M. PHARMACY

PHARMACY PRACTICE

I SEMESTER

Paper 101	**-**	**Modern Analytical Techniques**
Paper 102	**-**	**Research Methodologies**
Paper 103	**-**	**Clinical Pharmacy Practice**
Paper 104	**-**	**Pharmacotherapeutics - I**
Paper 105	**-**	**Clinical Pharmacy Practice - LAB**
Paper 106	**-**	**Pharmacotherapeutics - I - LAB**
Paper 107	**-**	**Seminar**

II SEMESTER

Paper 201	**-**	**Hospital & Community Pharmacy**
Paper 202	**-**	**Pharmacotherapeutics including Clinical Pharmacokinetics**
Paper 203	**-**	**Clinical Research, Pharmacoepidemiology & Pharmacoeconomics**
Paper 204	**-**	**Drug Regulatory Affairs**
Paper 205	**-**	**Hospital & Community Pharmacy - LAB**
Paper206	**-**	**Clinical Research, Pharmacoepidemiology & Pharmacoeconomics - LAB**
Paper 207	**-**	**Seminar**

III SEMESTER

Paper 301	**-**	**Project Seminar-I (On the proposed project work with aims and objectives) - 50 Marks**
Paper 302	**-**	**Project work - I**

IV SEMESTER

Paper 401	**-**	**Project Seminar-II (On the experimentation and results of the project work) – 50 Marks**
Paper 402	**-**	**Project work - II**

SCHEME OF INSTRUCTIONS AND EVALUATION

PHARMACY PRACTICE

FIRST SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 101	Modern Analytical Techniques	40	60			100	3
Paper – 102	Research Methodologies	40	60			100	3
Paper – 103	Clinical Pharmacy Practice	40	60			100	3
Paper – 104	Pharmaco therapeutics – I	40	60			100	3
Paper – 105	Clinical Pharmacy Practice – Practical			40	60	100	2
Paper – 106	Pharmaco therapeutics I – Practical			40	60	100	2
Paper – 107	Seminar					100	2
	TOTAL					700	18

SECOND SEMESTER

Paper No.	Title of the Paper	Evaluation / Marks				Total	Credits
		Theory		Practical			
		Mid Examination	University End Examination	Mid Examination	University End Examination		
Paper – 201	Hospital and Community Pharmacy	40	60			100	3
Paper –202	Pharmacotherapeutics including Clinical Pharmacokinetics	40	60			100	3
Paper – 203	Clinical Research. Pharmacoepidemiology & Pharmacoeconomics	40	60			100	3
Paper – 204	Drug Regulatory affairs	40	60			100	3
Paper – 205	Hospital and Community Pharmacy – Practical			40	60	100	2
Paper – 206	Clinical Research. Pharmacoepidemiology & Pharmacoeconomics - Practical			40	60	100	2
Paper – 207	Seminar					100	2
	TOTAL					700	18

THIRD AND FOURTH SEMESTERS

Paper No.	III Semester	Total	Credits ***
Paper - 301	Project Seminar – I (On the proposed project work with aims and objectives)	50	2
Paper - 302	Project work - I	----	20
	Total	50	22

Paper No.	IV Semester	Total	Credits ***
Paper - 401	Project Seminar – II (On the Completed project work)	50	2
Paper - 402	Project work - II	---	20
	TOTAL MARKS	50	22
	GRAND TOTAL FOR THE COURSE	1500	80

I SEMESTER

PAPER 101: MODERN ANALYTICAL TECHNIQUES

(Paper Common for all Specializations)

Principles, instrumentation and applications of the following Instruments and Chromatography techniques

Unit- I

i. UV- Visible spectrophotometry
ii. Infrared spectroscopy
iii. Spectrofluorimetry

Unit- II

i. NMR spectroscopy
ii. Electron Spin Resonance spectroscopy
iii. Atomic Emission spectroscopy

Unit- III

i. HPLC
ii. HPTLC
iii. Exclusion chromatography
iv. Super critical fluid chromatography

Unit- IV

i. Mass Spectroscopy including LCMS & GCMS
ii. GLC

Unit- V

i. Plasma Emission spectroscopy
ii. X-Ray diffractometry
iii. Optical Rotatory Diffusion
iv. Vapor phase chromatography
v. Affinity chromatography
vi. Ion-exchange chromatography

TEXT BOOKS

1. Practical Pharmaceutical Chemistry Vol. 1 &II by Beckett & Stenlake.
2. Instrumental Methods of Analysis by Scog and West.
3. Instrumental Methods of Analysis by B.K.Sharma
4. Vogel's text book of Quantitative Chemical Analysis.
5. Instrumental methods of Analysis by Willard & Merrit.
6. A text book of Pharmaceutical Analysis by K. A. Conners.

REFERENCE BOOKS

1. I.P.
2. B.P.
3. U.S.P.
4. Remington's Pharmaceutical Sciences.
5. Spectroscopy b Silversterin

PAPER 102 -RESEARCH METHODOLOGIES
(Paper common for all Specialisation)

UNIT I

Statistical Methods:

Chance Variation – Probability Distribution - Normal Distribution – Sampling Distribution

Error and its significance-Measures of Error- Control of Error in Experimental Investigations – Problem Solving.

UNIT II

Correlation and Regression., Multiple Regression - Problem Solving

UNIT III

Tests of Significance: Principles, t-test, z-test, F-ratio test, Chi-square test, Non-parametric tests- their applications in pharmacy research with examples – Problem Solving

UNIT IV

Design of Experiments

Criteria of a good design with examples.

Principles- Randomization, replication and local control.

Study of CRD, RBD, LSD and factorial designs- their applications in Pharmacy research with examples – Problem Solving

UNIT V

Analysis of Variance (ANOVA) – one way, two way and three way – principles and applications in pharmacy research- Problem Solving

Optimisation Techniques : Optimisation Techniques based on Factorial Experiments - Problem Solving.

PAPER - 103 : CLINICAL PHARMACY PRACTICE

UNIT-I

1. Definitions, development and scope of clinical pharmacy
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

UNIT-II

1. Medication history
2. Patient counseling
3. Pharmaceutical care
4. Drug utilisation evaluation (DUE) and review (DUR)
5. Quality assurance of clinical pharmacy services

UNIT-III

1. 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

UNIT-IV

1. Clinical laboratory tests used in the evaluation of disease states, and interpretation of test results
   - Haematological, Liver function, Renal function, thyroid function tests
   - Tests associated with cardiac disorders
   - Fluid and electrolyte balance
   - Microbiological culture sensitivity tests
   - Pulmonary Function Tests

UNIT-V

1. Drug information
   - Introduction to drug information
   - Resources required,
   - Systematic approach in answering Dl queries
   - Critical evaluation of drug information and literature
   - Preparation of written and verbal reports

Establishing a Drug Information Centre

1. Poison Information
   - Poisons information- organization & information resources, setting up of PlC.

PAPER – 4 : PHARMACOTHERAPEUTICS - I

UNIT-I

1. **General prescribing guidelines for**
   Paediatric patients,
   Geriatric patients,
   Pregnancy and breast feeding.

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

UNIT-II

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

Cardiovascular system

Hypertension, Congestive cardiac failure, Ischemic Heart disease, Myocardial infarction, Arrhythmias, Hyperlipidaemias

Respiratory system

• Asthma, Chronic obstructive airways disease, Drug induced pulmonary diseases

UNIT-III

1. Pathophysiology and pharmacotherapy of diseases associated with Haematological diseases and Renal system

Anemia, Deep vein thrombosis, Drug induced hematological disorders

Acute renal failure, Chronic renal failure, Renal dialysis and transplantation, Drug induced renal diseases

UNIT-IV

1. Pathophysiology and pharmacotherapy of Endocrine system

Diabetes, Thyroid diseases, Oral contraceptives, Hormone replacement therapy, Osteoporosis

UNIT-V

1. Pathophysiology and pharmacotherapy of Rheumatic diseases

Rheumatoid arthritis, Osteoarthritis, Gout, Systemic lupus erythematosus

PAPER – 105 : CLINICAL PHARMACY LAB

1. Patient medication history interview, answering drug information questions, patient medication counseling, participation in ward rounds.

2. 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
- 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

PAPER –106: PHARMACOTHERAPEUTICS - I LAB

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 arid 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 PulmonaryDisease
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

II SEMESTER

PAPER - 201 HOSPITAL & COMMUNITY PHARMACY

UNIT-I

1. Role of hospital pharmacy department and it's relationship with the other departments and staff.

2. Hospital Pharmacy

Objectives and Functions, Location, Organizational Structure

3. Hospital drug policy

Drug committees, Formulary and guidelines, other hospital committees such as infection control and research and ethics committee.

4. Hospital pharmacy management

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.

UNIT-II

1. Organization of hospital pharmacy services

1.1 Drug distribution

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

1.2 Manufacturing

Sterile and non-sterile production, including total parenteral nutrition,

1.3 Radiopharmaceuticals

Cytotoxics, Radiopharmaceuticals preparation and quality control, and dispensing.

2. additive service, prepackaging and labeling, quality control.

UNIT-III

1. Training of technical staff, Training and continuing education for pharmacists, Pharmacy students, Medical staff arid students, Nursing staff and students. Formal and informal meetings and lectures, Drug and therapeutics newsletter.

UNIT-IV

1. Introduction to community Pharmacy

1.1. Community pharmacy Practice — definition

1.2. The role of the community phannacy 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

3. Over-the-counter (OTC) sales

- Rational use of common OTC medications (Vitamins and tonics, iron preparations, analgesics, NSAIDs, cough mixtures, anti-diarrhoeal preparations)

UNIT-V

1. Primary health care in community pharmacy

Family planning, First aid, Participation in primary health programs, Smoking cessation, Screening programs, Nutrition, Responding to common ailments

2. Community pharmacy management 8

Financial, materials, staff, infrastructure requirements, drug information resources, in community pharmacies, computer applications in community pharmacy, Education and training 2

3. Home Medicines Review (HMR) program

3.1. Introduction to HMR

3.2. Guidelines to conduct FIMR

Text Books

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

2. Textbook of hospital pharmacy - Aliwood MC and Blackwell. Reference books (Latest editions)

1. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

2. Remington Pharmaceutical Sciences,

3. Relevant review articles from recent medical and pharmaceutical literature.

PAPER 202 - PHARMACOTHERAPEUTICS INCLUDING CLINICAL PHARMACOKINETICS

UNIT I

1 Pathophysiology and pharmacotherapy of diseases associated with Nervous system

Epilepsy, Parkinsons disease, Stroke and transient ischemic attacks, Headache

2 Pathophysiology and pharmacotherapy of diseases associated with Psychiatric disorders

Schizophrenia, Depression, Anxiety & Sleep disorders, Drug induced psychosis

UNIT II

1 Pathophysiology and pharmacotherapy of diseases associated with Infectious diseases

1.1. General guidelines for the rational use of antibiotics.

1.2. Pharmacotherapy of Meningitis, Respiratory tract infections, Gastroenteritis, Bacterial endocarditic, Septiceniia., Otitis media, Urinary tract infections,

1.3. Pharmacotherapy of Tuberculosis, Leprosy, Malaria, Helmenthiasis, HIV and opportunistic infections, Fungal infections, Rheumatic fever.

UNIT III

1.Oncology

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

UNIT IV

Paper — 1 : Clinical Pharmacokinetics and Biostatistics

1. Clinical Pharmacokinetics

1.1. Introduction to Clinical Pharmacokinetics

1.2. Clinical Pharmacokinetic models

2. Drug clearance

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

UNIT V

1. Estimation and determinants of bioavailability

2. Drug dosing

2.1 .Calculation of loading and maintenance doses

2.2.Dose adjustment in renal failure, hepatic dysfunction, geriatric and pediatric patients

3. Therapeutic Drug Monitoring (General aspects)

PAPER 203 - CLINICAL RESEARCH, PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS

UNIT-I

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

2.4. Planning and execution of clinical trials

2.5. Various Phases of clinical trials

2.6. Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification)

UNIT II

1. 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)

1.1. Health outcome measures (Clinical& Physiological, Humanistic and Economic) 3

- .Bioavailability and Bioequivalence studies
- .Ethics and Guidelines in Biomedical Research 7
- Ethical Issues in Biomedical Research — Principles of ethics in biomedical research,
- Ethical committee [institutional review board], its constitution and functions,
- Good clinical practice [ICR GCP guidelines, CDSCO regulations, MPA, European, Japan, Health Canada and MHRA guidelines, schedule Y and USFDA in the conduct of clinical

  trials]

UNIT III

1. Clinical research

• Establishing and functioning of Contract Research Organisation (CR0)

• 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

2. Data Management 4

2.1 .Medical Writing and Ethics of publication

2.2. Clinical data management (Data entry, data interpretation, data monitoring and auditing)

Reference books (Latest editions)

3. Avery's Drug Treatment, 4th Edn, 1997, Adis International Limited.

4. Designing Clinical Research. Edtd by Stephen B Hulley, Steven R Cummings

UNIT IV

Pharmacoepidemilogy

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

5. Applications of Pharmacoepidemiology

UNIT V

Pharmacoeconomics

1. Various Pharmacoeconomic models used in health care and

Apilications of Pharmacoeconomics

Reference Books

1. Pharmacoepidemiology Edt. Brian L Storm 4th Edn. Wiley Publisher

2. Avery's Drug Treatment. ADIS publication

PAPER 204: DRUG REGULATORY AFFAIRS:
(Paper Common for all Specializations)

Unit - I

Formulation development: Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, injections, ocular preparations as per the European community, United States and Indian regulatory authorities

Unit - II

Manufacturing: Regulatory requirements as per European community, United States and Indian regulatory authorities for manufacturing information, manufacturing formula, process, validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, International aspects of Excipients, approval as per guidelines of all the territories. Regulatory guidelines for packaging materials, test and evaluation of packaging materials, biological test, elastometer test, microbiological test and evaluation of closures.

Unit - III

Stability testing: Scientific and technical background to the design of stability testing regulatory requirements as per European community, United States and Indian regulatory authorities for testing of new active substances, bulk active drug substances, dosage form in their final packaging. Extension of shelf-life after authorization of drug international harmonization and current guidelines. Regulatory affairs in respect of residual solvents as per the ICH guidelines, analytical method validation, pharmacokinetic and toxicokinetic validation.

Biopharmaceutics: Different testing parameters and standards as per regulatory requirements of European community, United States and Indian regulatory authorities with respect to factors related to formulation, dosage form, manufacturing process, stability and storage.

Unit - IV

Preclinical aspects of Biopharmaceutics: Current guidelines and developments as per regulatory requirements of European community, United States and Indian regulatory authorities in respect of clinical bioavailability , study design, presentation documentation and statistical analysis

Clinical pharmacology and Pharmacodynamics: Regulatory guidelines as per European community, United States and Indian regulatory authorities on clinical study design, documentation, presentation and interpretation. Clinical trials: Definition, phase I, phase II, phase III and phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data and factorial design.

Unit - V

Intellectual property rights and patents: Introduction, purpose, international scenario and Indian scenario, guidelines as per European community, United States and Indian regulatory authorities, documentation, presentation and application, procedure for obtaining and writing a patent and patenting rules and regulations

References:

1. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
2. Drug formulation manual by D.P.S. Kohli and D.H.Shah. Eastern publishers, New Delhi.
3. How to practice GMPs by P.P.Sharma. Vandhana Publications, Agra.
4. Pharmaceutical Process Validation by Fra. R. Berry and Robert A. Nash.
5. Pharmaceutical Preformulations by J.J. Wells.
6. Applied production and operations management by Evans, Anderson, Sweeney and Williams.
7. Basic Principles of Clinical Research and Methodology by Gupta.
8. Biopharmaceutics and Clinical Pharmacokinetics-An introduction; 4th edition, Revised and expanded by Robert. E. Notari, Marcel Dekker Inc, New York and Basel, 1987

PAPER 205 - HOSPITAL & COMMUNITY PHARMACY LAB

(Practicals based on theory)

PAPER206- CLINICAL RESEARCH, PHARMACOEPIDEMIOLOGY & PHARMACOECONOMICS LAB

(Practicals based on theory)