KAKATIYA UNIVERSITY
VIDYARANYAPURI, WARANGAL – 506009

M. Pharm (Pharmacy Practice)

Semester I :

**Theory**
- Paper 1 Clinical Pharmacy Practice
- Paper 2 Pharmacotherapeutics – I
- Paper 3 Community Pharmacy
- Paper 4 Hospital Pharmacy

**Practicals**
- Paper 1 Clinical Pharmacy Practice
- Paper 2 Pharmacotherapeutics-I

Semester II :

**Theory**
- Paper 1 Clinical Pharmacokinetics & Biostatistics
- Paper 2 Pharmacotherapeutics – II
- Paper 3 Clinical Research
- Paper 4 Pharmacoepidemiology and Pharmacoeconomics

**Practicals**
- Paper 1 Clinical Pharmacokinetics & Biostatistics
- Paper 2 Pharmacotherapeutics-II

Semester III :
- Comprehensive Viva-voce
- Seminar on Dissertation Topic Project work

Semester IV :
- Final Seminar of Dissertation (Results)
- Dissertation work in Pharmacy Practice
Semester – I

Paper – 1 : Clinical Pharmacy Practice 42 HOURS

1. Definitions, development and scope of clinical pharmacy 1

2. Introduction to daily activities of a clinical pharmacist 16
   • Drug therapy monitoring (medication chart review, clinical review, pharmacist interventions)
   • Ward round participation
   • Adverse drug reaction management
   • Drug information and poisons information
   • Medication history
   • Patient counselling
   • Pharmaceutical care
   • Drug utilisation evaluation (DUE) and review (DUR)
   • Quality assurance of clinical pharmacy services
     \[2+2+2+2+2+2+2+1+1\]

3. Patient data analysis
   • The patient's case history, its structure and use in evaluation of drug therapy & understanding common medical abbreviations and terminologies used in clinical practices.
   • Communication skills, including patient counseling techniques, medication history interview, presentation of cases. Teaching skills

4. Clinical laboratory tests used in the evaluation of disease states, and interpretation of Test results 10
   • Haematological, Liver function, Renal function, thyroid function tests
   • Tests associated with cardiac disorders
   • Fluid and electrolyte balance
   • Microbiological culture sensitivity tests
   • Pulmonary Function Tests
     \[1+2+1+1+1+1+2+2+1\]

5. Drug information 07
   • Introduction to drug information
   • Resources required,
   • Systematic approach in answering DI queries
   • Critical evaluation of drug information and literature
   • Preparation of written and verbal reports
   Establishing a Drug Information Centre
     \[1+2+2+2\]

6. Poison Information 03
   • Poisons information- organization & information resources, setting up of PIC.
Clinical Pharmacy Practical

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

- **Answering drug information questions** (4)
  (Queries related to Dosage, administration, Contraindications, Adverse drug reactions, drug use in pregnancy and lactation, drug profile, efficacy and safety)

- **Patient medication counseling**
  (3) Common diseases like Diabetes, Asthma, Hypertension, TB, and COPD
3. **Case studies** related to laboratory investigations (4) LFT, Hematology, Thyroid, Renal, Cardiac enzymes

4. **Patient medication history interview** (2)
5. **Medication order Review** (2)
6. **Detection and assessment of adverse drug reactions and their documentation**

ASSIGNMENTS

- Drug information, Patient medication history interview, Patient medication counseling, Problem solving in Clinical Pharmacokinetics, Literature evaluation pertaining to therapeutic range used in therapeutic monitoring of any two drugs frequently subjected for TDM.
- Critical appraisal of two recently published articles in biomedical literatures that deals with drugs or therapeutic issue.
1. General prescribing guidelines for
   2.1 Paediatric patients
   2.2 Geriatric patients
   2.3 Pregnancy and breast feeding

2. Introduction to rational drug use
   - Definition
   - Essential drug concept
   - Rational drug formulations
   - Role of pharmacist in rational drug use

3. Pathophysiology and pharmacotherapy of diseases associated with following systems/diseases

   Cardiovascular system
   - Hypertension, Congestive cardiac failure, Ischemic Heart disease, Myocardial infarction, Arrhythmias, Hyperlipidaemias
     [2+2+2+2+2+2]
   
   Respiratory system
   - Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

4. Pathophysiology and pharmacotherapy of diseases associated with Haematological diseases and Renal system
   - Anemia, Deep vein thrombosis, Drug induced hematological disorders (1+1+1)
   - Acute renal failure, Chronic renal failure, Renal dialysis and transplantation, Drug induced renal diseases [1+1+1+1]

5. Pathophysiology and pharmacotherapy of Endocrine system
   - Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis [2+1+1+1+1]

6. Pathophysiology and pharmacotherapy of Rheumatic diseases
   - Rheumatoid arthritis, Osteoarthritis, Gout, Systemic lupus erythematosus [2+1+1+1]
PRACTICALS

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 10 cases should be presented and recorded covering most common diseases. The list of clinical cases should include follow up of the clinical cases mentioned below from the day of admission till discharge. The same cases should be entered in their practical records following SOAP [Subjective, Objective, Assessment, Plan] technique.

1. Hypertension
2. Heart Failure
3. Myocardial Infarction
4. Coronary Heart Disease
5. Asthma
6. Chronic Obstructive Pulmonary Disease
7. Anemia
8. Osteoarthritis
9. Rheumatoid arthritis
10. Gout
11. Peptic Ulcer
12. Gastro esophageal reflux disease
13. Hyperlipidaemia
14. Neuralgias
15. Psoriasis
16. Hepatitis
ASSIGNMENTS

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of TWO assignments [1500 – 2000 words] should be submitted in each semester for evaluation.

Model Assignments

1. Management of Idiopathic thrombocytic purpura
2. Therapy of Helicobacter pylori infection.
3. Role of oral corticosteroids in Chronic Obstructive Pulmonary Disease
1. **Introduction to community Pharmacy**
   1.1. Community pharmacy Practice – definition
   1.2. The role of the community pharmacy and its relationship to other local health care providers and services to nursing homes and clinics
   1.3. Professional responsibilities of community pharmacist (FIP & WHO Model)
   1.4. Prescribed medication order - interpretation and legal requirements

2. **Communication skills - communication with prescribers and patients**
   5

3. **Over-the-counter (OTC) sales**
   6
   - Rational use of common OTC medications (Vitamins and tonics, iron preparations, analgesics, NSAIDs, cough mixtures, anti-diarrhoeal preparations)

4. **Primary health care in community pharmacy**
   15
   - Family planning, First aid, Participation in primary health programs, Smoking cessation, Screening programs, Nutrition, Responding to common ailments

5. **Community pharmacy management**
   8
   - Financial, materials, staff, infrastructure requirements, drug information resources in community pharmacies, computer applications in community pharmacy, Education and training
   2

6. **Home Medicines Review (HMR) program**
   3
   6.1. Introduction to HMR
   6.2. Guidelines to conduct HMR

References

1. Remington Pharmaceutical Sciences (RPS)
2. Text Book of Drug Store and Business Management by Jyothi & Ali
3. Text Book of Pharmacy Practice by Leon Shargel

Articles published in Pharmaceutical Journal (Royal Pharmaceutical Society of Great Britain)
1. Role of hospital pharmacy department and its relationship with the other departments and staff. 1 Hour

2. Hospital Pharmacy 5 Hours
   Objectives and Functions, Location, Organizational Structure

3. Hospital drug policy 5 Hours
   Drug committees, Formulary and guidelines, other hospital committees such as infection control and research and ethics committee.

4. Hospital pharmacy management 9 Hours
   Staff (professional and non-professional), materials (drugs, non-drugs, consumables), financial (drug budget, cost centres, sources of revenue, revenue collection), policy and planning, infrastructure requirements (building, furniture and fittings, specialized equipment, maintenance and repairs), workload statistics.

5. Organization of hospital pharmacy services

5.1 Drug distribution 6 Hours
   Purchasing, warehousing (storage conditions, expiry date control, recycling of drugs, stocktaking, drug recalls), drug distribution methods (ward stock, individual patient dispensing, unit dose), specific requirements for inpatients, outpatients, casualty/emergency, operation theatres, ICU/ICCU, drugs of dependence, hospital waste management. Central sterile supply services

5.2 Manufacturing 6 Hours
   Sterile and non-sterile production, including total parenteral nutrition,

5.3 Radiopharmaceuticals 6 Hours
   Cytotoxics, Radiopharmaceuticals preparation and quality control, and dispensing.
   IV additive service, prepackaging and labeling, quality control.

6. Training of technical staff, Training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. 4 Hours
Text Books

1. Hospital Pharmacy - Hassan WE. Lec and Febiger publication.

Reference books (Latest editions)

2. Remington Pharmaceutical Sciences,
3. Relevant review articles from recent medical and pharmaceutical literature.

Assignments

1. Select a new drug, which has recently been marketed in India for the first time. Prepare a report for a hospital’s Drug and Therapeutics Committee, and make a case either for or against the addition of this new drug on to the hospital’s formulary. Issues, which you may need to cover, include the drug’s pharmacology, its clinical use, the opinions of relevant hospital consultants and a cost comparison with existing therapies for the same condition for which the new drug is indicated.
2. Describe and evaluate the layout and workflow patterns in the dispensary of a local hospital. Include in your report any improvements, which you would recommend to achieve more efficient work practices.
3. Examine and report on the drug distribution methods used in a local hospital.
4. Prepare one Inventory for the following Drugs and Surgicals, based on ABC and VED Analysis.
   b) Injection ASV    b) Injection Adrenaline
   c) Injection Deriphylline   d) Injection Garamycin
   e) Bandage cloth, Vasofix  f) Disposable Syringes
   g) Antacid tablets   h) Tablet Erythromycin
   i) Vitamin tablets
5. Study the Store Management in Teaching/ District/ local hospitals for the following aspects.
   a) Receipt of Stores    b) Storage
   c) Issue                d) Documentation.
6. Procurements and storage of vaccine, sera and biological preparations in District Health Office.
Paper – 1 : Clinical Pharmacokinetics and Biostatistics 42 Hours

1. Clinical Pharmacokinetics 30
   1.1. Introduction to Clinical Pharmacokinetics
   1.2. Clinical Pharmacokinetic models

2. Drug clearance 3
   2.1. Physiological determinants of drug clearance and volumes of distribution
   2.2. Renal and non-renal clearance
   2.3. Organ extraction and models of hepatic clearance 2

3. Estimation and determinants of bioavailability

4. Drug dosing 3
   4.1. Calculation of loading and maintenance doses
   4.2. Dose adjustment in renal failure, hepatic dysfunction, geriatric and pediatric patients

5. Therapeutic Drug Monitoring (General aspects) 4

6. Clinical Application of Statistical Analysis 12
   - Basic concepts of biomedical statistics
   - Descriptive and Differential statistics
   - Statistical tests-Parametric & Non-parametric
   - Sample size calculation
   - Confidence intervals
   - Test of significance

Practicals

Practicals based on bio pharmaceutics and pharmacokinetics
1 Pathophysiology and pharmacotherapy of diseases associated with Nervous system
Epilepsy, Parkinson's disease, Stroke and transient ischemic attacks, Headache 8

[2+2+1+1+2]

2 Pathophysiology and pharmacotherapy of diseases associated with Psychiatric disorders 8
Schizophrenia, Depression, Anxiety & Sleep disorders, Drug induced psychosis

[2+2+3+1]

3 Pathophysiology and pharmacotherapy of diseases associated with Infectious diseases 20
2.1. General guidelines for the rational use of antibiotics.
2.2. Pharmacotherapy of Meningitis, Respiratory tract infections, Gastroenteritis, Bacterial endocarditic, Septicemia, Otitis media, Urinary tract infections,
2.3. Pharmacotherapy of Tuberculosis, Leprosy, Malaria, Helmenthiasis, HIV and opportunistic infections, Fungal infections, Rheumatic fever.

(1+1+2+1+1+1+1+2+2+1+2+1+2+1+2+1+1)

4. Oncology 6
General principles of cancer chemotherapy, commonly used cytotoxic drugs,
Chemotherapy of lung cancer, hematological malignancies, Management of nausea and vomiting

[3+2+1+1+1]
PRACTICALS

Hospital postings in various departments designed to complement the lectures by providing practical clinical discussion; attending ward rounds; follow up the progress and changes made in drug therapy in allotted patients; case presentation upon discharge. Students are required to maintain a record of cases presented and the same should be submitted at the end of the course for evaluation. A minimum of 10 cases should be presented and recorded covering most common diseases. The list of clinical cases should include follow up of the clinical cases mentioned below from the day of admission till discharge. The same cases should be entered in their practical records following SOAP [Subjective, Objective, Assessment, Plan] technique.

1. Schizophrenia
2. Depression
3. Anxiety
4. Epilepsy
5. Parkinson's disease
6. Stroke
7. Infectious diseases [any five]
ASSIGNMENTS

Students are required to submit written assignments on the topics given to them. Topics allotted should cover recent developments in drug therapy of various diseases. A minimum of THREE assignments [1500 – 2000 words] should be submitted for evaluation.

Model for assignments

1. Management of Multidrug resistant tuberculosis
2. Use of antiplatelet in the secondary prevention of stroke
1. Introduction to Clinical Research

Definitions and terminology used in clinical trials

- Historical development in clinical research practice
- Drug development process

2. Research Design Methods

Planning and execution of clinical trials, Various Phases of clinical trials
Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification)
Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study)
Health outcome measures (Clinical & Physiological, Humanistic and Economic)

3. Bioavailability and Bioequivalence studies

4. Ethics and Guidelines in Biomedical Research

- Ethical Issues in Biomedical Research – Principles of ethics in biomedical research,
- Ethical committee [institutional review board], its constitution and functions,
- Good clinical practice [ICH GCP guidelines, CDSCO regulations, MPA, European, Japan, Health Canada and MHRA guidelines, schedule Y and USFDA in the conduct of clinical trials]

5. Clinical research

- Establishing and functioning of Contract Research Organisation (CRO)
- Roles and responsibilities of clinical trial personnel
- Trial initiation, volunteer recruitment, trial supplies and site management,
- Designing of clinical trial documents
- Monitoring and auditing of clinical trials
- Trial report generation
- Site closure

6. Data Management

Medical Writing and Ethics of publication
Clinical data management (Data entry, data interpretation, data monitoring and auditing)

Reference books (Latest editions)

2. Designing Clinical Research. Edtd by Stephen B Hulley, Steven R Cummings
ASSIGNMENTS FOR CLINICAL RESEARCH

1. Design of Protocol for different types of studies
2. Correspondence procedures for constitution of IRB
3. Designing of informed consent process
4. Designing of CRF
5. Clinical data monitoring
Paper – 4 : Pharmacoepidemiology and Pharmacoeconomics 42 Hours

Pharmacoepidemiology

1. Introduction to Pharmacoepidemiology and its perspective (Industry, academic and regulatory, Hospital) 7 hours
2. Pharmacoepidemiological study designs and source data 9 hours
3. Molecular Pharmacoepidemiology 4 hours
4. Biomedical issues and quality of life measurements in Pharmacoepidemiological research 8 hours
5. Applications of Pharmacoepidemiology 4 Hours

Pharmacoeconomics

6. Various Pharmacoeconomic models used in health care and Applications of Pharmacoeconomics 10 hours

Reference Books

1. Pharmacoepidemiology Edt. Brian L Storm 4th Edn. Wiley Publisher
2. Avery’s Drug Treatment. ADIS publication
Equipment Required for M. Pharm. Pharmacy Practice Course

A) 1) HPLC can be shared with other Department with one pump and one
detector apart from U.V. should be procured.

2) U.V. Spectrophotometer - 1 No.
3) Digital pH meter - 1 No.
4) Centrifuge - 1 No.
5) Micro pipette 0-200μl - 1 No.
6) Micro pipette 100 – 1000 μl - 1 No.
7) Vortex mixer - 1 No.
8) ELISA Reader - 1 No.
9) All glass distilled water plant - 1 No.
10) Sonicator (Bath or probe type) - 1 No.

B) 300 hundred beded multi speciality Hospital

c) Faculty as per AICTE Norms.

Some software on drug interactions, adverse drug reactions and drug information.