PARMACY PRACTICE-III (COMPUTER AND ITS APPLICATION IN PHARMACY) Practical

Paper 12 **Marks 50**

1. **INTERNET AND E-MAIL**: Internet and Microsoft Internet Explorer 5, Addresses, Links and Downloading, Searching the Internet, E-mail and Newsgroups, Favourites, security and Customizing Explorer.
2. **WEB PAGE DEVELOPMENT**: Introduction to Front-page, Creating a First Web site, Basic Formatting Techniques, Manipulating Tables within Front-page, Front-page, Picture and MultiMedia, Hyper linking, Bookmarks and Image Maps, Introducing Front-page "components", Front-page and Frames, Managing your Web, Good site design, Publishing and publicizing.
3. **DATA PRESENTATION SKILLS**: MS-Word, MS-Excel, MS-Power point.
4. **UNDERSTANDING AND APPLICATION OF STATISTICAL PACKAGES:** SPSS, Kinetica, Med Calc.

FOURTH PROFESSIONAL

PHARMACY PRACTICE-IV (HOSPITAL PHARMACY) (Theory)

Paper 1 **Marks 100**

1. **INTRODUCTION:**
   a. Role of Pharmacist in Hospital
   b. Minimum standards for pharmacies in Institutions/Hospitals
   c. Research in Hospital Pharmacy
2. **HOSPITAL AND ITS ORGANIZATION:**
   a. Classification of Hospitals
   b. Organizational Pattern
   c. Administration
   d. Clinical Departments
   e. Nursing, Dietetic, Pathology, Blood Bank, Radiology and other supportive services etc.
   f. Role of Pharmacy in Hospital
   g. Hospital Finances
3. **PHARMACY, ITS ORGANIZATION AND PERSONNEL:**
   a. Pharmacy specialist
   b. Drug information Centre
   c. Poison Control Centre and Antidote Bank
   d. Pharmacy Education
   e. Determining the Need of Professional and other departmental staff
   f. Professional services rendered

4. **PHARMACY AND THERAPEUTIC COMMITTEE:**
5. **THE HOSPITAL FORMULARY:**
    a. General Principles and guidelines to develop Formulary
    b. Format
    c. Preparation of the Formulary
    d. Role of Pharmacist
    e. Benefits and problems
    f. Keeping up to date Formulary
6. **DISPENSING TO IN-PATIENTS:**
    a. Methods of Dispensing & SOP's
    b. Unit dose dispensing
    c. Other concepts of dispensing, Satellite Pharmacy etc.
7. **DISPENSING TO AMBULATORY PATIENTS:**
8. **DISTRIBUTION OF CONTROL SUBSTANCES:**
9. **DISPENSING DURING OFF-HOURS:**
10. **SAFE USE OF MEDICATION IN THE HOSPITAL:** Medication error; Evaluation & Precautions of Medication Error; Role of Pharmacist in Controlling Medication Error.
11. **MANUFACTURING BULK AND STERILE:**
12. **THE PHARMACY; CENTRAL STERILE SUPPLY ROOM:**
13. **ASEPTIC DISPENSING:** TPN, I/V Admixtures, Cytotoxic Dispensing, Semi-sterile Dispensing (Eye drops, Ear drops) and Hyperalimentation.
14. **ROLE OF PHARMACIST IN SMALL HOSPITALS, NURSING HOMES etc:**
15. **PURCHASING, DISTRIBUTION AND CONTROL OF HOSPITAL MEDICINES, MEDICAL & SURGICAL SUPPLIES:** Purchasing, Stocking, Stock Control, Inventory Management, Drug Distribution, Relationship between purchasing, Distribution and Clinical Pharmacy Services.
16. **NUCLEAR PHARMACY:**
17. **THE PHYSICAL PLANT AND ITS EQUIPMENT:**
18. **INVESTIGATIONAL USE OF DRUGS:**
19. **HEALTH ACCESSORIES:**
20. **SURGICAL SUPPLIES:**
21. **INSPECTION OF WARDS WITH REFERENCE TO DRUG STORAGE AND ADMINISTRATION:**
22. **MANAGEMENT OF ACCIDENT & EMERGENCY PHARMACY (A & E):**

PHARMACY PRACTICE-V (CLINICAL PHARMACY-I) (Theory)

Paper 2 **Marks 100**

1. **GENERAL INTRODUCTION TO CLINICAL PHARMACY:**
   a. Introduction to clinical pharmacy and related terms, definition, basic components, comparison with other clinical fields, scope of services.
   b. Guidelines (General guidelines for Clinical Pharmacy Practice)
   c. Patient counseling compliance
   d. Laboratory Data interpretation
   e. Electrolytes management
   f. Clinical literature evaluation
   g. Drug interactions
   h. Medication errors

2. **DISEASE MANAGEMENT:**

   Disease management should be covered by considering aspects like diseases definition, etiology, pathogenesis, clinical presentation, diagnostic work out (briefly), pharmacotherapy.

   MODULES:
   - Unit I: Cardiovascular unit (hypertension, ischemic heart diseases e.g. angina pectoris, MI, Heart failure).
   - Unit II: Pulmonary unit (Asthma e.g. acute, chronic, status asthamaticus, childhood asthma, Pneumonia, COPD includes emphysema & chronic bronchitis)
   - Unit III: Gastroenterology unit [ulcer, liver cirrhosis, portal hypertension, hepatitis, diarrhea, inflammatory bowel disease (IBD)].

3. **PATIENT PROFILE & PATIENT COUNSELING:**
   a. Patient disease profile
   b. Taking case history
   c. Drug profile of at least 25 Important Medications e.g. Adrenaline, Aminoglycosides, Anti-TB Drugs, Antiepileptics, Atropine, Benzodiazepines, Cepahlosporins, Chlorpheniramine, Cimetidine, Digoxin, Dobutamine, Dopamine, Fluroquinolone, Furosemide, Lactulose, Macrolides, Metoclopramide, Morphine/Pethedine, Nifedipine, NSAIDS, ORS, Penicillins, Prednisolone, Salbutamol, Vancomycin.
   d. Patient Counseling

4. **CLINICAL TRIALS OF DRUG SUBSTANCES:** Designing of clinical trials, types of trials, Choice of patients, exclusion of patients and monitoring a clinical trial.

5. **EMERGENCY TREATMENT:** For example, Cardiopulmonary resuscitation (CPR), Cold Blue.

6. **DRUG INTERACTIONS:** Mechanism, Physiological factors affecting interaction, Types and level of drug interactions, Role of pharmacist in evaluating drug interaction & its management.

7. **PHARMACOVIGILANCE:**
   a. Scope, definition and aims of Pharmacovigilance

b. Adverse Drug Reactions and Side Effects: Classification, Excessive pharmacological response, Idiosyncrasy, Secondary pharmacological effects, Allergic drug reactions, Detection, Management of ADR, reporting of ADR in light of international health monitoring system.

8. **PHARMACOTHERAPY PLAN:**

I. Development, Implementation and Monitoring of Drug Therapy Plans:

a. Pharmacist work up of drug therapy (PWDT)
b. Documentation of Pharmacotherapy Plan
   - SOAP note
   - CORE Pharmacotherapy Plan
   - PRIME Pharmacotherapy problems
   - FARM note
c. Implementation of Drug Therapy Plan
d. Monitoring of Pharmacotherapeutic plan
e. Pharmaceutical care plan as ongoing process
f. Importance of drug therapy plan in today's pharmacy practice

II. Pharmacotherapy Decision-Making:

A. Pursue the role of drug therapy practitioner over that of drug therapy advisor.
B. Participate in pharmacotherapy decision-making by:
   a. Identifying opportunities for decision-making.
   b. Proactively engaging decision-making opportunities.
   c. Formulating decision rationale that is the result of rigorous inquiry, scientific reasoning, and evidence.
   d. Pursuing the highest levels of decision-making.
   e. Seeking independence in making decisions and accepting personal responsibility for the outcomes to patients resulting from one's decisions.
   f. Personally enacting decisions

9. **DRUG INDUCED DISEASES:**

10. **UTILIZATION OF CLINICAL DRUG LITERATURE:** Introduction, Drug literature selection, Drug literature evaluation and Drug literature communication.

11. **ONLINE PHARMACEUTICAL CARE SERVICES AND GLOBALIZATION:**

12. **PROVISION OF PHARMACEUTICAL CARE IN MULTIPLE ENVIRONMENTS:**
Professionalism, physical assessment, body substance precautions and the relationships between culture, race and gender to pharmaceutical care.

PHARMACY PRACTICE-IV (CLINICAL PHARMACY-I) (Practical)

Paper 6 **Marks 100**

1. **PHARMACY PRACTICE-V (CLINICAL PHARMACY-I) (PRACTICAL)**
   - Clerkship in the Clinical Setting. A report related to Clinical Pharmacy Practices will be completed by the students and will be evaluated by the external examiner.

- Students will also complete a report independently or in a group on a Drug Use Evaluation.
- Students will take the assignment tasks to enhance verbal presentation, communication, written and problem-solving skills, critical analysis of data and provision of care through a weekly conference and projects

PHARMACEUTICS-IV (INDUSTRIAL PHARMACY) (Theory)

Paper 3 **Marks 100**

1. **MASS TRANSFER.**
2. **HEAT TRANSFER.**
3. **DRYING:** Theories of drying, Drying of Solids, Classification of dryers, General Methods, Fluidized Bed systems, Pneumatic systems, Spray dryer, Freeze drying.
4. **COMMINUTION (SIZE REDUCTION):** Reasons for size reduction, Factors affecting size reduction, size analysis, Sieving, Energy Mills (Ball Mill, Endrumer, Edge Rumer, Disintegrant, Colloid Mill, Hammer Mill, Cutter Mill and Fluid Energy Mill etc).
5. **MIXING:** Fundamentals, Mechanisms, Mixing Equipment used in Liquid/Liquid, Liquid/Solid and Solid/Solid mixing.
6. **CLARIFICATION AND FILTRATION:** Theory, Filter Media, Filter aids, Filter selection and Equipment (Leaf filter, Filter press, Meta filters and Rotary filters).
7. **EVAPORATION:** General principles of Evaporation, Evaporators and Evaporation under reduced pressure.
8. **COMPRESSION AND COMPACTION:** The solid-air Interface, Angle of Repose, Flow rates, Mass volume relationship, Density, Heckel Plots, Consolidation, Granulation, Friability, Compression (dry method, wet method, slugging), Physics of Tabletting, tabletting machines and other equipment required, problems involved in tabletting, tablet coating, **Capsulation**: (Hard and Soft gelatin capsules).
9. **SAFETY METHODS IN PHARMACEUTICAL INDUSTRY:**
   (a) Mechanical, chemical and fire hazards problems.
   (b) Inflammable gases and dusts.
10. **EMULSIONS:** Mechanical Equipments, Specific formulation Considerations and Emulsion stability.
11. **SUSPENSIONS:** Formulation of suspensions, Equipment used in preparation and test methods for pharmaceutical suspensions.
12. **SEMISOLIDS:** Equipment used for Ointments, Pastes, Gels and Jellies, Packaging of ointments.
13. **STERILE PRODUCTS:** Sterile area and its Classification, Ophthalmic ointments, Preparation of parenterals (Building, Equipment), Complete Sterility (Aseptic area), air control, (Laminar flow etc.), air locks, Environmental monitoring methods, Sterilization, Filling/Packaging (Plastic and glass containers), Added substances (Preservatives, anti-oxidants, solubilizer, suspending agents, buffers, stabilizers etc.), In-process Quality Control of Parenterals (Sterility, leakage, pyrogens, clarity etc.).

14. **PACKING & PACKAGING:** Influence of Packaging materials, Stability, Packaging Lines, Packaging Area, Packaging Equipment.

STUDY TOUR: A visit to the pharmaceutical industries will be an integral part of the syllabi and will prepare and submit a report about operations in Pharmaceutical industry that will be evaluated in practical examination.

PHARMACEUTICS-IV (INDUSTRIAL PHARMACY) (Practical)

Paper 7 **Marks 100**

NOTE: Practical of the subject shall be designed from time to time on the basis of the above mentioned theoretical topics and availability of the facilities, e.g.

- Manufacture of Tablets by Wet Granulation Method, by Slugging and by Direct Compression.
- Coating of Tablets (Sugar Coating, Film coating and Enteric Coating).
- Clarification of liquids by various processes.
- Size Reduction, Homogenization.
- Ampoule filling, sealing and sterilization clarity and leakage tests in injectables.
- Capsule filling by semi automatic machines.
- Manufacture of sustained action drugs.
- Tablets Tests like Disintegration. Dissolution. Friability. Hardness and thickness tests.
- Determination of weight variation in tablets.
- Density of powder. Particle size analysis (Note: A minimum of 20 practicals will be conducted).

PHARMACEUTICS-V (BIOPHARMACEUTICS & PHARAMCOKINETICS) (Theory)

Paper 4 **Marks 100**

1. **DEFINITIONS AND TERMINOLOGY:** Biopharmaceutics, Generic Equivalence, Therapeutic Equivalents, Bioavailability, Bioequivalence, Drug Disposition, Pharmacokinetics (LADMER: Libration, absorption, distribution, metabolism, elimination and response).

2. **GASTRO-INTESTINAL ABSORPTION:** Forces which help in transmembrane movements, Anatomical and physiological factors influencing absorption of drugs. Physicochemical properties of drugs affecting absorption. Absorption of different oral dosage forms.

3. **BIOLOGICAL HALF LIFE AND VOLUME OF DISTRIBUTION:** Introduction, types, methods of determination and application.

4. **DRUG CLEARANCE:** Introduction, Mechanism, Models, determination and relationship of clearance with half-life.

5. **PHARMACOKINETICS:** Introduction, Linear and Non-linear Pharmacokinetics. Application of pharmacokinetics in clinical situations.

6. **BIOAVAILABILITY AND BIOEQUIVALENCE:**
   a. Introduction.
   b. Bioavailability types, parameters, significance and study protocol.
   c. Methods of Assessment of Bioavailability
   d. Bioequivalence study designs, components and application, report format

7. **CONCEPT OF COMPARTMENT(S) MODELS:**
   I. One compartment open model
      a. Intravenous Injection (Bolus)
      b. Intravenous infusion
   II. Multicompartment models
      a. Two compartment open model
      b. IV bolus, IV infusion and oral administration
   III. Non-compartmental Model
      a. Statistical Moment Theory
      b. MRT for various compartment models
      c. Physiological Pharmacokinetic model

8. **MULTIPLE DOSAGE REGIMENS:**
   a. Introduction: principles of superposition
   b. Factors: persistent, accumulation and loss factors
   c. Repetitive Intravenous injections-One Compartment Open Model
   d. Repetitive Extravascular dosing-One Compartment Open model
   e. Multiple Dose Regimen-Two Compartment Open Model

9. **ELIMINATION OF DRUGS:**
   d) Hepatic Elimination: Percent of Drug Metabolized, Drug Biotransformation reactions, (Phase-I reactions and phase-II reactions), First pass effect, Hepatic clearance of protein bound drugs and Biliary excretion of drugs.
   e) Renal Excretion of Drugs: Renal clearance, Tubular Secretion and Tubular Re-absorption.
   f) Elimination of Drugs through other organs: Pulmonary excretion, salivary excretion, Mammilary excretion, Skin excretion and Genital excretion.

10. **PROTEIN BINDING:** Introduction, types, kinetics, determination and clinical significance of drug-protein binding.

11. **PHARMACOKINETICS VARIATIONS IN DISEASE STATES:** Determination of pharmacokinetics variations in renal and hepatic diseases, general approaches for dose adjustment in renal disease and hepatic diseases.

12. **PHARMACOKINETICS OF INTRAVENOUS INFUSIONS:**

13. **BIOPHARMACEUTICAL ASPECTS IN DEVELOPING A DOSAGE FORM:** Drug considerations, drug product considerations, patient considerations, manufacturing considerations, pharmacodynamic considerations pharmacokinetic considerations.

14. **IN-VITRO-IN-VIVO CORRELATION (IVIVC):** Introduction, levels and determination of in-vitro/in-vivo correlation.

PHARMACEUTICS-V (BIOPHARMACEUTICS & PHARAMCOKINETICS) (Practical)

Paper 8 **Marks 100**

NOTE: Practical of the subject shall be designed from time to time on the basis of the above mentioned theoretical topics and availability of the facilities, e.g. Blood Sampling Techniques (In Laboratory Animals like dog, rabbits, mice etc. in human beings), In-vitro dissolution studies, Optional dose determination, Measurement of rate of Bioavailability, Determination of relative and absolute bioavailability. Plasma level-time curve (Determination of Pharmacokinetic parameters). Determination of plasma protein binding. Urinary sampling techniques. In Laboratory animals. In humans: Renal excretion of drugs or drug disposition.

PHARMACEUTICS-VI (PHARMACEUTICAL QUALITY MANAGEMENT) (Theory)

Paper 5 **Marks 100**

1. **INTRODUCTION:**
   Basic concepts and introduction of pharmaceutical industry in relevance to quality control departments, Testing, Quality Management System, Quality Assurance, Good Manufacturing Practices and Current Good Manufacturing Practices. General understanding of good laboratory practices and validation.

2. **QUALITY CONTROL OF SOLID DOSAGE FORMS** (conventional and modified release dosage forms):
   (a) Physical tests: Hardness, Thickness, Diameter, Friability, Disintegration, Weight Variation.
   (b) Chemical tests: Content uniformity, Assay of active Ingredient.
3. **QUALITY CONTROL OF SYRUPS, ELIXIRS, AND DISPERSE SYSTEM:** Viscosity, its determination and application in the Quality Control of Pharmaceuticals, Weight per ml and Assay of active Ingredient.
4. **QUALITY CONTROL OF SUPPOSITORIES:** Dissolution test, Uniformity of weight, Assay of active Ingredient, Liquefaction time test and Breaking test.
5. **QUALITY CONTROL OF STERILE PRODUCTS (PARENTERALS):** Sterility Test and Sterile section management, Leaker's test, Clarity test, Pyrogen test for Parenteral and other sterile preparations, Assay for active Ingredient.
6. **BIOLOGICAL ASSAYS:** Biological methods, Standard preparations and units of activity, Bioassay of antibiotics, Bioassay of insulin injection, Assay of prepared digitalis and Assay of Vitamin D.

7. **ALCOHOL DETERMINATION:** Alcoholometric methods, Problem during distillation of alcohol, Method for liquids containing less than 30% or more than 30% alcohol and special treatment before distillation.

8. **ALKALOIDAL DRUG ASSAY:** Weighing for assay, Extraction of drugs, Maceration, Percolation, Continuous extraction, Purification of Alkaloids and determination of alkaloids.

9. **QUALITY ASSURANCE OF VACCINES:** Introduction, Quality measures for stability of vaccines, potency testing, and post market surveillance of vaccines.

10. **MISCELLANEOUS DETERMINATIONS AND TESTS:** Determination of weight/ml, Water/Moisture content, Loss on Drying, Evaluation of Ointments, Ash contents and Alkalinity of Glass.

11. **STANDARDIZATION OF PHARMACEUTICALS:** An understanding of quality assurance system adopted in pharmaceutical industry. Good Manufacturing Practices and Current Good Manufacturing Practices.

12. **STATISTICAL INTERPRETATION OF QUALITY CONTROL CHARTS DURING MANUFACTURING PROCESSES:**

PHARMACEUTICS-VI (PHARMACEUTICAL QUALITY MANAGEMENT) (Practical)
Paper 9 **Marks 100**

NOTE: Practical of the subject shall be designed from time to time on the basis of the above mentioned theoretical topics and availability of the facilities e.g. Assay of various spirits, tinctures, extracts, syrups and elixirs, Assay of Ointments and suppositories, Assay of tablets and capsules, Test for alkalinity of glass, Determination of alcohol contents in the Pharmaceutical preparations and Pyrogen test. Sterility test, Determination of Ash contents, Determination of Moisture contents, Determination of total solids, Determination of viscosity of syrups, gels etc. Determination of emulsion types (Note: A minimum of 20 practicals will be performed).

FINAL PROFESSIONAL

PHARMACEUTICAL CHEMISTRY-IV (MEDICINAL CHEMISTRY) (Theory)
Paper 1 **Marks 100**

NOTE: The topics will be taught with special reference to their Pharmaceutical Applications.

1. **INTRODUCTION TO MEDICINAL CHEMISTRY:** Chemical constitution and biological activity: (Receptor, Theory, Structure Activity Relationships (SAR) and Drug Metabolism).