STUDY AND EVALUATION SCHEME

Course: M.Pharm (Clinical Pharmacy) Effective from Session 2010-11
SEMESTER I

Sl. N0	Course Code	Subject	Period (Hours/Week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR-118	Pharmacotherapeutics-I (including Pathophysiology)	4	-	30	-	70	-	100	4
2	MPHR-112	Phrmaceutical Statistics & Computer Application	4	-	30	-	70	-	100	4
3	MPHR-113	Drug Regulatory Affairs & Intellectual Property Rights	4	-	30	-	70	-	100	4
4	MPHR-119	Basic Principle of Clinical Pharmacy	4	-	30	-	70	-	100	4
PRACTICAL			Day to Day Evaluation							
5	MPHR-118P	Pharmacotherapeutics Clinical / Practicals-I	-	12	-	30	-	70	100	6
6	MPHR-119P	Clinical Pharmacy Practical	-	12	-	30	-	70	100	6
								TOTAL	600	28

T-Theory, P-Practical, IA-Internal Assessment, ESE-End Semester Examination Note: Duration of ESE-Theory exam will be of 3 hours and Practical exam of 8 hours

SEMESTER II

Sl. N0	Course Code	Subject	Period (Hours/Week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR 129A	Pharmacotherapeutics-II (including Pathophysiology)	4	-	30	-	70	-	100	4
2	MPHR 129B	Hospital & Community Pharmacy	4	-	30	-	70	-	100	4
3	MPHR 129C	Drug Toxicity & Management of DIS	4	-	30	-	70	-	100	4
4	MPHR 129	Clinical Trial Management	4	-	30	-	70	-	100	4
5	MPHR 120	Seminar (two of 50 marks each) internal evaluation only	4	-		-		-	100	4
PRACTICAL			Day to Day Evaluation							
5	MPHR 129A-P	Pharmacotherapeutics Clinical / Practicals-II	-	12	-	30	-	70	100	6
								TOTAL	600	26

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination Note: Duration of ESE- Theory exam will be of 3 hours and Practical exam of 8 hours

Semester-III

Sl.No	Course Code	Subject	ESE	Credits
1	MPHR-231	Synopsis of The Proposed Project & Evaluation of Project Work after Six Months	150	6

Semester-IV

Sl. No.	Course Code	Subject	ESE	Credits
1	MPHR – 241	Thesis	350	14
2	MPHR – 242	Presentation & Viva – voce	100	5

SEMESTER-I

MPHR 118

PHARMACOTHERAPEUTICS-I (INCLUDING PATHOPHYSIOLOGY)

Pathophysiology and applied therapeutics of diseases with following system/disease with special reference to the drugs of choice.

1. Cardiovascular System- Hypertension, congestive cardiac failure ischaemic heart disease, arrhythmias, hyperlipidemias.

2. Respiratory System- Asthma, chronic obstructive airways disease, drug induced pulmonary diseases.

3. Renal System- Acute renal failure, chronic renal failure, renal dialysis and transplantation, drug dosing in renal impairment, drug induced renal disease, electrolytes and fluid balance.
4. Haematological Disease- Anaemia, thrombo-embolic disorders, drug induced haematological disorders.

5. Endocrine System- Diabetes, thyroid diseases, oral contraceptive, hormone replacement therapy, osteoporosis.

6. Gastrointestinal System- Ulcer diseases, inflammatory bowel diseases, hepatitis, jaundice, drug dosing in liver dysfunction, diarrhea and constipation.

7. Skin and Sexually transmitted diseases- Psoriasis, acne, eczema, scabies, syphilis and gonorrhoea.

8. Nutrition Malnutrition and deficiency states- Enteral and parentral nutrition.

Books recommended

1. Roger and Walkar, Clinical Pharmacy and Therapeutics, Churchill Livingstone Publication.
2. Joseph T. Dipiro, Pharmacotherapy: A Patho-physiological Approach, Appleton Lange.
3. Cotran RS, Kumar V, Collins T, Robbins Pathologic basis of disease, WB Saunders 6 Editd.
4. Green RJ, Harris ND, Pathology and Therapeutics for Pharmacist: A basis for Clinical Pharmacy Practics, Chapman and Hall Publication.
5. Eric T Herfindal, Clinical Pharmacy and Therapeutics, William and Wilkins Publication.
6. Avery's Drug Treatment 4th Edn 1997, Adis Internatinal Ltd.
7. Relevant review articles from recent medical and Pharmaceutical literature.

MPHR- 112 Pharmaceutical Statistics and Computer Applications

Unit- I.

Basic Definitions and Concepts: Variables and Variation, Frequency Distributions and Cumulative Frequency Distributions, Sample and Population, Measures Describing the center of Date Distributions,

Data Graphics: Introduction, the Histogram, Construction and Labeling of Graphs, Scatter Plots (Correlation Diagrams), Semilogarithmic Plots, Other Descriptive Figures.

Introduction to Probability The Binomial and Normal Probability Distributions : Introduction, Some Basic Probability, Probability Distributions, the Binomial Distribution,.

Unit- II

Choosing Samples Sample Size and Power : Introduction, Random Sampling, Other Sampling Procedures: Stratified, Systematic, Cluster Sampling, Sampling in Quality Control Introduction, Determination of Sample Size for Simple Comparative Experiments for Normally Distributed Variables, Determination of Sample Size for Binomial Tests,.

Statistical Inference: Estimation and Hypothesis Testing: Statistical Estimation (Confidence Intervals), Statistical Hypothesis Testing, Comparison of Variances in Independent Samples, Test of Equality of More than Two Variances confidence limits for variance Tolerance Intervals.

Unit- III

Linear Regression and Correlation: Introduction of linear and non linear regression ,Analysis of Standard Curves in Drug Analysis: Application of Linear Regression and Drug stability studies,

Analysis of Variance: One- Way Analysis of Variance Planned Versus a Posteriori (Unplanned) Comparisons in ANOVA, Another Example of One- Way Analysis of Variance: Unequal Sample Sixes and the Fixed and Random Models, Two-Way Analysis of Variance (Randomized Blocks), Statistical Models, Analysis of Covariance, ANOVA for pooling regression lines as related to stability data.

Nonparametric Methods: Data Characteristics and an Introduction to Nonparametric Procedures, Sign Test, Wilcoson Signed Rank Test, Wilcoxon Rank Sum Test (Test for Differences Between Two Independent Groups), Kruskal Wallis Test (One- Way ANOVA),

Factorial Designs : Definitions Two Simple Hypothetical Experiments to Illustrate the Advantages of Factorial Designs, Performing Factorial Experiments: Recommendations and Notation, A Worked Example of a Factorial Experiment, Fractional Factorial Designs.

Unit- IV

Experimental Design in Clinical Trials: Introduction, Some Principles of Experimental Design and Analysis, Parallel Deign, Crossover Designs and Bioavailability / Bioequivalence Studies, Repeated Measures (Split- Plot) Designs, Multiclinic Studies, Interim Analyses.

Quality Control: Introduction, Control Charts, Acceptance Sampling and Operating Characteristic Curves, Statistical Procedures in Assay Development, Establishing In- House Limits, Some Statistical Aspects of Quality and the "Barr Decision",

Unit- V

Applications of Computers in Pharmaceutical Sciences

Computer Intensive Methods: Advance Computer application and software applicable for treating l data statical.

Book Recommended:

1. Bolton, S and Bon, C, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.

2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.

3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.

4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

5. William E. Fassett, Computer Application in Pharmacy.

6. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.

MPHR- 113 DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS

Unit- I

A. Drug Information

Introduction

Primary, Secondary & Tertiary Literature

Spectrum of information, finding and managing Drug Information.

B. Drugs and Cosmetics Act and rules with special reference to schedule M and Y.

Unit- II

International Drug Regulatory affairs- registration procedure (Pharmaceutical products) for International Marketing, Including preparation of dossiers SMF, Validation, Calibration and other documents like product development, stability data for different countries.

Unit- III

Facilities for manufacturing pharmaceutical products qualifying.

CGMP requirements - 21 CFR parts 210 and 211, Orange Guide, TRS, ICH, etc.

Unit- IV

Facilities for quality control lab qualifying GLP requirements, facilities for warehouse qualifying GWP requirements.

Unit- V

Intellectual property rights, patents Act, Trademark and Copyright Act

Books Recommended:

1. Gennaro A.R., Remington- The science and practice of pharmacy, Lippircott, Williams & Wilkins.

2. Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.

3. Malik Vijay, Drug & Cosmetics Act, 1940, Eastern Book Company, Lucknow.

4. Guarino R.A., New Drug Approval Process, Marcel Dekker.

5. Sharma P.P., How to practice GMP, Vandana Prakashan, New Delhi.

6. Sharma P.P., how to practice GLP, Vandana Prakashan, New Delhi,

7. World Health Organization, quality assurance of Pharmaceuticals I & I, Pharma Book Syndicate, Hyderabad.

8. Weinlerg S., Good Laboratory Poactices, Marcel Dekker.

9. The Patent Act, 1970

10. The Trade Marks Act, 1999.

11. The Copyright Act, 1958.

12. Potdar M.A., Current Good Manufacturing Practices for Pharmaceuticals, Pharma Med Press, Hyderabad.

13. Rick N.G., Drug from Discovery to Approval, Wiley Black Well.

14. Swarlerick J., Boylan J., Encyclopedia / Pharmaceutical Technology Relevant Welesites of Regulatory Anthoriter of different countries.

MPHR 119

BASIC PRINCIPLES OF CLINICAL PHARMACY

1. Definition, development and scope of Clinical Pharmacy.

2. Clinical Pharmacokinetics and Pharmacodynamics (Volume of distribution, Clearance, Plasma protein binding, concentration dependent clearance, flow dependent clearance, multicompartment models, physiologic model, pharmacodynamic models, time course of drug action, cumulative effects of drugs, steep concentration effect curves).
   (i) Hysteresis.
   (ii) Posteresis
   (iii) Target Concentration Strategy
   (iv) Variability and control Strategies in quantitative therapeutics Bioavailability.
   (v) Drug Biotransformation.

3. Clinical Laboratory Tests: Used in the evaluation of disease states, and interpretation of test results. Hematological, liver function, renal function tests, tests associated with cardiac disorders, fluid and electrolyte balance, common tests in urine, sputum, feaces, CSF.
   Sensitivity screening for common pathogenic micro-organisms, its significance, resistance in disease states and selection of appropriate anti microbial regimens.

4. Studies of Imaging Pharmaceuticals (contrast media): Introduction, parenteral injection methods, types of contrast media, characteristics of iodinated contrast media, pharmacodynamics, and pharmacokinetics of contrast media and clinical application), preventive care and emergency, response to contrast media, patient education and assessment, patient preparations, pre-medication, types of contrast medium reactions.

5. Drug in special Patient Groups (Pregnancy and Nursing, Neonates and Children, Elderly).

6. Clinical Importance of Genetics in Drugs effects.

7. Drug therapy Monitoring: Medication chart view, clinical review, TDM Pharmacist interventions, Ward round participation. Adverse drug reaction management. Medication history and patient counseling. Drug utilization evaluation (DUE) and review (DUR), quality assurances of clinical pharmacy services. Patient data analysis. Introduction of information sources available.

MPHR 118P

PHARMACOTHERAPEUTICS CLINICAL / PRACTICALS-I (INCLUDING PATHOPHYSIOLOGY)

The students are required to be posted in various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do tutorial as well as case presentation in the following clinical condition.

1. Cardiology
i) Arrhythmias, ii) Ischaemic heart disease, iii) Congestive heat failure, iv) Myocardial infarction, v) Hypertension, vi) Thrombo embolic disease, vii) Endocarditis.

2. Gastroenterology
i) Diarrhoea, Constipation, ii) Acid peptic disease, iii) Hepatic disease -hepatitis cirrhosis and drug induced hepatic disorder, iv) Oesophageal reflux, v) Helicobacterium pylori induced gastric disorders.

3. Respiratory medicine
i) Asthama, ii) Congestive obstructive airways disease (COAD), iii) Acute respiratory failure, iv) Respiratory tract infections, v) Interstitial lung disease, vi) Respiratory aids.

4. Surgery
i) Prophylactic antibiotic, ii) Anticoagulants-Heparin, warfarin, iii) Thrombolytic Adjunctive therapy, iv) Preoperative medications, v) Analgesia

5. Paediatrics
i) Acute otitis media, ii) Tonsillitis, iii) Paediatiric asthma, iv) Paediatric gastroenteritis, v) Colic, vi) Immunisation, vii) Attention deficit disorder, viii) Febrile neutropenia

6. Renal
i) Acute renal failure, ii) Chronic renal failure, iii) Drug induced renal disease.

7. Haematology
i) Leukaemias, ii) Lymphomas-Hodgkin's, Non-Hodgkin's , iii) Multiple myeloma, iv) Anaemia, v) Bleeding disorders.

13. Endocrinology
i) Diabetes, ii) Osteoporosis, iii) Thyroid disorders, iv) Syndrome of inappropriate antidiuretic hormone secretion, v) Adrenal disorders.

8. Dermatology
i) Psoriasis, ii) Dermatitis, iii) Drug induced skin disorders.

Books recommended

1. Cotran RS, Kumar V, Collins T., Robbins Pathologic basis of disease, WB Saunders 6 Editd.
2. Green RJ, Harris ND, Pathology and Therapeutics for Pharmacist: A basis for Clinical Pharmacy Practice, Chapman and Hall Publication.
3. Eric T Herfindal, Clinical Pharmacy and Therapeutics, William and Wilkins Publication.
4. Avery's drug treatment 4th Edn 1997, Adis International Ltd.
5. Relevant review articles from recent medical and Pharmaceutical literature.

MPHR 119P

CLINICAL PHARMACY PRACTICAL

An ability based outcome is composed a knowledge, skills and attitudes and is highlighted in bold text. The non-bold texts are the objectives discussed by the Advanced Practice Experience faculty members.

1. **The student should be able to evaluate, review or develop, implement and monitor therapeutic outcomes associated with a pharmaceutical care plan for a patient.**
   A. Understand the administration and delivery systems.
   B. Understand how to evaluate laboratory and patient data.
   C. Develop basic patient (including physical) assessment.
   D. Review patient's drug therapy for drug related problems (pharmaceutical care).
   E. Develop a pharmaceutical care plan for patients.
   F. Integrate problem solving in developing cost-effective therapy related plan toward achieving a desired therapeutic outcome, keeping in mind non-pharmacologic alternatives.
   G. Develop therapeutic parameters and become competent in monitoring the patients for therapeutic endpoints on an ongoing basis.
   H. Competently use pharmacokinetics in developing and monitoring the patient's drug therapy.
   I. Understand the responsibility and reporting mechanism for adverse drug reactions.

2. **The student should be able to identify and utilize drug information services in order to facilitate their role as a drug-information specialist for other health care professionals and patients to achieve positive therapeutic outcomes.**
   A. Interact appropriately with other members of the health care team.
   B. Know and use the sources of drug information for any given rotation.
   C. Apply drug information to obtain positive outcomes for patients.
   D. Serve as drug information specialists for patients and other health care professionals.
   E. Understand the responsibility and reporting mechanism for adverse drug reactions.

3. **The student should be able to develop oral or written presentations on a drug topic or drug-related topics to other health care professionals and patients.**
   A. Effectively communicate in verbal and/or written form, in concise and organized fashion, a pharmaceutical evaluation of the patient.
   B. Serve as drug information specialists for patients and other health care professionals.
   C. Develop presentation skills for variable audiences for interdisciplinary education.
   D. Develop communication skills for patient education.

SEMESTER-II

MPHR 129A

PHARMACOTHERAPEUTICS-II (INCLUDING PATHOPHYSIOLOGY)

Pathophysiology and applied therapeutics of diseases with following system/disease with special reference to the drugs of choice.

1. Nervous System- Epilepsy, Parkinson's disease, stroke and transient ischaemic attacks, headache, Alzheimer's disease, Huntingtion's chorea.

2. Psychiatric Disorders- Schizophrenia, depression, anxiety disorders, sleep disorders.

3. Pathophysiology of Inflammation and repair, immunology basic principles.

4. Rheumatic diseases- Rheumatoid arthritis, gout, juvenile rheumatoid arthritis

5. Infectious Diseases- Meningitis, respiratory tract infections, gastroenteritis, pneumonia, bacterial endocarditis, septicaemia, otitis media, urinary tract infections, tuberculosis, leprosy, protozoal infections, helmenthiasis, HIV, opportunistic infections and fungal infections.

6. Oncology cell cycle General principles of Cancer Chemotherapy- Commonly used cytotoxic drugs. Chemotherapy of lung cancer, breast cancer, head and neck cancer, prostate cancer, cervical cancer, haematological malignancies.

7. Ophthalmology- Glaucoma and eye infections.

8. Pain management- Pain pathways, analgesics and NSAIDs, opiates, local anaesthetics, neuralgia including trigeminal and glosso-pharyngeal neuralgias.

Books recommended

1. Roger and Walkar, Clinical Pharmacy and Therapeutics, Churchill Livingstone Publication.
2. Joseph T. Dipiro, Pharmacotherapy: A Patho-physiological Approach, Appleton Lange.
3. Cotran RS, Kumar V, Collins T, Robbins Pathologic basis of disease, WB Saunders 6 Editd.
4. Green RJ, Harris ND, Pathology and Therapeutics for Pharmacist: A basis for Clinical Pharmacy Practics, Chapman and Hall Publication.
5. Eric T Herfindal, Clinical Pharmacy and Therapeutics, William and Wilkins Publication.
6. Avery's Drug Treatment 4th Edn 1997, Adis Internatinal Ltd.
7. Relevant review articles from recent medical and Pharmaceutical literature.

MPHR 129B

HOSPITAL AND COMMUNITY PHARMACY

A. COMMUNITY PHARMACY

1. Introduction to the concept of community pharmacy, its activities and professional responsibilities.
2. The role of the community pharmacy and its relationship to other local health care providers.
3. Prescribed medication order interpretation and legal requirements.
4. Patient counseling in community pharmacy.
5. Over the Counter (OTC) sales.
6. Services to Nursing homes/Clinics.
7. Community Pharmacy Management: Financial material and staff management infrastructure requirements, drug information resources computers in community pharmacy.
8. Code of ethics for community pharmacists.
9. Polypharmacy and its implication.

B. HOSPITAL PHARMACY

10. The role of hospital pharmacy department and its relationship to other hospital departments and staff.
11. Hospital Drug Policy: Drug committee formulary and guidelines, other hospital committee such as infection control committee and research & ethics committee.
12. Hospital Pharmacy Management, Staff (professional and non professional), materials (drugs, non drugs, consumables), financial (drugs budget, cost centers, sources of revenue collection), policy and planning, infrastructure requirements (building furniture and fittings, specialized equipment, maintenance and repair), workload statistics, hospital formulary.
13. Organisation of hospital pharmacy services.
14. Drug Distribution: Purchasing warehousing (storage conditions, expiry date control recycling of drugs, stocktaking drug recalled, drug distribution method, ward stock, individual patient dispensing, specific requirements for inpatients, outpatients, casualty emergency theatre, ICU/ICCU, drugs of dependence
15. Manufacturing: Sterile and non sterile production, including total parental nutrition, cytotoxics.
16. Radio Pharmaceutics: IV additive service, pre packing and labeling, quality control.
17. Research: Practice based research. Research support including clinical trials laboratory based research.
18. Pharmacoepidemiology: Definitions and scope; methods (qualitative, quantitative and meta analysis models); system for monitoring drug effects; advantage and disadvantages of pharmacoepidemiology.
19. Pharmacoeconomics: Definitions and scope, types of economic evaluation, cost models and cost effectiveness analysis.
20. Public Health Policy and Health Care System.
21. Rational Prescription and Prescription Writing.

22. Communication Skills: Principle and elements of communication skills, non verbal communication in pharmacy, barriers in communication, listening skills, explaining skills and ethics in communication.

Books recommended

1. Hassan WE, Hospital Pharmacy,Lec and Febiger Publication.
2. Allwood MC and Blackwell, Textbook of Hospital Pharmacy.
3. Avery's drug treatment 4th Edn 1997, Adis International Ltd.

MPHR 129C

DRUG TOXICITY AND MANAGEMENT OF DRUG INFORMATION SERVICES

1. Introduction to toxicology, occupational and environmental toxicology, chelators and heavy metal intoxication, insecticide poisoning, toxic potentials of over the counter agents, dermatological toxicity, ototoxicity, nephrotoxicity, hemopoietic toxicity, carcinogenicity and teratogenecity, ocular toxicity, cardiotoxicity, hepatotoxicity, pulmonary toxicity, neurotoxicity, management of patient during drug toxicity (emergency treatment of poisoning), management and functioning of poisons information centre (day and night).

2. Adverse drug reactions, incidence of adverse drug reactions, recognizing of adverse drug reactions, types of adverse drug effects hypersensitivity reactions, selected adverse effect on selected organs, drug addiction and drug abuse, drug interactions: definitions of drug interactions: principles of prevention of adverse drug interactions, clinical importance of drug interactions involving enzyme induction, pharrnacoepiderniology, documentation of clinical pharmacokinetic and clinical pharmacology data for commonly used drugs, management of drug information's services.

3. Critical evaluation of drug information and literature preparation of writing and verbal reports.

MPHR 129 **CLINICAL TRIAL MANAGEMENT**

1. Introduction to Pharmaceutical Medicine

- The Drug Development Process
- New Drug Discovery
- Clinical Development of Drug
- Essential Clinical Trial Documents
- Clinical Trials Terminology

2. Good Clinical Practice (GCP) Foundations

- History of GCP - milestones in the evolution of GCP
- Principles of GCP
- Applicable GCP Guidelines
- Declaration of Helsinki
- Clinical Study Process
- The Management of Clinical Studies (Sponsor)
- Ethics in Clinical Research
- Informed Consent process
- Challenges in the Implementation of GCP Guidelines
- Creation of Trial Master File(s)

3. Drug Regulatory Affairs (Clinical Trials)

- Overview of Regulatory Environment in USA, Australia, Europe and India
- Clinical Trial Application Requirements in India
- Import- Export of Clinical Trial Drugs in India
- Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.
- IND/ANDA/New Drug Application
- Investigator Site Evaluation/Selection Process
- Audits and Quality Assurance *etc*

4. Roles and Responsibilities of Clinical Trial Personnel

- Roles and Responsibilities of Sponsor
- Roles and Responsibilities of Investigator
- Roles and Responsibilities of ERB/IRB/IEC
- Roles and Responsibilities of CRA /Monitor
- Roles and Responsibilities of Auditor
- Roles and Responsibilities of Clinical Research Coordinator or Site Manager
- Roles and Responsibilities of CRO's
- Roles and Responsibilities of Regulatory Authorities
- Roles and Responsibilities of Clinical Data Manager (CDM)
- Roles and Responsibilities of Clinical Biostatistician

5. Clinical Trial Monitoring

- Development of Monitoring Plan
- Site Initiation Visit, Review of Essential Trial Documents, Delegation of Duties and
- Responsibilities at Individual Site
- Routine Monitoring Visit
- Inventory Planning and Tracking
- Source Document Verification (SDV)
- CRF Review, Collection and Co-ordination of Data Management Activities
- Serious Adverse Event (SAE) Review and Regulatory Compliance
- Investigational Product Accountability and Management
- Escalation, Management and Prevention of Violations/Deviations
- Tracking of Enrolments, Payments and Ongoing Correspondence
- Site Closure Monitoring Visit *etc.*

MPHR 120

Seminar (two of 50 marks each) internal evaluation only

MPHR 129A-P

PHARMACOTHERAPEUTICS CLINICAL / PRACTICALS-II (INCLUDING PATHOPHYSIOLOGY)

The students are required to be posted in various clinical wards for their exposure with therapeutic management and other clinical aspects. They are expected to have experience and do tutorial as well as case presentation in the following clinical condition.

1. Rheumatology

i) Rheumatoid arthritis, ii) Gout, iii) Degenerative joint disease- Temporal arthritis, polymyalgia rheumatica, v) Systemic lupus erythematosus.

2. Geriatric Medicine

i) Postural hypotension, ii) Dementia and delirium, iii) Comliance assessment

3. Oncology

i) Breast cancer, ii) Lung cancer-Small cell, Non small cell, iii) Gastric cancer, iv) Colon cancer, v) Genitourinary tract, bladder, prostate and testicular cancer, vi) Skin cancer, radiation therapy, vii) Adjunctive therapy-Anti emetics, Mouth care, Nutrition extravasations, pain control, blood products, viii) Colony stimulating factors,
ix)Infectious disease in immuno-compromised patients, x) Hypercalcemia, xi) Cerebral oedema, xii) Malignant effusions.

4. Infections Disease

i) Respiratory tract infections, ii) Tuberculosis, iii) Urinary tract infections
iv) Joint and bone infections, v) Skin and soft tissue infections.

5. Critical Care

i) Haemodynamic monitoring, ii) Parenteral and enteral nutrition, iii) Pharmacotherpay ventilated patients, iv) hock-Septic, Cardiogenic

6. Neurology

i) Convulsive disorders, ii) Parkinson's disease, iii) Neurodegenerative disorders, iv) Stroke.

7. Psychiatry

i) Uni-polar and biopolar disorders, ii) Anxiety, iii) Psychosis, iv) Alcohol abuse,
v) Drug abuse.

8. Ophthalmology

i) Ocular infections, ii) Conjunctivitis, iii) Glaucoma, iv) Post-operative management.

Books recommended

1. Cotran RS, Kumar V, Collins T., Robbins Pathologic basis of disease, WB Saunders 6 Editd.
2. Green RJ, Harris ND, Pathology and Therapeutics for Pharmacist: A basis for Clinical Pharmacy Practice, Chapman and Hall Publication.
3. Eric T Herfindal, Clinical Pharmacy and Therapeutics, William and Wilkins Publication.
4. Avery's drug treatment 4th Edn 1997, Adis International Ltd.
5. Relevant review articles from recent medical and Pharmaceutical literature.

SEMESTER - III

MPHR 231 SYNOPSIS OF THE PROPOSED PROJECT & EVALUATION OF PROJECT WORK AFTER SIX MONTHS

SEMESTER- IV

MPHR 241 THESIS

MPHR 242 PRESENTATION & VIVA - VOCE

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmaceutics) Effective From Session 2010-11

SEMESTER – I

Sl. No.	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR – 111	Advanced Analytical Techniques	4	-	30	-	70	-	100	4
2	MPHR – 112	Pharmaceutical Statistics & Computer Application	4	-	30	-	70	-	100	4
3	MPHR – 113	Drug Regulatory Affairs & Intellectual Property Rights	4	-	30	-	70	-	100	4
4	MPHR – 115	Product Development – I	4	-	30	-	70	-	100	4
PRACTICAL			Day to Day Evaluation							
5	MPHR – 111 P	Advanced Analytical Techniques	-	8	-	30	-	70	100	4
6	MPHR – 115 P	Product Development – I	-	12	-	30	-	70	100	6
								TOTAL	600	26

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination

Note: Duration of ESE – Theory exam will be of 3 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmaceutics)

SEMESTER - II

Sl. No.	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total	Credits
		Theory	**T**	**P**	**T**	**P**	**T**	**P**		
1	MPHR – 124	Product Development – II	4	-	30	-	70	-	100	4
2	MPHR – 125	Biopharmaceutics & Pharmacokinetics	4	-	30	-	70	-	100	4
3	MPHR – 126	Advances in Drug Delivery Systems	4	-	30	-	70	-	100	4
4	MPHR – 120	Seminar (two of 50 marks each) internal evaluation only	-	-	-				100	4
PRACTICAL			Day to Day Evaluation							
5	MPHR – 125 P	Biopharmaceutics & Pharmacokinetics	-	10	-	30	-	70	100	5
6	MPHR – 126 P	Advances in Drug Delivery Systems	-	10	-	30	-	70	100	5
								TOTAL	600	26

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination

Note: Duration of ESE – Theory exam will be of 3 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M.Pharm (Pharmaceutics)
Semester-III

Sl. No	Course Code	Subject	ESE	Credits
1	MPHR – 231	Synopsis of The Proposed Project & Evaluation of Project Work after Six Months	150	6

STUDY AND EVALUATION SCHEME

Course: M.Pharm (Pharmaceutics)
Semester-IV

Sl. No.	Course Code	Subject	ESE	Credits
1	**MPHR – 241**	Thesis	350	14
2	**MPHR – 242**	Presentation & Viva – voce	100	5

SEMESTER -I
MPHR 111

ADVANCED ANALYTICAL TECHNIQUES

Unit –I:

UV-Visible spectroscopy- Introduction. Application in determination of pKa values, pharmaceutical quantitative analysis, preformulation and formulation. Difference spectrophotometry, derivative spectra.

Solid State Analysis: X-ray diffraction and crystallography, thermal analysis and calorimetry, micromeritic measurements.

Unit –II:

Infrared spectroscopy- Introduction, Application in structure elucidation and in identifying polymorphs. I R as a fingerprint technique. Near IR analysis and its applications, FTIR.

Unit –III:

a) Atomic spectrophotometry:

Atomic emission spectrophotometry: principle, instrumentation, interferences and applications.
Atomic absorption spectrophotometry: principle, instrumentation and applications.

b) Molecular emission spectroscopy:

Fluorescence spectroscopy: Principles, molecules exhibiting fluorescence, factors interfering with fluorescence intensity, application. Raman spectroscopy: Principle, instrumentation and applications.

Unit –IV:

a) Nuclear Magnetic Resonance Spectroscopy:

Introduction, instrumentation, chemical shifts, shielding and deshielding effects, spin-spin coupling, reference standard and solvents, proton NMR, carbon-13 NMR Application to structure elucidation.

b) Mass Spectrometry:

Principle, instrumentation, mass spectra obtained under electron impact (EI) ionization conditions, molecular fragmentation patterns, molecular ion, metastable ion, McLafferty rearrangement, EI mass spectra of some drug molecules. GC-MS and LC-MS: principle and applications.

Unit –V:

Chromatographic techniques:

Chromatographic Theory: void volume, capacity factor, band broadening, calculation of column efficiency, parameters used in evaluating column performance (resolution and peak asymmetry). HPLC: instrumentation, stationary phases, mobile phases and its selection, columns and detectors, applications in quantitative analysis of drugs in formulations, specialized HPLC techniques.

HPTLC, GC, High-performance capillary electrophoresis: principle, instrumentation and application.

MPHR- 112 Pharmaceutical Statistics and Computer Applications

Unit- I.

Basic Definitions and Concepts: Variables and Variation, Frequency Distributions and Cumulative Frequency Distributions, Sample and Population, Measures Describing the center of Date Distributions,

Data Graphics: Introduction, the Histogram, Construction and Labeling of Graphs, Scatter Plots (Correlation Diagrams), Semilogarithmic Plots, Other Descriptive Figures.

Introduction to Probability The Binomial and Normal Probability Distributions : Introduction, Some Basic Probability, Probability Distributions, the Binomial Distribution,.

Unit- II

Choosing Samples Sample Size and Power : Introduction, Random Sampling, Other Sampling Procedures: Stratified, Systematic, Cluster Sampling, Sampling in Quality Control Introduction, Determination of Sample Size for Simple Comparative Experiments for Normally Distributed Variables, Determination of Sample Size for Binomial Tests,.

Statistical Inference: Estimation and Hypothesis Testing: Statistical Estimation (Confidence Intervals), Statistical Hypothesis Testing, Comparison of Variances in Independent Samples, Test of Equality of More than Two Variances confidence limits for variance Tolerance Intervals.

Unit- III

Linear Regression and Correlation: Introduction of linear and non linear regression ,Analysis of Standard Curves in Drug Analysis: Application of Linear Regression and Drug stability studies,

Analysis of Variance: One- Way Analysis of Variance Planned Versus a Posteriori (Unplanned) Comparisons in ANOVA, Another Example of One- Way Analysis of Variance: Unequal Sample Sixes and the Fixed and Random Models, Two-Way Analysis of Variance (Randomized Blocks), Statistical Models, Analysis of Covariance, ANOVA for pooling regression lines as related to stability data.

Nonparametric Methods: Data Characteristics and an Introduction to Nonparametric Procedures, Sign Test, Wilcoson Signed Rank Test, Wilcoxon Rank Sum Test (Test for Differences Between Two Independent Groups), Kruskal Wallis Test (One- Way ANOVA),

Factorial Designs : Definitions Two Simple Hypothetical Experiments to Illustrate the Advantages of Factorial Designs, Performing Factorial Experiments: Recommendations and Notation, A Worked Example of a Factorial Experiment, Fractional Factorial Designs.

Unit- IV

Experimental Design in Clinical Trials: Introduction, Some Principles of Experimental Design and Analysis, Parallel Deign, Crossover Designs and Bioavailability / Bioequivalence Studies, Repeated Measures (Split- Plot) Designs, Multiclinic Studies, Interim Analyses.

Quality Control: Introduction, Control Charts, Acceptance Sampling and Operating Characteristic Curves, Statistical Procedures in Assay Development, Establishing In- House Limits, Some Statistical Aspects of Quality and the "Barr Decision",

Unit- V

Applications of Computers in Pharmaceutical Sciences

Computer Intensive Methods: Advance Computer application and software applicable for treating l data statical.

Book Recommended:

1. Bolton, S and Bon, C, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.

2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.

3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.

4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

5. William E. Fassett, Computer Application in Pharmacy.

6. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.

MPHR- 113 DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS

Unit- I

A. Drug Information

Introduction

Primary, Secondary & Tertiary Literature

Spectrum of information, finding and managing Drug Information.

B. Drugs and Cosmetics Act and rules with special reference to schedule M and Y.

Unit- II

International Drug Regulatory affairs- registration procedure (Pharmaceutical products) for International Marketing, Including preparation of dossiers SMF, Validation, Calibration and other documents like product development, stability data for different countries.

Unit- III

Facilities for manufacturing pharmaceutical products qualifying.

CGMP requirements - 21 CFR parts 210 and 211, Orange Guide, TRS, ICH, etc.

Unit- IV

Facilities for quality control lab qualifying GLP requirements, facilities for warehouse qualifying GWP requirements.

Unit- V

Intellectual property rights, patents Act, Trademark and Copyright Act

Books Recommended:

1. Gennaro A.R., Remington- The science and practice of pharmacy, Lippircott, Williams & Wilkins.

2. Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.

3. Malik Vijay, Drug & Cosmetics Act, 1940, Eastern Book Company, Lucknow.

4. Guarino R.A., New Drug Approval Process, Marcel Dekker.

5. Sharma P.P., How to practice GMP, Vandana Prakashan, New Delhi.

6. Sharma P.P., how to practice GLP, Vandana Prakashan, New Delhi,

7. World Health Organization, quality assurance of Pharmaceuticals I & I, Pharma Book Syndicate, Hyderabad.

8. Weinlerg S., Good Laboratory Poactices, Marcel Dekker.

9. The Patent Act, 1970

10. The Trade Marks Act, 1999.

11. The Copyright Act, 1958.

12. Potdar M.A., Current Good Manufacturing Practices for Pharmaceuticals, Pharma Med Press, Hyderabad.

13. Rick N.G., Drug from Discovery to Approval, Wiley Black Well.

14. Swarlerick J., Boylan J., Encyclopedia / Pharmaceutical Technology Relevant Welesites of Regulatory Anthoriter of different countries.

MPHR- 115 PRODUCT DEVELOPMENT- I

Unit- I

A study of the Indian pharmaceutical industry vis- a vis global scenario (detail studies about top ten Pharma industries including SWOT analysis).

Unit- II

Stages in product development - flow chart. (acceptance criteria)

Preformulation studies.ncluding decision tree .Incompatabilities with special empesis to drug excipient

Unit- III

Formulation additives with reference to solid semi solid liquid dosage .

Unit- IV

Basic concepts in designing and development of Pediatric and geriatric

Formulations and Development of various Padiartic formulations,

Unit- V

Stability testing – stress testing of drug substances, stability indicating assays. Role of kinetic studies. Stability testing protocols, retest period/ shelf life determination, Photo Stability Testing, Stability testing of biotechnological and phytopharmaceuticals, post approval changes.

Books Recommended

1. The drug Development Hand book series, part 1 & 2 Locum House Publication, USA.
2. Bankers & Rhodes , Modern Pharmaceutics", Marcel Dekker.
3. Swarbrick James & Boylan J.C. " Encyclopedia of pharmaceutical technology", Marcel Dekker.
4. Lachman, Leon, . Lieberman H.A, Kanig J. L., The theory & practice of industrial pharmacy", Varghese Publication House, Bombay.
5. Rowe R.C., Sheskey P.J., & Owen S.C., " Handbook of Pharmaceutical Excipients" Pharmaceutical Press, London.
6. .Aulton M.E , Pharmaceutics: The design & manufacture of medicine, Churchill Livingstone, London.
7. .Ansel H.C, Allen L.V.,.Popovich N.G, "Pharmaceutical Dosage forms and drug delivery systems" , Indian edition, Lippincott Williams & Wilkins, B.I.Publications.
8. .Carstensen, J.T, Rhodes C.T. "Drug stability", Marcel Dekker.
9. Wise D.L., "Handbook of Pharmaceutical Controlled release technology Marcel Dekker .
10. Indian Pharmacopoeia
11. British Pharmacopoeia
12. U.S.P./ N.F.
13. .Weiner M.L, Kotkoskie L.A., Excipient Toxicity & Safety, , Marcel Dekker.
14. .Guarino R.A, New Drug Approval process: the global challenge Marcel Dekker.
15. Rodriguer A.D. Drug- drug interaction, Marcel Dekker
16. Dressman J & Kramer J. Pharmaceutical Dissolution testing, Taylor & Frances.
17. Blaisdell Peter Twenty first century Pharmaceutical development , Interpharm press Denver, Colorado.
18. Relevant Websites.

MPHR – 111P

Advanced Analytical Techniques Practicals

1. Combination Drug Analysis (Any Five)
a. Vitamins
b. Oral antidiabetics
c. NSAIDs
d. Antimicrobials
e. Antihistamines
f. Antihypertensive
2. Illustrations of theoretical principles using assay of drugs official in various pharmacopoeias (Any 10). This should cover titrimetric, spectro-photometric (including flamephotometric) methods, HPLC etc.. The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.
3.Excersises on interpretation of IR MASS and NMR spectra

Books Recommended: (Latest Edition)

1- Watson, D.G., Pharmaceutical Analysis, A Textbook for Pharmacy Students and Pharmaceutical Chemists, Elsevier Churchill Livingstone.
2- Lee, D.C., Webb, M., Pharmaceutical Analysis, Blackwell Publishing, CRC Press, Wiley India Pvt. Ltd.
3- Willard, H. H., Merrit, L.L., Dean, J. A., Settle P. A., Instrumental Methods of Analysis, Von Nostrand.
4- Skoog, D.A., Holler, F.J., Nieman, T.A., Principles of Instrumental Analysis, Thomson Brooks/Cole.
5- Christian, G, D., Analytical Chemistry, John Wiley and Sons.
6- Ahuja,S., Rasmussen,H., HPLC method development for Pharmaceuticals, Elesevier Academic Press.
7- Silverstein, Spectrometric identification of Organic Compounds, Willy.
8- Kemp William, Organic Spectroscopy, Pal grave, New York.
9- Beckett and Stenlake, Practical Pharmaceutical Chemistry, CBS Publishers, New Delhi.
10- Sethi, P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulations, CBS Publishers, New Delhi.

MPHR- 115 P

Product Development – 1 (Practicals based on Theory syllabus)

SEMESTER - II

MPHR- 124 PRODUCT DEVELOPMENT – II

Unit- I- Pilot Plant Technique, Processes Validation
Unit-II - Processes optimization & Scale-up.
Unit-III - Technology Transfer
Unit-IV - Materials Management
Unit-V - Automation & Processes Control

Books Recommended

1. Lachman Leon,. Lieberman H.A, Kanig J. L. The theory & practice of industrial pharmacy", Varghese Publication House, Bombay.
2. Levin Michael Pharmaceutical process scale- up , Marcel Dekker.
3. Williams R.O., Taft D.R, Mc- Conville ., J.T. Advanced drug formulation design the optimize therapeutic outcomes , Marcel Dekker
4. Banker & Rhodes Modern Pharmaceutics", Marcel Dekker .
5. Nash Robert A, Wachter, A.H Pharmaceutical Process Validation., Marcel Dekker .
6. d'Spouts, J.F Automation & validation of information in pharmaceutical processing., Marcel Dekker.
7. Swarbrick J. & Boylan J.C., Encyclopedia of Pharmaceutical Technology, Marcel Dekker.

MPHR – 125 BIOPHARMACEUTICS AND PHARMACOKINETICS

Unit- I

Introduction to BCS classification of drugs.

· Gastrointestinal absorption of drugs- Biologic, Physicochemical consideration and role of dosage form.

· Drug distribution, drug binding in blood and tissues.

· Drug metabolism and excretion.

Unit- II

- Pharmacokinetics: compartment models - one compartment & multi compartment models.
- Non compartmentl & non linear Pharmacokinetics

Unit- III

Pharmacokinetic Variability – Body weight, Age, Sex, Genetic factors, Disease and Drug Interactions.

Unit- IV

Bioavailability **–** Introduction, measurement and enhancement, in vitro dissolution & in vivo bioavailability (In vitro – in vivo correlation) bioavailability and bioequivalence studies- protocol and regulatory requirement.

Unit- V

Dosage regimens - repetitive dosing and dose adjustments in renal and hepatic failure. Individualisation and optimization of drug dosing regimens.

Books Recommended

Shargel Leon Applied Biopharmaceutics & Pharmacokinetics, McGraw- Hill.
Notari R. E., Biopharmaceutics and Clinical Pharmacokinetics, an introduction, Marcel Dekker
Gilbaldi M and Perrier D, Pharmacokinetics, Marcel Dekker.
Venkateshwaralu v, Biopharmaceutics & Pharmacokinetics, Pharma Book Syndicate.
Gilbadi M, Biopharmaceutics and clinical Pharmacokinetics, Pharma Book
Rowland & Tozer, Clinical Pharmacokinetics- Concept and application, Waverly
Welling P.G., Tse F.L., Pharmaceutical Bioequivalence, Marcel Dekker.

MPHR – 126 ADVANCES IN DRUG DELIVERY SYSTEMS

Unit- I

Polymers- Definition, Classification and Characterisation, Biodegradable and non biodegradable polymers – properties and applications.

Unit- II

A) Controlled Drug Delivery System – Concept and system design, classification:- rate preprogrammed activation modulated, feedback regulated.

B) Formulation and evaluation of controlled release systems.– oral, dental and parenteral

Unit- III

Factors influencing delivery, formulation and evaluation of – Transmucosal, Gastroretentive and colonic drug delivery system.

Unit- IV

Transdermal Drug Delivery systems- factors influencing transdermal delivery, formulation and evaluation lonophoresis and Iontophoresis.

Unit- V

Target oriented drug delivery systems- prodrugs, Liposomes, Niosomes, Microparticles, Nano particles, anti bodies, cellular carriers, lipoproteins, 1 DNA, Glycoprotein Low
molecular weight proteins. Occular AND Nasal Drug Delivery systemTransungual DDS, Brain targeting DDS.

Books Recommended:

1. Chien Y.W., Novel Drug Delivery Systems, Marcel Dekker
2. Robinson J.R. and Lee V.H., Controlled Drug Delivery: Fundamentals & Applications, Marcel Dekker.
3. Tse F.L.S. and Jaffe J.J., Biodegradable Polymers as Drug Delivery Systems, Marcel Dekker
4. Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.
5. Wise D.L., Handbook of Pharmaceutical Controlled Release Technology, Marcel Dekker.
6. Guy R.H., Hadgraft J., Transdermal Drug Delivery, Marcel Dekker.
7. Rathbone M.J., Hadgraft J., Modified Release Drug Delivery Technology, Marcel Dekker.
8. Swarbrick J. & Boylan J.C., Encyclopedia of Pharmaceutical Technology, Marcel Dekker.

MPHR 120

Seminar (two of 50 marks each) internal evaluation only

MPHR - 125P

Biopharmaceutics & Pharmacokinetics Practical

Experiments Based on:

A. Permeability measurement of drugs using artificial and biological membranes.
B. Determination of Pharmacokinetics parameters from urinary execretion data.
C. Determination of Pharmacokinetic parameters from animal experimentation / Published data.
D. Determination of relative and absolute bioavailability from animal experimentation / published data.
E. In vitro dissolution studies of different formulation and study of different factors effecting dissolution.

MPHR – 126 P

Advances in Drug Delivery Systems Practicals

Practicals on Formulation and Evaluation of Drug Delivery Systems mentioned theory syllabus.

SEMESTER - III

MPHR 231 SYNOPSIS OF THE PROPOSED PROJECT & EVALUATION OF PROJECT WORK AFTER SIX MONTHS

SEMESTER- IV

MPHR 241 THESIS

MPHR 242 PRESENTATION & VIVA - VOCE

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmacology) Effective From Session 2010-2011

SEMESTER - I

Sl. No	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR – 110	Pharmacological Method & Toxicology	4	-	30	-	70	-	100	4
2	MPHR – 112	Pharmaceutical Statistics & computer Application	4	-	30	-	70	-	100	4
3	MPHR – 113	Drug Regulatory Affairs & Intellectual Property Rights	4	-	30	-	70	-	100	4
4	MPHR – 116	Pharmacology – I (Systemic Pharmacology)	4	-	30	-	70	-	100	4
Practical			Day to Day Evaluation							
5	MPHR – 119 P	Clinical Pharmacy Practical	-	8	-	30	-	70	100	4
6	MPHR – 116 P	Pharmacology – I	-	12	-	30	-	70	100	6
								TOTAL	600	26

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination
Note: Duration of ESE – Theory exam will be of 3 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmacology)
SEMESTER - II

Sl. No	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR – 127	Pharmacology – II (Basic Principles of Drug Therapy & Clinical)	4	-	30	-	70	-	100	4
2	MPHR – 128	Pharmacology – III (Recent Advances in Pharmacology & Pharmaceutical Medicine)	4	-	30	-	70	-	100	4
3	MPHR – 129	Clinical Trial Management	4	-	30	-	70	-	100	4
4	MPHR – 120	Seminar (two of 50 marks each) internal evaluation only	4	-					100	4
Practical			Day to Day Evaluation							
5	MPHR – 128 P	Pharmacology – II	-	10	-	30	-	70	100	5
6	MPHR – 129 P	Pharmacology – III	-	10	-	30	-	70	100	5
								TOTAL	600	26

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination
Note: Duration of ESE – Theory exam will be of 3 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M.Pharm (Pharmacology)
Semester-III

Sl No.	Course Code	Subject	ESE	Credits
1	MPHR – 231	Synopsis of The Proposed Project & Evaluation of Project Work after Six Months	150	6

STUDY AND EVALUATION SCHEME

Course: M.Pharm (Pharmacology)
Semester-IV

Sl No.	Course code	Subject	ESE	Credits
1	MPHR – 241	Thesis	350	14
2	MPHR – 242	Presentation & Viva – voce	100	5

Semester – 1

MPHR – 110

Pharmacological methods and Toxicology

Unit- I

Principles of Experimental Pharmacology:

Common laboratory animals in pharmacological research, limitations of animal tests, alternatives to animal use, anesthetics used in laboratory animals, some standard techniques used in laboratory animals, euthanasia of experimental animals. Regulations for the care and use of laboratory animals. In vivo and in vitro experimentation,its advantages and disadvantages

Unit-11

New Drug Development Process:

Preclinical evaluation: Pharmacological evaluation of acute, sub acute, and chronic toxicity studies.

Clinical Evaluation: Justification and purpose, clinical evaluation including phase I, II, III and IV studies, ethical and legal aspects of clinical trials, methods of randomization, size, documentation, monitoring and management of clinical trials

Unit- III

Principles of Biological Standardization:

a) Statistical treatment of model problems in evaluation of drugs.

b) Methods of biological assay, principles of biological assays with certain examples.

c) Development of new bioassay methods.

Essentials of Toxicology:

a) Physicochemical, Biochemical and genetic basis of toxicity, principles of mutagenesis and carcinogenesis.

b) Guidelines and regulatory agencies – CPCSEA, OECD, FDA, WHO etc.

c) cellular and sub-cellular toxicity hypersensitivity and immune response.

d) Acute poisoning and its treatment

Unit- IV

Pharmacological Techniques to evaluate drugs belonging to following categories.

a) Cardiovascular pharmacology– Anti-hypertensives, anti-arrythmics, vasodilators and diuretics.

b) Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers,

c) Respiratory pharmacology – Anti- asthmatics, Anti- allergic and antitussives

d) Reproductive pharmacology – and anti- fertility agents.

e) Analgesics, anti- inflammatory and antipyretic agent.

Unit- V

a) CNS pharmacology – behavioural and muscle co-ordination, CNS stimulants and depressants, anxiolytics, anti-epileptics and Nootropics

b) Gastrointestinal drugs – Anti- ulcer, anti-emetic, anti-diarrhoeal and laxatives.

c) Anti-cancer agents.

d) Drugs for metabolic disorders like anti-diabetic, anti- hyperlipidemic ,antiobesity, and hepatoprotective agents.

e) Screening of free radical scavenging activity.

Pharmacoepidemiology: Types, methods, and factors affecting drug utilization, applications of pharmacoepidemiology in health care and rational use of drugs.

Pharmacovigilance: Definition, scope and epidemiology of adverse events, product recall and withdrawal of drugs with specific examples and drug related deaths.

BOOKS RECOMMENDED

1. H.G. Vogel (ed), Drug Discovery and Evaluation-Pharmacological Assays, 2nd edition, Springer Verlag, Berlin, Germany, 2002.

2. M.N. Ghosh, Fundamentals of Experimental Pharmacology, 2nd edition, Scientific Book Agency, Calcutta, India, 1984.

3. D.R. Laurence and A.L. Bacharach (eds), Evaluation of Drug Activities: Pharmacometerics, Vol. 1

4. Academic Press, London, U.K., 1964.

5. David R. Gross, Animal Models in Cardiovascular Research, 2nd edition, Kluwer Academic Publishers, London, U.K., 1994.

MPHR- 112 Pharmaceutical Statistics and Computer Applications

Unit- I.

Basic Definitions and Concepts: Variables and Variation, Frequency Distributions and Cumulative Frequency Distributions, Sample and Population, Measures Describing the center of Date Distributions,

Data Graphics: Introduction, the Histogram, Construction and Labeling of Graphs, Scatter Plots (Correlation Diagrams), Semilogarithmic Plots, Other Descriptive Figures.

Introduction to Probability The Binomial and Normal Probability Distributions : Introduction, Some Basic Probability, Probability Distributions, the Binomial Distribution,.

Unit- II

Choosing Samples Sample Size and Power : Introduction, Random Sampling, Other Sampling Procedures: Stratified, Systematic, Cluster Sampling, Sampling in Quality Control Introduction, Determination of Sample Size for Simple Comparative Experiments for Normally Distributed Variables, Determination of Sample Size for Binomial Tests,.

Statistical Inference: Estimation and Hypothesis Testing: Statistical Estimation (Confidence Intervals), Statistical Hypothesis Testing, Comparison of Variances in Independent Samples, Test of Equality of More than Two Variances confidence limits for variance Tolerance Intervals.

Unit- III

Linear Regression and Correlation: Introduction of linear and non linear regression ,Analysis of Standard Curves in Drug Analysis: Application of Linear Regression and Drug stability studies,

Analysis of Variance: One- Way Analysis of Variance Planned Versus a Posteriori (Unplanned) Comparisons in ANOVA, Another Example of One- Way Analysis of Variance: Unequal Sample Sixes and the Fixed and Random Models, Two-Way Analysis of Variance (Randomized Blocks), Statistical Models, Analysis of Covariance, ANOVA for pooling regression lines as related to stability data.

Nonparametric Methods: Data Characteristics and an Introduction to Nonparametric Procedures, Sign Test, Wilcoson Signed Rank Test, Wilcoxon Rank Sum Test (Test for Differences Between Two Independent Groups), Kruskal Wallis Test (One- Way ANOVA),

Factorial Designs : Definitions Two Simple Hypothetical Experiments to Illustrate the Advantages of Factorial Designs, Performing Factorial Experiments: Recommendations and Notation, A Worked Example of a Factorial Experiment, Fractional Factorial Designs.

Unit- IV

Experimental Design in Clinical Trials: Introduction, Some Principles of Experimental Design and Analysis, Parallel Deign, Crossover Designs and Bioavailability / Bioequivalence Studies, Repeated Measures (Split- Plot) Designs, Multiclinic Studies, Interim Analyses.

Quality Control: Introduction, Control Charts, Acceptance Sampling and Operating Characteristic Curves, Statistical Procedures in Assay Development, Establishing In- House Limits, Some Statistical Aspects of Quality and the "Barr Decision",

Unit- V

Applications of Computers in Pharmaceutical Sciences

Computer Intensive Methods: Advance Computer application and software applicable for treating l data statical.

Book Recommended:

1. Bolton, S and Bon, C, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.

2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.

3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.

4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

5. William E. Fassett, Computer Application in Pharmacy.

6. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.

MPHR- 113 DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS

Unit- I

A. Drug Information

Introduction

Primary, Secondary & Tertiary Literature

Spectrum of information, finding and managing Drug Information.

B. Drugs and Cosmetics Act and rules with special reference to schedule M and Y.

Unit- II

International Drug Regulatory affairs- registration procedure (Pharmaceutical products) for International Marketing, Including preparation of dossiers SMF, Validation, Calibration and other documents like product development, stability data for different countries.

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Facilities for manufacturing pharmaceutical products qualifying.

CGMP requirements - 21 CFR parts 210 and 211, Orange Guide, TRS, ICH, etc.

Unit- IV

Facilities for quality control lab qualifying GLP requirements, facilities for warehouse qualifying GWP requirements.

Unit- V

Intellectual property rights, patents Act, Trademark and Copyright Act

Books Recommended:

1. Gennaro A.R., Remington- The science and practice of pharmacy, Lippircott, Williams & Wilkins.

2. Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.

3. Malik Vijay, Drug & Cosmetics Act, 1940, Eastern Book Company, Lucknow.

4. Guarino R.A., New Drug Approval Process, Marcel Dekker.

5. Sharma P.P., How to practice GMP, Vandana Prakashan, New Delhi.

6. Sharma P.P., how to practice GLP, Vandana Prakashan, New Delhi,

7. World Health Organization, quality assurance of Pharmaceuticals I & I, Pharma Book Syndicate, Hyderabad.

8. Weinlerg S., Good Laboratory Poactices, Marcel Dekker.

9. The Patent Act, 1970

10. The Trade Marks Act, 1999.

11. The Copyright Act, 1958.

12. Potdar M.A., Current Good Manufacturing Practices for Pharmaceuticals, Pharma Med Press, Hyderabad.

13. Rick N.G., Drug from Discovery to Approval, Wiley Black Well.

14. Swarlerick J., Boylan J., Encyclopedia / Pharmaceutical Technology Relevant Welesites of Regulatory Anthoriter of different countries.

MPHR – 116 PHARMACOLOGY – I
SYSTEMIC PHARMACOLOGY

Unit- I.

Basic Principles of Pharmacology: Mechanisms of drug action, membrane transporters and drug response, adverse drug reactions, and pharmacokinetics.

Pharmacology of the Autonomic Nervous System:

1. Neurotransmission: The Autonomic and Somatic Motor Nervous System
2. Muscarinic receptor agonists and antagonists
3. Anticholinesterase agents
4. Agents acting at neuromuscular junction and autonomic ganglia
5. Adrenergic agonists and antagonists drugs used in glaucoma
6. 5-Hydroxytryptamine receptor agonists and antagonists

Unit-11

Drugs acting on the Central Nervous System:

1) Neurotransmission and the Central Nervous System
2) General Anesthetics
3) Local Anesthetics
4) Hypnotics, Sedatives and Ethanol
5) Drugs effective in the therapy of Migr aine
6) Treatment of Central Nervous system degenerative disorders
7) Opioid Analgesics and Antagonists
8) Drug Addiction and Drug Abuse

Autacoids: Drug Therapy of Inflammation:

1) Introduction
2) Histamine, Bradykinin and their Antagonists
3) Lipid- Derived Autocoids : Eicosanoids and platelet Activating factor
4) Analgesic-Antipyretic and Anti-Inflammatory agents

Unit- 111

Drugs Affecting Renal and Cardiovascular Function:

1. Diuretics
2. Vasopressin and other agents affecting the renal conservation of water
3. Renin, angiotensin, and their modulators
4. Calcium channel blockers

Drugs Acting on the Blood and Blood-Forming Organs:

Hematopoietic agents: Growth factors, minerals, and vitamins Blood coagulation and anticoagulant, thrombolytic, and antiplatelet drugs

Unit-1V

Pharmacology of Chemotherapeutic and Antimicrobial Agents:

1. General considerations of antimicrobial therapy
2. Sulfonamides, trimethoprim, quinolones, other related agents
3. Penicillins, cephalosporins, and other beta- lactam antibiotics
4. Aminoglycosides
5. Protein synthesis inhibitors and miscellaneous antibacterial agents
6. Antifungal agents
7. Antiviral agents (Non-retroviral)
8. Antineoplastic Agents
9. Immunosuppressants, and Immunostimulants

Unit-V

Hormones and Their Antagonists:

1. Pituitatary hormones and their hypothala mic releasing factors
2. Thyroid and antithyroid drugs
3. Estrogens and progestins
4. Androgens
5. Adrenocortical steroids and their synthetic analogs, inhibitors of synthesis and actions of adrenocortical hormones

BOOKS RECOMMENDED

1) Modern Pharmcology by C.R. Craig and R.E. Stitzel
2) Goodman and Gilman's : The Pharmcological Basis of Therapeutics, edited by Alfred Goodman Gilman, Theodore W. Rall, Alan S Nies, and Palmar Taylor
3) Clinical Pharmcology by D.R. Laurence and P.N. Benett
4). Essentials of Pharmcotherapeutics by F.S.K. Barar
5) Pharmacology by H.P. Rang and M.M. Dale
6) Lewis's Pharmacology revised by James Crossland

MPHR 116P PHARMACOLOGY PRACTICALS – I

1. Experiments to study pharmacology of receptors (competitive and non-competitive antagonists) using guinea pig ileum, and rat colon preprations
2. Experiments to calculate pA2 using isolated rectus abdominus muscle of rat, vas deferens, muscle of rat, rat colon, and rat fundus preparations.
3 To study the effect of various agonists on isolated guinea pig tracheal chain, isolated phrenic nervediaphragm, isolated rat aorta, isolated rabbit atria and gastrocnemius muscle of rabbit
4. Effect of various agents on rat blood pressure.
5. Effect of various pharmacological agents on heart rate, coronary flow rate, and force of contraction on isolated mammalian heart.

BOOKS RECOMMENDED

1. Ghosh M.N., Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta, India,
2 Vogel (ed) H.G., Drug Discovery and Evaluation-Pharmacological Assays, Springer Verlag, Berlin, Germany,

MPHR 116P PHARMACOLOGY PRACTICALS – I

CLINICAL PHARMACY PRACTICAL

An ability based outcome is composed a knowledge, skills and attitudes and is highlighted in bold text. The non-bold texts are the objectives discussed by the Advanced Practice Experience faculty members.

4. **The student should be able to evaluate, review or develop, implement and monitor therapeutic outcomes associated with a pharmaceutical care plan for a patient.**
   J. Understand the administration and delivery systems.
   K. Understand how to evaluate laboratory and patient data.
   L. Develop basic patient (including physical) assessment.
   M. Review patient's drug therapy for drug related problems (pharmaceutical care).
   N. Develop a pharmaceutical care plan for patients.
   O. Integrate problem solving in developing cost-effective therapy related plan toward achieving a desired therapeutic outcome, keeping in mind non-pharmacologic alternatives.
   P. Develop therapeutic parameters and become competent in monitoring the patients for therapeutic endpoints on an ongoing basis.
   Q. Competently use pharmacokinetics in developing and monitoring the patient's drug therapy.
   R. Understand the responsibility and reporting mechanism for adverse drug reactions.

5. **The student should be able to identify and utilize drug information services in order to facilitate their role as a drug-information specialist for other health care professionals and patients to achieve positive therapeutic outcomes.**
   F. Interact appropriately with other members of the health care team.
   G. Know and use the sources of drug information for any given rotation.
   H. Apply drug information to obtain positive outcomes for patients.
   I. Serve as drug information specialists for patients and other health care professionals.
   J. Understand the responsibility and reporting mechanism for adverse drug reactions.

6. **The student should be able to develop oral or written presentations on a drug topic or drug-related topics to other health care professionals and patients.**
   E. Effectively communicate in verbal and/or written form, in concise and organized fashion, a pharmaceutical evaluation of the patient.
   F. Serve as drug information specialists for patients and other health care professionals.
   G. Develop presentation skills for variable audiences for interdisciplinary education.
   H. Develop communication skills for patient education.

SEMESTER – II

MPHR- 127 PHARMACOLOGY – II
BASIC PRINCIPLES OF DRUG THERAPY AND CLINICAL PHARMACOLOGY

Unit- I

Definition, Scope, Organization and growth of Clinical Pharmacology, Cellular Transduction Mechanisms, Monitoring of Drug Therapy, Adverse Drug Reactions, Patient Compliance, Paediatric and Geriatric Pharmacology, Drug Interactions, Drug Therapy during pregnancy and lactation.

Unit – II

Clinical Pharmacokinetics: Determination and clinical relevance of various armacokineticparameters. Concept and measurement of bioavailability, bioequivalence, renal and hepatic clearances.Calculation of loading and maintenance doses and dose adjustment in renal and hepatic impairments.

Unit- III.

Drug Therapy of Inflammatory Disorders:
Biology of inflammation, pathophysiology and drug therapy of osteoarthritis, rheumatoid arthritis, and gout

Drug Therapy of Respiratory Diseases:
Pathophysiology and drug therapy of asthma.

Drug Therapy of Gastrointestinal Diseases:
Pathophysiology and drug therapy of peptic ulcers, emesis, irritable bowel syndrome, and inflammatory bowel disease.

Unit – IV

Drug Therapy of Neurological Disorders:
Pathophysiology and drug therapy of epilepsy, Parkinson's disease, migraine, and myasthenia gravis.

Drug Therapy of Psychiatric Disorders:
Pathophysiology and drug therapy of anxiety, schizophrenia, Alzheimer’s disease, mood and sleep disorders, and memory.

Drug Therapy of Endocrine Disorders:
Pathophysiology and drug therapy of diabetes mellitus, contraception, and infertility.

Drug Therapy of Metabolic and Sexual Disorders:
Pathophysiology and drug therapy of obesity and erectile dysfunction

Unit - V

Drug Therapy of Cardiovascular Disorders:
Pathophysiology and drug therapy of congestive cardiac failure, hypertension, cardiac arrhythmia, ischemic heart disease, hyperlipidemia, and atherosclerosis

Drug Therapy of Infectious Diseases:
Pathophysiology and drug therapy of tuberculosis, leprosy, HIV and related opportunistic infections,malaria, amoebiasis, and helminth infections.

BOOKS RECOMMENDED

1. Dipiro J.T., Talbert R.L., , Yee G.C., Matzke G.R., Wells B.G., L. Michael Posey Pharmacotherapy : A Pathophysiologic Approach, The McGraw Hill Companies, Inc., .

2. Herfindal E.T. and Gourley D.R, Text Book of Therapeutics: Drug and Disease Management, Lippincott Williams & Wilkins, USA,

3. Speight T.M. and Holford NHG (ed.), Avery’s Drug Treatment: Principals and Practice of Clinical Pharmacology and Therapeutics, 4th ed., ADIS Press, Sydney, Australia,

4. Kasper Dennis L., Braunwald Eugene, Fauci Anthony S., Hauser Stephen L., Longo Dan, Jameson J. Larry and Isselbacher Kurt J., (Eds.), Harrison's Principles of Internal Medicine, , The McGraw Hill Companies, Inc

MPHR – 128 PHARMACOLOGY- III
(RECENT ADVANCES IN PHARMACOLOGY& PHARMACEUTICAL MEDICINE)

Unit-1

1. **Molecular Pharmacology:** Receptor occupancy and cellular signaling systems including G- proteins,cyclic nucleotides, calcium and calcium binding proteins, phospholipases.

***Pharmacology of receptors*:** Classification, cellular signaling systems, and pharmacology of agonists and antagonists of the following receptor types:

Excitatory Amino Acid receptors
Purinoreceptors
GABA and Benzodiazepine receptors
Neurosteroid receptors
Cannabinoid receptors
Melatonin receptors

***Ion Channels and Their Modulators*:** Classification and biology of potassium ionic channels, and pharmacology of their modulators

Unit-11

Neuropeptides: Biological functions, pharmacological implications, their agonists and antagonists,and therapeutic potentials of the following neuropeptides:

Neuropeptide Y
Cholecystokinin

Transporter Proteins: Classification and biology of ATP binding cassette (ABC) transporter superfamily Multidrug resistance (MDR) proteins Cystic fibrosis transmembrane regulator (CFTR)

Unit-111

Programmed Cell Death (Apoptosis): Molecular biology, physiological and pharmacological implications and therapeutic potentials of apoptosis.

Cytokines and Chemokines: Classification, physiology, pharmacology, pathological, and therapeutic implications of various cytokines and chemokines.

Growth Factors: Biology and therapeutic potentials of various growth factors.

Biology of Vascular Endothelium: Pharmacology of endothelins and nitric oxide. Clinical implications of endothelial dysfunction.

Unit-1V

Nucleic Acid Therapies: Basic concepts and clinical potentials of gene therapy,

Genomics: Impact of human genome sequence on the discovery of newer pharmacological agents. Basic concept and applications of bioinformatics in drug discovery.

Stem Cell Therapeutics: Biology of stem cells and their potentials in various disorders.

Pharmcoeconomics: Principles, methods, and applications of pharmcoeconomics to pharmacotherapy and managed health care.

BOOKS RECOMMENDED

1. Fletcher A.J., Edwards L.D., Fox A.W., Stonier P. (eds.), Principles and Practice of Pharmaceutical Medicine, John Wiley & Sons, Ltd., U.K.
2. Griffin J.P. and O`Grady J. (eds.), The Text Book of Pharmaceutical Medicine, Blackwell Publishing Ltd., India, 2006.
3. Good P.I., A Managers Guide to Design and Conduct of Clinical trials, Wiley- Liss, Hobokem, U.S.A.,
2. 5. Dipiro J.T., Talbert R.L., , Yee G.C., Matzke G.R., Wells B.G., Michael L. Posey (eds.), Pharmacotherapy: A Pathophysiologic Approach, The McGraw Hill Companies, Inc.,

RECOMMENDED REFERENCE JOURNALS

1. Annual Review Pharmacology and Toxicology
2. Drugs
3. Pharmacological Reviews
4. Trends in Pharmacological Sciences
5. Indian Journal of Physiology & Pharmacology
6. Indian Journal of Experimental Biology
7. Indian Journal of Pharmacology

CLINICAL TRIAL MANAGEMENT

1. Introduction to Pharmaceutical Medicine

- The Drug Development Process
- New Drug Discovery
- Clinical Development of Drug
- Essential Clinical Trial Documents
- Clinical Trials Terminology

2. Good Clinical Practice (GCP) Foundations

- History of GCP - milestones in the evolution of GCP
- Principles of GCP
- Applicable GCP Guidelines
- Declaration of Helsinki
- Clinical Study Process
- The Management of Clinical Studies (Sponsor)
- Ethics in Clinical Research
- Informed Consent process
- Challenges in the Implementation of GCP Guidelines
- Creation of Trial Master File(s)

3. Drug Regulatory Affairs (Clinical Trials)

- Overview of Regulatory Environment in USA, Australia, Europe and India
- Clinical Trial Application Requirements in India
- Import- Export of Clinical Trial Drugs in India
- Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.
- IND/ANDA/New Drug Application
- Investigator Site Evaluation/Selection Process
- Audits and Quality Assurance *etc*

4. Roles and Responsibilities of Clinical Trial Personnel

- Roles and Responsibilities of Sponsor
- Roles and Responsibilities of Investigator
- Roles and Responsibilities of ERB/IRB/IEC
- Roles and Responsibilities of CRA /Monitor
- Roles and Responsibilities of Auditor
- Roles and Responsibilities of Clinical Research Coordinator or Site Manager
- Roles and Responsibilities of CRO's
- Roles and Responsibilities of Regulatory Authorities
- Roles and Responsibilities of Clinical Data Manager (CDM)
- Roles and Responsibilities of Clinical Biostatistician

5. Clinical Trial Monitoring

- Development of Monitoring Plan
- Site Initiation Visit, Review of Essential Trial Documents, Delegation of Duties and
- Responsibilities at Individual Site
- Routine Monitoring Visit
- Inventory Planning and Tracking
- Source Document Verification (SDV)
- CRF Review, Collection and Co-ordination of Data Management Activities
- Serious Adverse Event (SAE) Review and Regulatory Compliance
- Investigational Product Accountability and Management
- Escalation, Management and Prevention of Violations/Deviations
- Tracking of Enrolments, Payments and Ongoing Correspondence
- Site Closure Monitoring Visit *etc.*

MPHR 120 Seminar (two of 50 marks each) internal evaluation only

MPHR 128 P

PHARMACOLOGY PRACTICALS – I1

1 Bioassays of various agonists and antagonists using guinea pig ileum, rat uterus, rat fundus .e.g.
a.5HT bioassay(Comparative,graphical,4 point)
b.oxytocin bioassay(graphical)
c.Ach bioassay(rat fundus)
d.Histamine bioassay using guinea pig ileum(graphical &4 point)
2. Exercises to calculate pharmacokinetic parameters, bioavailability and bioequivalence using serum/plasma and urine excretion data.

BOOKS RECOMMENDED

1. M.N. Ghosh, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta, India,
2. Pharmacologica experiments on isolated Preparations by Edinburgh University Pharmacology Staff.
3. Handbook of Experimental Pharmacology by S.K. Kulkarni,Vallabh Prakashan Delhi.

MPHR 129P

PHARMACOLOGY PRACTICALS – I11

.
1. Experiments in intact animals to evaluate local anesthetics, mydriatics, miotics, analgesics,anti- inflammatory agents, hypnotics, antianxiety agents, antiepileptic agents, antidepressants,antipsychotics, antiparkinsonian agents, nootropics, and antiulcer agents
2. Design and statistical analysis of experimental data.
3. Calculation of LD50 and experiments related to toxicity

BOOKS RECOMMENDED

1. M.N. Ghosh, Fundamentals of Experimental Pharmacology, Scientific Book Agency, Calcutta, India, .
2 H.G. Vogel (ed), Drug Discovery and Evaluation-Pharmacological Assays, Springer Verlag, Berlin, Germany,
3.Screening Methods in Pharmacology by turner ,vol.1& 2 ,Academic Press,New York
4.W.W. Daniel, Biostatistics: A Foundation for Analysis in the Health Sciences, 7th ed., John Wiley &Sons, Inc., India, 2000.
5. S.P. Gupta, Statistical Methods, 31st ed., Sultan Chand & Sons, India, 2003.

SEMESTER - III

MPHR 231 SYNOPSIS OF THE PROPOSED PROJECT & EVALUATION OF PROJECT WORK AFTER SIX MONTHS

SEMESTER- IV

MPHR 241 THESIS

MPHR 242 PRESENTATION & VIVA - VOCE

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmaceutical Chemistry) Effective From Session 2010-11

SEMESTER – I

Sl. No.	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR – 111	Advanced Analytical Technique	4	-	30	-	70	-	100	4
2	MPHR – 112	Pharmaceutical Statistics & Computer Application	4	-	30	-	70	-	100	4
3	MPHR – 113	Drug Regulatory Affairs & Intellectual Property Rights	4	-	30	-	70	-	100	4
4	MPHR – 114	Advanced Organic Chemistry	4	-	30	-	70	-	100	4
PRACTICAL			Day to Day Evaluation							
5	MPHR - 111P	Advanced Analytical Technique	-	8	-	30	-	70	100	4
6	MPHR – 114-P	Advanced Organic Chemistry	-	12	-	30	-	70	100	6
								TOTAL	600	26

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination

Note: Duration of ESE – Theory exam will be of 3 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmaceutical Chemistry)
SEMESTER - II

Sl. No.	Course Code	Subject	Period (hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR – 121	Drug Design	4	-	30	-	70	-	100	4
2	MPHR – 122	Advanced Medical Chemistry	4	-	30	-	70	-	100	4
3	MPHR – 123	Advanced Chemistry of Natural Products	4	-	30	-	70	-	100	4
4	MPHR – 120	Seminar (two of 50 marks each) internal evaluation only	-	-	-		-		100	4
PRACTICAL			Day to Day Evaluation							
5	MPHR – 122 P	Advanced Medicinal Chemistry	-	10	-	30	-	70	100	5
6	MPHR – 123 P	Advanced Chemistry of Natural Products	-	10	-	30		70	100	5
								Total	600	26

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination
Note: Duration of ESE – Theory exam will be of 3 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M.Pharm (Pharmaceutical Chemistry)
Semester-III

Sl No.	Course Code	Subject	ESE	Credits
1	MPHR – 231	Synopsis of The Proposed Project & Evaluation of Project Work after Six Months	150	6

STUDY AND EVALUATION SCHEME

Course: M.Pharm (Pharmaceutical Chemistry)
Semester-IV

Sl. No.	Course Code	Subject	ESE	Credits
1	MPHR – 241	Thesis	350	14
2	MPHR – 242	Presentation & Viva – voce	100	5

SEMESTER -I
MPHR 111

ADVANCED ANALYTICAL TECHNIQUES

Unit –I:

UV-Visible spectroscopy- Introduction. Application in determination of pKa values, pharmaceutical quantitative analysis, preformulation and formulation. Difference spectrophotometry, derivative spectra.

Solid State Analysis: X-ray diffraction and crystallography, thermal analysis and calorimetry, micromeritic measurements.

Unit –II:

Infrared spectroscopy- Introduction, Application in structure elucidation and in identifying polymorphs. I R as a fingerprint technique. Near IR analysis and its applications, FTIR.

Unit –III:

a) Atomic spectrophotometry:

Atomic emission spectrophotometry: principle, instrumentation, interferences and applications.

Atomic absorption spectrophotometry: principle, instrumentation and applications.

b) Molecular emission spectroscopy:

Fluorescence spectroscopy: Principles, molecules exhibiting fluorescence, factors interfering with fluorescence intensity, application. Raman spectroscopy: Principle, instrumentation and applications.

Unit –IV:

a) Nuclear Magnetic Resonance Spectroscopy:

Introduction, instrumentation, chemical shifts, shielding and deshielding effects, spin-spin coupling, reference standard and solvents, proton NMR, carbon-13 NMR Application to structure elucidation.

b) Mass Spectrometry:

Principle, instrumentation, mass spectra obtained under electron impact (EI) ionization conditions, molecular fragmentation patterns, molecular ion, metastable ion, McLafferty rearrangement, EI mass spectra of some drug molecules. GC-MS and LC-MS: principle and applications.

Unit –V:

Chromatographic techniques:

Chromatographic Theory: void volume, capacity factor, band broadening, calculation of column efficiency, parameters used in evaluating column performance (resolution and peak asymmetry). HPLC: instrumentation, stationary phases, mobile phases and its selection, columns and detectors, applications in quantitative analysis of drugs in formulations, specialized HPLC techniques.

HPTLC, GC, High-performance capillary electrophoresis: principle, instrumentation and application.

MPHR- 112 Pharmaceutical Statistics and Computer Applications

Unit- I.

Basic Definitions and Concepts: Variables and Variation, Frequency Distributions and Cumulative Frequency Distributions, Sample and Population, Measures Describing the center of Date Distributions,

Data Graphics: Introduction, the Histogram, Construction and Labeling of Graphs, Scatter Plots (Correlation Diagrams), Semilogarithmic Plots, Other Descriptive Figures.

Introduction to Probability The Binomial and Normal Probability Distributions : Introduction, Some Basic Probability, Probability Distributions, the Binomial Distribution,.

Unit- II

Choosing Samples Sample Size and Power : Introduction, Random Sampling, Other Sampling Procedures: Stratified, Systematic, Cluster Sampling, Sampling in Quality Control Introduction, Determination of Sample Size for Simple Comparative Experiments for Normally Distributed Variables, Determination of Sample Size for Binomial Tests,.

Statistical Inference: Estimation and Hypothesis Testing: Statistical Estimation (Confidence Intervals), Statistical Hypothesis Testing, Comparison of Variances in Independent Samples, Test of Equality of More than Two Variances confidence limits for variance Tolerance Intervals.

Unit- III

Linear Regression and Correlation: Introduction of linear and non linear regression ,Analysis of Standard Curves in Drug Analysis: Application of Linear Regression and Drug stability studies,

Analysis of Variance: One- Way Analysis of Variance Planned Versus a Posteriori (Unplanned) Comparisons in ANOVA, Another Example of One- Way Analysis of Variance: Unequal Sample Sixes and the Fixed and Random Models, Two-Way Analysis of Variance (Randomized Blocks), Statistical Models, Analysis of Covariance, ANOVA for pooling regression lines as related to stability data.

Nonparametric Methods: Data Characteristics and an Introduction to Nonparametric Procedures, Sign Test, Wilcoson Signed Rank Test, Wilcoxon Rank Sum Test (Test for Differences Between Two Independent Groups), Kruskal Wallis Test (One- Way ANOVA),

Factorial Designs : Definitions Two Simple Hypothetical Experiments to Illustrate the Advantages of Factorial Designs, Performing Factorial Experiments: Recommendations and Notation, A Worked Example of a Factorial Experiment, Fractional Factorial Designs.

Unit- IV

Experimental Design in Clinical Trials: Introduction, Some Principles of Experimental Design and Analysis, Parallel Deign, Crossover Designs and Bioavailability / Bioequivalence Studies, Repeated Measures (Split- Plot) Designs, Multiclinic Studies, Interim Analyses.

Quality Control: Introduction, Control Charts, Acceptance Sampling and Operating Characteristic Curves, Statistical Procedures in Assay Development, Establishing In- House Limits, Some Statistical Aspects of Quality and the "Barr Decision",

Unit- V

Applications of Computers in Pharmaceutical Sciences

Computer Intensive Methods: Advance Computer application and software applicable for treating l data statical.

Book Recommended:

1. Bolton, S and Bon, C, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.

2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.

3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.

4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

5. William E. Fassett, Computer Application in Pharmacy.

6. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.

MPHR- 113 DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS

Unit- I

A. Drug Information

Introduction

Primary, Secondary & Tertiary Literature

Spectrum of information, finding and managing Drug Information.

B. Drugs and Cosmetics Act and rules with special reference to schedule M and Y.

Unit- II

International Drug Regulatory affairs- registration procedure (Pharmaceutical products) for International Marketing, Including preparation of dossiers SMF, Validation, Calibration and other documents like product development, stability data for different countries.

Unit- III

Facilities for manufacturing pharmaceutical products qualifying.

CGMP requirements - 21 CFR parts 210 and 211, Orange Guide, TRS, ICH, etc.

Unit- IV

Facilities for quality control lab qualifying GLP requirements, facilities for warehouse qualifying GWP requirements.

Unit- V

Intellectual property rights, patents Act, Trademark and Copyright Act

Books Recommended:

1. Gennaro A.R., Remington- The science and practice of pharmacy, Lippircott, Williams & Wilkins.

2. Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.

3. Malik Vijay, Drug & Cosmetics Act, 1940, Eastern Book Company, Lucknow.

4. Guarino R.A., New Drug Approval Process, Marcel Dekker.

5. Sharma P.P., How to practice GMP, Vandana Prakashan, New Delhi.

6. Sharma P.P., how to practice GLP, Vandana Prakashan, New Delhi,

7. World Health Organization, quality assurance of Pharmaceuticals I & I, Pharma Book Syndicate, Hyderabad.

8. Weinlerg S., Good Laboratory Poactices, Marcel Dekker.

9. The Patent Act, 1970

10. The Trade Marks Act, 1999.

11. The Copyright Act, 1958.

12. Potdar M.A., Current Good Manufacturing Practices for Pharmaceuticals, Pharma Med Press, Hyderabad.

13. Rick N.G., Drug from Discovery to Approval, Wiley Black Well.

14. Swarlerick J., Boylan J., Encyclopedia / Pharmaceutical Technology Relevant Welesites of Regulatory Anthoriter of different countries.

MPHR 114

ADVANCED ORGANIC CHEMISTRY

Unit-I

Organic Reactions:

Mechanism, reactivity and reactions of

a) Aliphatic and Aromatic electrophilic substitution.
b) Aliphatic and Aromatic nucleophilic substitution.
c) Free radical reactions.
d) Elimination reactions.

Unit-II

Name reactions : Mechanism and applications in drug synthesis of following name reactions

a) Beckmann Rearrangement b) Birch reduction c) Claisen Schimidt d) Diel's Alder reaction e) Grignard f) Hoffmann rearrangement g) Mannich h) Meerwein Ponndorf-Verley reduction i) Oppenauer oxidation j) Perkin k) Reformatsky l) Wolf Kishner reduction.

Unit-III

Organic synthetic techniques involved in drug research, Protection and deprotection of functional groups, Introduction to asymmetric synthesis, Microwave reactions.

Unit-IV

Stereochemistry and Chiral Techniques:

Principles of stereochemistry, optical rotation and optical rotatory dispersion. Stereochemistry of five and six membered rings, fused and bridged rings. Concept of chirality, chiral drugs, resolution procedures of racemic mixtures, asymmetric synthesis of propranol, omeprazole,nifedipine and ethambutol.

Unit-V

Photochemical reaction: light absorption, electronic transition, photosensitization, photochemistry of conjugated dienes, enones.

Synthone Approach: Definition, terms, rules and guidelines used in synthesis of following drugstrimethoprim, ibuprofen, ciprofloxacin and diclofenac.

Books Recommended: (Latest Edition)

1. J. March, Advanced Organic Chemistry, Reactions, Mechanism and Structures, JohnWiley & Sons, New York.
2. M. E. Wolff, Burger's Medicinal Chemistry and Drug discovery, Principle and Practice, John Wiley & Sons, New York.
3. Nogrady, Medicinal Chemistry, A Bio Chemical Approach, Oxford University Press, Oxford.
4. Laszlo Kurti, Barbara Czako, Strategic Applications of name reactions in Organic synthesis, Elsevier, Academic Press, New York.
5. Eliel and H. Samuel, Stereochemistry of Organic compounds, John Wiley & Sons, New York.
6. Practical Organic Synthesis: A Student's Guide - Reinhart Keese, Martin Brändle, Trevor Toube
7. Norman, Principles of Organic Synthesis, Nelson Thornes, U.K.
8. Solomens and Fryhle, Organic Chemistry, John Wiley & Sons, Singapore.
9. Wade, Singh, Organic Chemistry, Dorly Kindersley, India.
10. Eliel, Willen, Mander, Stereochemistry of organic compounds, John Wiley & Sons, U.K.

MPHR – 111P

Advanced Analytical Technique Practicals

1. Combination Drug Analysis (Any Five)
a. Vitamins
b. Oral antidiabetics
c. NSAIDs
d. Antimicrobials
e. Antihistamines
f. Antihypertensive
2. Illustrations of theoretical principles using assay of drugs official in various pharmacopoeias (Any 10). This should cover titrimetric, spectro-photometric (including flamephotometric) methods, HPLC etc. The titrimetric methods should include argentometric, conductometric, and potent iometric end-point determination. The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.

3. Interpretation of UV and IR spectra of some unknown intermediates and drugs. (Any two)

Books Recommended: (Latest Edition)

11- Watson, D.G., Pharmaceutical Analysis, A Textbook for Pharmacy Students and Pharmaceutical Chemists, Elsevier Churchill Livingstone.
12- Lee, D.C., Webb, M., Pharmaceutical Analysis, Blackwell Publishing, CRC Press, Wiley India Pvt. Ltd.
13- Willard, H. H., Merrit, L.L., Dean, J. A., Settle P. A., Instrumental Methods of Analysis, Von Nostrand.
14- Skoog, D.A., Holler, F.J., Nieman, T.A., Principles of Instrumental Analysis, Thomson Brooks/Cole.
15- Christian, G, D., Analytical Chemistry, John Wiley and Sons.
16- Ahuja,S., Rasmussen,H., HPLC method development for Pharmaceuticals, Elesevier Academic Press.
17- Silverstein, Spectrometric identification of Organic Compounds, Willy.
18- Kemp William, Organic Spectroscopy, Pal grave, New York.
19- Beckett and Stenlake, Practical Pharmaceutical Chemistry, CBS Publishers, New Delhi.
20- Sethi, P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulations, CBS Publishers, New Delhi.

MPHR- 114P

Advanced Organic Chemistry Practicals

1. Experimental techniques – Fractional distillation, Vacuum distillation, Preparative chromatography- Column and TLC.
2. Synthesis of any five different heterocyclic compounds using reactions discussed under unit II of theory syllabus.
3. Practical illustrations of any five reactions described in the unit II of theory syllabus.
4. Principles, mechanism and techniques of stereo controlled synthesis of Nifedipine, Chloroxazone and Paracetamol.

Books Recommended: (Latest Edition)

1. J. March, Advanced Organic Chemistry, Reactions, Mechanism and Structures, JohnWiley & Sons, New York.
2. M. E. Wolff, Burger's Medicinal Chemistry and Drug discovery, Principle and Practice, John Wiley & Sons, New York.
3. Nogrady, Medicinal Chemistry, A Bio Chemical Approach, Oxford University Press, Oxford.
4. Laszlo Kurti, Barbara Czako, Strategic Applications of name reactions in Organic synthesis, Elsevier, Academic Press, New York.
5. Eliel and H. Samuel, Stereochemistry of Organic compounds, John Wiley & Sons, New York.
6. Practical Organic Synthesis: A Student's Guide - Reinhart Keese, Martin Brändle, Trevor Toube
7. Norman, Principles of Organic Synthesis, Nelson Thornes, U.K.
8. Solomens and Fryhle, Organic Chemistry, John Wiley & Sons, Singapore.
9. Wade, Singh, Organic Chemistry, Dorly Kindersley, India.
10. Eliel, Willen, Mander, Stereochemistry of organic compounds, John Wiley & Sons, U.K.

SEMESTER - II

MPHR-121 DRUG DESIGN

Unit-I

Introduction to Drug Design Concept, Lead Discovery, drug-receptor interactions Physicochemical Properties in Relation to Biological Action, Stereoche mical Aspects in Drug Design.

Unit-II

Drug metabolism- Phase-I & Phase-II Metabolic Reactions, Introduction to Drug Designing on the Basis of Metabolic Pathways, Analytical methods in drug metabolism.
Prodrugs - Bioprecursor & Carrier Linked Prodrugs, Hard and Soft Drugs.

Unit-III

Analog Based Drug Design-Introduction, Designing of Analogs.
Structure Based Drug Design- Introduction, Drug Design on Structure Based.

Unit-IV

Combinatorial Chemistry- Introduction, Solid Phase Sy
nthesis, Liquid Phase Synthesis, Methods of Parallel and Mixed Combinatorial Synthesis, Deconvolution and High Throughput Screening.

Unit-V

Molecular Modeling- Introduction to Molecular Mechanics, Quantum Mechanics, Molecular Dynamics, Molecular Graphics and Molecular Docking.
QSAR- Introduction, steric effects, methods used to correlate physicochemical Parameters with biological activity, Quantitative Models, Introduction to 2D and 3D QSAR.

Books Recommended

1. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
2. Silverman R.B. " The organic Chemistry of Drug Design and Drug Action" Academic Press New York.
3. Robert GCK,ed., " Drug Action at the Molecular Level" University Prak Press Baltimore.
4. Martin YC. " Quantitative Drug Design" Dekker, New York.
5. Lien EJ. SAR " Side effects and Drug Design" Dekker, New York.
6. William H, Malick JB " Drug Discovery and Dovelopment" Humana Press Clifton.
7. Delgado JN, Remers WA eds " Wilson & Gisvolds's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
8. Foye WO " Principles of Medicinal chemistry ' Lea & Febiger.
9. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
10. Wolf ME, ed "The Basis of Medic inal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
11. Ariens EJ " Drug Design" Academic Press New York.
12. Olson EC "Computer Assisted Drug Design" American Chemical Society ACS Symposium Series 112.
13. Roberts SM, Price B.J.Eds. " Medicinal Chemistry. The Role of Organic Chemistry in Drug Research " Academic Press New York.
14. Pope & Perruuns " Computer Aided Drug Design " Academic Press New York.
15. Thomas , G.Medicinal Chemistry-An Introduction John Wiley and sons Ltd.
16. Patrick Graham, L., An Introduction to Medicinal Chemistry, Oxford University Press.
17. Fischer Janos, Ganellin C. Robin "Analogue-based drug Discovery, Wiley-VCH Verlag Gmb H & Co. KG &A.
18. Pandi, Veerapandian "Structure based drug design New York Marcel Dekker, inc., 1997.
19. Wermuth GC, "The Practice of Medicinal Chemistry" Second edition, Academic Press, Elsevier

MPHR- 122 ADVANCED MEDICINAL CHEMISTRY

Unit- I

Psychopharmacological agents: a) Biochemical basis of mental disorders:- Abnormal protein factors, endogenous amines and related substances, faulty energy metabolism, geneticfactors and nutritional disorders; Phenothiazines: chemistry, synthesis and evaluation methods. The important pharmacological activities of phenothiazines; SAR of phenothiazines, toxicity and clinical significance of phenothiazines.

b) Antidepressants: MAO inhibitors, tricyclic antidepressants and miscellaneous compounds. Mechanism of action, clinical and biological uses side effects and their SAR studies. Synthesis of clinically useful drugs of each of the above classes.

Unit- II

Chemotherapy of Cancer: A detailed classification of antineoplatic agents, mechanisms of action of different classes; Alkylating agents and radiomimetic agents, antimetabolites, their SAR studies, sex hormones & analogs, and antibiotics. A mention of natural products used in cancer treatment; Vinca alkaloids (Vincristine and Vinblastine) podophyllum and paclitaxel.

Unit- III

Advances in therapeutic agents for cardiovascular disorders:

Antihypertensive, Antiarrhythmics, Antihyperlipidemics.

Unit- IV

Miscellaneous Classes of Drugs: Recent advances in the following classes of drugs:

Proton-pump inhibitors as antiulcer agents.

Immunosuppressive and immunostimulant agents.

Antiviral agents.

ß – Adrenergic blockers

Unit- V

Steroids:

Steroid nomenclature, stereochemistry and numbering; New insights on steroid receptors; chemical and physical properties of steroids; changes to modify pharmacokinetic properties of steroids. Sources and structure elucidation of cholesterol; sources and structures of related steroids – Ergosterol. Stigmasterol,

ß- sitosterol and Diosgenin.

Steroidal Anti- inflammatory Agents; structures; structure-activity relationships; therapeutic uses.

Steroidal Anti- fertility agents: Structures; mechanism of action; regimen.

Anabolic Steroids: Structures; uses.

Steroids in the treatment of cancers.

MPHR 123

ADVANCED CHEMISTRY OF NATURAL PRODUCTS

Unit-I

Natural sources of drugs (Plant, animal, microbial, and marine), Role of natural products in development of medicinal chemistry, providing "leads".

WHO Guidelines for assessment of crude drugs: Evaluation of identity, purity, and quality of crude drugs, Determination of pesticide residue, Determination of Micro-organisms.

Unit-II

Study of Herbal Extracts: Processing, equipment and analytical profiles. Sterility, stability and preservation of extracts.
Phytochemical screening of crude drugs: Extraction, isolation, purification,
characterization of following phytoconstituents.
Alkaloids: Caffeine, Morphine
Glycosides: Digoxin, Sennosides
Flavonoids: Rutin, Quercetin
Saponins: Glycyrrhizinic acid, Diosgenin

Unit-III

Brief introduction to Pharmacological Screening Methods with example of
Following category of medicinal herbs:
a) Hepatoprotecives
b) Antidaibetics
c) Hypolipidaemics
d) Antioxidants
e) Anti- inflammatory, analgesics.
f) Wound Healing

Unit-IV

Study of the following classes of alkaloids :

Alkaloids of Opium: Structure elucidation of Morphine, structure activity relationships in morphine molecule.
Alkaloids of Atropa belladonna: Atropine, Hyoscyamine and Hyoscine, Structure elucidation of
Atropine, Therapeutic uses.
Alkaloids of Vinca rosea: Vincristine and vinblastine, structure elucidations, Structural modifications and semisynthetic derivatives.
Alkaloids of Ergot: Classification, Structures, Structure elucidation of Ergometrine, therapeutic uses of ergot alkaloids and derivatives (vinyl and methylsergide).

Unit-V

A Brief Account of the Following:

a) Anticancer Agents of Plant Origin: Sources and structures of podophyllotoxin, Taxol and camptothecin; their semi synthetic derivatives, uses and mechanism of action.
b) Ginseng: Historical background, structures and uses of Ginsenosides, protopanaxadiols and triols.
c) Phototherapy: sources and structures of psoralens, Photodegradation of 8-methoxy psoralen, PUVA therapy in psoriasis and ritiligo.

MPHR 120

Seminar (two of 50 marks each) internal evaluation only

MPHR- 122P

Advanced Medicinal Chemistry Practicals

1. Synthesis of compounds using 3-4 steps, structure confirmation by spectroscopic methods.
2. Resolution of racemic mixture.
3. Determination of partition coefficient, pka.

Books Recommended

1. Foye: Principles of Medicinal Chemistry, 6th ed. (Lippincott).
2. Ariens: Medicinal Chemistry Series.
3. Ellis and West: Progress in Medicinal Chemistry Series.
4. Butterworthser: Progress in Medicinal Chemistry Series.
5. Burgers Medicinal chemistry-The Basis of Medicinal chemistry by Manfred E. Wolff part-I (John Wiley & Sons).
6. Medicinal chemistry – The Role of organic chemistry in drug research by S.M.Roberts and B.J.Price.
7. Vogel's Textbook of practical organic chemistry by Arthur I Vogel (ELBS and Lognman)
8. The Organic Chemistry of Drug Synthesis (3 volumes) by Daniel Lednicer & Laster A. Mitscher (John Wiley & Sons).
9. An Introduction to Organic Laboratory Manual by Pavia, Lampman and Chris.
10. Principles of Organic and Medicinal Chemistry – Munson.
11. Comprehensive Medicinal Chemistry – Hansch and Leo.

MPHR 123P

Advanced Chemistry of Natural Products Practicals

1. Extraction, isolation, purification and characterization of important phytoconstituents belonging to different classes.
    a. Eugenol from Clove
    b. Sennosides from Senna
    c. Curcumin from Turmeric
    d. Glycerrhizin from Liquorice
    e. Hesperidine from Orange Peels
    f. Caffeine from Tea
    g. Strychnine and Brucine from Nux Vomica
    h. Cineole from Eucalyptus

2. Study of UV, Visible, and IR Spectral data of some phytoconstituents.
3. Study of HPLC and HPLTC (if possible) Techniques for some important phytoconstituents.
4. Antimicrobial screening of plant extracts.
5. Screening of drugs for microbial count.
6. Experiments based on WHO guidelines of quality control of medicinal plant materials.

Books recommended: (Latest Edition)

1. Trease and Evans, Pharmacognosy, Saunders Company, London.
2. Tyler, Brady, and Robbers, Pharmacognosy, Lea Febiger, USA.
3. Kokate, Purohit, Gokhale, Pharmacognosy, Nirali Prakashan, Pune.
4. Agrawal O.P., Chemistry of Organic Natural Product, Vol. 1 and 2 Goel Publication House, UP.
5. Nadkarni, A.K., Indian Materia Medica. 2 volumes, Popular Prakashan Pvt. Ltd.
6. WHO, Quality Control methods for medicinal plant material.
7. Mukherjee Pulok, Quality Control of Herbal Drugs, Business Horizons.
8. Wagner, H., Bladt, S., Zgaimski, E.M. Plant Drug Analysis., Springer- Verlog, New York
9. Screening Methods of Pharmacology, by Robert Turner.
10. Biological Standardisation by, J. N. Barn, D. J. Finley and L. G. Goodwin
11. Matrindale, The extra Pharmacopoeia, Pharmaceutical press, London.
12. K.B.G. Torsell, Natural products chemistry, John Wiley & Sons, New York.
13. J. B. Harborne, Phytochemical methods, Chapman and Hall, London.
14. Monographs and relevant review articles appearing in various Periodicals and Journals.
15. Standardisation of Botanicals by V.Rajpal, Vol.1, Eastern Publishers, New Delhi.
16. Quality Standards of Indian Medicinal Plants, Vol 1, ICMR, New Delhi.

SEMESTER - III

MPHR 231 SYNOPSIS OF THE PROPOSED PROJECT & EVALUATION OF PROJECT WORK AFTER SIX MONTHS

SEMESTER- IV

MPHR 241 THESIS

MPHR 242 PRESENTATION & VIVA - VOCE

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmacognosy) Effective From Session 2010-11

SEMESTER – I

Sl.No	Course Code	Subject	Periods (Hours/week)		IA		ESE		Subject Total	Credits
		Theory	**T**	**P**	**T**	**P**	**T**	**P**		
1	**MPHR-111**	Advanced Analytical Technique	**4**	**-**	**30**	**-**	**70**	**-**	**100**	**4**
2	**MPHR-112**	Pharmaceutical Statistics & Computer Application	**4**	**-**	**30**	**-**	**70**	**-**	**100**	**4**
3	**MPHR-113**	Drug Regulatory Affairs & Intellectual Property Rights	**4**	**-**	**30**	**-**	**70**	**-**	**100**	**4**
4	**MPHR-117**	Advanced Pharmacognosy	**4**	**-**	**30**	**-**	**70**	**-**	**100**	**4**
Practical's			**Day to day Evaluation**							
5	**MPHR-111P**	Advanced Analytical Technique		**8**		**30**		**70**	**100**	**4**
6	**MPHR-117P**	**Advance Pharmacognosy**		**12**		**30**		**70**	**100**	**6**
TOTAL									**600**	**26**

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination
Note: Duration of ESE – Theory exam will be of 3 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmacognosy) Effective From Session 2010-11

SEMESTER – II

Sl.No	Course Code	Subject	Periods (Hours/week)		IA		ESE		Subject Total	Credits
		Theory	T	P	T	P	T	P		
1	MPHR-129D	Industrial Pharmacognosy	4	-	30	-	70	-	100	4
2	MPHR-129E	Herbal Drug Technology	4	-	30	-	70	-	100	4
3	MPHR-129F	Medicinal Plant Biotechnology	4	-	30	-	70	-	100	4
4	MPHR-120	Seminar (two of 50 marks each) internal evaluation only	4	-					100	4
Practical's			Day to day Evaluation							
5	MPHR-129D-P	Industrial Pharmacognosy		8		30		70	100	5
6	MPHR-129E-P	Herbal Drug Technology		12		30		70	100	5
TOTAL									600	26

T- Theory, P- Practical, IA- Internal Assessment, ESE- End Semester Examination
Note: Duration of ESE – Theory exam will be of 3 hours and Practical exam of 8 hours

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmacognosy) Effective From Session 2010-11

SEMESTER – III

S.No	Course Code	Subject	ESE	Credits
1	MPHR-231	Synopsis of The Proposed Project & Evaluation of Project Work after Six Months	150	6

STUDY AND EVALUATION SCHEME

Course: M. Pharm. (Pharmacognosy) Effective From Session 2010-11

Semester-IV

Sl. No.	Course Code	Subject	ESE	Credits
1	MPHR – 241	Thesis	350	14
2	MPHR – 242	Presentation & Viva – voce	100	5

SEMESTER -I
MPHR 111

ADVANCED ANALYTICAL TECHNIQUES

Unit –I:

UV-Visible spectroscopy- Introduction. Application in determination of pKa values, pharmaceutical quantitative analysis, preformulation and formulation. Difference spectrophotometry, derivative spectra.

Solid State Analysis: X-ray diffraction and crystallography, thermal analysis and calorimetry, micromeritic measurements.

Unit –II:

Infrared spectroscopy- Introduction, Application in structure elucidation and in identifying polymorphs. I R as a fingerprint technique. Near IR analysis and its applications, FTIR.

Unit –III:

a) Atomic spectrophotometry:

Atomic emission spectrophotometry: principle, instrumentation, interferences and applications.

Atomic absorption spectrophotometry: principle, instrumentation and applications.

b) Molecular emission spectroscopy:

Fluorescence spectroscopy: Principles, molecules exhibiting fluorescence, factors interfering with fluorescence intensity, application. Raman spectroscopy: Principle, instrumentation and applications.

Unit –IV:

a) Nuclear Magnetic Resonance Spectroscopy:

Introduction, instrumentation, chemical shifts, shielding and deshielding effects, spin-spin coupling, reference standard and solvents, proton NMR, carbon-13 NMR Application to structure elucidation.

b) Mass Spectrometry:

Principle, instrumentation, mass spectra obtained under electron impact (EI) ionization conditions, molecular fragmentation patterns, molecular ion, metastable ion, McLafferty rearrangement, EI mass spectra of some drug molecules. GC-MS and LC-MS: principle and applications.

Unit –V:

Chromatographic techniques:

Chromatographic Theory: void volume, capacity factor, band broadening, calculation of column efficiency, parameters used in evaluating column performance (resolution and peak asymmetry). HPLC: instrumentation, stationary phases, mobile phases and its selection, columns and detectors, applications in quantitative analysis of drugs in formulations, specialized HPLC techniques.

HPTLC, GC, High-performance capillary electrophoresis: principle, instrumentation and application.

MPHR- 112 Pharmaceutical Statistics and Computer Applications

Unit- I.

Basic Definitions and Concepts: Variables and Variation, Frequency Distributions and Cumulative Frequency Distributions, Sample and Population, Measures Describing the center of Date Distributions,

Data Graphics: Introduction, the Histogram, Construction and Labeling of Graphs, Scatter Plots (Correlation Diagrams), Semilogarithmic Plots, Other Descriptive Figures.

Introduction to Probability The Binomial and Normal Probability Distributions : Introduction, Some Basic Probability, Probability Distributions, the Binomial Distribution,.

Unit- II

Choosing Samples Sample Size and Power : Introduction, Random Sampling, Other Sampling Procedures: Stratified, Systematic, Cluster Sampling, Sampling in Quality Control Introduction, Determination of Sample Size for Simple Comparative Experiments for Normally Distributed Variables, Determination of Sample Size for Binomial Tests,.

Statistical Inference: Estimation and Hypothesis Testing: Statistical Estimation (Confidence Intervals), Statistical Hypothesis Testing, Comparison of Variances in Independent Samples, Test of Equality of More than Two Variances confidence limits for variance Tolerance Intervals.

Unit- III

Linear Regression and Correlation: Introduction of linear and non linear regression ,Analysis of Standard Curves in Drug Analysis: Application of Linear Regression and Drug stability studies,

Analysis of Variance: One- Way Analysis of Variance Planned Versus a Posteriori (Unplanned) Comparisons in ANOVA, Another Example of One- Way Analysis of Variance: Unequal Sample Sixes and the Fixed and Random Models, Two-Way Analysis of Variance (Randomized Blocks), Statistical Models, Analysis of Covariance, ANOVA for pooling regression lines as related to stability data.

Nonparametric Methods: Data Characteristics and an Introduction to Nonparametric Procedures, Sign Test, Wilcoson Signed Rank Test, Wilcoxon Rank Sum Test (Test for Differences Between Two Independent Groups), Kruskal Wallis Test (One- Way ANOVA),

Factorial Designs : Definitions Two Simple Hypothetical Experiments to Illustrate the Advantages of Factorial Designs, Performing Factorial Experiments: Recommendations and Notation, A Worked Example of a Factorial Experiment, Fractional Factorial Designs.

Unit- IV

Experimental Design in Clinical Trials: Introduction, Some Principles of Experimental Design and Analysis, Parallel Deign, Crossover Designs and Bioavailability / Bioequivalence Studies, Repeated Measures (Split- Plot) Designs, Multiclinic Studies, Interim Analyses.

Quality Control: Introduction, Control Charts, Acceptance Sampling and Operating Characteristic Curves, Statistical Procedures in Assay Development, Establishing In- House Limits, Some Statistical Aspects of Quality and the "Barr Decision",

Unit- V

Applications of Computers in Pharmaceutical Sciences

Computer Intensive Methods: Advance Computer application and software applicable for treating l data statical.

Book Recommended:

1. Bolton, S and Bon, C, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.

2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.

3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.

4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.

5. William E. Fassett, Computer Application in Pharmacy.

6. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.

MPHR- 113 DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS

Unit- I

A. Drug Information

Introduction

Primary, Secondary & Tertiary Literature

Spectrum of information, finding and managing Drug Information.

B. Drugs and Cosmetics Act and rules with special reference to schedule M and Y.

Unit- II

International Drug Regulatory affairs- registration procedure (Pharmaceutical products) for International Marketing, Including preparation of dossiers SMF, Validation, Calibration and other documents like product development, stability data for different countries.

Unit- III

Facilities for manufacturing pharmaceutical products qualifying.

CGMP requirements - 21 CFR parts 210 and 211, Orange Guide, TRS, ICH, etc.

Unit- IV

Facilities for quality control lab qualifying GLP requirements, facilities for warehouse qualifying GWP requirements.

Unit- V

Intellectual property rights, patents Act, Trademark and Copyright Act

Books Recommended:

1. Gennaro A.R., Remington- The science and practice of pharmacy, Lippircott, Williams & Wilkins.

2. Banker G.S., Rhodes C.T., Modern Pharmaceutics, Marcel Dekker.

3. Malik Vijay, Drug & Cosmetics Act, 1940, Eastern Book Company, Lucknow.

4. Guarino R.A., New Drug Approval Process, Marcel Dekker.

5. Sharma P.P., How to practice GMP, Vandana Prakashan, New Delhi.

6. Sharma P.P., how to practice GLP, Vandana Prakashan, New Delhi,

7. World Health Organization, quality assurance of Pharmaceuticals I & I, Pharma Book Syndicate, Hyderabad.

8. Weinlerg S., Good Laboratory Poactices, Marcel Dekker.

9. The Patent Act, 1970

10. The Trade Marks Act, 1999.

11. The Copyright Act, 1958.

12. Potdar M.A., Current Good Manufacturing Practices for Pharmaceuticals, Pharma Med Press, Hyderabad.

13. Rick N.G., Drug from Discovery to Approval, Wiley Black Well.

14. Swarlerick J., Boylan J., Encyclopedia / Pharmaceutical Technology Relevant Welesites of Regulatory Anthoriter of different countries.

MPHR - 117 Advance Pharmacognosy

Unit – 1

1.1 Methods of investigation of Biosynthetic pathways, tracer techniques, autoradiography.

1.2 Study of Biosynthesis of :-
Ephedrine, Hyocyamine, Quinine, Morphine, Ergometrine, Reserpine, Vincristin, Digitoxin, Scillaren, Glycerrhitinic acid, Sitosterols, Diosgenin, Hecogenin, Umbelliferone, Hesperidin, Rutin, Penicillins, Griseofulvin, Tetracyelines

Unit – 2

2.1 Study of Techniques of Mutation, Polyploidy and Hybridization for improving the Quality of crops and their applications.

2.2 Plant growth regulators, their classification, use, scope and limitations.

Unit – 3

Plant tissue culture techniques & its application in relation to Phytopharmaceuticals: Techniques of initiation & maintenance of various types of cultures, Immobilized cell techniques (survey of recent advances), Germ plasm storage, biotransformation studies, recent advances in elicitor techniques and production of biological active constituents and other applications of plant tissue culture techniques. Biosynthetic potential of tissue cultures and factors affecting production of secondary metabolites by tissue culture techniques.

Unit – 4

6 Review of recent literature along with methods used for bioscreening of Antiinflammatory, Hypolipidemic, Diuretics, Cardiovascular, Hepatoprotectives, Anticancer, Antidiabetics, Antiulceratives, Antioxidants, Immunomodulators, Antimalarial, Antimicrobial, Antiallergic and Antifertility drugs of Herbal origin.

Unit – 5

5.1 Alkaloids, definition, methods of separation of weak, tertiary, Quarternary and N-oxides from plant sources.

5.2 TLC & HPTLC fingerprinting.

5.3 Methods used for extraction of herbal drugs and study of the principals involved therein.

5.4 Structure elucidation of simple molecules of herbal origin using degredative and spectral methods (UV, 1R, 1_{HNMR}, 13_{CNMR} and mass spectroscopy) (only interpretation of Data).

MPHR – 111P

Advanced Analytical Techniques Practicals

1. Combination Drug Analysis (Any Five)
a. Vitamins
b. Oral antidiabetics
c. NSAIDs
d. Antimicrobials
e. Antihistamines
f. Antihypertensive
2. Illustrations of theoretical principles using assay of drugs official in various pharmacopoeias (Any 10). This should cover titrimetric, spectro-photometric (including flamephotometric) methods, HPLC etc.. The students should be exposed to handling of as many instruments as possible by themselves or under the guidance of a teacher.
3.Excersises on interpretation of IR MASS and NMR spectra

Books Recommended: (Latest Edition)

21- Watson, D.G., Pharmaceutical Analysis, A Textbook for Pharmacy Students and Pharmaceutical Chemists, Elsevier Churchill Livingstone.
22- Lee, D.C., Webb, M., Pharmaceutical Analysis, Blackwell Publishing, CRC Press, Wiley India Pvt. Ltd.
23- Willard, H. H., Merrit, L.L., Dean, J. A., Settle P. A., Instrumental Methods of Analysis, Von Nostrand.
24- Skoog, D.A., Holler, F.J., Nieman, T.A., Principles of Instrumental Analysis, Thomson Brooks/Cole.
25- Christian, G, D., Analytical Chemistry, John Wiley and Sons.
26- Ahuja,S., Rasmussen,H., HPLC method development for Pharmaceuticals, Elesevier Academic Press.
27- Silverstein, Spectrometric identification of Organic Compounds, Willy.
28- Kemp William, Organic Spectroscopy, Pal grave, New York.
29- Beckett and Stenlake, Practical Pharmaceutical Chemistry, CBS Publishers, New Delhi.
30- Sethi, P.D., Quantitative Analysis of Drugs in Pharmaceutical Formulations, CBS Publishers, New Delhi.

MPHR – 117P

Advance Pharmacognosy Practical

Practicals:

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus. The industrial visit and in national/ international conferences is also required to attend during the course.

Books Recommended:

1. Manske- The Alkaloid- Chemistry and Physiology.
2. Sim - Medicinal Plant Glycosides.
3. Sim - Medicinal Plant Alkaloids.
4. IUPAC - Chemistry of Natural Products - International symposium.
5. Zechmeister - Progress in the Chemistry of Organic Natural Products.
6. Reinhold - Liwschitz - Progress in Phytochemistry.
7. Wagner - Wolf- New Natural Products and Plant Drugs with Pharmacological, Biological or Therapeutic Activity
8. Finar- Organic Chemistry.
9. Peach - Tracey - Modern Methods of Plant Analysis.
10. Geissman - Modem Methods of Plant Analysis.
11. Garatt - The Quantitative Analysis of Drugs.
12. Backett - Stenlake - Practical Pharmaceutical Chemistry,
13. Arthur-Symposium on Phytochemistry.
14. Pridham - Swain - Biosynthetic Pathways in Higher Plants.
15. Greenbury - Metabolic Pathways.
16. Margaret - Brain - Secondary Plant Metabolism.
17. Wagner - Horhammer - Pharmacognosy and Phytochemistry
18. Harborne - Comparative Biochemistry of Flavonoids.
19. Lehninger - Principles of Biochemistry,
20. Bonner - Plant Biochemistry.
21. Harborne - Phytochemical Methods.
22. Rosenthaler - The Chemical Investigation of Plants.
23. Cheronis - Organic Functional Group Analysis.
24. Nakanishi -Natural Products Chemistry, Vol. 1 & Vol. 2

Semester – II (Pharmacognosy)
MPHR – 129 D Industrial Pharmacognosy Theory

Unit – 1
Commercial source, method of isolation & separation, chemical properties, Qualitative Chemical test, uses and method of analysis* of (*only those drugs which are underlined)
Hesperidin, Rutin, Rhein, Sennosides, Hecogenin, Diosgenin, Digitoxin, Digoxin, Glycerrhetinic acid, Artemesin, Taxol, Podophyllotoxin, Ergotamine, Ergometrin, Morphine, Codeine, Vincristin, Quinine, Quinidine, Reserpine, Recinnamine, Atropine, Strychnine, Brucine, Nicoline, Solasodine.

Unit – 2
2.1 Role of medicinal plants in National Economy.
2.2 Study of worldwide Trade, production and utilization of Some Important medicinal plants and plant derived products.
2.3 Study of Indian Trade in spices and some aromatic plants.
2.4 Naturally occurring photosensitizing agents, their reactions, classification, and uses.

Unit – 3
3.1 Evaluation methods of crude drugs; Quantitative microscopy including Lycopodium spore analysis; Study of powder microscopy to identify diagnostic features of herbal drugs and their quantitation, Micro crystalloscopy.
3.2 Principles and procedures of microtomy.
3.3 Flourescence analysis of crude drugs / crude drug products

Unit – 4
4.1 Study of Traditional and alternative systems of medicine in relation to each other; Ayurvedic, Siddha and Unani systems of medicine; Homaeopathy, Aromatherapy, Tibetan and Chinese Traditional systems of medicine.
4.2 Study of bioallergens and biohallucinogenic drugs.

Unit – 5
5.1 Source, Chemistry, Significance uses and tests (if any) of important Lignans, Quassinoids.
5.2 Ulilization of lignocellulosic waste from essential oil Industry ligno cellulosic; Chemistry and Technology of obtaining vanillin from Sawdust.

MPHR – 129 E

Herbal Drug Technology

Unit – 1

1. Commerce and Quality control of drugs:-
   - 1.1 Indian and International Trade in medicinal and aromatic plants
   - 1.2 Quality control methods for medicinal plants:-
     - 1.2.1 Factors affecting herbal quality
     - 1.2.2 WHO guidelines for assessment of crude drugs:-
       - a) Evaluation of identity, purity & quality of crude drugs
       - b) Determination of pesticide residues, arsenic & heavy metals and microorganisms
   - 1.3 Pharmacopoeial studies: Study of herbal pharmacopoeia and compendia, I. P., Ayurvedic pharmacopoeia, chinese and united states pharmacopoeia for their herbal monographs.

Unit – 2

2. Herbal formulations, standardization and herbal based Industries:-
   - 2.1 Study of Infrastructure (process & equipment) of different types of Industries involved in making standard extracts and various dosage forms (including traditional Ayurvedic dosage forms)
   - 2.2 Application of pharmacy concepts, methods of analysis and clinical evaluation techniques in respect of herbal formulation.
   - 2.3 Quality assurance of herbal drug Industry, Concepts of TQM, GMP, I S O – 9000 in Traditional system of medicine.
   - 2.4 Shelf life and study of stabilization of herbal based products, their scope and limitations.

Unit – 3

3. Neutraceuticals and cosmeceuticals
   - 3.1 Herbal neutraceuticals as source of medicine, classification, uses advantages and limitations.
   - 3.2 Herbs / Herbal products used as ingredients in different cosmetic preparations e. g. creams, powders, lotious, hair products, nail polishes, lipsticks, depilatories, toilatories and their analysis.

Unit – 4

4. Marine Pharmacognosy
   - 4.1 Definitions, present status, classification of important bioactive agents.
   - 4.2 Study of Important bioactive agents their sources, isolation chemistry and uses.

Unit – 5

5. Plant Drug Cultivation
   - 5.1 Conservation of medicinal plants bio diversity laws, factors involved in the production of crude drug.
   - 5.2 Commercial cultivation Technology, Post harvest Care, processing of medicinal and aromatic plants:- Ashwagandha, Periwinkle, Medicinal yams, Guggul, Senna, Isaphgal, Steroid bearing solanum, Digitalis, Lemongrass, Geranium, Basil, Vetiver, Patchouli, Celery, Davana.
   - 5.3 Study of pesticides and weedicides from natural origin and their role in management of disease in medicinal / aromatic plants.

MPHR – 129 F

Medicinal Plant Biotechnology Theory

Unit - I

1.0 Historical perspectives, prospects for development of plant biotechnology as source of medicinal agents. Applications in pharmacy and allied fields.

2.0 Types, techniques, nutritional requirements and growth of plant tissue cultures. Organogenesis and embryogenisis. Protoplast fusion and cultures, artificial seeds, micropropogation of medicinal and aromatic plants. Genetic stability of tissue cultures.

Unit - II

3.1 Secondary metabolism in tissue cultures with emphasis on production of medicinal agents and its impact in pharmacy. Screening and selection of high yielding cell lines. Effect of cultural practices, precursors and elicitors on production of biomedicinals.

3.2 Plant finger print analysis: Methods used in gene identification, localization and sequencing of genes. Application of PCR to plant genome analysis

4.0 Biotransformation, bioreactors, industrially potential tissue culture systems for pilot and large scale cultures of plant cells, cellular totipotency, cryopreservation and retention of biosynthetic potential in cell cultures.

Unit - III

5.0 Immobilized plant cell culture systems, immobilization techniques, effect of immobilization on secondary metabolism and realization of chemosynthetic potential in immobilized cells.

6.0 Genetic transformation methods, Hairy root cultures and their applications.

Unit - IV

6.1 Basic metabolic pathways and techniques employed in elucidation of biosynthetic pathway. Biogenesis of tropane, quionoline, Imidazole, Isoquinoline and Indole alkaloids; Sterols, Anthraquinone and Saponin glycosides; Flavanoids; and Isoprenoid compounds of pharmaceutical significance.

Books Recommended:

1. Elements in biotechnology by P. K. Gupta.
2. Molecular biology and biotechnology by J. M. Walker and E. D. Gingold.
3. An introduction to plant tissue culture by M. K. Razdan.
4. Breeding field crops by John. M. P and David A. S.
5. Advanced methods in plant breeding and biotechnology by David. R. Murray.
6. Experiments in plant tissue culture by John H. D and Lorin W. R.
7. Pharmaceutical biotechnology by S. P. Vyas and V. K. Dixit.
8. Plant cell and tissue culture by Jeffrey W. Pollard and John M. Walker.
9. Plant tissue culture by Dixon.
10. Plant tissue culture by Street.
11. Pharmacognosy by G. E. Trease and W. C. Evans.
12. Biotechnology by Purohit and Mathur.
13. Biotechnological applications to tissue culture by Shargool.
14. Pharmacognosy by Varro E. Tyler, Lynn R. Brady and James E. Robberrt.
15. Introduction to biotechnology by Bullock John.
16. Biotechnology of higher plants by Gordon E. Russel.
17. Antibiotics isolation and separation by M. L. Wenisten and G. H. Wagman.
18. Plant cell culture technology by M. M. Yeoman.
19. Plant tissue culture by Dennis N. Butcher and David .S. Ingram.
20. Plant tissue culture by Pitman.
21. Plant tissue culture – Theory and practice by S. S. Bhajwani and M. K. Razdan.
22. Secondary plant metabolism by Margaret L. Vikery and Brian Vikery.
23. Plant tissue culture by W. E. George.

MPHR 120

Seminar (two of 50 marks each) internal evaluation only

MPHR – 129 D-P

Industrial Pharmacognosy Practical

Practicals:
Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus. The industrial visit and in national/ international conferences is also required to attend during the course.

MPHR – 129 E-P

Herbal Drug Technology Practical

Practicals:
Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus. The industrial visit and in national/ international conferences is also required to attend during the course.

SEMESTER - III

MPHR 231 SYNOPSIS OF THE PROPOSED PROJECT & EVALUATION OF PROJECT WORK AFTER SIX MONTHS

SEMESTER- IV

MPHR 241 THESIS

MPHR 242 PRESENTATION & VIVA - VOCE