# HOSPITAL PHARMACY

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## Seminar/Assignment
MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MHP101T)

Scope
This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives
After completion of course student is able to know,
Chemicals and Excipients
  The analysis of various drugs in single and combination dosage forms Theoretical and practical skills of the instruments

THEORY

1 a. UV-Visible spectroscopy: Introduction, Theory, Laws,
  Instrumentation associated with UV-Visible spectroscopy,
  Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy.


2. NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR, Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.


4. Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
  a) Paper chromatography b) Thin Layer chromatography
  c) Ion exchange chromatography d) Column chromatography
  e) Gas chromatography f) High Performance Liquid chromatography g) Affinity chromatography.

5. a. Electrophoresis: Principle, Instrumentation, Working condition factors affecting separation and application of the following:
  a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Isoelectric focusing
  b. X Ray Crystallography: Production of x rays, different x rays diffraction methods, Bragg’s law, rotating crystal technique, X rays powder technique, types of crystals and application of x rays diffraction.

6. immunological assays: RIA (Radio Immuno assay), ELISA, Bioluminescence assays
REFERENCES
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
Etiopathogenesis and pharmacotherapy of diseases associated with following systems
2. Respiratory system: Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases
3. Endocrine system: Diabetes, Thyroid diseases
4. Gastrointestinal system: Peptic ulcer diseases, Reflux esophagitis, Inflammatory bowel diseases, Jaundice & hepatitis
5. Gastrointestinal system: Cirrhosis, Diarrhoea and Constipation, Drug-induced liver disease
6. Hematological diseases: Anemia, Deep vein thrombosis, Drug induced hematological disorders
7. Bone and joint disorders: Rheumatoid arthritis, Osteoarthritis, Gout, Osteoporosis
8. Dermatological Diseases: Psoriasis, Eczema and scabies, impetigo, drug induced skin disorders
9. Ophthalmology: Conjunctivitis, Glaucoma
REFERENCES
1. Roger and Walker. Clinical Pharmacy and Therapeutics – Churchill Livingstone publication
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
7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins
9. Relevant review articles from recent medical and pharmaceutical literature
HOSPITAL & COMMUNITY PHARMACY (MHP103T)

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

1. Introduction to Hospitals – Definition, classification, organizational structure
   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

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

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

REFERENCES
1. Hospital Pharmacy - Hassan WE. Lea and Febiger publication.
3. Avery’s Drug Treatment, Adis International Limited.
5. Remington Pharmaceutical Sciences.
6. Relevant review articles from recent medical and pharmaceutical literature
MANUFACTURING PHARMACY (MHP104T)

Scope
This course is designed to provide sufficient knowledge regarding the role of hospital pharmacist in manufacturing and related aspects

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

Understand the process of manufacturing of various formulations
Understand the handling of various formulation
Understand about the quality control of products
Have knowledge of various techniques of sterilization

THEORY

1. Hospital formulation, fundamental principles and processes, composition; manufacturing storage and preservation of tablets, liquid, oral products, capsules and dermatological in IP, BPC and NF
2. Study of formulation, manufacture, packing of IV fluids used in hospitals, layout of such units, equipment needed for washing; drying, filtration, filling. Sterilization and labeling of these preparation; merits of manufacturing of IV fluids in hospitals.
3. Study of injectable, vehicle used and manufacturing
4. Study of formulation and preparation of sterile products used in hospitals and different sections of hospitals like ophthalmic solutions; nasal solutions; dialysis solutions; contact lens solution and solution used in organ transplant
5. Organization and development of parenteral admixture, some physical and chemical incompatibility of IV admixture
6. Sterilization; methods and techniques as applicable to hospital pharmacy.
7. Radiopharmaceuticals; procurement; storage; handling dosage and precautions.
8. Pharmacopoeial quality control requirement for all dosage forms handled in hospitals
9. Blood transfusion; collection, storage and administration

REFERENCES
Hospital Pharmacy Practical-1 (MHP105P)

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on HPLC
4. Experiments based on Gas Chromatography
5. Estimation of riboflavin/quinine sulphate by fluorimetry
6. Estimation of sodium/potassium by flame photometry
7. Preparation; sterilization and quality control of several batches of I.V. fluids used in hospitals.
8. Preparation and quality control of a) Injections; b) Ophthalmic solution; c) Nasal Solutions; d) Dialysis fluids; e) Contact lens solutions; f) Dermatological preparations.
9. Sterility testing
10. Maintenance and quality control of sterile room.
11. Any other experiment relevant to topics covered in the theory.
SECOND SEMESTER

PRINCIPLES OF QUALITY USE OF MEDICINES (MHP201T)

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
1. Introduction to Quality use of medicines (QUM): Definition and Principles of QUM, Key partners and responsibilities of the partners, Building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost effective prescribing.
2. Concepts in QUM
   Evidence based medicine: Definition, concept of evidence based medicine, Approach and practice of evidence based medicine 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 drug use, Rational drug prescribing, Role of pharmacist in rational drug use.
3. QUM in various settings: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine and multidisciplinary care. QUM in special population: Paediatric prescribing, Geriatric prescribing, Prescribing in pregnancy and lactation, Prescribing in immune compromised and organ failure patients.
4. Regulatory aspects of QUM in India: Regulation including scheduling, Regulation of complementary medicines, Regulation of OTC medicines, Professional responsibility of pharmacist, Role of industry in QUM in medicine development.
5. Medication errors: Definition, categorization and causes of medication errors, Detection and prevention of medication errors, Role of pharmacist in monitoring and management of medication errors

Pharmacovigilance: Definition, aims and need for pharmacovigilance, Types, predisposing factors and mechanism of adverse drug reactions (ADRs), Detection, reporting and monitoring of ADRs, Causality assessment of ADRs, Management of ADRs, Role of pharmacist in pharmacovigilance.
REFERENCES:
2. Andrews EB, Moore N. Mann’s Pharmacovigilance
3. Dipiro JT, Talbert RL, Yee GC. Pharmacotherapy: A Pathophysiologic Approach
4. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-Based Medicine: How to practice and teach it
5. Cohen MR. Medication Errors
6. Online:
   http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
7. Relevant review articles from recent medical and pharmaceutical literature.
Scope
This course aims to enable the students to understand the different treatment approaches in managing various disease conditions. Also, it imparts knowledge and skill 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
2. Psychiatric disorders: Schizophrenia, Depression, Anxiety disorders, Sleep disorders Drug induced psychiatric disorders Renal system: Acute renal failure, Chronic renal failure, Renal dialysis, Drug induced renal disease
3. Infectious diseases: General guidelines for the rational use of antibiotics and surgical prophylaxis, Urinary tract infections, Respiratory tract infections, Gastroenteritis, Tuberculosis, Malaria, Bacterial endocarditis, Septicemia.
5. Oncology: General principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung cancer, head & neck cancer, hematological malignancies, Management of nausea and vomiting, Palliative care

REFERENCES
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

   Pharmacotherapy Principles and practice—McGraw Hill Publication

7. Carol Mattson Porth. Principles of Pathophysiology- Lippincott Williams and Wilkins


9. Relevant review articles from recent medical and pharmaceutical literature
Scope
This course is designed to provide knowledge regarding the quality aspects of manufacturing in hospital pharmacy setup. Moreover, it imparts knowledge regarding the regulatory considerations while handling drug products.

Objectives
Upon completion of this course it is expected that students shall be able to:
Understand the Preformulation aspects of drug product
Understand the quality control and quality assurance aspects of manufacturing
Have knowledge of various regulatory frameworks
Have knowledge of process of clinical trial with respect to own role

THEORY
1. Preformulation studies; pka, solubility, dissolution rate, partition coefficient, crystal morphology, polymorphism, powder flow, surface characteristics.
2. Solubilization techniques; methods of solubilization including addition of co solvents, surface active agents, complexation, hydro trophy, chemical modification.
3. Dissolution testing; dissolution apparatus (basket & paddle), dissolution rate testing for suspension, topical, suppositories and sustained release products in-vivo in-vitro correlation.
4. Formulation of sustained release products: calculation of dose where maintenance dose is released by zero order and first order process. Oral sustained release dosage form e.g. diffusion system, dissolution system, osmotic system and ion exchange system. Parenteral S.R. dosage form, I. M. injection (aqueous suspension and oil formulation), implants (subcutaneous device, intra uterine device), transdermal device. Targeted drug delivery system e.g. nanoparticle liposome, resealed erythrocytes.
5. Product stability; chemical and physical stability of pharmaceutical dosage form, accelerated solubility testing & shelf life evaluation, influence of packaging component, dosage form stability.
6. Quality assurance: quality assurance concept, operation of a quality assurance system, function of quality control, analytical control, quality control charts, GMP, process development manufacturing facilities, procedure records, product recall, documentation, good laboratory practices.
7. Drug regulatory affairs. Definition of drug label, new drug, investigational drug as per D&C act (India) & FDA (USA), new drug application, drug efficacy study, implementation review, labeling requirements of OTC drugs, prescription drugs (schedule H, X narcotics), warning notice package inserts, CGMP.
8. Clinical trial of drug substances; pre-trial testing, design of clinical trials, choice of patients, monitoring of clinical trials, documentation, compatibility of performance, manufacturing & quality control of products & placebo, analysis of results, role of pharmacists in clinical trial

9. Post marketing surveillance of new products

REFERENCES


5. Good manufacturing practices for pharmaceuticals: A plan for total quality control, second edition; By Sidney H. Willig


PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS (MHP 204T)

Scope
This course enables students to understand various pharmacoepidemiological methods and their clinical applications. Also, it aims to impart knowledge on basic concepts, assumptions, terminology, and methods associated with Pharmacoeconomics and health related outcomes, and when should be appropriate Pharmacoeconomic model should be applied for a health care regimen.

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 associated with pharmacy products and services.

Perform the key Pharmacoeconomics analysis methods

- Understand the Pharmacoeconomic decision analysis methods and its applications. Describe current Pharmacoeconomic methods and issues.
- Understand the applications of Pharmacoeconomics to various pharmacy settings.

THEORY
1. Introduction to Pharmacoepidemiology: Definition, Scope, Need, Aims & Applications;
   - Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number of prescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis and Therapy surveys, Prevalence, Incidence rate, Monetary units, number of prescriptions, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements.
   - Concept of risk: Measurement of risk, Attributable risk and relative risk, Time-risk relationship and odds ratio

2. Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review;
   - Quantitative models: case reports, case series, Cross sectional studies, Cohort and case control studies, Calculation of Odds’ ratio, Meta analysis models, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Record linkage systems, Applications of Pharmacoepidemiology

3. Introduction to Pharmacoeconomics: Definition, history of Pharmacoeconomics, Need of Pharmacoeconomic studies in Indian healthcare system.
   - Cost categorization and resources for cost estimation: Direct costs. Indirect costs. Intangible costs.
   - Outcomes and Measurements of Pharmacoeconomics: Types of outcomes: Clinical outcome, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, Disability Adjusted
Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. Person Time, Willingness To Pay, Time Trade Off and Discounting.

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


5. George E Mackinnon III. Understanding health outcomes and pharmacoeconomics.


7. Walley, Pharmacoeconomics.

8. Pharmacoeconomic – ed. by Nowakowska – University of Medical Sciences, Poznan.

9. Relevant review articles from recent medical and pharmaceutical literature.
HOSPITAL PHARMACY-2 PRACTICAL (MHP205P)

1. To find partition coefficient of aspirin in chloroform & buffer of various pH.
2. Solubilisation of paracetamol by solvents, surface active agents.
3. Dissolution rate study of marketed capsule dosage form.
5. Preparation of tablets by various granulation methods.
6. Preparation of layered tablets.
7. Preparation of effervescent tablets.
8. Preparation of film coated tablets.
11. Preparation of aqueous suspension by using different surface active agent, suspending agents, evaluation of physical stability.
12. Preparation of ophthalmic ointments and to evaluate release profile.
13. To evaluate shelf life of formulation from Arrhenius plots.