SEMESTERWISE DISTRIBUTION OF MARKS AND CREDITS

SEMESTER	THEORY			PRACTICAL			TOTAL MARKS	TOTAL CREDITS
	NUMBER OF PAPERS	MARKS	CREDITS	NUMBER OF PAPERS	MARKS	CREDITS		
Semester-I	4	375	15	2	250	10	625	25
Semester-II	4	375	15	1	250	10	625	25
Semester-III & IV	-	-	-	*Thesis & Viva	-	50	-	50
	8	**750**	**30**	**3**	**500**	**70**	**1250**	**100**

*The candidate shall carry out research work under the guidance of research supervisor(s) assigned after Semester-II examination. Semester III shall have no separate examination.

*The combined examination of Semester III & IV shall consist of a thesis and a presentation in an open seminar. The thesis shall be submitted at the end of Semester-IV.

*The result of the combined examination of Semester-III & IV will be given as **pass** or **fail** without marks.

GROUP - 1: M. PHARM. (PHARMACEUTICAL CHEMISTRY)
SCHEME OF TEACHING AND EXAMINATION

Paper	Subject	Teaching Hours/Week	Credits	Examination Marks

GROUP - 2: M. PHARM. (PHARMACEUTICS)
SCHEME OF TEACHING AND EXAMINATION

Paper	Subject	Teaching Hours/Week		Credits		Examination Marks
FIRST SEMESTER		**T**	**P**	**T**	**P**	
THEORY						
MPCEU-1021	Dosage Form Design and Development	3+1(Tutorial)	-	4	-	100
MPCEU-1022	Advances in Drug Delivery-I	3+1(Tutorial)	-	4	-	100
MPCEU-1023	Advanced Pharmacokinetics and Biopharmaceutics-I	3+1(Tutorial)	-	4	-	100
MPCOM-1071	Modern Analytical and Pharmaceutical Techniques	3	-	3	-	75
PRACTICAL						
MPCEU-1121	Pharmaceutics Practical-I	-	8	-	6	150
MPCOM-1171	Modern Analytical and Pharmaceutical Techniques Practical	-	6	-	4	100
Total		15	14	15	10	625

Total hours: 29; Total Credits 25

SECOND SEMESTER
THEORY

MPCEU-2021	Advances in Drug Delivery-II	3+1(Tutorial)	-	4	-	100
MPCEU-2022	Advanced Pharmacokinetics and Biopharmaceutics-II	3+1(Tutorial)	-	4	-	100
MPCEU-2023	Pharmaceutical Technology and Biotechnology	3+1(Tutorial)	-	4	-	100
MPCOM-						

GROUP - 3: M. PHARM. (PHARMACOGNOSY)

SCHEME OF TEACHING AND EXAMINATION

Paper	Subject	Teaching Hours/Week		Credits		Examination Marks
FIRST SEMESTER		**T**	**P**	**T**	**P**	
THEORY						
MPCOG-1031	Drug Discovery from Natural Sources	3+1(Tutorial)	-	4	-	100
MPCOG-1032	Phytochemical Techniques	3+1(Tutorial)	-	4	-	100
MPCOG-1033/ MPQUA-1053	Plant Drug Standardization	3+1(Tutorial)	-	4	-	100
MPCOM-1071	Modern Analytical and Pharmaceutical Techniques	3	-	3	-	75
PRACTICAL						
MPCOG-1131	Pharmacognosy Practical-I	-	8	-	6	150
MPCOM-1171	Modern Analytical and Pharmaceutical Techniques Practical	-	6	-	4	100
Total		15	14	15	10	625

Total hours: 29; Total Credits 25

SECOND SEMESTER

THEORY

MPCOG-2031	Advances in Pharmacognosy-I	3+1(Tutorial)	-	4	-	100
MPCOG-2032	Advances in Pharmacognosy-II	3+1(Tutorial)	-	4	-	100
MPCOG-2033	Plant Drug Cultivation	3+1(Tutorial)	-	4	-	100
MPCOM-2084	Intellectual Property Rights and Drug Regulatory Affairs	3	-	3	-	75
PRACTICAL						
MPCOG-2131	Pharmacognosy Practical-II	-	14	-	10	250
Total		15	14	15	10	625

Total hours: 29; Total Credits 25

THIRD & FOURTH SEMESTER

Third and fourth semester shall comprise of research work only.
The examinatst

GROUP - 4: M. PHARM. (PHARMACOLOGY)

GROUP -

SYLLABUS FOR MASTER OF PHARMACY (M. PHARM.)

GROUP-1: M. PHARM. (PHARMACEUTICAL CHEMISTRY)

SEMESTER-I

MPCHM-1011: Advanced Organic Chemistry-I

MPCHM-1012: Advances in Chemistry of Natural Products

MPCHM-1013: Advances in Medicinal Chemistry-I

MPCOM-1071: Modern Analytical and Pharmaceutical Techniques

MPCHM-1111: Pharmaceutical Chemistry Practical-I

MPCOM-1171: Modern Analytical and Pharmaceutical Techniques Practical

MPCHM-1011: Advanced Organic Chemistry-I

4 hours/week

1. Concept of aromaticity involving ring systems and antiaromaticity, bondings weaker than covalent bondings, hydrogen bonding, EDTA complexes, crown ethers and inclusion compounds.

(4 Lectures)

2. Acids and Bases

Bronsted and lewis concepts, acidic and basic catalysis, hard and soft acids and bases, effect of structure on the strength of acids and bases, effect of medium on the acidic and basic strength.

(2 Lectures)

3. Mechanisms and Methods for Determination

Thermodynamic requirements for reaction, kinetic requirements for reaction, basic mechanistic concepts, kinetics versus thermodynamic control.

Methods for determining mechanisms:

a. Non-kinetic: Identification of products, determination of the presence of intermediate, isolation of an intermediate, detection of an intermediate, trapping of an intermediate and addition of suspected intermediate, study of catalysis, isotopic labelling stereochemical evidences and crossover experiments.

b. Kinetic studies: First order reactions, second order reactions, third order reactions, determination of the order of reaction and reversible reactions.

(4 Lectures)

Reading Material Recommended

1. Carey FA and Sundberg RJ. Advanced Organic Chemistry. Part B: Reactions and Synthesis. Plenum Press, London. Latest Edition.
2. Ernest EI and Samuel H. Stereochemistry of Organic Compounds. John Wiley and Sons, New York. Latest Edition.
3. Lehr RE and Marchand AP. Orbital Symmetry: A Problem Solving Approach. Academic Press, New York. Latest Edition.
4. March J. Advanced Organic Chemistry: Reactions, Mechanisms and Structures. John Wiley and Sons, New York. Latest Edition.

MPCHM-1012: Advances in Chemistry of Natural Products

2. Drug Design Tools

2.1 Conventional methods of drug design: Lead, discovery of lead, lead optimization, objective of lead optimization, pharmacophoric identification and analog approach of drug designing.

2.2 Various approaches in QSAR: Objectives of QSAR, Hansch approach, Free-Wilson model, statistical methods, non-computer assisted search operations like Topliss decision tree simplex method, Fibonacci search technique.

2.3 Parameterisation of groups / molecules: Electronic, steric and lipophilic molecular descriptions, quantum chemical calculations.

2.4 Introduction to molecular modeling.

2.5 Currently used drug discovery tools in pharmaceutical industry.

(7 Lectures)

3. Genetic Engineering

Basic principles, important tools of genetic engineering, restriction endonucleases, DNA ligase, cloning vector, transcription, recombinant DNA, cloning of gene, detection and purification of desired clone, expression of desired clone, pharmaceutical applications, production of insulin and somatostatin, polymerase chain reaction (PCR).

Biotechnology products as drugs

Streptokinase and Interferons.

(5 Lectures)

4. Prostaglandins and Other Eicosanoids

Nomenclature, biosynthesis, design of eicosanoid drugs, biological activity, metabolism, structure activity relationship, eicosanoids approved for human clinical use.

(5 Lectures)

5. Rational Design of Enzymes Inhibitors

5.1 Design of non-covalently binding enzymes inhibitors: Rapid reversible inhibitors, slow, tight and slow-tight inhibitors, transition state analogues, multisubstrate inhibitors.

5.2 Current developments with respect to the inhibition of the following enzymes: Reverse transcriptase, catechol-*O*-methyl transferase, acetylcholinesterase, glycinamide ribonucleotide transformylase, HMG CoA reductase inhibitors ;

antimetabolites: dihydrofolate reductase inhibitors, phospodiesterase, protein kinase.

5.3 Design of covalently binding enzyme inhibitors: Mechanism based inhibitors, affinity labels, pseudoirreversible inhibitors. One representative example each from pyridoxyl phosphate dependent enzyme, GABA transferase, ornithine decarboxylase, monoamineoxidase, -glucosidase inhibitors.

(12 Lectures)

6. Nitric Oxide (Second Messenger)

Introduction, chemical properties of nitric oxide, reaction of nitric oxide with metals, interplay between the reactions of nitric oxide in biological systems, nitric oxide synthetase iso-enzymes, mechanism of NOS-mediated nitric oxide biosynthesis, NOS inhibitors, cytotoxic role of nitric oxide, therapeutic significance of NOS inhibitors and nitric oxide.

(4 Lectures)

7. Endorphins

Discovery of enkephalins and endorphins, latest advances.

(2 Lectures)

Reading Material Recommended

1. Wolff ME. Burger's Medicinal Chemistry and Drug Discovery, Principle and Practice. John Wiley and Sons, New York. Latest Edition.
2. Alnley W. and James EF. Martindale, The Extra Pharmacopoeia. Pharmaceutical Press, London. Latest Edition.
3. Williams DA, Lemke TL. Foye's Principles of Medicinal Chemistry. Lippincott WilliamLaFTm [(s)-1(0.9998 0 0 1)MF2 11.68 Tfm5(Ll)10(e56.) of Medi0.9998 0 0 1m [( )] TJ ET

MPCOM-1071: Modern Analytical and Pharmaceutical Techniques

3 hours/week

A. Advanced Statistics

General concepts, two-tail student t-test and paired sample t-test, two samples t-test, Wilcoxon rank-sum test, Mann-Whitney test, one-way analysis of variance, Kruskal-Wallis test, two-way analysis of variance, multiple comparison procedures in ANOVA: Fischer's LSD test, Tukey's studentized range test and Dunnett's test. Non-linear regression: Introduction, iterative method.

(6 Lectures)

B. Pharmaceutics

1. Basic elements of Novel drug delivery systems.

4. Nuclear Magnetic Resonance Spectroscopy

Introduction, nuclear spin states, nuclear magnetic moments, absorption of energy, the mechanism of resonance, chemical equivalence, spin-spin coupling, basics of instrumentation techniques, pharmaceutical applications.

(2 Lectures)

5. Mass Spectrometry

Basic principle and theory involved, basics of instrumentation techniques, pharmaceutical applications.

(2 Lectures)

6. Thermal Analysis

Introduction to various thermal methods of analysis, basic principles and theory, pharmaceutical applications.

(10 Lectures)

D. Pharmacognosy

1. General principles, classification, normal and reversed phase, bonded phase, separation mechanisms.
2. Introduction to paper chromatography, TLC, HPTLC, HPLC, GC.

(7 Lectures)

E. Pharmacology

Definition of bioassay, various types of bioassays, advantages and limitations of bioassays with suitable examples, radioimmunoassay, ELISA and their applications in medicine.

(7 Lectures)

Reading Material Recommended

1. Silverstein RM and Webster FX. Spectrometric Identification of Organic Compounds. John Wiley and Sons, New York. Latest Edition.
2. Pavia DL, Lampman GM and Kriz GS. Introduction to Spectroscopy. Harcourt College Publishers, Orlando. Latest Edition.
3. Vogel HG and Vogel WH. Drug Discovery and Evaluation. Springer-Verlag, Berlin. Latest Edition.
4. Kulkarni SK. Handbook of Experimental Pharmacology. Vallabh Prakashan, New Delhi. Latest Edition.

5. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata. Latest Edition.

MPCHM-1111: Pharmaceutical Chemistry Practical-I

8 hours/week

(Including Tutorials/Workshops/Seminars/Field work etc.)

1. Separation and qualitative analysis of organic mixtures
2. Workshops on stereomodels, QSAR and Molecular Modelling.
3. Paper reading/Seminar with respect to the latest developments in pharmaceutical chemistry (Paper I-IV).
4. Writing of papers, projects and reports.
5. Skills in oral presoral presoaod/23(r)-34(r)24(e)-8 tharals/r 1 101.52 464.64 Tm [(S)-19(k)6(i)-9(l)10(l)-

Reading Material Recommended

1.

SEMESTER-II

MPCHM 2011: Advanced Organic Chemistry-II

MPCHM-2012/
MPQUA-2052: Advanced Analytical Techniques

4. Synthetic Strategies

Protection and deprotection of various groups; Polymorphism in drug discovery; Polymers: monomers and polymers, addition polymers, stereochemistry of polymers, copolymers of two or more monomers, condensation polymers, applications.

(8 Lectures)

5. Rearrangements

5.1 Carbon to carbon migration: Wagner-Meerwein and related reactions, expansion and contraction of rings, acid catalyzed rearrangements of aldehydes and ketones, dienones-phenol rearrangement228(x)27(p)-1(o)b8(s)-13(g)6(e)z10(d)613(lET Q q

3. Lehr RE and Marchand AP. Orbital Symmetry: A Problem Solving Approach. Academic Press, New York. Latest Edition.

4.

Correlation NMR spectrometry: introduction to ^{1}H -^{1}H cosy and ^{1}H - ^{13}C cosy and its applications. Introduction and applications of 2D NMR; solid state NMR.

^{13}C-NMR spectroscopy

Introduction, peak

b. High Pressure Liquid Chromatography: Partition, adsorption, ion exchange, size exclusion; pharmaceutical applications of HPLC and LC-MS. Super critical fluid chromatography; brief introduction to HPTLC.

(7 Lectures)

9. Optical Rotatory Dispersion and Circular Dichroism

Definition, cotton effect and stereochemistry, octet rule and applications.

(2 Lectures)

Reading Material Recommended

1. Silverstein RM and Webster FX. Spectrometric Identification of Organic Compounds. John Wiley and Sons, New York. Latest Edition.
2. Chatten LG. Pharmaceutical Chemistry, Vol I & II. Marcel Dekker, New York. Latest Edition.
3. James WD and Kenneth HT. Analytical Chemistry by Open Learning: Thermal Methods. John Wiley and Sons, New York. Latest Edition.
4. Abraham RJ, Fisher J and Bftus P. Introduction to NMR Spectroscopy. John Wiley and Sons, New York. Latest Edition.
5. Pavia DL, Lampman GM and Kriz GS. Introduction to Spectroscopy. Harcourt College Publishers, Orlando. Latest Edition.

MPCHM 2013: Advances in Medicinal Chemistry-II

3. **Psychopharmacological Agents**

Antidepressant drugs, Antianxiety agents and Antipsychotic agents: Introduction, biochemical basis of mental

3. Bansal P. IPR Handbook for Pharma Student.12 Tm [( )] TJ ET Q q B

SEMESTER III & IV

Research work during third and fourth semester.

The examination shall consist of thesis submitted at the end of fourth semester and presentation in the open seminar.

The result of the examination will be given as **pass or fail** without marks.

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GROUP-2: M. PHARM. (PHARMACEUTICS)

SEMESTER-I

MPCEU-1021: Dosage Form Design and Development

MPCEU-1022: Advances in Drug Delivery-I

MPCEU-1023: Advanced Pharmacokinetics & Biopharmaceutics–I

MPCOM-1071: Modern Analytical and Pharmaceutical Techniques

MPCEU-1121: Pharmaceutics Practical-I

MPCOM-1171: Modern Analytical and Pharmaceutical Techniques Practical

MPCEU-1021: Dosage Form Design and Development

4 hours/week

1. Preformulation Studies

Introduction, goals of preformulation, physicochemical properties, criteria for selection of drug and excipients, compatibility tests.

(4 Lectures)

2. Solubility and Solubilization

Development of theoretical relationships of prognostic relevance, techniques of solubilization of drugs including surfactant systems, co-solvents, solid state manipulations, complexation and chemical modifications.

(4 Lectures)

3. Partition Coefficient

Pharmaceutical significance of partition coefficient, correlation with in-vivo performance, techniques to estimate log P values, shake flask method, choice of solvent systems, chromatographic determination, theoretical computation using Hansch & Leo/Rekker principle, effect of various variants like temperature, pH, etc. on partition coefficient.

(4 Lectures)

4. Solid State Pharmaceutics

Crystalinity, crystal habit, polymorphism, amorphous state, solvates hydrates and analytical techniques for characterization. (4 Lectures)

6.

8. Nasal pulmonary drug delivery systems.

(3 Lectures)

9.

3. Non-linear Pharmacokinetics

Definition, significance and applications with literature examples, recognition of non-linearity, computation of non-linear pharmacokinetic parameters (V_m, K_m, AUC, etc.) from the time course and AUC of a drug in body being eliminated by single Michaelis Menten kinetics, computation of pharmacokinetic parameters (V_m, K_m, K, AUC, etc.) from the time course of a drug being eliminated by Michaelis Menten kinetics and by a blend of Michaelis Menten kinetics and first-order kinetics, problem solving.

(8 Lectures)

4. Protein Binding

Theory of plasma protein binding and implications, elements of Scatchard, Klotz and Rosenthal analyses for computation of binding parameters, experimental techniques to determine protein binding with their merits and limitations, factors influencing protein binding, effect of binding on drug pharmacokinetics.

(5 Lectures)

5. Physiologically Based Pharmacokinetic (PBPK) Models

Basic concepts of PBPK models, development of a PBPK model, limitations with respect to classical compartmental approaches, permeation limited *versus* diffusion-limited models, interspecies scaling, applications.

(4 Lectures)

6. Pharmacokinetic and Pharmacodynamic (PK/PD) Models

Basic concepts of PK/PD modelling, methodology including linear, log-linear, E_{max}, E_{max}-sigmoidal models, non-steady state and time-dependant models, biophase distribution model, tolerance and signal transduction models, biomarkers, non-linear mixed effect modelling, Naïve pool approach, hysteresis of pharmacodynamic response, applications.

(5 Lectures)

Reading Material Recommended

1. Wagner JG. Fundamentals of Clinical Pharmacokinetics, Drug

6. Dressman B and Lennernas H. Oral Drug Absorption: Prediction & Assessment, Marcel Dekker, New York. Latest Edition.
7. Garett ER and Hitz JL. Drug, Fate and Metabolism, Vol. 4, Marcel Dekker, New York. Latest Edition.

MPCOM-1071: Modern Analytical and Pharmaceutical Techniques

3 hours/week

A. Advanced Statistics

General concepts, two-tail student t-test and paired sample t-test, two samples t-test, Wilcoxon rank-sum test, Mann-Whitney test, one-way analysis of variance, Kruskal-Wallis test, two-way analysis of variance, multiple comparison procedures in ANOVA: Fischer's LSD test, Tukey's studentized range test and Dunnett's test. Non-linear regression: Introduction, iterative method.

(6 Lectures)

B. Pharmaceutics

1. Basic elements of t

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3. European Pharmacopoeia. Latest Edition.
4. British Pharmacopoeia. Latest Edition.
5.

SEMESTER-II

MPCEU-2021: Advances in Drug Delivery–II

MPCEU-2022: Advanced Pharmacokinetics and Biopharmaceutics-II

MPCEU-2023: Pharmaceutical Technology and Biotechnology

MPCOM-2084: Intellectual Property Rights and Drug Regulatory Affairs

MPCEU-2121: Pharmaceutics Practical–II

MPCEU-2021: Advances in Drug Delivery –II

4 hours/week

1. Colloidal and Supramolecular Delivery Systems

a. Closed bilayered system: Historical background, structural aspects, preparation, characterization, evaluation and applications, specialized liposomes in drug targeting; Niosomes, erythrosomes, pharmacosomes and aquasomes.

b. Nanoparticles, Solid lipid nanoparticles (SLNs): Method of preparation, characterization, evaluation and pharmaceutical applications.

c. Multiple w/o/w emulsions as drug vehicles: Introduction, composition of the multiple emulsion and stability, influence of the nature of oil phase, methods for stabilizing w/o/w multiple emulsions, mechanisms of transport of solutes, *in-vivo* studies.

d. Microemulsions: Introduction, structure of microemulsions, solubilization and formulation of microemulsions, transport properties and pharmaceutical applications of emulsions.

(18 Lectures)

2. Protein and Peptide Drug Delivery

Considerations in the physiological delivery of therapeutic proteins: Carrier-mediated transport of peptides and p

2. Biopharmaceutics

Review of physicochemical, pharmaceutical and physiological variables affecting absorption.

Bioavailability and bioequivalence concepts, assessment of bioavailability from serum and urine level data, crossover design and analysis of bioequivalence trials, biowaiver, Federal perspectives, problem solving.

(8 Lectures)

3. *In vitro* and *In vivo* Correlations (IVIVC)

Concepts, biopharmaceutical classification scheme, various IVIVC approaches with applications and limitations, dissolution as a surrogate to bioavailability for immediate release and extended release formulations, A-D levels, validation, IVIVR, IVIVM, federal perspectives.

(8 Lectures)

4. Pharmacokinetic Simulations and Allied Pharmacokinetic Approaches

Pharmacokinetic simulations using pharmacokinetic parameters, simple problem solving. Basics of chronopharmacokinetics, toxicokinetics, population pharmacokinetics, etc.

(8 Lectures)

5. Computer Use in Pharmacokinetics

Introduction, strategy for model building, selection and application of suitable

control needs and product characteristics, environmental control zone groupings and functional groupings, personnel flow, design concepts. Steam, its generation and use in sterilization, compressed air.

(6 Lectures)

B. Biotechnology

1. Recombinant DNA technology: Types of genetic recombination, genetic transformation, transduction, plasmids and their biological significance, conjugation, transposons, various cloning vectors including plasmids and bacteriophages, host for cloning vectors, expression vectors, practical applications of genetic recombination.

   (9 Lectures)

2. Monoclonal antibodies: Production of monoclonal antibodies, diagnostic therapeutic and analytical applications. An introduction to their role in drug targeting.

   (4 Lectures)

3. Gene Therapy: An introduction to genetic disorders, approaches used, viral and non-

PART B: Drug Regulatory Affairs

1. Regulation on manufacture of drugs in India.
2. Drug regulatory controls and authorities.
3. Requirements of GMP, CGMP, GLP.
4. Guidelines of WHO, inputs of international bodies, national agencies, harmonization.
5. Preparation and submission of marketing application of India, US and Europe.
6. Approval, appeals and issues of confidentiality.
7. ISO 9000 series.
8. Drugs and cosmetics acts and rules.
9. Important regulations related to import and export of drugs.

(12 Lectures)

Reading Material Recommended

1. Treece DJ. Managing Intellectual Capital: Organizational, Strategic and Policy Dimension. Oxford University Press, England. Latest Edition.
2. Wadedhra BL. Law Relating to Patents, Trademarks, Copyright Design and Geographical Indications. Universal Law Publishing, New Delhi. Latest Edition.
3. Bansal P. IPR Handbook for Pharma Students and Researchers, Pharma Book Syndicate, Hyderabad. Latest Edition.
4. Copyright Protection in India [website: http:copyright.gov.in].
5. Information on Orange Book [website: www.fda.gov/cder/ob/default.htm].
6. World Trade Organization [w

2.6. Preparation of plant material for biological evaluation (preliminary treatment of material, preparation of extracts and enrichment of constituents, dose and mode of administration for pharmacological screening).

(5 Lectures)

2.7. Bioactivity directed fractionation

(1 Lecture)

2.8. Applications, advantages and limitations of various separation techniques (column chromatography, centrifugally accelerated chromatography, HPLC and MPLC) for isolation of lead molecules.

7. Hostettmann K, Hostettmann M and Marston A. Preparative Chromatography Techniques: Applications in Natural Product Isolation. Springer-Verlag, Berlin. Latest Edition.
8. WHO guidelines on relevant topics.
9. Heinrich M, Barnes J, Gibbons S and Williamson EM. Fundamentals of Pharmacognosy and Phytotherapy. Churchill Livingstone. Latest Edition.
10. Sukh Dev. A Selection of Prime Ayurvedic Plant Drugs: Ancient-Modem Concordance. Anamaya Publishers, New Delhi. Latest Edition.
11. European Medicines Evaluation Agency Guidelines on Quality of Herbal Medicinal Products issued from time to time and available at http: //www.emea.eu.int.
12. Gupta MP, Handa SS and Vasisht K. Eds. Biological Screening of Plant Constituents. Training Manual, ICS-UNIDO, Trieste (2006).

MPCOG-1032: Phytochemical Techniques

4 hours/week

1. General Methods of Extraction, Isolation and Characterization of Bioactive Constituents

1.1. Different extraction methods including advanced extraction techniques like supercritical fluid extraction, microwave-assisted extraction, ultrasound assisted extraction, solid-phase microextraction including headspace technique.

(10 Lectures)

1.2. Isolation techniques.

1.2.1. Fractionation and solvent partitioning.

(1 Lecture)

1.2.2. Chromatography.

1.2.2.1. General principles, classification, normal and reversed phase, bonded phase, separation mechanisms.

(5 Lectures)

1.2.2.2. Chromatographic separations including column chromatography, vacuum liquid chromatography, flash chromatography (medium pressure liquid chromatography), preparative TLC & HPLC, droplet counter-current chromatography (DCCC), ion-exchange chromatography, centrifugal counter-current chromatography (CCC), centrifugally accelerated chromatography, GC.

(20 Lectures)

1.2.3. Purification techniques for isolated phytoconstituents.

(2 Lectures)

3.2. Physico-chemical.

3.2.1.

MPCOM-1171: Modern Analytical and Pharmaceutical Techniques

3 hours/week

A. Advanced Statistics

General concepts, two-tail student t-test and paired sample t-test, two samples t-test, Wilcoxon rank-sum test, Mann-Whitney test, one-way analysis of variance, Kruskal-Wallis test, two-way analysis of variance, multiple comparison procedures in ANOVA: Fischer's LSD test, Tukey's studentized range test and Dunnett's test. Non-linear regression: Introduction, iterative method.

4.

MPCOG-1131: Pharmacognosy Practical-I

8 hours/week

(Including Tutorials/Workshops/Seminars/Field Work etc.)

1. Exercises on standardization and quality control of plant drugs.

2. Tutorial / Journal club

MPCOM-1171: Modern Analytical and Pharmaceutical Techniques Practical

6 hours/week

A. Pharmaceutical Chemistry

1. Assay procedures of various drugs using UV spectroscopy, spectroflourimetry and IR.
2. Basics of spectral analysis.
3. Thermal analysis using DSC technique.

B. Pharmaceutics

1. Exercises based on degradation kinetics and shelf-life determination.
2. Dissolution studies of marketed formulations.
3. Any other practical based on theory.

C. Pharmacology

1. Bioassay designs using various in-vitro preparations.
2. Experimental Toxicology: Calculations of LD_{50} values and therapeutic index.

D. Pharmacognosy

Exercises on chromatographic techniques.

Reading Material Recommended

1. Indian Pharmacopoeia. Latest Edition.
2. U. S. Pharmacopoeia - NF. Latest Edition.
3. European Pharmacopoeia. Latest Edition.
4. British Pharmacopoeia. Latest Edition.

5. Mendham J, Denney RC, Barnes JD and Thomas M. Vogel’s

SEMESTER-II

MPCOG-2031: Advances in Pharmacognosy-I

MPCOG-2032: Advances in Pharmacognosy-II

MPCOG-2033: Plant Drug Cultivation

MPCOM-2084: Intellectual Property Rights and Drug Regulatory Affairs

MPCOG-2131: Pharmacognosy Practical-II

MPCOG-2031: Advances in Pharmacognosy-I

4 hours/week

1. General Introduction, Classification, Biosynthesis, Extraction, Isolation and Characterization of following Groups with at least One Example from Each Class:

1.1. Quassinoids. (3 Lectures)

1.2. Triterpenoids. (6 Lectures)

1.3. Steroids. (6 Lectures)

1.4. Flavonoids. (5 Lectures)

1.5. Lignans. (2 Lectures)

1.6. Coumarins. (4 Lectures)

1.7. Glycosides. (5 Lectures)

1.8. Alkaloids. (9 Lectures)

Recommended Reading Material

1. Evans WC. Ed. Trease and Evans, Pharmacognosy. Gopson Papers Ltd., Noida, India. Latest Edition.

2. Tyler VE, Brady LR and Robbers JE. Pharmacognosy. Lea and Febiger, Philadelphia. Latest Edition.
3. Various Journals like Natural Product Reports, Journal of Ethnopharmacology, Journal of Natural Products, Journal of Medicinal and Aromatic Plants, Fitoterapia, Pharmaceutical Biology, Phytotherapy Research etc.
4. Robbres JE, Speedie MK, Tyler VE. Pharmacognosy and Pharmacobiotechnology. Lippincott Williams & Wilkins, New York. Latest Edition.
5. Heinrich M, Barnes J, Gibbons S and Williamson EM. Fundamentals of Pharmacognosy and Phytotherapy. Churchill Livingstone. Latest Edition.
6. Bruneton J. Pharmacognosy, Phytochemistry, Medicinal Plants. Intercept Ltd., UK. Latest Edition.
7. Vogel HG and Vogel WH. Drug Discovery and Evaluation. Springer-Verlag, Berlin. Latest Edition.

MPCOG-2032: Advances in Pharmacognosy-II

4 hours/week

1. Study of Plants with Special Emphasis on Active Constituents having following

2. Biologically Active Compounds from Marine Sources. (4 Lectures)

3. Toxic/Poisonous Plants. (4 Lectures)

Recommended Reading Material

1. Evans WC. Ed. Trease and Evans, Pharmacognosy. Gopson Papers Ltd., Noida, India. Latest Edition.
2. Tyler VE, Brady LR and Robbers JE. Pharmacognosy. Lea and Febiger, Philadelphia. Latest Edition.
3. Various Journals like Natural Product Reports, Journal of Ethnopharmacology, Phytotherapy Research, Journal of Natural Products, Pharmaceutical Biology, Journal of Medicinal and Aromatic Plants, Fitoterapia, etc.
4. Robbres JE, Speedie MK, Tyler VE. Pharmacognosy and Pharmacobiotechnology. Lippincott Williams & Wilkins. Latest Edition.
5. Heinrich M, Barnes J, Gibbons S and Williamson EM. Fundamentals of

3. **Integrated pest management, scope of biological control and use of environment friendly pesticides of plant origin. Brief account of pheromones and juvenile hormones.**

(5 Lectures)

4.

MPCOM-2084: Intellectual Property Rights and Drug Regulatory Affairs

3 hours/week

PART A: Intellectual Property Rights

1. Intellectual Property

Concepts and fundamentals: The emergence and growth of the concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); economic importance, mechanism for protection of intellectual property - patents, copyright, trademarks; role of IP in pharmaceutical industry; global ramifications and financial implications.

(6 Lectures)

2. Trade Related Aspects of Intellectual Property Rights

technology (TOT), bottlenecks, managing technology transfer, guidelines for research students, scientists and related personnel, TOT agencies in India APCTD, NRDC, TIFAC, IBCIL, TBSE/SIDBI. TOT related documentation: Confidentiality agreements, licensing, MOUs, legal issues, compulsory licensing and issuing of access to medicines, DOHA declaration.

(10 Lectures)

5. **Ethics and Values in IP**

IP and ethics, positive and negative aspects of IPP, social responsibility, avoiding unethical practices, eco-responsibility–economic, social and environmental benefits of modern biotechnology.

(3 Lectures)

PART B: Drug Regulatory Affairs

1. Regulation on manufacture of drugs in India.
2. Drug regulatory controls and authorities.
3. Requirements of GMP, CGMP, GLP.
4. Guidelines of WHO, inputs of international bodies, national agencies, harmonization.
5. Preparation and submission of marketing application of India, US and Europe.
6. Approval and appeals present and issues of confidentiality.
7. ISO 9000 series.
8. Drugs and cosmetics acts and rules.
9. Important regulations related to import and export of drugs.

(12 Lectures)

Reading Material Recommended

1. Treece DJ. Managing Intellectual Capital: Organizational, Strategic and Policy Dimension. Oxford University Press, England. Latest Edition.
2. Wadedhra BL. Law Relating to Patents, Trademarks, Copyright Design and Geographical Indications. Universal Law Publishing, New Delhi. Latest Edition.
3. Bansal P. IPR Handbook for Pharma Students and Researchers, Pharma Book Syndicate, Hyderabad. Latest Edition.
4. Copyright Protection in India [website: http:copyright.gov.in].
5. Information on Orange Book [website: www.fda.gov/cder/ob/default.htm].
6. World Trade Organization [website: www.wto.org].

7. Trivedi PR. Encylcopedia of Intellectual Property Rights. Jnanada Prakashan, New Delhi. Latest Edition.

MPCOG-2131: Pharmacognosy Practical-II

14 hours/week

(Including Tutorials/Workshops/Seminars/Field Work etc.)

1. Extraction, isolation and purification of bioactive phytocon3(t)1039J ET Q q 0 0 1 84234ldcs ldcs

GROUP-4: M. PHARM. (PHARMACOLOGY)

SEMESTER-I

MPCOL-1041:

6. Pathophysiology and Drug Therapy of Gastrointestinal Disorders

Peptic ulcer, *Helicobacter pylori* and inflammatory bowel disease.

(2 Lectures)

7. Pathophysiology and Drug Therapy of Respiratory Disorders

Asthma, tuberculosis and pneumonia.

(2 lectures)

8. Chemotherapy of Microbial and Parasitic Diseases

Sulfonamides, quinolones, chloramphenicol, aminoglycosides. tetracyclines, penicillins, cephalosporins, antiviral, antifungal, helminthiasis, malaria, leprosy and antineoplastic agents.

(8 Lectures)

9. Multi-drug resistance and its mechanism, drug resistant tuberculosis and malaria.

(3 Lectures)

Reading Material Recommended

1. Brunton LL, Lazo JS and Parker KL, Eds. Goodman & Gilman's The Pharmacological Basis of Therapeutics. McGraw-Hill, New York. Latest Edition.
2. Katzung BG. Basic and Clinical Pharmacology. Lange/Mc Graw-Hill Medical Publications, New York. Latest Edition.
3. Kalant H and Roschlan WHE. Principles of Medical Pharmacology. Oxford University Press, New York. Latest Edition.
4. Rang HP, Dale MM and Ritter JM. Pharmacology. Churchill Livingstone, New York. hLatest Edition.

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MPCOL-1042: Experimental Pharmacological Techniques

4 hours/week

1. Development and Scope of Experimental Pharmacology

Common laboratory animals, breeding methods, anesthesia & euthanasia of experimental animals, different routes of drug administration.

(6 Lectures)

2. Alternatives to Animal Screening

Cell lines and other in-vitro techniques (ELISA, PCR techniques).

(4 Lectures)

3. Experimental Techniques Employed in the Screening of Drugs Belonging to Following Categories:

3.1. Antipsychotics, antianxiety agents, nootropics, antidepressants, antiparkinsonian agents, antiepileptics, analgesics and anti-inflammatory agents.

(12 Lectures)

3.2. Antianginals, antiarrhythmics, antiatherosclerotics, antihypertensive agents and drugs for myocardial infarction.

(10 Lectures)

3.3. Antidiabetic and antiobesity drugs.

(3 Lectures)

3.4. Antiulcer, antimalarial and anthelmintic agents.

(3 Lectures)

Hepatoprotectiv

(2 Lectures)

– – vivo antioxidant profile. Evaluation of in

(1 Lecture)

4.

(5 Lectures)

Reading Material Recommended

1. -Verlag, Berlin.

2. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata. Latest Edition.
3.

C. Pharmaceutical Chemistry

1. Infrared Spectroscopy

Introduction, the infrared absorption process, the modes of vibrations, stretching and bending, bond properties and absorption trends, basics of instrumentation techniques, pharmaceutical applications.

(2 Lectures)

2. Ultraviolet Spectroscopy

Introduction, the nature of electronic excitation, the origin of UV band structure, principle of absorption spectroscopy, chromophore-
transitions, basics of instrumentation techniques, pharmaceutical applications.

(2 Lectures)

3. Fluorimetric Analysis

Introduction to the principles of fluorescence, applications of fluorimetry in pharmaceutical analysis.

(1 Lecture)

4. Nuclear Magnetic Resonance Spectroscopy

Introduction, nuclear spin states, nuclear magnetic moments, absorption of energy, the mechanism of resonance, chemical equivalence, spin-spin coupling, basics of instrumentation techniques, pharmaceutical applications.

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E. Pharmacology

Definition of bioassay, various types of bioassays, advantages and limitations of bioassays with suitable examples, radioimmunoassay, ELISA and their applications in medicine.

(7 Lectures)

4.2.

4. Muller RF and Youngh ID, Eds. Emmery's Elements of Medical Genetics. Churchill Livingstone, New York. Latest Edition.

MPCOL-2043: Recent Advances in Pharmacology

4 hours/week

1. Receptor Pharmacology

Classification and structure of receptors: dopamine receptors, serotonin receptors, endothelin receptors, GABA-benzodiazepine receptors, excitatory amino acid receptors, sigma receptors, adenosine and cannabinoids.

(8 Lectures)

2. Neurotrophins

Nerve growth factor, brain derived neurotrophic factor, neurotrophin 3 & 4, neurotrophin receptors and their involvement in depression and neurodegenerative disorders.

(4 Lectures)

3. Neurotransporters

Plasma membrane neurotransmitter transporters (Na^+/Cl^- dependent neurotransmitter transporters, Na^+/K^+ dependent glutamate transporters), vesicular neurotransmitter transporters (monoamine transporters and acetylcholine transporters.

(4 Lectures)

4. Apoptosis

Necrosis, apotototic cell death cascade, implications in inflammation and asthma, beta cell apoptosis in diabetes.

(4 Lectures)

5. Cytokines

Classification, cytokines receptors, chemokine receptors and their role in CNS and CVS disorders.

(3 Lectures)

6. Nanomedicine

Principle, applications, nanodevices and nanoparticles in medicine.

(2 Lectures)

7. Probiotics

Pre and probiotics, mechanism of action, therapeutic applications, ethical issues & safety considerations.

(2 Lectures)

8.

2. Trade Related Aspects of Intellectual Property Rights

Intellectual property and international trade, concept behind WTO (World Trade Organization), WIPO (World Intellectual Property Organization), GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trades in Services), status in India and other developing countries, case studies and examples, TRIPS issues on herbal drugs.

(7 Lectures)

3. Nuts and Bolts of Patenting

Copyright and trade mark protection, criteria for patentability, Indian patent act. 1970: WTO and modifications under TRIPS, filing of a patent application, precautions before patenting - disclosures/non-disclosures, publication - article/ thesis, prior art search – published patents search, internet search patent sites, specialized service search requests, costs, patent application forms and guidelines, fee structure, time frames, jurisdiction aspects, types of patent application - provisional, non-provisional, PCT and convention patent applications, international patenting requirement procedures and costs. Patent infringement: Meaning, scope, litigation, drug related patents infringements, case studies and examples, patenting by research students. Trademarks legislation and registration system in India - an introduction, meaning of trademark, criteria for eligibility, filling application for trademark registration, trade secrets - scope modalities and protection case studies.

(10 Lectures)

4. Technology Development/Transfer Commercialization Related Aspects

Technology development: Meaning, drug related technology development, toxicological studies, bio(r)24(i8( )-119(s)T5/F1 11.68)31(o)-1F2 1hl se7-34(0)-B(a)-1U1(e7-3)-140(

alalo( )23(s)-22O q BT /F2 11.68 Tf 0 0 0 rg 0.9998 0 0 1 114.72 415.12 Tm00 0 0 (l)-IJ EI2 EI2 E74(d)-13956(p)-34

2. Experimental Toxicology

Calculations of LD_{50} values and therapeutic index.

3. Biochemical Pharmacology

Estimation of lipid peroxidation, glutathione, superoxide dismutase, catalase, myeloperoxidase enzyme, liver and renal function tests, mitochondrial enzyme complex.

4. Computer aided learning in experimental pharmacology using BIOPAC system.

Reading Material Recommended

1. Bennett PN and Brown MJ. Clinical Pharmacology. Churchill Livingstone, Edinburgh. Latest Edition.
2. Walker R and Edwards C. Clinical Pharmacy and Therapeutics. Churchill Livingstone, London. Latest Edition.
3. Shargel L, Mutnick AH, Souney PF and Swanson LN. Comprehensive Pharmacy Review. Wolters Kluwer Health / Lippincott William & Wilkins, New Delhi. Latest Edition.
4. Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG and Posey LM, Eds. Pharmacotherapy: A Pathophysiologic Approach. McGraw-Hill, New York. Latest Edition.
5. Smith DGG and Aronson JK. Oxford Textbook of Clinical Pharmacology and Drug Therapy. Oxford University Press, New York. Latest Edition.
6. Laurence DR. Clinical Pharmacology. Churchill Livingstone, London. Latest Edition.

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SEMESTER – III & IV

Research work during third and fourth semester.

The examination shall consist of thesis submitted at the end of fourth semester and presentation in the open seminar.

The result of the examination will be given as **pass** or **fail** without marks.

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4. Pharmacopoeial Assays with Suitable Examples of Various Drugs Pertaining to:

4.1. Chemical methods

4.1.1. Titrimetry

1. Acid/base: Aspirin tablets, benzoic acid, boric acid, indomethacin, calamine, ephedrine, milk of magnesia, sodium bicarbonate.
2. Non aqueous: Ethosuximide, flourouracil, sulfafurazole, adrenaline, levodopa, pentazocine.
3. Precipitation: Aminophylline, chlorbutol, cyclophosphamide, lomustine.
4. Complexometry: Aluminium hydroxide tablets, calcium gluconate injection, magnesium sulphate, sodium fluoride.
5. Redox: Potassium bromide, nifedipine tablets, ascorbic acid, dimercaprol.

4.1.2. Gravimetry**:** Hydantoin, phenytoin, codeine phosphate, procaine penicillin.

(7 Lectures)

4.2. Instrumental methods

4.2.1. Electrochemical: Conductometry, polarography, coulometry and potentiometry (acebutolol hydrochloride, diphenoxylate hydrochloride, hydralazine hydrochloride, phenytoin sodium). (3 Lectures)

4.2.2. Spectrophotometry: UV spectrophotometry, fluorimetry, flame photometry (rifampicin, chloramphenicol, carbamazepine, spironolactone, thiamine, riboflavin, human albumin, sodium chloride injection). (7 Lectures)

4.2.3. Chromatography: HPLC, GC (alprazolam, methotrexate, omeprazole, enalapril maleate). (5 Lectures)

5. Expression of analytical results: Solid and liquid samples. (2 Lectures)

Reading Material Recommended

1. Christin GD. Analytical Chemistry. John Wiley and Sons, New York. Latest Edition.
2. Indian Pharmacopoeia. Latest Edition.
3. U. S. Pharmacopoeia - NF. Latest Edition.
4. European Pharmacopoeia. Latest Edition.

5. British Pharmacopoeia. Latest Edition.

MPQUA-1052: Good Manufacturing Practices (GMPs)

4 hours/week

1. Concepts and philosophy, general guidelines. (1 Lecture)

2. Organization and personnel responsibilities, training, hygiene, safety programs, personnel.
(3 Lectures)

3. Building and premises: Location, design, plan layout, construction, lighting, ventilation, maintenance and sanitations, environmental control, air handling systems, sterile areas, control of contamination, sterilization of an area (TP & STP).
(4 Lectures)

4. Equipment: Selection, purchase specifications, cleaning and maintenance.
(2 Lectures)

5. Raw materials: Quality assurance monograph of raw materials, quarantine, testing, sampling records, drug product containers and closures, purchase specifications, maintenance of stores, selection of vendors, controls on raw materials.
(4 Lectures)

6. Warehousing: Warehousing procedures and distribution procedure, distribution of records, handling of returned goods, recovered materials and reprocessing.
(4 Lectures)

7. Manufacture and controls on dosage forms : Before start checks, in process checks, manufacturing documents, master formula, batch formula records, standard operating procedure (SOP) for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration, etc. and documents, control and assurance of finished products.
(5 Lectures)

8. Finished product release: Quality audits of manufacturing processes, facilities and finished products, quality review, batch release document.
(3 Lectures)

9. Packaging and labeling controls: Specifications for containers and closures, packaging components, testing of packaging, and packaging material, control for labeling, labeling issuance, packaging and labeling operations, drug product inspection.
(4 Lectures)

10. Records and reports: General requirement for quality control documentation. (2 Lectures)

11. Waste and scrap disposal: Procedure and records. (2 Lectures)

12. Complaints and recalls: Evaluation of complaints, recall procedures, related records and documents. (3 Lectures)

13. Loan license auditing: Concepts, auditing. (2 Lectures)

14. Inspections: Inspections of pharmaceutical manufacturers, role of the inspectors, methods of inspection - routine, concise, follow-up and special inspections, frequency and duration of inspection, preparation for inspections, conduct, report and regulatory actions. (4 Lectures)

Reading Material Recommended

1. William H. GMP for Pharmaceutics. Marcel Dekker, New York. Latest Edition.
2. Sharma PP. How to Practice GMP, Vandana Publication, New Delhi. Latest Edition.

MPCOG-1033/MPQUA-1053: Plant Drug Standardization

4 hours/week

1. Definitions

Definitions of a range fs40v9(c)123( )8(r)4(a)12(c(r)24(a)45(i)-9(n)-13(i)-9(t)] TJ ET Q q BT /

3.1. Macroscopic

3.1.1. Organoleptic methods including gross morphology, sampling, preliminary examination and foreign matter. (2 Lectures)

3.2. Physico-chemical

3.2.1. Solubility, specific gravity, optical rotation, specific rotation, refractive index, melting point, swelling index, foaming index and bitterness value. (2 Lectures)

3.2.2. Moisture content. (1 Lecture)

3.2.3. Ash values. (1 Lecture)

3.2.4. Extractive values including volatile oil. (1 Lecture)

3.2.5. Qualitative chemical tests. (2 Lectures)

3.2.6. Quantitative chemical tests: Acid value, iodine value, saponification value, ester value, unsaponifiable matter and acetyl value. (2 Lectures)

3.3. Microscopic

3.3.1. General microscopy. (1 Lecture)

3.3.2. Histochemistry. (1 Lecture)

3.3.3. Quantitative microscopy: Lycopodium spore method, palisade ratio, stomatal number, stomatal index, veinislet number and veinlet termination number. (2 Lectures)

3.3.4. **Microbiological (including microbial limits)**. (1 Lecture)

3.3.5. **Biological evaluation**. (1 Lecture)

4.

4.1.1. Marker analysis / fingerprinting by HPLC / HPTLC / GC / fluorimetry / spectroscopy of single plant drugs / extracts and compound formulations. (6 Lectures)

4.2. Chemical assays. (2 Lectures)

4.3. Radioimmunoassays. (1 Lecture)

4.4. Determination of toxic residues.

4.4.1. Pesticide residues. (2 Lectures)

4.4.2. Arsenic and heavy metals. (2 Lectures)

5. Single Plant Drugs

Overview of monographs of API, Indian Council of Medical Research (ICMR), WHO, ESCOP, USP, EP and Pharmacopoeia of People's Republic of China. (3 Lectures)

6. Compound Formulations

Quality aspects of compound formulations of medicinal plants. Monographs of compound formulations of API, control of excipients, stability indicating parameters. (2 Lectures)

Reading Material Recommended

1. Guidelines for the Assessment of Herbal Medicines - WHO Report, Geneva, 1991, Fitoterapia Vol. LXIII, 105-110.
2.

MPCOM-1071: Modern Analytical and Pharmaceutical Techniques

3 hours/week

A. Advanced Statistics

General concepts, two-tail student t-test and paired sample t-test, two samples t-test, Wilcoxon rank-sum test, Mann-Whitney test, one-way analysis of variance, Kruskal-Wallis test, two-way analysis of variance, multiple comparison procedures in ANOVA: Fischer's LSD test, Tukey's studentized range test and Dunnett's test. Non-linear regression: Introduction, iterative method. (6 Lectures)

B. Pharmaceutics

1. Basic elements of Novel drug delivery systems.
2. Bioavailability and bioequivalence testing, significance of terminology, conduct of bioavailability trials.
3. Introduction to validation of manufacturing facilities I.Q. / O.Q. and certification, preparation of validation protocols.
4. Stability testing: Stress testing of drug substances, stability testing protocols, shelf-life determination, ICH guidelines. (10 Lectures)

C. Pharmaceutical Chemistry

1. Infrared Spectroscopy

Introduction, the infrared absorption process, the modes of vibrations, stretching and bending, bond properties

4. Nuclear Magnetic Resonance Spectroscopy

Introduction, nuclear spin states, nuclear magnetic moments, absorption of energy, the mechanism of resonance, chemical equivalence, spin-spin coupling, basics of instrumentation techniques, pharmaceutical applications. (2 Lectures)

5. Mass Spectrometry

Basic principle and theory involved, basics of instrumentation techniques, pharmaceutical applications. (2 Lectures)

6. Thermal Analysis

Introduction to various

MPQUA-1151: Pharmaceutical Analysis Practical-I

8 hours/week

MPCOM-1171: Modern Analytical and Pharmaceutical Techniques Practical

6 hours/week

A. Pharmaceutical Chemistry

1. Assay procedures of various drugs using UV spectroscopy, spectroflourimetry and IR.
2. Basics of spectral analysis.
3. Thermal analysis using DSC technique.

B. Pharmaceutics

1. Exercises based on degradation kinetics and shelf-life determination.
2. Dissolution studies of marketed formulations.
3. Any other practical based on theory.

C. Pharmacology

1. Bioassay designs using various in-vitro preparations.
2. Experimental Toxicology: Calculations of LD

6. Pharmacopoeial assays involved in the analysis of some selected drugs (aminophylline, phenytoin and others). (3 Lectures)

7. Impurity profiling

Impurities, drug master files, profiling of impurities, official guidelines for impurities. (5 Lectures)

8. Clinical chemistry

Composition of blood, collection and preservation of samples, clinical analysis of serum electrolytes, blood glucose and blood urea nitrogen (BUN), uric acid, albumin and globulins, acid and alkaline phosphatases, barbiturates. (3 Lectures)

9. Immunological methods of analysis

Principles of immunoassay, specificity of immunoassays, preparation of immunoassays, preparation of the antibody, incubation period for the assay, separation of the bound and free antigen, fluorescence immunoassay, enzyme immunoassay. (3 Lectures)

Reading Material Recommended

1. Christin GD. Analytical Chemistry. John Wiley and Sons, New York. Latest Edition.
2. Indian Pharmacopoeia. Latest Edition.
3. U. S. Pharmacopoeia - NF. Latest Edition.
4. European Pharmacopoe-8(a)32( )3(a)12(n)-13w816 Tm [( )] TJ ET Q q BT /F2 11.6(p)6(eq BT

Near-IR spectroscopy, absorption and reflectance spectrophotometry, Instrumentation, applications, Far Infrared spectroscopy. Introduction to FTIR and its applications.

Raman spectroscopy: Introduction, theory and polarization measurement, rules of selection and polarization, instrumentation, applications in pharmaceutical sciences. Comparison of infrared and Raman spectra.

(5 Lectures)

2. Ultraviolet/Visible Spectroscopy and Fluorimetry

Energy level and selection rules, effect of substituents, effect of conjugation, conformation and geometry, the Woodward-Fisher rules, the Fisher-Kuhn rules, applications of UV with reference to different electronic systems. Derivative spectroscopy and its applications.

Fluorescence and chemical structure, fluorescence intensity, factors affecting fluorescence, instrumentation, comparison of fluorometry with spectrophotometry, applications of fluorimetry in pharmaceutical analysis.

(5 Lectures)

3. Nuclear Magnetic Resonance Spectroscopy

^{1}H-NMR spectroscopy

Magnetic equivalence, failure of the N+1 rule, chemical shifts, local diamagnetic shielding, hybridization effects, magnetic anisotropy, mechanism of spin-spin coupling, the origin of spin-spin splitting, Pascal's triangle, the coupling constant, protons on oxygen, nitrogen and sulphur, diastereomeric protons, chemical shift reagents, long range coupling, spin decoupling methods, nuclear over Hauser effect. Correlation NMR spectrometry: Introduction to ^{1}H -^{1}H cosy and ^{1}H - ^{13}C cosy and its applications. Introduction and applications of 2D NMR; solid state NMR.

^{13}C-NMR spectroscopy

Introduction, peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts, spin coupling.

Spectrometry of other important nuclei

Introduction to ^{15}N, ^{19}F, ^{31}P, basic concepts.

(8 Lectures)

4. Electron Spin Resonance Spectroscopy

Introduction, derivative curves, g values, hyperfine splitting, ESR instrumentation, ESR spectra of free radicals, applications.

(1 Lecture)

2. Chatten LG. Pharmaceutical Chemistry, Vol I & II. Marcel Dekker, New York. Latest Edition.
3. James WD and Kenneth HT. Analytical Chemistry by Open Learning: Thermal Methods. John Wiley and Sons, New York. Latest Edition.
4. Abraham RJ, Fisher J and Bftus P. Introduction to NMR Spectroscopy. John Wiley and Sons, New York. Latest Edition.
5. Jeremy KMS and Brain KH. Modern NMR Spectroscopy: A Guide for Chemist's. Oxford University Press. Latest Edition.
6. Ladd MFC and Palmer RA. Structure Determination by X-Rays Crystallography. Plenum Press, New York. Latest Press.
7. Jenny P, Glusker ML and Rossi M. Crystal Structure Analysis for Chemists and Biologists. VCH Publishers, New York. Latest Edition.

MPQUA-2053: Quality Management and Validation

4 hours/week

1. Total quality management (TQM).

(3 Lectures)

2. Testing of pharmaceutical dosage forms: Solutions, disperse systems, tablets including modified and delayed release formulations, capsules, injectables, aerosols, suppositories, semisolid, transdermal patches and liposomes as per manufacturers and compendia requirements.

(14 Lectures)

3. Bioavailability and bioequivalence: Testing protocols and evaluation, biopharmaceutical classification scheme (BCS), biowaivers especially using BCS and *in vitro/in vivo* correlations (IVIVC).

(5 Lectures)

4. Stability testing: Stability indicating assays, methods, protocols and parameters for physical stability testing programs, stabilization, shelf life determination, equipment, ICH guidelines, Impurity profiling.

(3 Lectures)

5. In process statistical quality control (SQC): Principles of SQC, sampling plans, application of various types of control charts.

(3 Lectures)

6. Introduction to validation of manufacturing facilities I.Q. / O.Q. and certification, preparation of validation protocols, validation of process (sterile and non-sterile

products), validation of sterilization methods and equipments, validation of purified water system, distilled water and water for injection, validation of air handling system, sterile and non-sterile areas.

(12 Lectures)

Reading Material Recommended

1. Mailk V. Drug and Cosmetics Act, 1940. Eastern Book Company, Lucknow (Latest Edition)
2. Indian Pharmacopoeia. Latest Edition.
3. U. S. Pharmacopoeia - NF. Latest Edition.
4. European Pharmacopoeia. Latest Edition.
5. British Pharmacopoeia. Latest Edition.
6. Remington JP, Science and Practice of Pharmacy. Lippincot Williams and Wilkins, New York. Latest Edition.
7.

2. Workshops on spectral interpretations.

Pharmaceutics

Practicals based on:

1. Testing of conventional and modified delivery systems (transdermal patches and liposome).
2. Determination of bioavailability of given dosage-forms.
3. Inter and intra brand dissolution testing of formulations.
4. Shelf-life determination of a dosage form.
5. Stability testing of API.
6. Preparation of control charts for weight variation data of tablets and capsules.

Reading Material Recommended

1. Indian Pharmacopoeia. Latest Edition.
2. U. S. Pharmacopoeia - NF. Latest Edition.
3. European Pharmacopoeia. Latest Edition.
4. British Pharmacopoeia. Latest Edition.
5. Mendham J, Denney RC, Barnes JD and Thomas M. Vogel's Textbook of Quantitative Chemical Analysis. Pearson Education Limited, Singapore. Latest Edition.
6. Silverstein RM and Webster FX. Spectrometric Identification of Organic Compounds. John Wiley and Sons, New York. Latest Edition.

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SEMESTER – III & IV

Research work during third and fourth semester.

The examination shall consist of thesis submitted at the end of fourth semester and

GROUP 6: M. PHARM. (DRUG DISCOVERY AND DRUG DEVELOPMENT)

SEMESTER-I

MPDRD-1061:	**Drug Discovery Processes**
MPDRD-1062:	**Preclinical Drug Discovery and Drug Development**
MPDRD-1063:	**Pharmacokinetics and Pharmacodynamics in New Drug Development**
MPCOM-1071:	**Modern Analytical and Pharmaceutical Techniques**
MPDRD-1161:	**Drug Discovery Practical-I**
MPCOM-1171:	**Modern Analytical and Pharmaceutical Techniques Practical**

MPDRD-1061: Drug Discovery Processes

4 hours/week

1. Model Approaches of Drug Discovery from Natural Sources

Selection of natural sources for drug discovery based on phytoconstituents, chemotaxonomy, ethnopharmacological records and random approach. Chemical constituents and compound extract as drugs, synergy principle in plant drugs. Plant secondary metabolites as new drug templates. Preparation of plant material for biological evaluation (various methods of extraction, solvent choices, dose selection, preparation and mode of administration). Bioactivity guided fractionation. Separation techniques (column chromat

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3. Drug Design Tools

3.1. Conventional methods of drug design: Lead, discovery of lead, lead optimization, objective of lead optimization, pharmacophoric identification and analog approach of drug designing.

3.2.

4. Ricky NG. Drugs from Discover to Development. Wiley

4. Bioavailability and Bioequivalence

Basic concepts, design and evaluation of bioequivalence trials. Federal (US FDA & DCGI) guidelines for oral drug delivery systems: Immediate release and extended release formulations.

(7 Lectures)

5. Biopharmaceutical Classification Scheme (BCS) and IVIVC

In vitro and *in vivo* correlations (IVIVC): Concepts, *In vitro* dissolution as a surrogate to *In vivo* bioavailability, various IVIVC/IVIVR approaches in the light of BCS, applications and limitations, Federal perspectives.

(6 Lectures)

6. Recent Advances in Pharmacokinetics and Biop342(d)1(q BT /01T /F6 11.68 Tf 0 0 0 r0a)-34

MPCOM-1071: Modern Analytical and Pharmaceutical Techniques

3 hours/week

A. Advanced Statistics

General concepts, two-tail student t-test and paired sample t-test, two samples t-test, Wilcoxon rank-sum test, Mann-Whitney test, one-way analysis of variance, Kruskal-Wallis test, two-way analysis of variance, multiple comparison procedures in ANOVA: Fischer's LSD test, Tukey's studentized range test and Dunnett's test. Non-linear regression: Introduction, iterative method.

(6 Lectures)

B. Pharmaceutics

1. Basic elements of novel drug delivery systems.
2. To prepare and evaluate matrix tablet of given drug.
3.

MPDRD-1161: Drug Discovery Practical-I

8 hours/week

Pharmaceutical Chemistry

1. Qualitative analysis of organic mixtures.
2. Workshops on stereomodels, QSAR and Molecular Modelling.

Pharmaceutics

1. Bioavailability and bioequivalence testing, significance of terminology, conduct of

MPCOM-1171: Modern Analytical and Pharmaceutical Techniques Practical

6 hours/week

A. Pharmaceutical Chemistry

1. Assay procedures of various drugs using UV spectroscopy, spectroflourimetry and IR.
2. Basics of spectral analysis.
3. Thermal analysis using DSC technique.

B. Pharmaceutics

1. Exercises based on degradation kinetics and shelf-life determination.
2. Dissolution studies of marketed formulations.
3. Any other practical based on theory.

C. Pharmacology

1. Bioassay designs using various in-vitro preparations.
2. Experimental Toxicology: Calculations of LD_{50} values and therapeutic index.

D. Pharmacognosy

Exercises on chromatographic techniques.

Reading Material Recommended

1. Indian Pharmacopoeia. Latest Edition.
2. U. S. Pharmacopoeia - NF. Latest Edition.
3. European Pharmacopoeia. Latest Edition.
4. British Pharmacopoeia. Latest Edition.
5. Mendham J, Denney RC, Barnes JD and Thomas M. Vogel's Textbook of Quantitative Chemical Analysis. Pearson Education Limited, Singapore. Latest Edition.
6. Silverstein RM and Webster FX. Spectrometric Identification of Organic Compounds. John Wiley and Sons, New York. Latest Edition.
7. Vogel HG and Vogel WH. Drug Discovery and Evaluation. Springer-Verlag, Berlin. Latest Edition.
8. Kulkarni SK. Handbook of Experimental Pharmacology. Vallabh Prakashan, New Delhi. Latest Edition.
9. Ghosh MN. Fundamentals of Experimental Pharmacology. Hilton & Company, Kolkata. Latest Edition.

8. Chemical contraceptives (latest advances and FDA approved drugs).

(2 Lectures)

9. Current scenario of drug discovery in national research laboratories and Indian pharmaceutical industry.

(2 Lectures)

Reading Material Recommended

1. March J. Advanced Organic Chemistry Reactions, Mechanisms and Structures. John Wiley and Sons, New York. Latest Edition.
2. Wolff ME. Burger's Medicinal Chemistry and Drug Discovery. John Wiley and Sons, New York. Latest Edition.
3. Silverman RB. The Organic Chemistry of Drug Design and Action. Academic Press Inc., San Diego. Latest Edition.
4. Nogrady T. Medicinal Chemistry: A Biochemical Approach. Oxford University Press, New York. Latest Edition.
5. Williams DA, Lemke TL. Foye's Principles of Medicinal Chemistry. Lippincott Williams and Wilkins, Philadelphia. Latest Edition.
6. Wade LG and Singh MS. Organic Chemistry. Pearson Education, India. Latest Edition.

MPDRD-2062: Clinical Drug Development

4 hours/week

1. Introduction

Definition, scope and development of clinical pharmacology, essential drugs and national drug policy, pharmacoepidemiology, pharmacovigilance and drug information centre.

(2 Lectures)

2. Clinical Trials

2.1. Requirements of clinical trials, good clinical practice, ICH guidelines for clinical trial, Helsinki declaration, ethical and legal issues in clinical trials.

(6 Lectures)

2.2. Clinical trial team, sponsor, monitor and their qualifications, site of clinical trials, staff, role of ethical committee.

(2 Lectures)

2.3. Design (placebo, multicentric clinical trials, randomization, blinding) and different phases of clinical trials (Phase 1 to 4), principles of controlled clinical trials.

(4 Lectures)

2.4. Protocol designing, CRF, patient informed consent & enrolment for clinical trials, inclusion and exclusion criteria, withdrawals and drop outs, wash out and run in period.

(4 Lectures)

2.5. Monitoring of clinical trial, report preparation, deviation in clinical trials.

(4 Lectures)

3. Clinical Data Management

Regulatory requirement, data base development, CRF, data entry, query, correction and data validation.

(4 Lectures)

4. Recent Trends in Clinical Trial

e-Clinical trial, clinical trial regulatory affairs, dossier and its components, DMF, CRO, challenges, limitations and its role in drug development.

(4 Lectures)

5. Drug Therapy in Specialized Patient Populations

5.1. Neonates: Special childhood diseases and their management, national immunization programmes, relevant paediatric management issues as dosages

4. Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG and Posey LM, Eds. Pharmacotherapy: A Pathophysiologic Approach. McGraw-Hill, New York. Latest Edition.
5. Laurence DR. Clinical Pharmacology. Churchill Livingstone, London. Latest Edition.
6. Lloyd J and Raven A. Handbook of Clinical Research. Churchill Livingstone, London. Latest Edition.

MPDRD-2063: Drug Delivery Issues in New Drug Development

4 hours/week

1. Pre-formulation Studies

Introduction, goals of pre-formulation, physico-chemical properties, criteria for selection of drug and excipients, compatibility tests.

(5 Lectures)

2. Solid State Pharmaceutics

Crystallinity, crystal habit, polymorphism, amorphous state, solvates, hydrates and analytical techniques for characterization.

(5 Lectures)

3. Drug Solubility Studies and Improvement

Factors influencing solubility, prognostic approaches and solubilization technique.

(5 Lectures)

4. Stability Testing

Stress testing of drug substances, stability testing protocols, shelf-life determination, photostability testing, post-approval changes (SUPAC), packaging influence on stability, ICH guidelines.

(5 Lectures)

5. Modified Drug Delivery Approaches

Fundamentals of controlled release (CR) drug delivery: Rationale of sustained/controlled drug delivery, physicochemical and biological factors influencing design and performance of CR products. Regulatory requirements.

(8 Lectures)

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7. Targeted Drug Delivery

Concept, types and key elements for ideal carrier system and approach with special reference to organ targeting (e.g. brain, tumor, lung, liver and lymphatic).

(5 Lectures)

8. Gene therapy

An introduction to genetic disorders, approaches, viral and non viral mediated gene therapy, safety and ethical considerations.

(3 Lectures)

Recommended Reading Material

1.

2. Trade Related Aspects of Intellectual Property Rights

Intellectual property and international trade, concept behind WTO (World Trade Organization), WIPO (World Intellectual Property Organization), GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trades in Services), status in India and other developing countries, case studies and examples, TRIPS issues on herbal drugs.

(7 Lectures)

3. Nuts and Bolts of Patenting

Copyright and trade mark protection, criteria for patentability, Indian patent act. 1970: WTO and modifications under TRIPS, filing of a patent application, precautions before patenting-disclosures/non-disclosures, publication-article/ thesis, prior art search – published patents search, internet search patent sites, specialized service search requests, costs, patent application forms and guidelines, fee structure, time frames, jurisdiction aspects, types of patent application- provisional, non-provisional, PCT and convention patent applications, international patenting requirement procedures and costs. Patent infringement: Meaning, scope, litigation, drug related patents infringements, case studies and examples, patenting by research students. Trademarks legislation and registration system in India - an introduction,

PART B: Drug Regulatory Affairs

1. Regulation on manufacture of drugs in India.
2. Drug regulatory controls and authorities.
3. Requirements of GMP, CGMP, GLP.
4. Guidelines of WHO, inputs of international bodies, national agencies, harmonization.
5.

SEMESTER – III & IV

Research work during third and fourth semester.

The examination shall consist of thesis submitted at the end of fourth semester and presentation in the open seminar.