economic)

   Clinical Trial Study team: Roles and responsibilities of:Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.

3. ClinicaltrialDocuments:Guidelinestothepreparationoffollowingdocuments: Protocols,Investigator'sBrochure,InformedConsentForm,Casereportforms, Contractsandagreements,DairyCards — 12Hrs

   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

4. InvestigationalProduct:ProcurementandStorageofinvestigationproduct — 12Hrs

   Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit,Conduct,ReportandFollowupClinicalTrialMonitoringandCloseout:

   Preparationandconductofmonitoringvisit:Reviewofsourcedocuments,CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications,Safetyreporting,Monitoringvisitreportingandfollow-up

   Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.

5. QualityAssuranceandQualityControlinClinicalTrials:Typesofaudits,Audit criteria,Auditprocess,Responsibilitiesofstakeholdersinauditprocess,Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections,Fraudandmisconductmanagement — 12Hrs

   Data Management

   InfrastructureandSystemRequirementforDataManagement:Electronicdata capture systems, Selection and implementation of new systems, System validationandtestprocedures,Codingdictionaries,Datamigrationandarchival

   Clinical Trial Data Management: Standard Operating Procedures, Data managementplan,CRF&Databasedesignconsiderations,Studyset-up,Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADRdata,Datatransferanddatabaselock,QualityControlandQuality Assurance in CDM, Data mining and warehousing.

**REFERENCES**


1. Principlesandpracticeofpharmaceuticalmedicine,Secondedition.Authors:Lionel.D. Edward,Aadrew.J.FletherAnthonyWFos,PeterDSloaierPublisher:Wiley;
2. Handbookofclinicalresearch.JuliaLloydandAnnRavenEd.ChurchillLivingstone
3. PrinciplesofClinicalResearcheditedbyGiovannadiIgnazio,DiGiovannaandHaynes.

4. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines for ClinicalTrialsonPharmaceuticalProductsinIndia.NewDelhi:MinistryofHealth.
5. InternationalConferenceonHarmonisationofTechnicalrequirementsforregistrationof Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for GoodClinicalPractice.E6;May1996.
6. EthicalGuidelinesforBiomedicalResearchonHumanSubjects.IndianCouncilof MedicalResearch,NewDelhi.
7. TextbookofClinicalTrialseditedbyDavidMachin,SimonDayandSylvanGreen,John Wiley andSons.
8. ClinicalDataManagementeditedbyRKRondels,SAVarley,CFWebbs.SecondEdition, Jan 2000, WileyPublications.
9. Goodman&Gilman:JGHardman,LELimbard,McGrawHillPublications.10.Relevant reviewarticlesfromrecentmedicalandpharmaceuticalliterature.

## PHARMACY PRACTICE PRACTICAL – I (MPP 105P)

PharmacyPracticepracticalcomponentincludesexperimentscoveringimportanttopicsofthe coursesClinicalPharmacyPractice,Pharmacotherapeutics-I,Hospital&CommunityPharmacy and ClinicalResearch.

List of Experiments (24)

1. Treatment Chart Review(one)
2. MedicationHistoryInterview(one)
3. PatientMedicationCounseling(two)
4. DrugInformationQuery(two)
5. PoisonInformationQuery(one)
6. Lab Data Interpretation(two)
7. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model(eight)
8. ABCAnalysisofagivenlistofmedications(one)
9. Preparationofcontentofamedicine,withproperjustification,fortheinclusioninthe hospital formulary(one)
10. FormulationanddispensingofagivenIVadmixtures(one)
11. Preparationofapatientinformationleaflet(two)
12. PreparationofStudyProtocol(one)
13. PreparationofInformedConsentForm(one)

## PRINCIPLESOFQUALITYUSEOFMEDICINES (MPP201T)

**Scope:**

Thiscourseisdesignedtoimpartbasicknowledgeandskillsthatarerequiredtopracticequality useofmedicines(QUM)indifferenthealthcaresettingsandalsotopromotequalityuseof medicines,inclinicalpractice,throughevidence-basedmedicineapproach.

**Objectives:**

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

- Understandtheprinciplesofqualityuseofmedicines
- Knowthebenefitsandrisksassociatedwithuseofmedicines
- Understandregulatoryaspectsofqualityuseofmedicines
- Identifyandresolvemedicationrelatedproblems
- Promotequalityuseofmedicines
- Practice evidence-basedmedicines

**THEORY** **60Hrs**

1. IntroductiontoQualityuseofmedicines(QUM):DefinitionandPrinciplesof QUM,Keypartnersandresponsibilitiesofthepartners,BuildingblocksinQMC, EvaluationprocessinQMC,CommunicationinQUM,Costeffectiveprescribing. 12Hrs

2. Concepts in QUM 12Hrs

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

   Essentialdrugs:Definition,need,conceptofessentialdrug,Nationalessential drug policy andlist

   Rationaldruguse:Definition,conceptandneedforrationaldruguse,Rational drugprescribing,Roleofpharmacistinrationaldruguse.

3. QUM in various settings: Hospital settings, Ambulatory care/Residential care, RoleofhealthcareprofessionalsinpromotingtheQUM,Strategiestopromote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinarycare. 12Hrs

   QUM in special population: Pediatric prescribing, Geriatric prescribing,

Prescribinginpregnancyandlactation,Prescribinginimmunecompromisedand organ failure patients.

4. RegulatoryaspectsofQUMinIndia:Regulationincludingscheduling,Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibilityofpharmacist,RoleofindustryinQUMinmedicinedevelopment. 12Hrs

5. Medicationerrors:Definition,categorizationandcausesofmedicationerrors, Detectionandpreventionofmedicationerrors,Roleofpharmacistinmonitoring andmanagementofmedicationerrors 12Hrs

   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.

**REFERENCES:**


1. ATextbookofClinicalPharmacyPractice–Essentialconceptsandskills–Parthasarathi G,KarinNyfort-HansenandMilapNahata
2. AndrewsEB,MooreN.Mann'sPharmacovigilance
3. DipiroJT,TalbertRL,YeeGC.Pharmacotherapy:APathophysiologicApproach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teachit
5. CohenMR.MedicationErrors
6. Online:
   - http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Reduced.pdf
   - http://curriculum.racgp.org.au/statements/quality-use-of-medicines/
   - http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceuticalliterature.

## PHARMACOTHERAPEUTICS II (MPP 202T)

**Scope**

Thiscourseaimstoenablethestudentstounderstandthedifferenttreatmentapproachesin managingvariousdiseaseconditions.Also,itimpartsknowledgeandskillsinoptimizingdrug therapyofapatientbyindividualizingthetreatmentplanthroughevidence-basedmedicines.

**Objectives**

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

- Describeandexplaintherationalefordrugtherapy
- Summarize the therapeutic approach for management of various disease conditions includingreferencetothelatestavailableevidence
- Discusstheclinicalcontroversiesindrugtherapyandevidencebasedmedicine
- Prepareindividualizedtherapeuticplansbasedondiagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, and monitoringtherapy(includingalternatives,time-courseofclinicalandlaboratory indicesoftherapeuticresponseandadverseeffect/s)

**THEORY** **60Hrs**

| | | |
|---|---|---|
| 1. | Nervoussystem:Epilepsy,Parkinson'sdisease,Stroke,Headache,Alzheimer's disease, Neuralgias and Pain pathways and Pain management. | 12Hrs |
| 2. | Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders, Drug induced psychiatric disorders<br><br>Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease | 12Hrs |
| 3. | Infectious diseases: General guidelines for the rational use of antibiotics and surgicalprophylaxis,Urinarytractinfections,Respiratorytractinfections, Gastroenteritis,Tuberculosis,Malaria,Bacterialendocarditis,Septicemia. | 12Hrs |
| 4. | Infectious diseases: Meningitis, HIV and opportunistic infections, Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, Fungal infections<br>Gynecological disorders: Dysmenorrhea, Hormone replacement therapy. | 12Hrs |
| 5. | Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care | 12Hrs |

## REFERENCES

1. RogerandWalker.ClinicalPharmacyandTherapeutics–ChurchillLivingstonepublication.
2. JosephT.Dipiroetal.Pharmacotherapy:APathophysiologicApproach-Appleton&Lange
3. RobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication
4. EricT.Herfindal.ClinicalPharmacyandTherapeutics-WilliamsandWilkinsPublication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs-LippincottWilliamsandWilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principlesandpractice-–McGrawHillPublication
7. CarolMattsonPorth.PrinciplesofPathophysiology-LippincottWilliamsandWilkins
8. Harrison's.PrinciplesofInternalMedicine-McGrawHill
9. Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

## CLINICALPHARMACOKINETICSANDTHERAPEUTICDRUGMONITORING (MPP203T)

### Scope

Thiscourseisdesignedtoenablestudentstounderstandthebasicsprinciplesandapplications ofpharmacokineticsindesigningtheindividualizeddosageregimen,tointerprettheplasma drugconcentrationprofileinalteredpharmacokinetics,druginteractionsandintherapeutic drugmonitoringprocessestooptimizethedrugdosageregimen.Also,itenablesstudentsto understand the basic concepts of pharmacogenetics, pharmacometrics for modeling and simulationofpharmacokineticdata.

### Objectives

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

- Designthedrugdosageregimenforindividualpatients
- Interpretandcorrelatetheplasmadrugconcentrationswithpatients'therapeutic outcomes
- Recommenddosageadjustmentforpatientswithrenal/hepaticimpairment
- Recommenddosageadjustmentforpaediatricsandgeriatrics
- Managepharmacokineticdruginteractions
- Applypharmacokineticparametersinclinicalsettings
- Interprettheimpactofgeneticpolymorphismsofindividualsonpharmacokinetics andorpharmacodynamicsofdrugs
- Do pharmacokinetic modeling for the given data using the principles of

pharmacometrics

**THEORY** **60Hrs**

1. Introduction to Clinical pharmacokinetics: Compartmental and Non compartmentalmodels,Renalandnon-renalclearance,Organextractionand models of hepatic clearance, Estimation and determinants of bioavailability, Multipledosing,Calculationofloadingandmaintenancedoses — 12Hrs

   Designing of dosage regimens: Determination of dose and dosing intervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations in designing dosage regimen.

2. Pharmacokinetics of Drug Interaction: Pharmacokinetic drug interactions, InhibitionandInductionofDrugmetabolism,InhibitionofBiliaryExcretion — 12Hrs Hrs

   Pharmacogenetics:GeneticpolymorphisminDrugmetabolism:CytochromeP- 450 Isoenzymes, Genetic Polymorphism in Drug Transport and Drug Targets, PharmacogeneticsandPharmacokinetic/Pharmacodynamicconsiderations

   Introduction to Pharmacometrics: Introduction to Bayesian Theory, Adaptive methodorDosingwithfeedback,AnalysisofPopulationpharmacokineticData.

3. NonLinierMixedEffectsModelling:TheStructuralorBaseModel,Modeling RandomEffects,ModelingCovariateRelationships,MixtureModel,Estimation Methods,ModelBuildingTechniques,CovariateScreeningMethods,Testingthe modelassumptions,Precisionoftheparameterestimatesandconfidence intervals,Modelmisspecificationandviolationofthemodelassumptions,Model Validation, Simulation of dosing regimens and dosing recommendations, Pharmacometricssoftware. — 12Hrs

4. Altered Pharmacokinetics: Drug dosing in the elderly, Drug dosing in the paediatrics,Drugdosingintheobesepatients,Drugdosinginthepregnancyand lactation,Drugdosingintherenalfailureandextracorporealremovalofdrugs, Drugdosingintheinhepaticfailure. — 12Hrs

5. 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 Correlationindrugtherapy,TDMofdrugsusedinthefollowingconditions: 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. — 12Hrs

**REFERENCES**


1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics & Pharmacokinetics.NewYork:McGrawHill.
2. PeterL.Bonate.Pharmacokinetic-PharmacodynamicModelingandSimulation.Springer Publications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans. Applied Pharmacokinetics&Pharmacodynamics:PrinciplesofTherapeuticDrugMonitoring. Iippincott Williams &Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of Analytical Therapeutic Drug MonitoringandToxicology.CRCPress,USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: PharmaceuticalPress.
6. JosephT.Dipiro,WilliamJ.Spruill,WilliamE.Wade,RobertA.BlouinandJaneM.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-System Pharmacists, USA.
7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics and pharmacodynamics: conceptsandapplications.IippincottWilliams&Wilkins,USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health system Pharmacists,USA.
9. MichaelE.Winter.BasicClinicalPharmacokinetics.IippincottWilliams&Wilkins,USA.
10. MiloGibaldi.BiopharmaceuticsandClinicalPharmacokinetics.PharmaBookSyndicate,USA.
11. DhillonandKostrzewski.Clinicalpharmacokinetics.PharmaceuticalPress,London.
12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: American Society of Health-System Pharmacist,USA.
13. Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

## PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MPP 204T)

**Scope**

Thiscourseenablesstudentstounderstandvariouspharmacoepidemiologicalmethodsand theirclinicalapplications.Also,itaimstoimpartknowledgeonbasicconcepts,assumptions, terminology,andmethodsassociatedwithPharmacoeconomicsandhealthrelatedoutcomes, andwhenshouldbeappropriatePharmacoeconomicmodelshouldbeappliedforahealthcare regimen.

**Objectives**

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

- Understandthevariousepidemiologicalmethodsandtheirapplications
- UnderstandthefundamentalprinciplesofPharmacoeconomics.
- Identifyanddeterminerelevantcostandconsequencesassociatedwithpharmacy products andservices.
- PerformthekeyPharmacoeconomicsanalysismethods
- UnderstandthePharmacoeconomicdecisionanalysismethodsanditsapplications.
- DescribecurrentPharmacoeconomicmethodsandissues.
- UnderstandtheapplicationsofPharmacoeconomicstovariouspharmacysettings.

**THEORY** **60Hrs**

1. Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications;Outcomemeasurement:Outcomemeasures,Drugusemeasures: Monetaryunits,Numberofprescriptions,unitsofdrugdispensed,defineddaily 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 adherencemeasurements. 12Hrs

   Conceptofrisk:Measurementofrisk,Attributableriskandrelativerisk,Time-riskrelationshipandoddsratio

2. Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review; Quantitativemodels:casereports,caseseries,Crosssectionalstudies,Cohort andcasecontrolstudies,CalculationofOdds'ratio,Meta-analysismodels,Drug effectsstudyinpopulations:Spontaneousreporting,Prescriptionevent monitoring,Postmarketingsurveillance,Recordlinkagesystems,Applicationsof Pharmacoepidemiology 12Hrs

3. Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system. 12Hrs

   Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.

   Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinicaloutcome,Economicoutcomes,Humanisticoutcomes;QualityAdjusted LifeYears,DisabilityAdjustedLifeYearsIncrementalCostEffectiveRatio, AverageCostEffectiveRatio.PersonTime,WillingnessToPay,TimeTradeOff andDiscounting.

4. 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). 12Hrs

5. Definition,Stepsinvolved,Applications,Advantagesanddisadvantagesofthe following: 12Hrs

   Healthrelatedqualityoflife(HRQOL):Definition,Needformeasurementof HRQOL,CommonHRQOLmeasures.

   Definition, Steps involved, Applications of the following:

   DecisionAnalysisandDecisiontree,Sensitivityanalysis,MarkovModeling, Software used in pharmacoeconomic analysis, Applications of Pharmacoeconomics.


**REFERENCES**

1. RascatiKL.EssentialsofPharmacoeconomics,WoultersKluwerLippincottWilliams& Wilkins,Philadelphia.
2. ThomasEGetzen.Healtheconomics.FundamentalsandFlowofFunds.JohnWiley&Sons, USA.
3. AndrewBriggs,KarlClaxton,MarkSculpher.DecisionModellingforHealthEconomic Evaluation,OxfordUniversityPress,London.
4. MichaelDrummond,MarkSculpher,GeorgeTorrence,BernieO'BrienandGregStoddart. MethodsfortheEconomicEvaluationofHealthCareProgrammesOxfordUniversityPress,

London.
5. GeorgeEMackinnonIII.Understandinghealthoutcomesandpharmacoeconomics.
6. Graker,Dennis.Pharmacoeconomicsandoutcomes.
7. Walley,Pharmacoeconomics.
8. Pharmacoeconomic–ed.byNowakowska–UniversityofMedicalSciences,Poznan.
9. Relevant review articles from recent medical and pharmaceutical literature

## PHARMACY PRACTICE PRACTICAL - II (MPP 205P)

PharmacyPracticepracticalcomponentincludesexperimentscoveringimportanttopicsofthe courses Principles of Quality Use of Medicines, Pharmacotherapeutics-II, Clinical Pharmacokinetics & Therapeutic Drug Monitoring and Pharmacoepidemiology and Pharmacoeconomics.

List of Experiments (24)

1. Causalityassessmentofadversedrugreactions(three)
2. Detectionandmanagementofmedicationerrors(three)
3. Rationaluseofmedicinesinspecialpopulation(three)
4. PresentationofclinicalcasesofvariousdiseaseconditionsadoptingPharmaceuticalCare Plan Model(eight)
5. CalculationofBioavailabilityandBioequivalencefromthegivendata(two)
6. InterpretationofTherapeuticDrugMonitoringreportsofagivenpatient(three)
7. CalculationofvariousPharmacoeconomicoutcomeanalysisforthegivendata(two)

## RESEARCH METHODOLOGY & BIOSTATISTICS (MRM 301T)

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, types of research, scientific methods of research, types of studies, study design.

Review of literature - Sources of information. Searching of library documents and databases online and offline (Pubmed, Biological abstracts, other databases in pharmaceutical sciences). Introduction to internet searching using advanced search tools.

UNIT – II

Collection and analysis of data: Types of data and data collection techniques, processing of data, coding, tabulation and analysis of data.

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (Student's 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, different software for statistical analysis.

UNIT – III

Medical Research: History, values in medical ethics, strategies to eliminate errors/bias, controls, randomisation, cross over design, placebo, blinding techniques 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, vendor relationships, treatment of family members.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Technical writing, thesis/research report writing, structure of thesis, editing and formatting, reference citations, abstracting, plagiarism and paraphrasing, tools for writing good research report.

UNIT – VI

Research reporting - poster presentation, seminar and conference presentation, publishing in journals, copyright.

**REFERENCE BOOKS**


1. AtiyaKhanum Irfan Ali Khan , Biostatistics for Pharmacy, 2nd Edition , 2007, UkaazPublications, Hyderabad
2. C. George Thomas . Research Methodology and Scientific Writing First edition, 2016, AneBooks Pvt. Ltd.;New Delhi,
3. C. R Kothari. Research Methodology: Methods and Techniques. New Age International (P)Ltd, Publishers. New Delhi
4. Mahajan, B.K. Methods in Biostatistics. For Medical Students and Research workers, 7th edition 2008 Jaypee Brothers
5. PutulMahanta , Medical Writing: A Guide for Medicos, Educators and Researchers JaypeeBrothers Medical Publishers; First edition (2018)
6. RanjanDas . Biomedical Research Methodology :IincludingBiostatistical Applications. 1st Edn .Jaypee BrothersRanjit Kumar, Research Methodology: A Step-by-Step Guide for Beginners, 3rd Edition 2011,Sage Publications India Pvt. Ltd. , New Delhi
7. Sharma Suresh.Research Methodology and Biostatistics. A Comprehensive Guide for HealthCare Professionals. 1st Edn . Elsevier India
8. Sunder Rao. P.S.S and Richard, J. An introduction to Biostatistics: A manual for students inhealth sciences. Prentice-Hall of India Pvt.Ltd Publishers


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