PHARMACY PRACTICE (MPP)

CLINICAL PHARMACY PRACTICE (MPP 101T)

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. 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) — 12 Hrs

2 Clinical Pharmacy Services: Patient medication history interview, Basic concept of medicine and poison information services, Basic concept of pharmacovigilance, Hemovigilance, Materiovigilance and AEFI, Patient medication counselling, Drug utilisation evaluation, Documentation of clinical pharmacy services, Quality assurance of clinical pharmacy services. — 12 Hrs

3 Patient Data Analysis:
Patient Data & Practice Skills: Patient's case history - its structure and significances in drug therapy management, Common medical abbreviations and terminologies used in clinical practice, Communication skills: verbal and non-verbal communications, its applications in patient care services. — 12 Hrs

	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	12 Hrs
5	Medicines & Poison Information Services Medicine Information Service: Definition and need for medicine information service, Medicine information resources, Systematic approach in answering medicine information queries, Preparation of verbal and written response, Establishing a drug information centre. Poison Information Service: Definition, need, organization and functions of poison information centre.	12 Hrs

REFERENCES

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

PHARMACOTHERAPEUTICS-I
(MPP 102T)

Scope

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

Objectives

Upon completion of 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 diseases associated with following systems

1.	Cardiovascular system: Hypertension, Congestive cardiac failure, Acute coronary syndrome, Arrhythmias, Hyperlipidemias.	12 Hrs
2	Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases Endocrine system: Diabetes, Thyroid diseases	12 Hrs
3	Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis	12 Hrs
4	Gastrointestinal system: Cirrhosis, Diarrhea and Constipation, Drug-induced liver disease	12 Hrs
	Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders	

5	Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis	12 Hrs
	Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders	
	Ophthalmology: Conjunctivitis, Glaucoma	

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. Robins SL. Pathologic basis of disease -W.B. Saunders publication
4. Eric T. Herfindal. Clinical Pharmacy and Therapeutics- Williams and Wilkins Publication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs- Lippincott Williams and Wilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro. Pharmacotherapy Principles and practice-- McGraw Hill Publication
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
8. Harrison's. Principles of Internal Medicine - McGraw Hill
9. Relevant review articles from recent medical and pharmaceutical literature

HOSPITAL & COMMUNITY PHARMACY
(MPP 103T)

Scope

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

Objectives

Upon completion of 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. Introduction to Hospitals – Definition, classification, organizational structure — 12 Hrs

   Hospital Pharmacy: Definition, Relationship of hospital pharmacy department with other departments, Organizational structure, legal requirements, work load statistics, Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacy management

   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, Drug procurement process, and methods of Inventory control, Methods of Drug distribution, Intravenous admixtures, Hospital Waste Management — 12 Hrs

3. Education and training: Training of technical staff, training and continuing education for pharmacists, Pharmacy students, Medical staff and students, Nursing staff and students, Formal and informal meetings and lectures, Drug and therapeutics newsletter. — 12 Hrs

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

Community Pharmacy management: Legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, Good dispensing practices, Different softwares & databases used in community pharmacies. Entrepreneurship in community pharmacy.

4	Prescription – Legal requirements & interpretation, prescription related problems Responding to symptoms of minor ailments: Head ache, pyrexia, menstrual pains, food and drug allergy, OTC medication: Rational use of over the counter medications Medication counseling and use of patient information leaflets Medication adherence – Definition, factors influencing adherence behavior, strategies to improve medication adherence Patient referrals to the doctors ADR monitoring in community pharmacies	12 Hrs
5	Health Promotion – Definition and health promotion activities, family planning, Health screening services, first aid, prevention of communicable and non-communicable diseases, smoking cessation, Child & mother care National Health Programs- Role of Community Pharmacist in Malaria and TB control programs Home Medicines review program – Definition, objectives, Guidelines, method and outcomes Research in community pharmacy Practice	12 Hrs

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

CLINICAL RESEARCH
(MPP 104T)

Scope

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

Objectives

Upon completion of 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. Drug development process: Introduction, various approaches to drug discovery, Investigational new drug application submission Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, Ethical committee [institutional review board] – its constitution and functions, Challenges in implementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines in conduct of Clinical trials, Drug Safety Reporting.	12 Hrs
2 Types and Designs used in Clinical Research: Planning and execution of clinical trials, Various Phases of clinical trials, Bioavailability and Bioequivalence studies, Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification), Types of research designs based on Controlling Method (Experimental, Quasi experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) Clinical Trial Study team: Roles and responsibilities of: Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization.	12 Hrs

3	Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission	12 Hrs
4	Investigational Product: Procurement and Storage of investigation product Filing procedures: Essential documents for clinical trial, Trial Master File preparation and maintenance, Investigator Site File, Pharmacy File, Site initiation visit, Conduct, Report and Follow up Clinical Trial Monitoring and Close out: Preparation and conduct of monitoring visit: Review of source documents, CRF, ICF, IP storage, accountability and reconciliation, Study Procedure, EC communications, Safety reporting, Monitoring visit reporting and follow-up Close-Out visit: Study related documents collection, Archival requirement, Investigational Product reconciliation and destruction, Close-Out visit report.	12 Hrs
5	Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Fraud and misconduct management Data Management Infrastructure and System Requirement for Data Management: Electronic data capture systems, Selection and implementation of new systems, System validation and test procedures, Coding dictionaries, Data migration and archival Clinical Trial Data Management: Standard Operating Procedures, Data management plan, CRF & Data base design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.	12 Hrs

REFERENCES

1. Principles and practice of pharmaceutical medicine, Second edition. Authors:Lionel. D. Edward, Aadrew.J.Flether Anthony W Fos , Peter D Sloaier Publisher:Wiley;
2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Churchill Livingstone
3. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health.
5. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
6. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. 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.

PHARMACY PRACTICE PRACTICAL – I
(MPP 105P)

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. Presentation of clinical cases of various disease conditions adopting Pharmaceutical Care Plan Model (eight)
8. ABC Analysis of a given list of medications (one)
9. Preparation of content of a medicine, with proper justification, for the inclusion in the hospital formulary (one)
10. Formulation and dispensing of a given IV admixtures (one)
11. Preparation of a patient information leaflet (two)
12. Preparation of Study Protocol (one)
13. Preparation of Informed Consent Form (one)