JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmacy Practice
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

I YEAR - I Semester

S. No	Course Code	Subjects	L	T	P	C
1	17S09101	Clinical Pharmacy Practice	4	-	-	4
2	17S09102	Pharmacotherapeutics-I	4	-	-	4
3	17S09103	Hospital &Community Pharmacy	4	-	-	4
4	17S09104	Clinical Research	4	-	-	4
5	17S09105	Pharmacy Practice Practical I	-	-	6	3
6	17S09106	Pharmacy Practice Practical II	-	-	6	3
7	17S09107	Seminar/Assignment	-	-	7	4
		Total	16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S09201	Principles of Quality Use of Medicines	4	-	-	4
2	17S09202	Pharmacotherapeutics II	4	-	-	4
3	17S09203	Clinical Pharmacokinetics and Therapeutic Drug Monitoring	4	-	-	4
4	17S09204	Pharmacoepidemiology & Pharmacoeconomics	4	-	-	4
5	17S09205	Pharmacy Practice Practical III	-	-	6	3
6	17S09206	Pharmacy Practice Practical IV	-	-	6	3
7	17S09207	Seminar/Assignment	-	-	7	4
		Total	16	-	19	26

III SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S01301	Research Methodology and Biostatistics	4	-	-	4
2.	17S09301	Journal Club	1	-	-	1
3.	17S09302	Teaching Assignment	10	-	-	2
4.	17S09303	Comprehensive viva voce	-	-	-	2
5.	17S09304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S09305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S09401	Journal Club	1	-	-	1
2.	17S09402	Research work	31	-	-	16
3.	17S09403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S09101) CLINICAL PHARMACY PRACTICE

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 :

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

THEORY 60 Hrs

1. 12Hrs

Introduction to Clinical Pharmacy: 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)

2 12Hrs

Clinical Pharmacy Services: Patient medication historyinterview, Basic concept of medicine and poison informationservices, Basic concept of pharmacovigilance, Hemovigilance,Materiovigilance and AEFI, Patient medication counseling, Drugutilization evaluation, Documentation of clinical pharmacyservices, Quality assurance of clinical pharmacy services.

3 12Hrs

Patient Data Analysis:

Patient Data & Practice Skills: Patient's case history – itsstructure and significances in drug therapy management,Common medical abbreviations and terminologies used in clinicalpractice,

Communication skills: verbal and non-verbalcommunications, its applications in patient care services.

Lab Data Interpretation: Hematological tests, Renal functiontests, Liver function tests

4 12Hrs

Lab Data Interpretation: Tests associated with cardiacdisorders, Pulmonary function tests, Thyroid function tests, Fluidand electrolyte balance, Microbiological culture sensitivity tests

5 12Hrs

Medicines & Poison Information Services

Medicine Information Service: Definition and need for medicineinformation service, Medicine information resources, Systematicapproach in answering medicine information queries, Preparationof verbal and written response, Establishing a drug informationcentre.

Poison Information Service: Definition, need, organization andfunctions of poison information centre.

REFERENCES

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills –Parthasarathi G, Karin Nyfort-Hansen and MilapNahata

2. Practice Standards and Definitions - The Society of Hospital Pharmacistsof Australia

3. Basic skills in interpreting laboratory data - Scott LT, American Society ofHealth System Pharmacists Inc

4. Relevant review articles from recent medical and pharmaceutical literature.

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M. Pharm – I year I Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S09102) PHARMACOTHERAPEUTICS-I

Scope

This course aims to enable the students to understand the different treatmentapproaches in managing various disease conditions. Also, it imparts knowledgeand skills in optimizing drug therapy of a patient by individualizing the treatmentplan through evidence-based medicines.

Objectives

Upon completion of this course it is expected that students 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
- 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)

THEORY 60 Hrs

Etiopathogenesis and pharmacotherapy of diseasesassociated with following systems

1. 12Hrs

Cardiovascular system: Hypertension, Congestive cardiacfailure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.

2 12Hrs

Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseasesEndocrine system: Diabetes, Thyroid diseases

3 12Hrs

Gastrointestinal system: Peptic ulcer diseases, Refluxesophagitis, inflammatory bowel diseases, Jaundice & hepatitis

4 12Hrs

Gastrointestinal system: Cirrhosis, Diarrhea and Constipation,Drug-induced liver disease

Hematological diseases: Anemia, Deep vein thrombosis, Druginduced hematological disorders

5 12Hrs

Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis,Gout, OsteoporosisDermatological Diseases: Psoriasis, Eczema and scabies,impetigo, drug induced skin disorders

Ophthalmology: Conjunctivitis, Glaucoma

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics – ChurchillLivingstone 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 andWilkins Publication

5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Useof 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 Williamsand Wilkins

8. Harrison's. Principles of Internal Medicine - McGraw Hill

9. Relevant review articles from recent medical and pharmaceutical literature

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	4	**0**	**0**	**4**

(17S09103) HOSPITAL & COMMUNITY PHARMACY

Scope

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

Objectives

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

- Understand the organizational structure of hospital pharmacy
- Understand drug policy and drug committees
- Know about procurement & drug distribution practices
- Know the admixtures of radiopharmaceuticals
- Understand the community pharmacy management
- Know about value added services in community pharmacies

THEORY 60 Hrs

1. 12Hrs

Introduction to Hospitals – Definition, classification,organizational structureHospital Pharmacy: Definition, Relationship of hospitalpharmacy department with other departments, Organizationalstructure, legal requirements, work load statistics, Infrastructuralrequirements, Hospital Pharmacy Budget and Hospital Pharmacymanagement

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

2 12Hrs

Hospital Formulary Guidelines and its development, DevelopingTherapeutic guidelines, Drug procurement process, and methodsof Inventory control, Methods of Drug distribution, Intravenousadmixtures, Hospital Waste Management

3 12Hrs

Education and training: Training of technical staff, training andcontinuing education for pharmacists, Pharmacy students,Medical staff and students, Nursing staff and students, Formaland informal meetings and lectures, Drug and therapeuticsnewsletter.

Community Pharmacy Practice: Definition, roles &responsibilities of community pharmacists, and their relationshipwith other health care providers.

Community Pharmacy management: Legal requirements tostart community pharmacy, site selection, lay out & design, drugdisplay, super drug store model, accounts and audits, Gooddispensing practices, Different softwares & databases used incommunity pharmacies. Entrepreneurship in communitypharmacy.

4 12Hrs

Prescription – Legal requirements & interpretation, prescriptionrelated problemsResponding to symptoms of minor ailments: Head ache,pyrexia, menstrual pains, food and drug allergy,OTC medication: Rational use of over the counter medicationsMedication counseling and use of patient information leafletsMedication adherence – Definition, factors influencing adherencebehavior, strategies to improve medication adherencePatient referrals to the doctorsADR monitoring in community pharmacies

5 12Hrs

Health Promotion – Definition and health promotion activities,family planning, Health screening services, first aid, prevention ofcommunicable and non-communicable diseases, smokingcessation, Child & mother careNational Health Programs- Role of Community Pharmacist inMalaria and TB control programsHome Medicines review program – Definition, objectives,Guidelines, method and outcomesResearch in community pharmacy Practice

REFERENCES

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

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M. Pharm – I year I Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S09104) CLINICAL RESEARCH

Scope

This course aims to provide the students an opportunity to learn drugdevelopment process especially the phases of clinical trials and also the ethicalissues involved in the conduct of clinical research. Also, it aims to impartsknowledge and develop skills on conceptualizing, designing, conducting andmanaging clinical trials.

Objectives

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

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

THEORY 60 Hrs

1. 12Hrs

Drug development process: Introduction, various approaches todrug discovery, Investigational new drug application submissionEthics in Biomedical Research: Ethical Issues in BiomedicalResearch – Principles of ethics in biomedical research, Ethicalcommittee [institutional review board] - its constitution andfunctions, Challenges in implementation of ethical guidelines, ICHGCP guidelines and ICMR guidelines in conduct of Clinical trials,Drug Safety Reporting.

2 12Hrs

Types and Designs used in Clinical Research: Planning andexecution of clinical trials, Various Phases of clinical trials,Bioavailability and Bioequivalence studies, Randomizationtechniques (Simple randomization, restricted randomization,blocking method and stratification), Types of research designsbased on Controlling Method (Experimental, Quasi experimental,and Observational methods) Time Sequences (Prospective andRetrospective), Sampling methods (Cohort study, case Controlstudy 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, ContractResearch Organization.

3 12Hrs

Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, InformedConsent Form, Case report forms, Contracts and agreements,Dairy CardsClinical Trial Start up activities: Site Feasibility Studies,Site/Investigator selection, Pre-study visit, Investigator meeting,Clinical trial agreement execution, Ethics committee documentpreparation and submission

4 12Hrs

Investigational Product: Procurement and Storage ofinvestigation productFiling procedures: Essential documents for clinical trial, TrialMaster File preparation and maintenance, Investigator Site File,Pharmacy File, Site initiation visit, Conduct, Report and Follow upClinical Trial Monitoring and Close out:Preparation and conduct of monitoring visit: Review of sourcedocuments, CRF, ICF, IP storage, accountability andreconciliation, Study Procedure, EC communications, Safetyreporting, Monitoring visit reporting and follow-upClose-Out visit: Study related documents collection, Archivalrequirement, Investigational Product reconciliation anddestruction, Close-Out visit report.

5 12Hrs

Quality Assurance and Quality Control in Clinical Trials:Types of audits, Audit criteria, Audit process, Responsibilities ofstakeholders in audit process, Audit follow-up and documentation,Audit resolution and Preparing for FDA inspections, Fraud andmisconduct management

Data Management

Infrastructure and System Requirement for DataManagement: Electronic data capture systems, Selection andimplementation of new systems, System validation and testprocedures, Coding dictionaries, Data migration and archival

Clinical Trial Data Management: Standard OperatingProcedures, Data management plan, CRF & Data base designconsiderations, Study set-up, Data entry, CRF tracking andcorrections, Data cleaning, Managing laboratory and ADR data,Data transfer and database lock, Quality Control and QualityAssurance in CDM, Data mining and warehousing.

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition.Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter DSloaierPublisher:Wiley;

2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. ChurchillLivingstone

3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovannaand Haynes.

4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. NewDelhi: Ministry of Health.

5. International Conference on Harmonisation of Technical requirements forregistration of Pharmaceuticals for human use. ICH HarmonisedTripartiteGuideline. Guideline for Good Clinical Practice.E6; May 1996.

6. Ethical Guidelines for Biomedical Research on Human Subjects. IndianCouncil of Medical Research, New Delhi.

7. Textbook of Clinical Trials edited by David Machin, Simon Day and SylvanGreen, John Wiley and Sons.

8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs.Second Edition, Jan 2000, Wiley Publications.

9. Goodman & Gilman: JG Hardman, LE Limbard, McGraw Hill Publications.

10. Relevant review articles from recent medical and pharmaceutical literature.

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M. Pharm – I year I Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S09105) PHARMACY PRACTICE PRACTICAL – I

Pharmacy Practice practical component includes experiments covering important topics of the courses Clinical Pharmacy Practice, Pharmacotherapeutics-I, Hospital & Community Pharmacy and Clinical Research.

List of Experiments (24)

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. ABC Analysis of a given list of medications (one)

8. Preparation of content of a medicine, with proper justification, for theinclusion in the hospital formulary (one)

9. Formulation and dispensing of a given IV admixtures (one)

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	0	**0**	**6**	**3**

(17S09106) PHARMACY PRACTICE PRACTICAL – II

1. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)

2. Preparation of a patient information leaflet (two)

3. Preparation of Study Protocol (one)

4. Preparation of Informed Consent Form (one)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S09201) PRINCIPLES OF QUALITY USE OF MEDICINES

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 it is expected that students shall be able to:

- Understand the principles of quality use of medicines
- Know the benefits and risks associated with use of medicines
- Understand regulatory aspects of quality use of medicines
- Identify and resolve medication related problems
- Promote quality use of medicines
- Practice evidence-based medicines

THEORY 60 Hrs

1. 12Hrs

Introduction to Quality use of medicines (QUM): Definition andPrinciples of QUM, Key partners and responsibilities of thepartners, Building blocks in QMC, Evaluation process in QMC,Communication in QUM, Cost effective prescribing.

2 12Hrs

Concepts in QUM

Evidence based medicine: Definition, concept of evidencebased medicine, Approach and practice of evidence basedmedicine 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 druguse, Rational drug prescribing, Role of pharmacist in rational druguse.

3 12Hrs

QUM in various settings: Hospital settings, Ambulatorycare/Residential care, Role of health care professionals inpromoting the QUM, Strategies to promote the QUM, Impact ofQUM on E-health, integrative medicine and multidisciplinary care.

QUM in special population: Pediatric prescribing, Geriatricprescribing, Prescribing in pregnancy and lactation, Prescribing inimmune compromised and organ failure patients.

4 12Hrs

Regulatory aspects of QUM in India: Regulation includingscheduling, Regulation of complementary medicines, Regulationof OTC medicines, Professional responsibility of pharmacist, Roleof industry in QUM in medicine development.

5 12Hrs

Medication errors: Definition, categorization and causes ofmedication errors, Detection and prevention of medication errors,Role of pharmacist in monitoring and management of medicationerrors

Pharmacovigilance: Definition, aims and need forpharmacovigilance, Types, predisposing factors and mechanismof adverse drug reactions (ADRs), Detection, reporting andmonitoring of ADRs, Causality assessment of ADRs,Management of ADRs, Role of pharmacist in pharmacovigilance.

REFERENCES:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills –Parthasarathi G, Karin Nyfort-Hansen and MilapNahata

2. Andrews EB, Moore N. Mann's Pharmacovigilance

3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A PathophysiologicApproach

4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-BasedMedicine: How to practice and teach it

5. Cohen MR. Medication Errors

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 pharmaceutical literature.

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M. Pharm – I year II Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S09202) PHARMACOTHERAPEUTICS II

Scope

This course aims to enable the students to understand the different treatmentapproaches in managing various disease conditions. Also, it imparts knowledgeand skills in optimizing drug therapy of a patient by individualizing the treatmentplan through evidence-based medicines.

Objectives

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

- Describe and explain the rationale for drug therapy
- Summarize the therapeutic approach for management of variousdisease conditions including reference to the latest available evidence
- Discuss the clinical controversies in drug therapy and evidence basedmedicine
- Prepare individualized therapeutic plans based on diagnosis
- Identify the patient specific parameters relevant in initiating drugtherapy, and monitoring therapy (including alternatives, time- course ofclinical and laboratory indices of therapeutic response and adverseeffect/s)

THEORY 60 Hrs

1. 12Hrs

Nervous system: Epilepsy, Parkinson's disease, Stroke,Headache, Alzheimer’s disease, Neuralgias and Pain pathwaysand Pain management.

2 12Hrs

Psychiatric disorders: Schizophrenia, Depression, Anxietydisorders, Sleep disorders, Drug induced psychiatric disordersRenal system: Acute renal failure, Chronic renal failure, Renaldialysis, Drug induced renal disease

3 12Hrs

Infectious diseases: General guidelines for the rational use ofantibiotics and surgical prophylaxis, Urinary tract infections,Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria,Bacterial endocarditis, Septicemia.

4 12Hrs

Infectious diseases: Meningitis, HIV and opportunistic infections,Rheumatic fever, Dengue fever, H1N1, Helmenthiasis, FungalinfectionsGynecological disorders: Dysmenorrhea, Hormonereplacement therapy.

5 Oncology: General principles of cancer chemotherapy,pharmacotherapy of breast cancer, lung cancer, head & neckcancer, hematological malignancies, Management of nausea andvomiting, Palliative care

REFERENCES

1. Roger and Walker. Clinical Pharmacy and Therapeutics –ChurchillLivingstone 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 andWilkins Publication

5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Useof 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 Williamsand Wilkins

8. Harrison's. Principles of Internal Medicine - McGraw Hill

9. Relevant review articles from recent medical and pharmaceutical literature

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S09203) CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUGMONITORING

Scope

This course is designed to enable students to understand the basics principlesand applications of pharmacokinetics in designing the individualized dosageregimen, to interpret the plasma drug concentration profile in alteredpharmacokinetics, drug interactions and in therapeutic drug monitoringprocesses to optimize the drug dosage regimen. Also, it enables students tounderstand the basic concepts of pharmacogenetics, pharmacometrics formodeling and simulation of pharmacokinetic data.

Objectives

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

- Design the drug dosage regimen for individual patients
- Interpret and correlate the plasma drug concentrations with patients'therapeutic outcomes
- Recommend dosage adjustment for patients with renal/ hepaticimpairment
- Recommend dosage adjustment for paediatrics and geriatrics
- Manage pharmacokinetic drug interactions
- Apply pharmacokinetic parameters in clinical settings
- Interpret the impact of genetic polymorphisms of individuals onpharmacokinetics and or pharmacodynamics of drugs
- Do pharmacokinetic modeling for the given data using the principles ofpharmacometrics

THEORY 60 Hrs

1. 12Hrs

Introduction to Clinical pharmacokinetics: Compartmental andNon compartmental models, Renal and non-renal clearance,Organ extraction and models of hepatic clearance, Estimation anddeterminants of bioavailability, Multiple dosing, Calculation ofloading and maintenance dosesDesigning of dosage regimens: Determination of dose anddosing intervals, Conversion from intravenous to oral dosing,Nomograms and Tabulations in designing dosage regimen.

2 12Hrs

Pharmacokinetics of Drug Interaction: Pharmacokinetic druginteractions, Inhibition and Induction of Drug metabolism,Inhibition of Biliary Excretion

Pharmacogenetics: Genetic polymorphism in Drug metabolism:Cytochrome P-450 Isoenzymes, Genetic Polymorphism in DrugTransport and Drug Targets, Pharmacogenetics andPharmacokinetic / Pharmacodynamic considerations

Introduction to Pharmacometrics: Introduction to BayesianTheory, Adaptive method or Dosing with feedback, Analysis ofPopulation pharmacokinetic Data.

3 12Hrs

Non Linier Mixed Effects Modelling: The Structural or BaseModel, Modeling Random Effects, Modeling CovariateRelationships, Mixture Model, Estimation Methods, ModelBuilding Techniques, Covariate Screening Methods, Testing themodel assumptions, Precision of the parameter estimates andconfidence intervals, Model misspecification and violation of themodel assumptions, Model Validation, Simulation of dosingregimens and dosing recommendations, Pharmacometricssoftware.

4 12Hrs

Altered Pharmacokinetics: Drug dosing in the elderly, Drugdosing in the paediatrics, Drug dosing in the obese patients, Drugdosing in the pregnancy and lactation, Drug dosing in the renalfailure and extracorporeal removal of drugs, Drug dosing in the inhepatic failure.

5

Therapeutic Drug monitoring: Introduction, Individualization ofdrug dosage regimen (Variability – Genetic, age, weight, diseaseand Interacting drugs), Indications for TDM, Protocol for TDM,Pharmacokinetic/Pharmacodynamic Correlation in drug therapy,TDM of drugs used in the following conditions:

Cardiovasculardiseases: Digoxin, Lidocaine, Amiodarone;

Seizure disorders:Phenytoin, Carbamazepine, Sodium Valproate;

Psychiatricconditions: Lithium, Fluoxetine, Amitriptyline;

Organtransplantations: Cyclosporine;

Cytotoxic Agents: Methotrexate,5-FU, Cisplatin;

Antibiotics: Vancomycin, Gentamicin,Meropenem.

REFERENCES

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics& Pharmacokinetics. New York: Mc Graw Hill.

2. Peter L. Bonate. Pharmacokinetic - Pharmacodynamic Modeling andSimulation. Springer Publications.

3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E.Evans.Applied Pharmacokinetics & Pharmacodynamics: Principles of TherapeuticDrug Monitoring. Iippincott Williams & Wilkins.

4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic Drug Monitoring and Toxicology. CRC Press, USA.

5. SorayaDhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London: Pharmaceutical Press.

6. Joseph T.Dipiro, William J.Spruill, William E.Wade, Robert A.BlouinandJaneM.Pruemer .Concepts in Clinical Pharmacokinetics. AmericanSociety of Health-System Pharmacists, USA.

7. Malcolm Rowland, Thomas N. Tozer .Clinical Pharmacokinetics andpharmacodynamics: concepts and applications. Iippincott Williams &Wilkins, USA.

8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society ofHealth system Pharmacists, USA.

9. Michael E. Winter. Basic Clinical Pharmacokinetics. Iippincott Williams &Wilkins, USA.

10. Milo Gibaldi. Biopharmaceutics and Clinical Pharmacokinetics. PharmaBook Syndicate, USA.

11. Dhillon and Kostrzewski. Clinical pharmacokinetics. Pharmaceutical Press,London.

12. John E .Murphy. Clinical Pharmacokinetics. 5th edition. US: AmericanSociety of Health-System Pharmacist, USA.

13. Relevant review articles from recent medical and pharmaceutical literature

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M. Pharm – I year II Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S09204) PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

Scope

This course enables students to understand various pharmaco-epidemiologicalmethods and their clinical applications. Also, it aims to impart knowledge onbasic concepts, assumptions, terminology, and methods associated withPharmacoeconomics and health related outcomes, and when should beappropriate Pharmacoeconomic model should be applied for a health careregimen.

Objectives

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

- Understand the various epidemiological methods and their applications
- Understand the fundamental principles of Pharmacoeconomics.
- Identify and determine relevant cost and consequences associatedwith pharmacy products and services.
- Perform the key Pharmacoeconomics analysis methods
- Understand the Pharmacoeconomic decision analysis methods and itsapplications.
- Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to variouspharmacy settings.

THEORY 60 Hrs

1. 12Hrs

Introduction to Pharmacoepidemiology: Definition, Scope,Need, Aims & Applications; Outcome measurement: Outcomemeasures, Drug use measures: Monetary units, Number ofprescriptions, units of drug dispensed, defined daily doses,prescribed daily doses, Diagnosis and Therapy surveys,Prevalence, Incidence rate, Monetary units, number ofprescriptions, unit of drugs dispensed, defined daily doses andprescribed daily doses, medications adherence measurements.

Concept of risk: Measurement of risk, Attributable risk andrelative risk, Time- risk relationship and odds ratio

2 12Hrs

Pharmacoepidemiological Methods: Qualitative models: DrugUtilization Review; Quantitative models: case reports, case series,Cross sectional studies, Cohort and case control studies,Calculation of Odds' ratio, Meta analysis models, Drug effectsstudy in populations:

Spontaneous reporting, Prescription eventmonitoring, Post marketing surveillance, Record linkage systems,Applications of Pharmacoepidemiology

3 12Hrs

Introduction to Pharmacoeconomics: Definition, history ofPharmacoeconomics, Need of Pharmacoeconomic studies inIndian healthcare system.

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

Outcomes and Measurements of Pharmacoeconomics: Typesof outcomes: Clinical outcome, Economic outcomes, Humanisticoutcomes; Quality Adjusted Life Years, Disability Adjusted LifeYears Incremental Cost Effective Ratio, Average Cost EffectiveRatio. Person Time, Willingness To Pay, Time Trade Off andDiscounting.

4 12Hrs

Pharmacoeconomic evaluations: Definition, Steps involved,Applications, Advantages and disadvantages of the followingPharmacoeconomic models: Cost Minimization Analysis (CMA),Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), CostUtility Analysis (CUA), Cost of Illness (COI), Cost ConsequencesAnalysis (COA).

5 12Hrs

Definition, Steps involved, Applications, Advantages anddisadvantages of the following:

Health related quality of life (HRQOL): Definition, Need formeasurement of HRQOL, Common HRQOL measures.

Definition, Steps involved, Applications of the following:

Decision Analysis and Decision tree, Sensitivity analysis, MarkovModeling, Software used in pharmacoeconomic analysis,Applications of Pharmacoeconomics.

REFERENCES

1. Rascati K L. Essentials of Pharmacoeconomics, WoultersKluwerLippincott 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 HealthEconomic Evaluation, Oxford University Press, London.

4. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien andGregStoddart. Methods for the Economic Evaluation of Health CareProgrammes Oxford University Press, London.

5. George E Mackinnon III. Understanding health outcomes andpharmacoeconomics.

6. Graker, Dennis. Pharmacoeconomics and outcomes.

7. Walley, Pharmacoeconomics.

8. Pharmacoeconomic – ed. by Nowakowska – University of MedicalSciences, Poznan.

9. Relevant review articles from recent medical and pharmaceutical literature

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S09205) PHARMACY PRACTICE PRACTICAL - III

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.

List of Experiments (24)

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. Interpretation of Therapeutic Drug Monitoring reports of a given patient(three)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S09206) PHARMACY PRACTICE PRACTICAL - IV

1. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)

2. Calculation of Bioavailability and Bioequivalence from the given data (two)

3. Calculation of various Pharmacoeconomic outcome analysis for the given, data (two)

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmacy Practice)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01301) RESEARCH METHODOLOGY & BIOSTATISTICS

UNIT – I

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.

UNIT – II

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.

UNIT – III

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.

UNIT – IV

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, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.