Course structure, Scheme of Instruction and Examination
(Effective from Academic Year 2013-2014)

FACULTY OF PHARMACY

OSMANIA UNIVERSITY
HYDERABAD – 500 007

Proposed M. Pharm (Pharmacy Practice) Syllabus
Course structure, Scheme of Instruction and Evaluation

Semester – I

<table>
<thead>
<tr>
<th>COURSE NO.</th>
<th>SUBJECTS/PAPER</th>
<th>Th/Pr.</th>
<th>Instruction Hours/Week</th>
<th>Evaluation</th>
<th>DURATION OF EXT EXAM.</th>
</tr>
</thead>
<tbody>
<tr>
<td>M PP T.1-101</td>
<td>Pharmaceutical Analytical Techniques</td>
<td>Th. 4</td>
<td>-</td>
<td>30</td>
<td>70</td>
</tr>
<tr>
<td>M PP T.1-102</td>
<td>Pharmacotherapeutics I</td>
<td>Th. 4</td>
<td>-</td>
<td>30</td>
<td>70</td>
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<tr>
<td>M PP T.1-103</td>
<td>Pharmacy practice</td>
<td>Th. 4</td>
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<tr>
<td>M PP T.1-104</td>
<td>Clinical research and clinical toxicology</td>
<td>Th. 4</td>
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<tr>
<td>M PP P.1-105</td>
<td>Pharmaceutical Analytical Techniques</td>
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<td>- 6</td>
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<tr>
<td>M PP P.1-106</td>
<td>Pharmacotherapeutics I</td>
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<tr>
<td>M PP T.1-107</td>
<td>Scientific and Technical Writing</td>
<td>Tutorial</td>
<td>8</td>
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<tr>
<td></td>
<td>Seminar + Assignments</td>
<td>-</td>
<td>8</td>
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Semester – II

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<tr>
<th>COURSE NO.</th>
<th>SUBJECTS/PAPER</th>
<th>Th/Pr.</th>
<th>Instruction Hours/Week</th>
<th>Evaluation</th>
<th>DURATION OF EXT EXAM.</th>
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<tr>
<td>M PP T.1-201</td>
<td>Intellectual Property Rights &amp; Regulatory Affairs</td>
<td>Th. 4</td>
<td>-</td>
<td>30</td>
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<tr>
<td>M PP T.1-202</td>
<td>Pharmacotherapeutics-II</td>
<td>Th. 4</td>
<td>-</td>
<td>30</td>
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<tr>
<td>M PP T.1-203</td>
<td>Biopharmaceutics &amp; pharmacokinetics</td>
<td>Th. 4</td>
<td>-</td>
<td>30</td>
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<tr>
<td>M PP T.1-204</td>
<td>Pharmacoepidemiology &amp; pharmacovigilance</td>
<td>Th. 4</td>
<td>-</td>
<td>30</td>
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<tr>
<td>M PP P.1-205</td>
<td>Pharmacotherapeutics-II</td>
<td>Pr.</td>
<td>- 6</td>
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<tr>
<td>M PP P.1-206</td>
<td>Biopharmaceutics &amp; pharmacokinetics</td>
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<td>M PP T.1-207</td>
<td>Entrepreneurship Management</td>
<td>Tutorial</td>
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<td>Seminar + Assignments</td>
<td>-</td>
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<td>50</td>
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Semester III & IV

Diss Original research work carried out by the candidate under the guidance of Regular Teaching Faculty / Visiting Faculty of the Department should be submitted in a bound form.

Evaluation of the Dissertation shall be done by the external & internal examiners appointed by the university

Dissertation Viva-Voce

Grade A/B/C/D/F

Dissertation Report

Grade A/B/C/D/F

A: Excellent  B: Very Good  C: Good  D: Fair  F: Fail
UNIT – I


UNIT – II


UNIT – III

Mass Spectrometry: Basic principles and instrumentation (components and their significance). Ionization techniques, mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.

UNIT – IV

Chromatographic Techniques: Classification of chromatographic methods based on mechanism of separation and their basic principles. Gas chromatography: Instrumentation,
column efficiency parameters, derivatisation methods, applications in pharmaceutical analysis.

**Liquid chromatography:** Comparison of GC and HPLC, instrumentation in HPLC, normal and reversed phase packing materials, column selection, mobile phase selection, efficiency parameters, applications in pharmaceutical analysis. Instrumentation and applications of HPTLC, ion exchange chromatography, gel permeation chromatography, chiral chromatography, flash chromatography, and supercritical fluid chromatography (SFC).

**UNIT – V**

**Electrophoresis:** Principles, instrumentation and applications of moving boundary electrophoresis, zone electrophoresis (ZE), isotachphoresis, isoelectric focusing (IEF), continuous electrophoresis (preparative) and capillary electrophoresis. SDS gel electrophoresis and blotting techniques.

**Radio immunoassay and ELISA:** Principle, instrumentation, applications and limitations.

**Recommended books:**


List of Experiments

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
2. Effect of solvents and pH on UV spectrum of drugs (2 experiments).
3. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations. (2 experiments).
4. Experiments based on the application of derivative spectroscopy. (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradient elution) techniques. (2 experiments).
6. Interpretation of drugs by IR spectra.
7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).
9. Any other relevant experiments based on theory.
PHARMACO THERAPEUTICS-I

M.PP T.1.102
Period / Week: 4
Sessional: 30
Examinations: 70
Duration of Exam: 3 hrs
Nature of Exam: Theory

Pathophysiology and applied therapeutics of diseases associated with following systems/ diseases with special reference to the drugs of choice.

UNIT – I

Cardiovascular system
Hypertension, Congestive cardiac failure, Ischaemic heart disease (Angina, Myocardial infarction), Arrhythmias, Hyperlipidaemias, Endocarditis, Thromboembolic disorders, Cardiac arrest – resuscitation.

UNIT – II
Respiratory system: Pulmonary function tests, Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases. Hydrogen ion hemostasis and blood gases
Endocrine system.
Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis.

UNIT –III
Ophthalmology: Glaucoma, Eye infections
General Prescribing Guidelines for: Paediatric patients; Geriatric patients.
Pregnancy & lactation.

UNIT IV
4. Gastrointestinal system Ulcer diseases, inflammatory bowel diseases, Hepatitis, Jaundice, Diarrhoea and constipation.
Skin diseases Psoriasis, Eczema and scabies, Drug induced skin diseases

UNIT – V

Oncology
Cell cycle, General principles of cancer chemotherapy, Commonly used cytotoxic drugs, Chemotherapy of lung cancer, breast cancer, head and neck cancer, prostate cancer, colorectal cancer, haematological malignancies.

TEXT BOOKS
3. Appleton and Lange.

REFERENCE BOOKS
1. Pathologic basis of diseases—Robins SL, W.B.Saunders publication.
2. Pathology and therapeutics for pharmacists: a basis for clinical Pharmacy Practice.
3. Green and Harris, Chapman and Hall Publication.
7. Relevant review articles from recent medical and pharmaceutical literature.
The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format. The cases may be selected from the following diseases:

1. **Cardiology**
   a) Arrhythmias, b) Ischaemic heart disease, c) Congestive heart failure, d) Myocardial Infarction, e) Hypertension, f) Thrombo-embolic disease, g) Endocarditis.

2. **Respiratory medicine**
   a) Asthma, b) Congestive obstructive airways disease (COAD), c) Acute respiratory failure, d) respiratory tract infections, e) Interstitial lung disease f) Respiratory aids.

3. **Oncology**
   a) Breast Cancer, b) Lung cancer - Small cell, Non small cell, c) Gastric cancer, d) Colon cancer, e) Genitourinary tract cancer - Bladder, Prostate, Testicular, f) Skin cancer, g) Radiation therapy h) Adjunctive therapy - Anti-emetics, Mouth care, Nutrition, Extravasations, Pain control, Blood products, i) Colony stimulating factors, j)Infectious disease in immuno-compromised patients, k) Hypercalcemia l) Cerebral oedema m) Malignant effusions.

4. **Endocrinology**
   a) Diabetes, b) Osteoporosis, c) Thyroid disorders, d) Syndrome of inappropriate anti-diuretic hormone secretion e) Adrenal disorders.

5. **Ophthalmology**
a) Ocular infections, b) Conjunctivitis, c) Glaucoma, d) Post-operative management.

6. Geriatric Medicine
a) Postural hypotension, b) Dementia & delirium, c) Compliance assessment.

7. Paediatrics
a) Acute otitis media, b) Tonsillitis, c) Paediatric asthma, d) Paediatric gastroenteritis, e) Colic, f) Immunisation, g) Attention deficit disorder, h) Febrile neutropaenia.

8. Dermatology
a) Psoriasis, b) Dermatitis, c) Drug induced skin disorders.

Assignments:
The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.

TEXT BOOKS

REFERENCE BOOKS
1. Pathologic basis of diseases-Robins SL, W.B. Saunders publication.
6. Relevant review articles from recent medical and pharmaceutical literature.

JOURNALS
UNIT I
INTRODUCTION TO CLINICAL PHARMACY, Definition, development and scope, Roles and responsibilities of clinical pharmacist. DAILY ACTIVITIES OF CLINICAL PHARMACISTS Drug therapy monitoring (Medication chart view, clinical review, TDM of Cardiovascular drugs, CNS drugs, pharmacist interventions). Ward round participation, Pharmaceutical care, Drug information and poison information, Introduction to information resources available, Systematic approach in answering drug information queries, Critical evaluation of drug information and literature, Preparation of written and verbal reports, Establishing a Drug Information Centre, Drug utilisation evaluation (DUE) and review (DUR). Quality assurance of clinical pharmacy services, Medication errors and various types of medication errors.

UNIT II
PATIENT DATA ANALYSIS
The patient’s case history, its structure and use in evaluation of drug therapy, presentation of cases, Communication skills including patient medication history interview, patient counseling, teaching skills, Understanding common medical abbreviations and terminologies used in clinical practices. Hematological, Liver function, Renal function, Tests associated with cardiac disorders., Fluid and electrolyte balance, Common tests in urine, sputum, faeces, CSF, Sensitivity screening for common pathogenic micro-organisms, its significance, resistance in disease states and selection of appropriate anti-microbial regimens.

UNIT III.
The role of hospital pharmacy department in the hospital and its relationship to other hospital departments and staff, Pharmacy and Therapeutics Committee, Selection of drugs, Hospital formulary development and management, Assessing drug efficacy, Assessing and managing drug safety, evaluating the cost of pharmaceuticals, identifying and addressing drug use problems including standard treatment guidelines. Other hospital committees such as infection control committee and research & ethics committee, Hospital Pharmacy Services Purchasing, storage, stability and safety of drugs, drug distribution, Radiopharmaceuticals handling and packing, IV
additive services and total parenteral nutrition. Inventory control methods (ABC, VED, EOQ, LEAD TIME, SAFETY STOCK METHODS)

UNIT IV
CONCEPT OF RATIONAL USE OF DRUGS Importance of rational drug use, Pharmacists role, Drug use indicators, Guidelines for rational prescribing.


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 lecturers, drug and therapeutics newsletter Ethical issues in biomedical research – Principles of ethics in biomedical research, good clinical practice [ICH GCP guidelines], Ethical committee [institutional review board], its constitution and functions, ethics of publication.

UNIT V
Definition, scope of community pharmacist, Roles and responsibilities of community Pharmacist, community pharmacy management a) selection of site space, lay out, design b) staff, materials-coding , stocking c) Legal requirements d) maintenance of various registers e) use of computers : Business and health care software.

REFERENCES
1. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.
   1. Clinical Pharmacy Practice by G.Parthasarathi Kavin Nyfort- Hansin
   2. Community Pharmacy Basic principle concept by Kamal Dua, Kavita Pabveja
   3. Basic skills in interpreting laboratory data – Scott LT, American Society of Health System Pharmacists, Inc., USA.
Unit: I

**Drug development process:**


5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines 6. Challenges in the implementation of guidelines

**CLINICAL PHARMACOKINETICS:** Introduction to clinical pharmacokinetics, Pharmacokinetics of drug interactions A) Pharmacokinetic drug interactions B) Inhibition and induction of drug metabolism C) Inhibition of biliary excretion, Dosage adjustment in renal and hepatic disease general approach for dosage adjustment in renal disease, measurement of GFR, and creatinine clearance, Extra corporeal removal of drugs. Effect of hepatic disease on Pharmacokinetics

Unit: II


Unit: III

General principles of regulatory toxicology. Use of animals in preclinical toxicity studies, role of preclinical toxicology in drug discovery and development process. Experimental considerations for assessing possible human risk. Flow chart for development of preclinical testing. Dose conversion factors, clinical signs toxicity. Preclinical toxicological requirements for biologicals and biotechnological products; safety analysis; problems specific to recombinant products, toxicokinetics, principles of GLP as per OECD guidelines for conducting preclinical toxicity studies
UNIT IV
General Principles involved in the management of poisoning, Clinical symptoms and management of Acute & chronic poisoning with the following agents: Opiates over dose, anti depressants, barbiturates and benzodiazepines, alcohol: ethanol, methanol, paracetamol and salicylates, NSAIDS, Pesticide poisoning: organo phosphorous compounds, carbamates, plant poisoning mushroom and mycotoxins, Venomous snake bites: clinical effects of venoms, general management as first aid, early manifestations, complications and snake bite injuries

UNIT V
Basics of testing hypothesis
a) Null hypothesis, level of significance, power of test, P value, statistical estimation of confidence intervals. b) Level of significance (Parametric data) - students t test (paired and unpaired), chi Square test, Analysis of Variance (one-way and two-way), F-test c) Level of significance (Non-parametric data) - Sign test, Wilcoxon’s signed rank test, Wilcoxon rank sum test, Mann Whitney U test, Kruskal-Wallis test (one way ANOVA) d) Correlation - Introduction, Pearsonn’s and Spearmann’s correlation and correlation co-efficient. e) Regression and its types, Least square method. f) Introduction to statistical software: SPSS, Epi Info, SAS.


Books recommened for clinical toxicology
1. Drug safety Evaluation, Shayne C Gad, Wiley Interscience
2. The toxicologist’s pocket handbook, Michael J derelanko 2 Ed, 2008, CRC press
3. Relevant OECD guidelines (Internet resources)

**Reference books for biostatistics:**  
c. Biostatistics, P.N. Arora  
e) Fundamentals of Biostatistics by Khan and Khanum.
II SEMESTER

IPR & REGULATORY AFFAIRS

M PP.T.1.201
Period / Week: 4
Sessional: 30
Examinations: 70

Duration of Exam: 3 hrs
Nature of Exam: Theory

UNIT – 1
Patents and Intellectual Property Rights (IPR): Definition, scope, objectives, sources of patent information, patent processing & application, Patents, copyrights, trademarks, salient features, trade related aspects (TRIPS), international & regional agreements.

UNIT – 2

UNIT – 3
Regulatory Affairs: Indian context – Requirements and guidelines of GMP, understanding of Drugs and Cosmetic Act 1940 and Rules 1945, with reference to Schedule M, U and Y.

UNIT – 4

UNIT – 5
Documentation: Types related to pharmaceutical industry, protocols, ammonizing formulation development for global filings, NDA, ANDA, CTD, dealing with post-approval changes – SUPAC, handling and maintenance including electronic documentation.

Recommended books:

2. Protection of Industrial Property Rights, P. Das and Gokul Das.
3. Law and Drugs, law publ. SN Katju.
4. Original laws published by Govt. of India.
5. Laws of drugs in India, Hussain.
PHARMACO THERAPEUTICS-II

M PP.T.1.202  
Period / Week: 4
Sessional: 30  
Duration of Exam: 3 hrs
Examinations: 70  
Nature of Exam: Theory

UNIT I.

Haematological diseases
Blood and body fluids, Complications of blood transfusion and blood substitutes,
Anaemia, Drug induced haematological disorders

Immunology
Immune disease – pathogenesis, mechanism of action of drugs,
Glucocorticoids – anti-inflammatory, anti-allergic and immunosuppressive
actions in tissue as well as organ transplantation, Vaccines – management of
primary immunodeficiencies

UNIT II.

Bone and joint Disorders
Osteoporosis, rheumatoid arthritis, osteoarthritis, gout, Paget’s disease of bones.

Pain management: Pathophysiology of inflammation and repair, Pain pathways, Analgesics and
NSAIDs, Opiates, Local anaesthetics, Neuralgia, muscle relaxants.

UNIT III.

Nervous system
Epilepsy, Parkinson’s disease, Stroke and transient ischaemic attacks, Headache, Migraine.

Psychiatric disorders
Schizophrenia, Depression, Anxiety disorders, Sleep disorders.

UNIT IV

Infectious diseases
Meningitis, Respiratory tract infections, Gastroenteritis, Pneumonia, Bacterial endocarditis,
Septicaemia, Otitis media, Urinary tract infections, Tuberculosis, Leprosy, Protozoal infections
and helmenthiasis, HIV and opportunistic infections, Fungal infections. sexually transmitted
diseases Syphilis and Gonorrhoea.
UNIT – V

Renal system

Diuretic therapy, Potassium depletion, Hyperkalemia, Alkalosis, Acute renal failure, Chronic renal failure, Dialysis, Renal replacement therapy, End-stage renal disease, Drug induced renal diseases.

TEXT BOOKS


REFERENCE BOOKS

1. Pathologic basis of diseases-Robins SL, W.B. Saunders publication.
6. Relevant review articles from recent medical and pharmaceutical literature.

JOURNALS

The students are required to be posted to various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do a tutorial as well as case presentation in the following clinical conditions. The students have to make at least 10 case presentations covering most common diseases found in the hospital to which the college is attached. The student should also submit a record of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge and presented in the SOAP (Subjective, Objective, Assessment and Plan) format. The cases may be selected from the following diseases:

1. Gastroenterology
a) Diarrhoea, Constipation, b) Acid peptic disease, c) Hepatic diseases - Hepatitis, Cirrhosis & Drug induced hepatic disorders, d) Oesophageal reflux, e) Helicobacter pylori induced gastric disorders.

2. Rheumatology
a) Rheumatoid arthritis, b) Gout, c) Degenerative joint disease - Temporal arthritis, Polymyalgia rheumatica etc., d) Systemic lupus erythmatosis.

3. Surgery

4. Haematology
a) Leukaemias, b) Lymphomas - Hodgkin’s, Non-Hodgkin’s, c) Multiple myeloma, d) Anaemia, e) Bleeding disorders.

5. Infectious Disease
a) Respiratory tract infections b) Tuberculosis c) Urinary tract infections, d) Joint and bone infections, e) Skin and Soft tissue infections.

6. Critical Care
a) Haemodynamic monitoring, b) Parenteral & enter nutrition, c) Pharmacotherapy of ventilated patients, d) Shock - Septic, Cardiogenic.

7. Renal
a) Acute renal failure, b) Chronic renal failure, c) Drug induced renal disease.

8. a) Convulsive disorder b) Parkinson’s disease, c) Neuro-degenerative disorders, d) Stroke, e) TIAs.

9. Psychiatry
a) Uni-polar and bipolar disorders, b) Anxiety, c) Psychosis, d) Alcohol abuse, e) Drug abuse

Assignments:
The students are required to submit a minimum of three written assignments (1500 to 2000 words) selected from the topics on different disease conditions given to them. The students are required to discuss both the clinical and therapeutic aspects in the same.
UNIT - I

Bioavailability and Bioequivalence: Objectives, bioavailability & variations, measurements of bioavailability, enhancing bioavailability, concepts of equivalents, official bioequivalence protocols & therapeutic equivalence.

UNIT - II

Drug Absorption: General consideration, absorption / drug transport mechanisms, role factors affecting absorption, absorption of drug non-peroral routes, methods of determining absorption-
in-vitro, in-situ, and in-vivo methods.

Drug Distribution: Factors affecting, protein & tissue binding, kinetics, determination of rate constants & different plots (direct, Scatchard, & reciprocal).

UNIT - III

Pharmacokinetics: Parameters & determination, pharmacokinetic models – one compartment, multi compartment in IV bolus, IV infusion & extra vascular, drug & metabolites levels in blood, urine and other biological fluids. Integration of kinetics.

Application of pharmacokinetics in new drug development, design of dosage forms and novel drug delivery systems.

UNIT - IV

Drug Disposition and Excretion: Biotransformation, factors affecting biotrasformation, Phase I & Phase-II reactions.

Clearance: Concept, renal, non-renal clearance, mechanism, determination, % drug metabolized, different volume of distribution.

UNIT – V

Pharmacokinetics of Multiple Dosing: Various terminology, determination, adjustment of dosage in renal & hepatic impairment, individualization of therapy, therapeutic drug monitoring.

Non-linear kinetics: Cause of non-linearity, estimation of various parameters, bioavailability of drugs that follow non-linear kinetics. Chronopharmacokinetics & pharmacokinetics of elderly and infants.
Recommended books

3. Theory & Practice of Industrial Pharmacy, L.Lachman, Varghese Publ, Bombay.
BIOPHARMACEUTICS AND PHARMACOKINETICS

Subject Code : M.PP.P.1.206  Sessional : 30
Period / Week: 6  Examinations : 70
Nature of Exam: Practicals  Duration of Exam: 6 hrs

Suggested experiments

1. Comparative dissolution studies on different dosage forms for drugs.
2. Effect of pH / particle size on dissolution studies.
3. Plasma protein binding studies on different drugs.
5. Estimation of creatinine clearance.
6. Estimation of pharmacokinetic parameters for the given urinary excretion data.
7. Estimation of pharmacokinetic parameters for the given oral absorption data.
PHARMACOEPIDEMIOLOGY AND PHARMACOVIGILANCE (THEORY)

Subject Code : M.PP T.1.204
Sessional : 30
Periods/Week : 4
Examination : 70
Nature of Exam : Theory
Exam Duration : 3 Hrs

Unit: I
Pharmacoepidemiology:
**Definition and scope:** Origin and evaluation of pharmacoepidemiology need for pharmacoepidemiology, aims and applications.

**Measurement of outcomes in pharmacoepidemiology** Outcome measure and drug use measures Prevalence, incidence and incidence rate. Monetary units, number of prescriptions, units of drugs dispensed, defined daily doses and prescribed daily doses, medication adherence measurement, **Concept of risk in pharmacoepidemiology** Measurement of risk, attributable risk and relative risk, time-risk relationship and odds ratio

Unit: II
Pharmacoepidemiological methods Includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods Drug utilization review, case reports, case series, surveys of drug use, cross – sectional studies, cohort studies, case control studies, case –cohort studies, meta – analysis studies, spontaneous reporting, prescription event monitoring and record linkage system. **Sources of data for pharmacoepidemiological studies** Ad Hoc data sources and automated data systems. **Selected special applications of pharmacoepidemiology** Studies of vaccine safety, hospital pharmacoepidemiology, pharmacoepidemiology and risk management, drug induced birth defects.

Unit: III
Pharmacoconomics:
**Definition, history, needs of pharmacoeconomic evaluations** Role in formulary management decisions **Pharmacoeconomic evaluation** Outcome assessment and types of evaluation includes theoretical aspects of various methods and practical study of various methods with the help of case studies for individual methods: Cost – minimization, cost- benefit, cost – effectiveness, cost utility **Applications of Pharmacoeconomics** Software and case studies
UNIT IV
Pharmacovigilance

A. Scope, definition and aims of pharmacovigilance, Definitions of the following:
   - Adverse drug reaction (ADR), Adverse events (AE), serious adverse event (SAE),
   - Serious adverse reaction (SAR), Suspected unexpected serious adverse reaction (SUSAR)

B. Adverse drug reactions – Classification, mechanism, Predisposing factors, causality
   assessment (different scales used)

C. Current methods of Pharmacovigilance, Signal detection in Pharmacovigilance,
   Post marketing surveillance.

D. Reporting, Evaluation, Monitoring, Prevention & Management of ADRs

E. Role of pharmacist in management of ADR.

F. Setting up of a pharmacovigilance center, benefit-risk assessment in Pharmacovigilance

UNIT V

a. FDA rules and regulations for reporting ADRs for various classes of drugs
b. Common databases used in pharmacovigilance (eg: ARGUS 15.1 version, Vigi base)
c. Various countries ADR reporting systems (eg: India, EU, Switzerland, U.S.A)
d. The council for international organizations of medical sciences (CIOMS) ADR
   reporting system, Pharmacovigilance programme in india(PVPI)

REFERENCE BOOKS:

1. A textbook of Pharmacoepidemiology by brian l. Strom and stephen e. Kimmel
   University of Pennsylvania, Philadelphia.
3. Text Book of Pharmacovigilance by S.K. Guptha Jaypee publications
4. Essentials of Pharmacoeconomics Karen Rascati (Author) Wolters kulwer Lippincott
   Williams Publications
5. Principles of Pharmacoeconomics second edition W Harvey whitney books company
   J. Lyle Bootman (Author, Editor), Raymond J. Townsend (Editor), William F. McGhan
   (Editor)