

**DEVI AHILYA  
VISHWAVIDYALAYA, INDORE  
SCHOOL OF PHARMACY**

**M.PHARM.  
SYLLABUS**

**(Prescribed by Pharmacy Council of India)  
w.e.f academic session 2016-17**

**M. PHARM. PHARMACEUTICAL CHEMISTRY (MPC)****FIRST SEMESTER****Table 1: Course of study**

Course code	Course	Credit hours	Credit points	Hrs./week	Marks
MPC 101 T	Modern Pharmaceutical Analytical Techniques	4	4	4	100
MPC 102 T	Advanced Organic Chemistry-I	4	4	4	100
MPC 103 T	Advanced Medicinal Chemistry	4	4	4	100
MPC 104 T	Chemistry of Natural Products	4	4	4	100
MPC 105 T	Pharmaceutical Chemistry Practical I	12	6	12	150
	Seminar/Assignment	7	4	7	100
	<b>Total</b>	<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

**Table 2: Scheme for Internal Assessments and end semester examinations**

Course code	Course	Internal Assessment				End semester exams		Total Marks	
		Continuous mode	Sessional Exams.		Total	Marks	Duration		
			Marks	Duration					
MPC 101 T	Modern Pharmaceutical Analytical Techniques	10	15	1 Hr	25	75	3Hrs	100	
MPC 102 T	Advanced Organic Chemistry-I	10	15	1 Hr	25	75	3Hrs	100	
MPC 103 T	Advanced Medicinal Chemistry	10	15	1 Hr	25	75	3Hrs	100	
MPC 104 T	Chemistry of Natural Products	10	15	1 Hr	25	75	3Hrs	100	
MPC 105 T	Pharmaceutical Chemistry Practical I	20	30	6 Hr	50	100	6Hrs	150	
-	Seminar/Assignment	-	-	-	-	-		100	
		<b>Total</b>							<b>650</b>

**MPC 101T: MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES****Course of study**

Course code	Credit hours	Credit points	Hrs./week	Teaching Hrs/semester	Marks
MPC 101 T	<b>4</b>	<b>4</b>	<b>4</b>	<b>60</b>	<b>100</b>

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment			End semester exams		Total Marks	
	Continuous mode	Sessional Exams.		Total	Marks		Duration
		Marks	Duration				
MPC 101 T	<b>10</b>	<b>15</b>	<b>1 Hr</b>	<b>25</b>	<b>75</b>	<b>3Hrs</b>	<b>100</b>

**Scope**

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

**Objectives**

After completion of course student is able to know about:

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

**Unit 1 (10 Hrs.)**

- a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy, Difference/ Derivative spectroscopy.
- b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy, Data Interpretation.
- c. Spectrofluorimetry: Theory of Fluorescence, Factors affecting fluorescence (Characteristics of drugs that can be analysed by fluorimetry), Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.
- d. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

**Unit 2 (10 Hrs.)**

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

**Unit 3 (10 Hrs.)**

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of

Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy.

**Unit 4 (10 Hrs.)**

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution, isolation of drug from excipients, data interpretation and applications of the following:

- a. Thin Layer chromatography
- b. High Performance Thin Layer Chromatography
- c. Ion exchange chromatography
- d. Column chromatography
- e. Gas chromatography
- f. High Performance Liquid chromatography
- g. Ultra High Performance Liquid chromatography
- h. Affinity chromatography, Gel Chromatography

**Unit 5 (10 Hrs.)**

- a. Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following: a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) Iso electric focusing
- b. X ray Crystallography: Production of X rays, Different X ray methods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction

**Unit 6 (10 Hrs.)**

- a. Potentiometry: Principle, working, Ion selective Electrodes and Application of potentiometry.
- b. Thermal Techniques: Principle, thermal transitions and Instrumentation (Heat flux and power-compensation and designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, source of errors) and their influence, advantage and disadvantages, pharmaceutical applications. Differential Thermal Analysis (DTA): Principle, instrumentation and advantage and disadvantages, pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle, instrumentation, factors affecting results, advantage and disadvantages, pharmaceutical applications.

**REFERENCES**

- 1 Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
- 2 Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
- 3 Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

- 5 Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991
- 6 Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997
- 7 Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol. 11, Marcel. Dekker Series
- 8 Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
- 9 Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

**MPC 102T: ADVANCED ORGANIC CHEMISTRY - I****Course of study**

Course code	Credit hours	Credit points	Hrs./week	Teaching Hrs/semester	Marks
MPC 102 T	<b>4</b>	<b>4</b>	<b>4</b>	<b>60</b>	<b>100</b>

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment			End semester exams		Total Marks	
	Continuous mode	Sessional Exams.		Total	Marks		Duration
		Marks	Duration				
MPC 102 T	<b>10</b>	<b>15</b>	<b>1 Hr</b>	<b>25</b>	<b>75</b>	<b>3Hrs</b>	<b>100</b>

**Scope**

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

**Objectives**

Upon completion of course, the student shall be to understand

- The principles and applications of retrosynthesis
- The mechanism & applications of various named reactions
- The concept of disconnection to develop synthetic routes for small target molecule.
- The various catalysts used in organic reactions
- The chemistry of heterocyclic compounds

**Unit 1 (12 Hrs.)**

Basic Aspects of Organic Chemistry:

1. Organic intermediates: Carbocations, carbanions, free radicals, carbenes and nitrenes. Their method of formation, stability and synthetic applications.
2. Types of reaction mechanisms and methods of determining them.
3. Detailed knowledge regarding the reactions, mechanisms and their relative reactivity and orientations.

Addition reactions: 1.Nucleophilic uni- and bimolecular reactions (SN1 and SN2)

2. Elimination reactions (E1 & E2; Hoffman & Saytzeff's rule) 3. Rearrangement reactions.

**Unit 2 (12 Hrs.)**

Study of mechanism and synthetic applications of following named Reactions: Ugi reaction, Brook rearrangement, Ullmann coupling reactions, Dieckmann Reaction, Doebner-Miller Reaction, Sandmeyer Reaction, Mitsunobu reaction, Mannich reaction, Vilsmeier-Haack Reaction, Sharpless asymmetric epoxidation, Baeyer-Villiger oxidation, Shapiro & Suzuki reaction, Ozonolysis and Michael addition reaction.

**Unit 3 (12 Hrs.)**

Synthetic Reagents & Applications: Aluminium isopropoxide, N-bromosuccinamide, diazomethane, dicyclohexylcarbodiimide, Wilkinson reagent, Wittig reagent. Osmium tetroxide, titanium chloride, diazopropane, diethyl azodicarboxylate, Triphenylphosphine, Benzotriazol-1-

xyloxy) tris (dimethylamino) phosphonium hexafluoro-phosphate (BOP).

Protecting groups : a. Role of protection in organic synthesis, b. Protection for the hydroxyl group, including 1,2-and1,3-diols: ethers, esters, carbonates, cyclic acetals & ketals, c. Protection for the Carbonyl Group: Acetals and Ketals, d. Protection for the Carboxyl Group: amides and hydrazides, esters, e. Protection for the Amino Group and Amino acids: carbamates and amides.

#### Unit 4 (12 Hrs.)

Heterocyclic Chemistry: Organic Name reactions with their respective mechanism and application involved in synthesis of drugs containing five, six membered and fused heterocyclics such as Debus-Radziszewski imidazole synthesis, Knorr Pyrazole Synthesis Pinner Pyrimidine Synthesis, Combes Quinoline Synthesis, Berntsen Acridine Synthesis, Smiles rearrangement and Traube purine synthesis.

Synthesis of few representative drugs containing these heterocyclic nucleus such as Ketoconazole, Metronidazole, Miconazole, celecoxib, antipyrin, Metamizole sodium, Terconazole, Alprazolam, Triamterene, Sulfamerazine, Trimethoprim, Hydroxychloroquine, Quinine, Chloroquine, Quinacrine, Amsacrine, Prochlorperazine, Promazine, Chlorpromazine, Theophylline, Mercaptopurine and Thioguanine.

#### Unit 5 (12 Hrs.)

Synthon approach and retrosynthesis applications: a. Basic principles, terminologies and advantages of retrosynthesis; guidelines for dissection of molecules. Functional group interconversion and addition (FGI and FGA) b. C-X disconnections; C-C disconnections- alcohols and carbonyl compounds; 1,2-, 1,3-,1,4-, 1,5-, 1,6-difunctionalized compounds c. Strategies for synthesis of three, four, five and six-membered ring.

#### REFERENCES

- 1 Advanced Organic chemistry, Reaction, Mechanisms and Structure”, J March, John Wiley and Sons, New York.
- 2 Mechanism and Structure in Organic Chemistry”, ES Gould, Hold Rinchart and Winston, New York.
- 3 Organic Chemistry, Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
- 4 Organic Chemistry, Vol I and II. I.L. Finar. ELBS, Pearson Education Ltd, Dorling Kindersley (India) Pvt. Ltd.,
- 5 A guide to mechanisms in Organic Chemistry, Peter Skyes (Orient Longman, New Delhi).
- 6 Reactive Intermediates in Organic Chemistry, Tandom and Gowel, Oxford & IBH Publishers.
- 7 Combinational Chemistry – Synthesis and applications – Stephen R Wilson & Anthony W Czarnik, Wiley – Blackwell
- 8 Carey, Organic Chemistry, 5th Edition (Viva Books Pvt. Ltd.)
- 9 Organic Synthesis - The Disconnection Approach, S. Warren, Wiley India
- 10 Principles of Organic Synthesis, ROC Norman and JM Coxan, Nelson Thorns.

- 11 Organic Synthesis - Special Techniques. VK Ahluwalia and R Agarwal, Narosa Publishers.
- 12 Organic Reaction Mechanisms IVth Edtn, VK Ahluwalia and RK Parashar, Narosa Publishers.



**MPC 103 T: ADVANCED MEDICINAL CHEMISTRY****Course of study**

Course code	Credit hours	Credit points	Hrs./week	Teaching Hrs/semester	Marks
MPC 103 T	<b>4</b>	<b>4</b>	<b>4</b>	<b>60</b>	<b>100</b>

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment				End semester exams		Total Marks
	Continuous mode	Sessional Exams.		Total	Marks	Duration	
		Marks	Duration				
MPC 103 T	<b>10</b>	<b>15</b>	<b>1 Hr</b>	<b>25</b>	<b>75</b>	<b>3Hrs</b>	<b>100</b>

**Scope**

The subject is designed to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.

**Objectives**

At completion of this course it is expected that students will be able to understand

- Different stages of drug discovery
- Role of medicinal chemistry in drug research
- Different techniques for drug discovery
- Various strategies to design and develop new drug like molecules for biological targets
- Peptidomimetics

**Unit 1 (12 Hrs.)**

Drug discovery: Stages of drug discovery, lead discovery; identification, validation and diversity of drug targets.

Biological drug targets: Receptors, types, binding and activation, theories of drug receptor interaction, drug receptor interactions, agonists vs antagonists, artificial enzymes.

**Unit 2 (12 Hrs.)**

Prodrug Design and Analog design:

a) Prodrug design: Basic concept, Carrier linked prodrugs/ Bioprecursors, Prodrugs of functional group, Prodrugs to improve patient acceptability, Drug solubility, Drug absorption and distribution, site specific drug delivery and sustained drug action. Rationale of prodrug design and practical consideration of prodrug design.

b) Combating drug resistance: Causes for drug resistance, strategies to combat drug resistance in antibiotics and anticancer therapy, Genetic principles of drug resistance.

c) Analog Design: Introduction, Classical & Non classical, Bioisosteric replacement strategies, rigid analogs, alteration of chain branching, changes in ring size, ring position isomers, design of stereo isomers and geometric isomers, fragments of a lead molecule, variation in inter atomic distance.

### Unit 3 (12 Hrs.)

Medicinal chemistry aspects of the following class of drugs Systematic study, SAR, Mechanism of action and synthesis of new generation molecules of following class of drugs:

a) Anti-hypertensive drugs, Psychoactive drugs, Anticonvulsant drugs, H1 & H2 receptor antagonist, COX1 & COX2 inhibitors, Adrenergic & Cholinergic agents, Antineoplastic and Antiviral agents.

b) Stereochemistry and Drug action: Realization that stereo selectivity is a pre-requisite for evolution. Role of chirality in selective and specific therapeutic agents. Case studies, Enantio selectivity in drug adsorption, metabolism, distribution and elimination.

### Unit 4 (12 Hrs.)

Rational Design of Enzyme Inhibitors Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzyme inhibitors in basic research, rational design of non-covalently and covalently binding enzyme inhibitors.

### Unit 5 (12 Hrs.)

Peptidomimetics: Therapeutic values of Peptidomimetics, design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally. Chemistry of prostaglandins, leukotrienes and thromboxones.

### REFERENCES

- 1 Medicinal Chemistry by Burger, Vol I –VI.
- 2 Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, 12th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
- 3 Comprehensive Medicinal Chemistry – Corwin and Hansch.
- 4 Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore
- 5 Introduction to Quantitative Drug Design by Y.C. Martin.
- 6 Principles of Medicinal Chemistry by William Foye, 7th Edition, Ippincott Williams & Wilkins, Woltess Kluwer (India) Pvt.Ltd, New Delhi.
- 7 Drug Design Volumes by Arienes, Academic Press, Elsevier Publishers, Noida, Uttar Pradesh
- 8 Principles of Drug Design by Smith.
- 9 The Organic Chemistry of the Drug Design and Drug action by Richard B.Silverman, II Edition, Elsevier Publishers, New Delhi
- 10 An Introduction to Medicinal Chemistry, Graham L.Patrick, III Edition, Oxford University Press, USA
- 11 Biopharmaceutics and pharmacokinetics, DM.Brahmankar, Sunil B. Jaiswal II Edition, 2014, Vallabh Prakashan, New Delhi.
- 12 Peptidomimetics in Organic and Medicinal Chemistry by Antonio Guarna and Andrea Trabocchi, First edition, Wiley publishers.

**MPC 104 T: CHEMISTRY OF NATURAL PRODUCTS****Course of study**

Course code	Credit hours	Credit points	Hrs./week	Teaching Hrs/semester	Marks
MPC 104 T	<b>4</b>	<b>4</b>	<b>4</b>	<b>60</b>	<b>100</b>

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment				End semester exams		Total Marks
	Continuous mode	Sessional Exams.		Total	Marks	Duration	
		Marks	Duration				
MPC 104 T	<b>10</b>	<b>15</b>	<b>1 Hr</b>	<b>25</b>	<b>75</b>	<b>3Hrs</b>	<b>100</b>

**Scope**

The subject is designed to provide detail knowledge about chemistry of medicinal compounds from natural origin and general methods of structural elucidation of such compounds. It also emphasizes on isolation, purification and characterization of medicinal compounds from natural origin.

**.Objectives**

At completion of this course it is expected that students will be able to understand-

- Different types of natural compounds and their chemistry and medicinal importance
- The importance of natural compounds as lead molecules for new drug discovery
- The concept of rDNA technology tool for new drug discovery
- General methods of structural elucidation of compounds of natural origin
- Isolation, purification and characterization of simple chemical constituents from natural source

**Unit 1 (12 Hrs.)**

Study of Natural products as leads for new pharmaceuticals for the following class of drugs

- a) Drugs Affecting the Central Nervous System: Morphine Alkaloids
- b) Anticancer Drugs: Paclitaxel and Docetaxel, Etoposide, and Teniposide
- c) Cardiovascular Drugs: Lovastatin, Teprotide and Dicoumarol
- d) Neuromuscular Blocking Drugs: Curare alkaloids
- e) Anti-malarial drugs and Analogues
- f) Chemistry of macrolide antibiotics (Erythromycin, Azithromycin, Roxithromycin, and Clarithromycin) and  $\beta$  - Lactam antibiotics (Cephalosporins and Carbapenem)

**Unit 2 (12 Hrs.)**

Alkaloids: General introduction, classification, isolation, purification, molecular modification and biological activity of alkaloids, general methods of structural determination of alkaloids, structural elucidation and stereochemistry of ephedrine, morphine, ergot, emetine and reserpine.

Flavonoids : Introduction, isolation and purification of flavonoids, General methods of structural determination of flavonoids; Structural elucidation of quercetin.

Steroids: General introduction, chemistry of sterols, sapogenin and cardiac glycosides. Stereochemistry and nomenclature of steroids, chemistry of contraceptive agents, male & female sex hormones (Testosterone, Estradiol, Progesterone), adrenocorticoids (Cortisone), contraceptive

agents and steroids (Vit.-D).

### Unit 3 (12 Hrs.)

a. Terpenoids : Classification, isolation, isoprene rule and general methods of structural elucidation of Terpenoids; Structural elucidation of drugs belonging to mono (citral, menthol, camphor), di (retinol, Phytol, taxol) and tri terpenoids (Squalene, Ginsenoside) carotenoids ( $\beta$  carotene).

b. Vitamins : Chemistry and Physiological significance of Vitamin A, B1, B2, B12, C, E, Folic acid and Niacin.

### Unit 4 (12 Hrs.)

a. Recombinant DNA technology and drug discovery rDNA technology, hybridoma technology, New pharmaceuticals derived from biotechnology; Oligonucleotide therapy. Gene therapy: Introduction, Clinical application and recent advances in gene therapy, principles of RNA & DNA estimation.

b. Active constituent of certain crude drugs used in Indigenous system Diabetic therapy- *Gymnema sylvestre*, *Salacia reticulata*, *Pterocarpus marsupium*, *Swertia chirata*, *Trigonella foenum graecum*; Liver dysfunction-*Phyllanthus niruri*; Antitumor-*Curcuma longa* Linn.

### Unit 5 (12 Hrs.)

Structural Characterization of natural compounds : Structural characterization of natural compounds using IR, <sup>1</sup>HNMR, <sup>13</sup>CNMR and MS Spectroscopy of specific drugs e.g., Penicillin, Morphine, Camphor, Vit-D, Quercetin and Digitalisglycosides.

## REFERENCES

- 1 Modern Methods of Plant Analysis, Peech and M.V.Tracey, Springer-Verlag, Berlin, Heidelberg.
- 2 Phytochemistry Vol. I and II by Miller, Jan Nostrand Rein Hld.
- 3 Recent advances in Phytochemistry Vol. I to IV – Scikel Runeckles, Springer Science & Business Media
- 4 Chemistry of natural products Vol I onwards IWPAC
- 5 Natural Product Chemistry Nakanishi Gggolo, University Science Books, California.
- 6 Natural Product Chemistry “A laboratory guide” – Rapheal Khan.
- 7 The Alkaloid Chemistry and Physiology by RHF Manske, Academic Press.
- 8 Introduction to molecular Phytochemistry – CHJ Wells, Chapmanstall.
- 9 Organic Chemistry of Natural Products Vol I and II by Gurdeep and Chatwall, Himalaya Publishing House.
- 10 Organic Chemistry of Natural Products Vol I and II by O.P. Agarwal, Krishan Prakashan.
- 11 Organic Chemistry Vol I and II by I.L. Finar, Pearson education.
- 12 Elements of Biotechnology by P.K. Gupta, Rastogi Publishers.
- 13 Pharmaceutical Biotechnology by S.P.Vyas and V.K.Dixit, CBS Publishers.
- 14 Biotechnology by Purohit and Mathur, Agro-Bios, 13th edition
- 15 Phytochemical methods of Harborne, Springer, Netherlands.
- 16 Burger’s Medicinal Chemistry

**MPC 105 P: PHARMACEUTICAL CHEMISTRY PRACTICAL I**

**Course of study**

Course code	Credit hours	Credit points	Hrs./week	Marks
MPC 105 P	<b>12</b>	<b>6</b>	<b>12</b>	<b>150</b>

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment				End semester exams		Total Marks
	Continuous mode	Sessional Exams.		Total	Marks	Duration	
		Marks	Duration				
MPC 105 P	<b>20</b>	<b>30</b>	<b>6Hr</b>	<b>50</b>	<b>100</b>	<b>6Hrs</b>	<b>150</b>

1. Analysis of Pharmacopoeial compounds and their formulations by UV Vis spectrophotometer, RNA & DNA estimation.
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
3. Experiments based on Column chromatography
4. Experiments based on HPLC
5. Experiments based on Gas Chromatography
6. Estimation of riboflavin/quinine sulphate by fluorimetry
7. Estimation of sodium/potassium by flame photometry

**To perform the following reactions of synthetic importance**

1. Purification of organic solvents, column chromatography
2. Claisen-schmidt reaction.
3. Benzylic acid rearrangement.
4. Beckmann rearrangement.
5. Hoffmann rearrangement
6. Mannich reaction
7. Synthesis of medicinally important compounds involving more than one step along with purification and Characterization using TLC, melting point and IR spectroscopy (4 experiments)
8. Estimation of elements and functional groups in organic natural compounds
9. Isolation, characterization like melting point, mixed melting point, molecular weight determination, functional group analysis, co-chromatographic technique for identification of isolated compounds and interpretation of UV and IR data.
10. Some typical degradation reactions to be carried on selected plant constituents.

**SEMINAR/ASSIGNMENTS**

**Course of study**

Course code	Credit hours	Credit points	Hrs./week	Marks
-	7	4	7	100

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment			End semester exams		Total Marks	
	Continuous mode	Sessional Exams.		Total	Marks		Duration
		Marks	Duration				
-	-	-	-	-	-	100	

M. PHARM. PHARMACEUTICAL CHEMISTRY (MPC)

SECOND SEMESTER

Table 1: Course of study

Course code	Course	Credit hours	Credit points	Hrs./week	Marks
MPC 201 T	Advanced Spectral Analysis	4	4	4	100
MPC 202 T	Advanced Organic Chemistry-II	4	4	4	100
MPC 203 T	Computer Aided Drug Design	4	4	4	100
MPC 204 T	Pharmaceutical Process Chemistry	4	4	4	100
MPC 205 P	Pharmaceutical Chemistry Practical II	12	6	12	150
	Seminar/Assignment	7	4	7	100
	<b>Total</b>	<b>35</b>	<b>26</b>	<b>35</b>	<b>650</b>

Table 2: Scheme for Internal Assessments and end semester examinations

Course code	Course	Internal Assessment				End semester exams		Total Marks	
		Continuous mode	Sessional Exams.		Total	Marks	Duration		
			Marks	Duration					
MPC 201 T	Advanced Spectral Analysis	10	15	1 Hr	25	75	3Hrs	100	
MPC 202 T	Advanced Organic Chemistry-II	10	15	1 Hr	25	75	3Hrs	100	
MPC 203 T	Computer Aided Drug Design	10	15	1 Hr	25	75	3Hrs	100	
MPC 204 T	Pharmaceutical Process Chemistry	10	15	1 Hr	25	75	3Hrs	100	
MPC 205 P	Pharmaceutical Chemistry Practical II	20	30	6 Hr	50	100	6Hrs	150	
-	Seminar/Assignment	-	-	-	-	-		100	
		<b>Total</b>							<b>650</b>

**ADVANCED SPECTRAL ANALYSIS**  
**(MPC 201T)**

**Course of study**

Course code	Credit hours	Credit points	Hrs./week	Teaching Hrs/semester	Marks
MPC 201 T	<b>4</b>	<b>4</b>	<b>4</b>	<b>60</b>	<b>100</b>

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment			End semester exams		Total Marks	
	Continuous mode	Sessional Exams.		Total	Marks		Duration
		Marks	Duration				
MPC 201 T	<b>10</b>	<b>15</b>	<b>1 Hr</b>	<b>25</b>	<b>75</b>	<b>3Hrs</b>	<b>100</b>

**Scope**

This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are LC-MS, GC-MS, ATR-IR, DSC etc.

**Objectives**

At completion of this course it is expected that students will be able to understand-

1. Interpretation of the NMR, Mass and IR spectra of various organic compounds
2. Theoretical and practical skills of the hyphenated instruments
3. Identification of organic compounds

**Unit I (12 Hrs)**

UV and IR spectroscopy: Woodward – Fieser rule for 1,3-butadienes, cyclic dienes and  $\alpha,\beta$ -carbonyl compounds and interpretation compounds of enones. ATR-IR, IR Interpretation of organic compounds.

**Unit II (12 Hrs)**

NMR spectroscopy: 1-D and 2-D NMR, NOESY and COSY, HECTOR, INADEQUATE techniques, Interpretation of organic compounds.



### Unit III (12 Hrs)

Mass Spectroscopy :Mass fragmentation and its rules, Fragmentation of important functional groups like alcohols, amines, carbonyl groups and alkanes, Meta stable ions, Mc Lafferty rearrangement, Ring rule, Isotopic peaks, Interpretation of organic compounds.

### Unit IV (12 Hrs)

Chromatography: Principle, Instrumentation and Applications of the following :

- a) GC-MS b) GC-AAS c) LC-MS d) LC-FTIR e) LC-NMR f) CEMS
- g) High Performance Thin Layer chromatography h) Super critical fluid chromatography i) Ion Chromatography j) I-EC (Ion- Exclusion Chromatography) k) Flash chromatography

### Unit V (12 Hrs)

- a). Thermal methods of analysis Introduction, principle, instrumentation and application of DSC, DTA and TGA.
  - b). Raman Spectroscopy Introduction, Principle, Instrumentation and Applications.
  - c). Radio immuno assay
- Biological standardization , bioassay, ELISA, Radioimmunoassay of digitalis and insulin.

### REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein, Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.
5. Quantitative analysis of Pharmaceutical formulations by HPTLC - P D Sethi, CBS Publishers, New Delhi.
6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series

## ADVANCED ORGANIC CHEMISTRY – II (MPC 202T)

### Course of study

Course code	Credit hours	Credit points	Hrs./week	Teaching Hrs/semester	Marks
MPC 202 T	4	4	4	60	100

### Scheme for Internal Assessments and end semester examinations

Course code	Internal Assessment			End semester exams		Total Marks	
	Continuous mode	Sessional Exams.		Total	Marks		Duration
		Marks	Duration				
MPC 202 T	10	15	1 Hr	25	75	3Hrs	100

### Scope

The subject is designed to provide in-depth knowledge about advances in organic chemistry, different techniques of organic synthesis and their applications to process chemistry as well as drug discovery.

### Objectives

Upon completion of course, the student shall able to understand

1. The principles and applications of Green chemistry
2. The concept of peptide chemistry.
3. The various catalysts used in organic reactions
4. The concept of stereochemistry and asymmetric synthesis.

### Unit I (12 Hrs)

Green Chemistry:

- a. Introduction, principles of green chemistry
- b. Microwave assisted reactions: Merit and demerits of its use, increased reaction rates, mechanism, superheating effects of microwave, effects of solvents in microwave assisted synthesis, microwave technology in process optimization, its applications in various organic reactions and heterocycles synthesis
- c. Ultrasound assisted reactions: Types of sonochemical reactions, homogenous, heterogeneous liquid-liquid and liquid-solid reactions, synthetic applications
- d. Continuous flow reactors: Working principle, advantages and synthetic applications.

### Unit II (12 Hrs)

Chemistry of peptides

- a. Coupling reactions in peptide synthesis
- b. Principles of solid phase peptide synthesis, t-BOC and Fmoc protocols, various solid supports and linkers: Activation procedures, peptide bond formation, deprotection and cleavage from resin, low and high HF cleavage protocols, formation of free peptides and peptide amides, purification and case studies, site-specific chemical modifications of peptides
- c. Segment and sequential strategies for solution phase peptide synthesis with any two case studies
- d. Side reactions in peptide synthesis: Deletion peptides, side reactions initiated by proton abstraction, protonation, overactivation and side reactions of individual amino acids.

### Unit III (12 Hrs)

Photochemical Reactions Basic principles of photochemical reactions. Photo-oxidation, photo-addition and photo-fragmentation. Pericyclic reactions Mechanism, Types of pericyclic reactions such as cyclo addition, electrocyclic reaction and sigmatropic rearrangement reactions with examples

### Unit IV (12 Hrs)

Catalysis:

- a. Types of catalysis, heterogeneous and homogeneous catalysis, advantages and disadvantages
- b. Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
- c. Homogeneous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogeneous catalysis used in synthesis of drugs
- d. Transition-metal and Organo-catalysis in organic synthesis: Metal-catalyzed reactions
- e. Biocatalysis: Use of enzymes in organic synthesis, immobilized enzymes/cells in organic reaction.
- f. Phase transfer catalysis - theory and applications

### Unit V (12 Hrs)

#### Stereochemistry & Asymmetric Synthesis

- a. Basic concepts in stereochemistry – optical activity, specific rotation, racemates and resolution of racemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudo asymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Z notation.
- b. Methods of asymmetric synthesis using chiral pool, chiral auxiliaries and catalytic asymmetric synthesis, enantiopure separation and Stereo selective synthesis with examples.

#### REFERENCES

1. “Advanced Organic chemistry, Reaction, mechanisms and structure”, J March, John Wiley and sons, New York.
2. “Mechanism and structure in organic chemistry”, ES Gould, Hold Rinchart and Winston, New York.
3. “Organic Chemistry” Clayden, Greeves, Warren and Wothers., Oxford University Press 2001.
4. “Organic Chemistry” Vol I and II. I.L. Finar. ELBS, Sixth ed., 1995.
5. Carey, Organic chemistry, 5th edition (Viva Books Pvt. Ltd.)
6. Organic synthesis-the disconnection approach, S. Warren, Wiley India
7. Principles of organic synthesis, ROC Norman and JMCoxan, Nelson thorns
8. Organic synthesis- Special techniques VK Ahluwalia and R Aggarwal, Narosa Publishers.
9. Organic reaction mechanisms IV edtn, VK Ahluwalia and RK Parashar Narosa Publishers.

**COMPUTER AIDED DRUG DESIGN**  
**(MPC 203T)**

**Course of study**

Course code	Credit hours	Credit points	Hrs./week	Teaching Hrs/semester	Marks
MPC 203 T	4	4	4	60	100

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment			End semester exams		Total Marks	
	Continuous mode	Sessional Exams.		Total	Marks		Duratio
		Marks	Duration				
MPC 203 T	10	15	1 Hr	25	75	3Hrs	100

**Scope**

The subject is designed to impart knowledge on the current state of the art techniques involved in computer assisted drug design.

**Objectives**

At completion of this course it is expected that students will be able to understand

1. Role of CADD in drug discovery
2. Different CADD techniques and their applications
3. Various strategies to design and develop new drug like molecules.
4. Working with molecular modeling softwares to design new drug molecules
5. The in silico virtual screening protocols

**Unit I (12 Hrs)**

Introduction to Computer Aided Drug Design (CADD) History, different techniques and applications. Quantitative Structure Activity Relationships: Basics History and development of QSAR: Physicochemical parameters and methods to calculate physicochemical parameters: Hammett equation and electronic parameters ( $\sigma$ ), lipophilicity effects and parameters ( $\log P$ ,  $\pi$ -substituent constant), steric effects (Taft steric and MR parameters) Experimental and theoretical approaches for the determination of these physicochemical parameters.

### **Unit II (12 Hrs)**

Quantitative Structure Activity Relationships: Applications Hansch analysis, Free Wilson analysis and relationship between them, Advantages and disadvantages; Deriving 2D-QSAR equations. 3D-QSAR approaches and contour map analysis. Statistical methods used in QSAR analysis and importance of statistical parameters.

### **Unit III (12 Hrs)**

Molecular Modeling and Docking

- a) Molecular and Quantum Mechanics in drug design.
- b) Energy Minimization Methods: comparison between global minimum conformation and bioactive conformation
- c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Agents acting on enzymes such as DHFR, HMG-CoA reductase and HIV protease, choline esterase ( AchE & BchE)

### **Unit IV (12 Hrs)**

Molecular Properties and Drug Design

- a) Prediction and analysis of ADMET properties of new molecules and its importance in drug design.
- b) De novo drug design: Receptor/enzyme-interaction and its analysis, Receptor/enzyme cavity size prediction, predicting the functional components of cavities, Fragment based drug design.
- c) Homology modeling and generation of 3D-structure of protein.

### **Unit V (12 Hrs)**

Pharmacophore Mapping and Virtual Screening Concept of pharmacophore, pharmacophore mapping, identification of Pharmacophore features and Pharmacophore modeling; Conformational search used in pharmacophore mapping.

In Silico Drug Design and Virtual Screening Techniques Similarity based methods and Pharmacophore based screening, structure based In-silico virtual screening protocols.

### **REFERENCES**

1. Computational and structural approaches to drug discovery, Robert M Stroud and Janet. F Moore, RCS Publishers.

2. Introduction to Quantitative Drug Design by Y.C. Martin, CRC Press, Taylor & Francis group.
3. Drug Design by Ariens Volume 1 to 10, Academic Press, 1975, Elsevier Publishers.
4. Principles of Drug Design by Smith and Williams, CRC Press, Taylor & Francis.
5. The Organic Chemistry of the Drug Design and Drug action by Richard B. Silverman, Elsevier Publishers.
6. Medicinal Chemistry by Burger, Wiley Publishing Co.
7. An Introduction to Medicinal Chemistry –Graham L. Patrick, Oxford University Press.
8. Wilson and Gisvold's Text book of Organic Medicinal and Pharmaceutical Chemistry, Ippincott Williams & Wilkins.
9. Comprehensive Medicinal Chemistry – Corwin and Hansch, Pergamon Publishers.
10. Computational and structural approaches to drug design edited by Robert M Stroud and Janet. F Moore

**PHARMACEUTICAL PROCESS CHEMISTRY**  
**(MPC 204T)**

**Course of study**

Course code	Credit hours	Credit points	Hrs./week	Teaching Hrs/semester	Marks
MPC 204 T	<b>4</b>	<b>4</b>	<b>4</b>	<b>60</b>	<b>100</b>

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment				End semester exams		Total Marks
	Continuous mode	Sessional Exams.		Total	Marks	Duration	
		Marks	Duration				
MPC 204 T	<b>10</b>	<b>15</b>	<b>1 Hr</b>	<b>25</b>	<b>75</b>	<b>3Hrs</b>	<b>100</b>

**Scope**

Process chemistry is often described as scale up reactions, taking them from small quantities created in the research lab to the larger quantities that are needed for further testing and then to even larger quantities required for commercial production. The goal of a process chemist is to develop synthetic routes that are safe, cost-effective, environmentally friendly, and efficient. The subject is designed to impart knowledge on the development and optimization of a synthetic route/s and the pilot plant procedure for the manufacture of Active Pharmaceutical Ingredients (APIs) and new chemical entities (NCEs) for the drug development phase.

**Objectives**

At completion of this course it is expected that students will be able to understand

1. The strategies of scale up process of APIs and intermediates
2. The various unit operations and various reactions in process chemistry

**Unit I (12 Hrs)**

Process chemistry : Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities.

**Unit II (12 Hrs)**



#### Unit operations

- a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction.
- b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration,
- c) Distillation: azeotropic and steam distillation
- d) Evaporation: Types of evaporators, factors affecting evaporation.
- e) Crystallization: Crystallization from aqueous, nonaqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

### **Unit III (12 Hrs)**

#### Unit Processes- I

- a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration,
- b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
- c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H<sub>2</sub>O<sub>2</sub>, sodium hypochlorite, Oxygen gas, ozonolysis.

### **Unit IV (12 Hrs)**

#### Unit Processes - II

- a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process.
- b) Fermentation: Aerobic and anaerobic fermentation. Production of
  - i. Antibiotics; Penicillin and Streptomycin,
  - ii. Vitamins: B<sub>2</sub> and B<sub>12</sub>
  - iii. Statins: Lovastatin, Simvastatin
- c) Reaction progress kinetic analysis
  - i. Streamlining reaction steps, route selection,
  - ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

### Unit V (12 Hrs)

#### Industrial Safety

- a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE)
- b) Fire hazards, types of fire & fire extinguishers
- c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO 14001(Environmental Management System), Effluents and its management

#### REFERENCES

1. Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate-An Overview; K. Gadamasetti, CRC Press.
2. Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
3. Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
4. W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7<sup>th</sup> edition, McGraw Hill
5. Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
6. Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
7. Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis Rethinking the Routes to Scale-Up
8. P.H.Groggins: Unit processes in organic synthesis (MGH)
9. F.A.Henglein: Chemical Technology (Pergamon)
10. M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
11. Clausen, Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
12. Lowenheim & M.K. Moran: Industrial Chemicals
13. S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
14. J.K. Stille: Industrial Organic Chemistry (PH)
15. Shreve: Chemical Process, Mc Grawhill.
16. B.K.Sharma: Industrial Chemistry, Goel Publishing House
17. ICH Guidelines
18. United States Food and Drug Administration official website [www.fda.gov](http://www.fda.gov)

**PHARMACEUTICAL CHEMISTRY PRACTICALS – II**  
**(MPC 205P)**

**Course of study**

Course code	Credit hours	Credit points	Hrs./week	Marks
MPC 205 P	<b>12</b>	<b>6</b>	<b>12</b>	<b>150</b>

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment			End semester exams		Total Marks	
	Continuous mode	Sessional Exams.		Marks	Duration		
		Marks	Duration				
MPC 205 P	<b>20</b>	<b>30</b>	<b>6Hr</b>	<b>50</b>	<b>100</b>	<b>6Hrs</b>	<b>150</b>

1. Synthesis of organic compounds by adapting different approaches involving (3 experiments)
  - a) Oxidation
  - b) Reduction/hydrogenation
  - c) Nitration
2. Comparative study of synthesis of APIs/intermediates by different synthetic routes (2 experiments)
3. Assignments on regulatory requirements in API (2 experiments)
4. Comparison of absorption spectra by UV and Wood ward – Fieser rule
5. Interpretation of organic compounds by FT-IR
6. Interpretation of organic compounds by NMR
7. Interpretation of organic compounds by MS
8. Determination of purity by DSC in pharmaceuticals
9. Identification of organic compounds using FT-IR, NMR, CNMR and Mass spectra
10. To carry out the preparation of following organic compounds
11. Preparation of 4-chlorobenzhydrylpiperazine. (an intermediate for cetirizine HCl).
12. Preparation of 4-iodotoluene from p-toluidine.
13. NaBH<sub>4</sub> reduction of vanillin to vanillyl alcohol
14. Preparation of umbelliferone by Pechhman reaction
15. Preparation of triphenyl imidazole
16. To perform the Microwave irradiated reactions of synthetic importance (Any two)

17. Determination of log P, MR, hydrogen bond donors and acceptors of selected drugs using softwares
18. Calculation of ADMET properties of drug molecules and its analysis using softwares  
Pharmacophore modeling
19. 2D-QSAR based experiments
20. 3D-QSAR based experiments
21. Docking study based experiment
22. Virtual screening based experiment

**SEMINAR/ASSIGNMENTS**

**Course of study**

Course code	Credit hours	Credit points	Hrs./week	Marks
-	7	4	7	100

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment			End semester exams		Total Marks
	Continuous mode	Sessional Exams.		Marks	Duration	
		Marks	Duration			
-	-	-	-	-	-	100

**M. PHARM.-PHARMACEUTICAL CHEMISTRY (MPC)  
. THIRD SEMESTER**

**Table 1 : Course of study**

Course code	Course	Credit hours	Credit points
MRM 301 T	Research Methodology and Biostatistics*	4	4
-	Journal Club	1	1
-	Research Work	28	14
-	Discussion/Presentation (Proposal Presentation)	2	2
	<b>Total</b>	<b>35</b>	<b>21</b>

\* Non-University Examination

**Table 2 : Scheme for Internal Assessments and end semester examinations**

Course code	Course	Internal Assessment				End semester exams		Total Marks	
		Continuous mode	Sessional Exams.		Total	Marks	Duration		
			Marks	Duration					
MRM 301T	Research Methodology and Biostatistics*	10	15	1 Hr	25	75	3Hrs	100	
-	Journal Club	-	-	-	25	-	-	25	
-	Research Work	-	-	-	50	350	1Hr	350	
-	Discussion/Presentation (Proposal Presentation)	-	-	-	50	-	-	50	
		<b>Total</b>							<b>525</b>

\* Non-University Examination

**MPC 301 T: Research Methodology & Biostatistics**

**Course of study**

Course code	Credit hours	Credit points	Hrs./week	Teaching Hrs/semester	Marks
MPC 301 T	4	4	4	-	100

**Scheme for Internal Assessments and end semester examinations**

Course code	Internal Assessment				End semester exams		Total Marks
	Continuous mode	Sessional Exams.		Total	Marks	Duration	
		Marks	Duration				
MPC 301 T	10	15	1 Hr	25	75	3Hrs	100

**Unit 1**

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

**Unit 2**

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests (students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxon rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

**Unit 3**

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality

**Unit 4**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals

**Unit 5**

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.

**M. PHARM. PHARMACEUTICAL CHEMISTRY (MPC)**

**FOURTH SEMESTER**

**Table 1 : Course of study**

Course code	Course	Credit hours	Credit points
-	Journal Club	1	1
-	Research Work	31	16
-	Discussion/ Final Presentation	3	3
	<b>Total</b>	<b>35</b>	<b>20</b>

**Table 2 : Scheme for Internal Assessments and end semester examinations**

**SEMESTER IV**

Course code	Course	Internal Assessment			End semester exams		Total Marks	
		Continuous mode	Sessional Exams.		Total	Marks		Duration
			Marks	Duration				
-	Journal Club	-	-	-	25	-	-	25
-	Research Work and Colloquium	-	-	-	-	400	1Hr	400
-	Discussion/ Final Presentation	-	-	-	75	-	-	75
-		<b>Total</b>						<b>500</b>



**DEVI AHILYA  
VISHWAVIDYALAYA, INDORE  
SCHOOL OF PHARMACY**

**M.PHARM.  
SYLLABUS**

**(Choice Based Credit System)**

**w.e.f academic session 2015-16**



**M.Pharm I sem**

**PYM-PC 701T Modern Analytical Techniques-I**

**Credits: 4, Contact Hrs: 4**

**Unit I: Analytical method development and Validation**

Physicochemical properties of drugs and solvents in relation to analytical method development

Preparation of drug samples for analysis: Pharmaceutical solids, Pharmaceutical liquids, biological samples ~~blood samples, urine samples, fecal samples.~~ 7

Fundamental theories controlling preparation techniques, ~~Validation,~~ 7 Specific

Sample preparation techniques: Soxhlet extraction, liquid-liquid extraction, Solid-Phase extraction, Column-Switching techniques, Solid phase micro extraction, Protein Precipitation methods, Ultrafiltration, Dialysis, Other methods to study protein binding, sample preparation of drug conjugates, direct-injection techniques for plasma samples, Derivatization techniques, Residual-solvent sample preparation for gas chromatography, ~~Sample preparation for Capillary electrophoresis,~~ 7 Calibration methods.

~~ICH Q2A and Q2B~~ 7 Guidelines for Validation of analytical methods.

**Unit II: UV-Spectroscopy and FT-IR Spectroscopy**

(A) Woodward-Fischer rule

Multi-component analysis by UV spectroscopy (Simultaneous equation, Absorbance ratio, Dual wave length, Area under Curve, Derivative spectroscopy, Geometric corrections, Orthogonal Polynomial, Difference spectroscopy, Chemical derivatization)

Optimum conditions for Spectrophotometric Measurement

Structural Analysis

(B) Basics of FT-IR, Recent advances in instrumentation and sample handling, Factors affecting vibrational frequency in IR (Fundamental, degenerate, overtone,

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combination bands, coupled vibrations, Fermi resonance), Interpretation of IR spectrum, Characteristic group frequencies of organic molecules: Hydrocarbons, Ethers, Alcohols and Phenols, Aldehydes, Ketones, Carboxylic acids and their derivatives, Amines, Nitriles, Organic Sulphur compounds, Compounds containing sulphur-oxygen bonds, Organic halogen compounds.

**Unit III: Chromatography:** Basic principle: Chromatographic behaviour of solutes (retention behavior, partition coefficient, partition ratio, relative retention), column efficiency and resolution (plate number and plate height, band asymmetry, resolution), Column processes and band broadening (eddy diffusion, longitudinal diffusion, mass transfer), time of analysis and resolution, quantitative determinations (peak area integration, evaluation methods)

**Unit IV: HPLC:** Measurement of column performance, recent advances in instrumentation, Mobile phase: Characteristics, NP and RP mobile phase, selection and optimization of mobile phase), different types of column and their application, pre and guard column, selection of solvent for analyte, modes of HPLC, selection criterion for detectors and selection of suitable wavelength in UV and PDA detector, strategy for the development of HPLC method for Ionic and non ionic compounds, extra column effect, common HPLC trouble shooting.

**Unit V: Gas Chromatography:** Instrumentation of GLC: Carrier gas, sample injection systems, column, tubing, gas chromatographic detectors (TCD, FID, ECS FPD, etc) recorders, integrators and computers. Column selection and column efficiency: solid support, open tubular column, liquid phases. Effect of Temperature and flow rate. Optimization of experimental conditions.

GSC: Adsorbent, multicolumn system.

Qualitative analysis, quantitative analysis, peak area determination, peak height determination, relative precision of peak size measurement techniques, Pharmaceutical applications.

**Unit VI: TLC and HPTLC:** Criterion for identification of an analyte, Method development (Plates; handmade and pre coated plates, plate size, sequential steps, selection of solvent, mobile phase and stationary phase), Common detectors and visualizing agents.

### Books Recommended:

1. Spectroscopy – D. L. Pavia, G.M. Lampman, G. S. Kriz, J.A. Vyvyan
2. Organic spectroscopy - William Kemp
3. Spectroscopic Methods in Organic Chemistry – D. H. Williams & I. Fleming
4. Spectrometric Identification of Organic Compounds - R. M. Silverstein, F. X. Webster, D. J. Kiemie
5. Fundamentals of Molecular Spectroscopy – C.N. Banwell & E.M. McCash
6. Textbook of Pharmaceutical Analysis- A. Connors
7. Instrumental methods of analysis- H.H. Willard, L. L. Merrit, J. A. Dean & F. A. Settle
8. Instrumental methods of Chemical Analysis – E. W. Ewing
9. Pharmaceutical analysis, Modern methods part A & B - Munson, J. W. (Ed.)
10. Fundamentals of analytical chemistry- D. A. Skoog, D. M. West, F. J. Holler
11. Handbook of Pharmaceutical Analysis - L. Ohannesian and A.J. Streeter (Eds.)
12. Principles and Practice of Bioanalysis - R.F.Venn (Ed.).

### PYM-PC 703T Impurity profiling and Stability studies

**Credits: 4, Contact Hrs: 4**

**Unit I: Introduction:** Definition, Classification of impurities in pharmaceutical products, origin of impurities, types of impurities: process impurities, degradation impurities, and contamination impurities. Nature of impurities: organic, inorganic, and residual solvent impurities. Differences between impurities and degradation products. Impurity-drug interaction.

**Toxicological perspectives of impurities in pharmaceutical products:** Classes of genotoxic impurity, analytical challenge of genetic toxins, determination of genotoxic impurities.

**Unit II: Impurity identification, structure elucidation and synthesis:** Introduction of systematic approaches for isolation, identification, and structure elucidation of unknown impurities. Synthesis, purification, standardization, and quantification of impurities of active drug substances. Designing and optimization of different routes for synthesis of impurities. Case studies for impurity identification and

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structure elucidation.

**Unit III: Regulatory requirements of impurity profiling:** ICH guidelines, EMEA guideline, PhRMA approach, USFDA guidance, European pharmacopoeial guidance, Guidance for oncology products, Identification, qualification, and quantification threshold of impurities, Regulatory perspective of impurities for different New Drug Applications (NDA). Pharmacopoeial limits of impurities in drug substance and drug products. Setting of limits for impurities in drug products.

**Unit IV: Stability of drugs and drug products:** Introduction, regulatory Standards for drug stability, Drug decomposition mechanisms: (i) Hydrolysis and acyltransfers (ii) Oxidation (iii) Photolysis, Solid state chemical decomposition: Pure drugs, drug excipient and drug-drug interaction in solid state, Factors affecting drug degradation and methods of stabilization.

**Unit V: The kinetics of drug degradation :** Overview of kinetic concepts , Order of reaction First, second and pseudo orders. , and their applications in predicting shelf life and half life of pharmaceutical formulations, Complex order kinetics, Interpretation of kinetic data

**Stability prediction:** Applications of Arrhenius theory for stability prediction, activation energy calculation and its application in shelf life prediction, Q10 value calculation. Shelf life determination, calculation of overages.

**Unit VI: Stability studies:** Basic concept and objectives of stability study, Importance of accelerated stability study.

**Statistical and regulatory aspect of drug stability studies:** Current regulations and guidance, ICH and WHO stability guidelines, Protocols for stress testing program of a drug substances and drug product. Photostability testing conditions and procedures. Matrixing and bracketing designs for stability studies. Postapproval FDA stability requirements.

**Physical stability testing:** Requirement, study parameters, and applications of physical stability testing for tablets, dispersed systems, semisolids and liquid dosage forms. Preservatives stability studies, Pharmacopoeial methods, acceptance criteria.

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### Books Recommended:

1. Analysis of drug impurities - R. J. Smith, M. L. Webb.
2. ICH harmonized tripartite guideline, Impurities in new drug products Q3B(R2)
3. ICH harmonized tripartite guideline, Impurities: guideline for residual solvents Q3C(R3)
4. USFDA, Guidance for Industry ANDAs: Impurities in drug products.
5. USFDA, Guidance for Industry ANDAs: Impurities in drug substances.
6. Modern pharmaceuticals- G. S. Banker, J. Siepmann, C. Rhodes
7. Handbook of stability testing in pharmaceutical development: regulations, methodologies, and best practices - Kim Huynh-Ba
8. United States Pharmacopoeia.
9. *Remington's pharmaceutical sciences.*
10. Drug stability: Principles and practices – J. T. Carstensen.
11. Pharmaceutical Dosage Form: Tablets (Vol I,II & III )-L. Lachman, H.H. Lieberman, J.B. Schwartz
12. Theory and Practice of Industrial Pharmacy - L. Lachman, H.A. Lieberman, J. L. Kanig
13. Stability Testing of Drug Products - W.Grimm.
14. Physical Pharmacy - A. Martin
15. Stability of Drugs and Dosage Forms – S. Yoshioka and V.J. Stella.
16. *Q1 Stability*, ICH Guidelines.
17. *International stability testing*- D. J. Mazzo

### PYM-PC 705T Medicinal Chemistry (Drug Discovery and Development) Credits: 4, Contact Hrs: 4

- Unit-I** Overview of historical perspectives of drug discovery, detailed study of strategies and steps involved drug discovery, basic principles and methods, drug targets, finding a lead, structure-activity relationship and optimization.
- Unit-II** Physico-chemical properties (lipophilicity, pka, solubility, membrane permeation, blood-brain barrier permeability, drug-likeness: Lipinski rule, verber rule) pharmacokinetic, hERG toxicity basis for drug discovery, structural aspects of drug

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design: bio-isosterism and stereochemical aspects of drug design (chirality, molecular symmetry, and macromolecular stereochemistry).

**Unit-III** Receptors and their types, structure, agonist, antagonist, signal transduction mechanism: G-protein coupled receptor, G-protein coupled receptor and cAMP,; Ion channels, ligand gated ion channels, drug-receptor interaction forces (Covalent, ionic, ion-dipole, hydrogen bonding, hydrophobic, charge-transfer complexes, Van der Waals interactions) drug receptor theories (occupancy, modified occupancy, rate, induced-fit, macromolecular perturbation, activation aggregation, two state model for receptor activation theories) and design of agonist and antagonists of opioid receptors, histamine and dopamine receptors.

**Unit-IV** Structure of proteins and enzymes, kinetics, enzymes as catalysts, mechanisms of enzyme catalysis, co-enzyme catalysis, enzyme inhibition and inactivation, reversible, irreversible enzyme inhibitors and inhibitor design strategies of cyclooxygenase (COX), matrix metalloproteinase (MMPs) and dipeptidyl peptidase-IV (DPP-IV) inhibitors.

**Unit-V** Fundamentals of metabolism and metabolism stability, pathways for drug deactivation and elimination: Phase-I and Phase-II transformations, structure modification strategy for Phase-I and Phase-II, CYP450 inhibition, Prodrug design strategies and applications.

**Unit-VI Case studies on the discovery of new drugs:**

- Bioprecursor prodrug approach: OMEPRAZOLE as antiulcer drug.
- Enzyme-substrate based inhibitor design: RITONAVIR as anti-HIV drug.
- Physical organic chemistry (Tautomerism) based design: CIMETIDINE (H<sub>2</sub>-Receptor Antagonist) as antiulcer drug.
- Analogue-based design approach: IMATINIB as anticancer drug.
- Peptide mimics based approach: MARIMASTAT (MMPs) as anticancer drug.
- Receptor based design RALOXIFENE (selective estrogen receptor modulator) as breast cancer drug.

**Books Recommended:**

- An introduction to Medicinal Chemistry- G. L. Patrick
- The organic chemistry of drug design and drug action - Von R. B. Silverma



3. Foye's Principles of Medicinal Chemistry- D. A. Williams
4. Burger's Medicinal Chemistry and Drug Discovery (Vol-I-VI) - Donald J. Abraham (Ed.)
5. Drug-like properties, concepts, structure design and methods- Edward H.Kerns and Li Di.
6. Comprehensive Medicinal Chemistry (Series – I-VI) - C. Hansch
7. Advanced drug design and development: A medicinal Chemistry approach - P.N. Kourounakis and E.Rekka.
8. Progress in medicinal Chemistry series- G.P.Ellis and G.B.West.
9. Annual reports in medicinal Chemistry, Vol 25- James A Bristol
10. Drug design-(Medicinal chemistry: A series of monograph)- E. J. Ariens (Ed.)
11. Monographs and relevant review articles appearing in various periodicals and journals.

### PYM-PC 707T (A) Pharmacological Screening

**Credits: 3, Contact Hrs: 3**

**Unit I:** Introduction to pharmacology, mechanism of drug action and drug targets, neurotransmitters, receptors, screening methods in pharmacology, Introduction to pharmacokinetics, Drug discovery process: Principles, Techniques and Strategies used in new drug discovery, Pharmacological studies and relation to bioavailability and bioequivalence for drugs and drug products.

**Unit II:** Animals used in pharmacological research, limitations of animal tests, CPCSEA guidelines for performing experiments on animals, anesthetics used in laboratory animals, Anatomical specifications, advantage and limitations of various anatomical sites of blood collection in laboratory animals, maintenance and breeding of Laboratory animals, Protocol development for animal experimentation, Transgenic animals.

**Unit III:** Bioassays: Introduction, Principle, types and methods of bioassays, advantages over other assays, various isolated organs used for bioassay. Experimental models and statistical experimental designs employed in biological standardization.

**Unit IV:** In vitro testing of Drugs: Introduction to *in vitro* techniques as (*In vitro* techniques ELISA, RIA, Enzyme inhibition Assays, Gel electrophoresis, Antioxidant assays) modern techniques like ligand-binding studies and use of

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tissue culture in biological evaluation of drugs, Alternatives to animal studies, Animal cell lines and their uses, limitation of in vitro testing of drug. Application of invitro testing in new drug discovery, enzyme kinetic studies, metabolite profiling, bioanalysis etc.

**Unit V:** Preclinical evaluation of following categories of drugs.

- (a) Analgesics, antipyretics, anti inflammatory agents
- (b) Anticonvulsants, antipsycotics, CNS stimulants, antianxiety, antidepressants, sedative, hypnotic
- (d) Histamine antagonists
- (e) Hypoglycemics
- (f) Antimalarials.
- (g) Anti ulcer, diuretics.

**Unit VI:** Toxicity studies: Principles of toxicity evaluation, Determination of ED50, LD50 and TD values, toxicity tests, Methods of acute, sub acute, and chronic toxicity studies. Elementary knowledge of systemic toxicology, OECD guideline for animal testing, regulatory standards and requirements for toxicity data of various regulatory bodies, Histopathological studies of various organs.

**Books recommended**

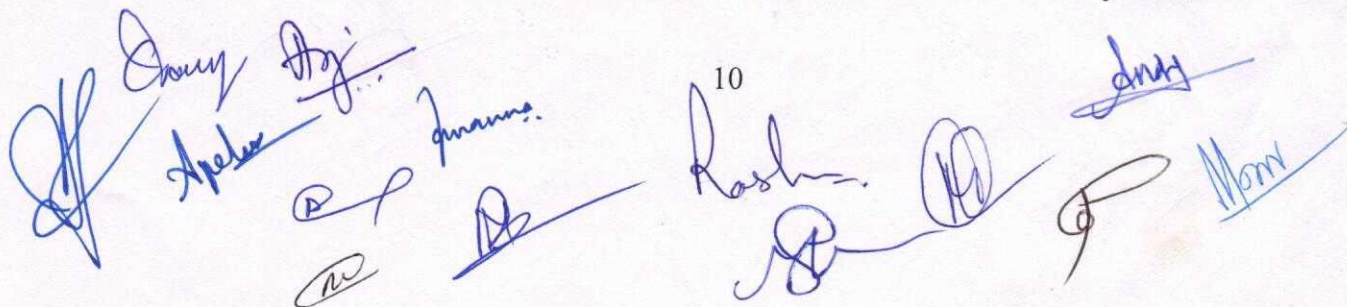
1. Basic and Clinical Pharmacology- B.G. Katzung
2. Essentials of Pharmacotherapeutics- F.S.K. Barar
3. Pharmacology - H.P. Rang and M.M. Dale
4. Essentials Of Medical Pharmcology – K.D. Tripathi
5. Handbook of Experimental Pharmacology- S.K. Kulkarni
6. Fundamental of Experimental Pharmacology - M.N. Ghosh
7. Screening methods in Pharmacology- R.A. Turner
8. Drug Discovery and Evaluation: Pharmacological Assays – H.G. Vogel and W. H. Vogel.

**PYM-PC 709T Laboratory Practicals-1**

**Credits: 6, Contact Hrs: 12**

**Laboratory practicals based on the subjects mentioned in the syllabus.**

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# Syllabus of M.Pharm. II Sem. under CBCS

DEVI AHILYA VISHWAVIDYALAYA, INDORE  
SCHOOL OF PHARMACY

CHOICE BASED CREDIT SYSTEM (w.e.f. academic session 2015-16)

## M.PHARM SEMESTER-II

PYM-PC 702 T Modern Analytical Techniques-II  
Credits: 4, Contact Hrs: 4

- Unit 1 Mass spectrometry  
Ionization Methods, Mass Analyzers, Isotope abundance, molecular ion, index of hydrogen deficiency, the rule of thirteen, Meta stable ions, Structural analysis and fragmentation pattern.  
Fragmentation associated functional groups: Alkanes and alkane groups, cycloalkanes, alkenes and alkene groups, cycloalkenes, alkynes, aromatic hydrocarbon groups, halides, alcohols, phenols, ethers, acetals, ketals, carbonyl compounds in general, aldehydes, ketones and quinines, carboxylic acids, esters, amides, anhydrides, acid chlorides, nitriles, nitro compounds, sulphur compounds, amines and nitrogen heterocycles.  
Strategic approach in analyzing mass spectra and solving problems  
Hyphenated techniques : LC-MS, GC-MS, GC-MS-MS, LC-MS-MS
- Unit 2 X-ray diffraction: Bragg condition, Miller indices, Experimental methods of X-ray diffraction, Identification of unit cells from systematic absences in diffraction pattern, Description of the procedure for an X-ray structure analysis.  
General principle, Instrumentation and applications of Differential Scanning Calorimetry (DSC).
- Unit 3 General principle, Instrumentation and applications of Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM), Atomic Force Microscopy (AFM), Optical Rotatory Dispersion (ORD), Circular Dichroism (CD).
- Unit 4 Proton Magnetic Resonance Spectroscopy  
Overview on principle and instrumentation, Chemical shift, Spin-spin splitting, Coupling constant, Protons exchange reactions and hydrogen bonding, Rotations about single bonds, Simplification of complex proton spectra, Nuclear overhauser effect, 2 Dimensional NMR Spectroscopy  
Interpretation of proton spectra : Alkanes, alkenes, aromatic compounds, alkyl halides, alcohols, ethers, amines, nitriles, aldehydes, ketones, carboxylic acids, esters, amides, nitroalkanes, Compounds containing fluorine and phosphorous, spectra of carbocation
- Unit 5 <sup>13</sup>C Nuclear Magnetic Resonance Spectroscopy  
The Carbon-13 nucleus, Carbon-13 chemical shifts, proton coupled <sup>13</sup>C spectra: Spin-spin splitting of Carbon-13 signals, Proton decoupled <sup>13</sup>C spectra, Problems with integration in <sup>13</sup>C spectra, Carbon-13 NMR solvents,

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- Heteronuclear coupling of Carbon-13 to fluorine and phosphorous.  
Interpretation of Carbon-13 spectra : Alkanes, alkenes, aromatic compounds, alkyl halides, alcohols, ethers, amines, nitriles, aldehydes, ketones, carboxylic acids, esters, amides, nitroalkanes, Compounds containing fluorine and phosphorous, spectra of carbocation
- Unit 6 Radioimmunoassay and related Immunoassay techniques: Theory and principle, methods in radioimmunoassay, related immunoassay procedures, applications of radioimmunoassay techniques.

### Books recommended:

1. Spectroscopy – D. L. Pavia, G.M. Lampman, G. S. Kriz, J.A. Vyvyan
2. Organic spectroscopy - William Kemp
3. Spectroscopic Methods in Organic Chemistry – D. H. Williams & I. Fleming
4. Spectrometric Identification of Organic Compounds - R. M. Silverstein, F. X. Webster, D. J. Kiemie.
5. Practical Pharmaceutical Chemistry- A.H. Beckett and J.B. Stenlake, Vol. II.
6. Instrumental methods of analysis- H.H. Willard, L. L. Merrit, J. A. Dean & F. A. Settle
7. Instrumental methods of Chemical Analysis – E. W. Ewing
8. Pharmaceutical analysis, Modern methods Part A - Munson, J. W. (Ed.)
9. Fundamentals of analytical chemistry- D. A. Skoog, D. M. West, F. J. Holler
10. Handbook of Pharmaceutical Analysis - L. Ohannesian and A.J. Streeter (Eds.)
11. Mass Spectrometry Handbook-Mike S. Lee (Ed.)

### PYM-PC 704T: Drug Design

Credits: 4, Contact Hrs: 4

- Unit I: **Analog based drug design:** Introduction, Bio-isosteric replacement, rigid analogue, Alteration of chain branching, changes in ring size, ring position isomers, alteration of stereochemistry and design of stereoisomer and geometric isomers, fragmentation of a lead molecule. Methodologies in analog design: Topliss Tree approach, Craig Plot.
- Unit II: **Molecular modeling:** Introduction, Molecular mechanics, force-field, molecular dynamics, molecular simulation, monte carlo, quantum mechanics (semi empirical; CNDO, MNDO, INDO, NDDO, AM1, PM3, MOPAC, empirical; Ab initio, Gaussian, hybrid QM/MM, Energy minimization; geometry optimization, steepest descent, conjugate gradient, conformational analysis. Applications of Molecular modeling in drug design.
- Unit III: **Ligand based drug design:** Background and historical perspective of QSAR. **2D-QSAR approaches:** Hansch, Free-Wilson, Fujita Ban. Physicochemical descriptors in QSAR (Lipophilicity parameters; Hydrophobic constant, Electronic parameters; Hammett Constant, HOMO, LUMO polarizability parameters; MR, topological descriptors; Es, verloop sterimol parameter). Statistical methods for

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development and validation of QSAR Models. Interpretation of QSAR models. (Case study: works carried out at Smith, Kline, & French on the antiallergic activity of a series of pyranenamines).

**Unit IV: Ligand based drug design: 3D-QSAR approaches:** Introduction to 3D, 4D & 5D QSAR. Pharmacophore Mapping, CoMFA, CoMSIA, H-QSAR. (Case study: inhibitors of tubuline polymerization, 3D QSAR studies on analogues of SB 221284)

**Unit V: Structure based drug design:** Introduction, molecular docking, rigid docking, flexible docking, scoring functions, search for the correct binding mode, virtual screening. Case study (Design of ACE Inhibitors: development of captopril, Identification of Novel DAT Inhibitors through 3D Pharmacophore-based Database Search; Discovery of Novel Matriptase Inhibitors through Structure-Based 3D Database Screening).

**Unit VI: Pharmacokinetics in drug design:** Metabolism induced toxicity, structure related toxicity, insilico toxicity prediction, Toxicogenomics, high through put ADME studies and Physiologically-Based Pharmacokinetic (PBPK) Modelling.  
**Informatics methods in drug design:** Bioinformatics, Cheminformatics, Pharmacoinformatics, Chemogenomics, Pharmacogenomics, Protein Data Bank, chemical biochemical and pharmaceutical databases.

### Books Recommended:

1. Computer Aided Drug Design Edited by Thomas J Perun, Marcel Dekker: New York, NY.
2. Pharmacokinetics and Metabolism in Drug Design, Edited by D. A. Smith, H. van de Waterbeemd, D. K. Walker, R. Mannhold, H. Kubinyi, H. Timmerman
3. Structure based Drug Design Pandi Veerapandian, Taylor and Francis
4. Smith and Williams Introduction to Principles of Drug Design and Action Edited by H. John Smith, Taylor and Francis
5. Textbook of Drug Design and Discovery Edited by Povl Krogsgard-Larson, Taylor and Francis
6. Molecular Modeling: Principles and Applications, Andrew R. Leach.
7. Ariens, Drug design-
8. Burger's Medicinal Chemistry and Drug Discovery
9. Hansch Comprehensive Medicinal Chemistry

### PYM-PC 706T ADVANCED ORGANIC CHEMISTRY

Credits: 4, Contact Hrs: 4

**Unit I:** Basic Concepts of aromaticity involving ring systems, hydrogen bonding and other weaker bondings, EDA complexes, crown ethers and inclusion compounds, Study of stability and reactivity of reaction intermediates: carbocations, carbonions, carbenes, nitrenes, and free radicals.

**Unit II: Carbanion Chemistry:** Generation of carbanions by deprotonation and other means of generating enolates. Alkylation of enolates, oxygen versus carbon as the site of alkylation, alkylation of aldehydes, ester, amides, & nitrile. The nitrogen analogs of enols & enolate enamines and imine anions.

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## Syllabus of M.Pharm. II Sem. under CBCS

### Unit III: Substitution and Elimination reactions:

Free radical substitution, Nucleophilic Aliphatic (SN1, SN2, SN1 vs SN2, SNi, Neighboring group effect), Nucleophilic Acyl substitution, Nucleophilic Aromatic Substitution. 1, 2 Elimination reactions: E1, E2, E1cb, E1 vs E2, Elimination vs Substitution.

### Unit IV: Study of reaction mechanism of following Synthetically Important reactions:

Methods of determining reaction mechanisms, Kinetic and non-kinetic methods; Energy profile diagrams, reaction intermediates, crossover experiments and isotopic labelling; order of reactions; Reversible, consecutive and parallel reactions; Solvent, ionic strength and salt effects; Acid-base catalysis.

- Arndt-Eistert Synthesis
- Baylis-Hillman Reaction
- Favorskii rearrangement
- Lawesson's Reagent
- Ring Closing Metathesis
- Ring Opening Metathesis (Polymerization)
- Suzuki Coupling reaction

### Unit V: Stereochemistry:

Stereoisomerism, enantiomers, elements of symmetry, chirality, racemic modification, resolution, configuration, specification of configuration, sequence rule, conformational isomers, reactions involving stereoisomers, asymmetric synthesis. optical isomerism in compounds containing no chiral atom: biphenyls, allenes, compounds with exocyclic double bonds, spirans, chirality due to helical shape, chirality caused by restricted rotation of other types, "cis" "trans" isomerism resulting from double bonds, mono cyclic compounds, fused ring systems.

### Unit VI: Reaction of ylides:

a) PhosphorSemester-lous ylides: Structure and reactivity, stabilized and Non-stabilized ylides, effects of ligands on reactivity, Wittig reaction, Schlosser modification, Wittig-Horner and Horner-Wadsworth-Emmons olefination reactions, Mechanism reactions and synthesis of various scaffolds.

b) Sulphur Ylides: Stabilized and non-stabilized ylides; thermodynamically and kinetically controlled reactions with carbonyl compounds, regio- and stereo-selective reactions.

#### Books Recommended:

- J. March, Advanced organic chemistry, reactions mechanism and structures, John Wiley and sons, New York latest edition.
- Reinhard Bruckner, Advanced organic chemistry reaction mechanism, Academic Press.
- Francis, A.C and Richard J.S, Advanced organic chemistry, 3rd edition, Reaction & Sythesis, plenum press, New york.
- Laszlo Kurti and Barbara Czako, Strategic Applications of Named Reactions in Organic Synthesis, Elsevier Academic Press publications.
- Iyer R.P., Ghone S.A, Degani M.S., Mohanraj k. and Jain N., Synthesis of drug, vol I sevak publications p.Ltd, Mumbai, 2008.

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## Syllabus of M.Pharm. II Sem. under CBCS

6. A. Carey and R. J. Sundberg, Advanced Organic Chemistry, Part B, Fifth Edition, 2007.
7. G. S. Zweifel and M. H. Nantz, Modern Organic Synthesis-An Introduction, W. H. Freeman and Company, 2006.

### PYM-PC 708T (A) LOGICS IN ORGANIC SYNTHESIS-I

Credits: 3, Contact Hrs: 3

- Unit I: Principles of synthetic analysis and planning:** Logic-centered molecular synthesis; Dislocation, synthetic tree, synthons, Structure-functionality relationships, functionality and unsaturation levels; Protocol for synthetic design. Retrosynthetic analysis and synthetic equivalent, Retrosynthesis of acyclic saturated and unsaturated systems, aliphatic and aromatic compounds. Retrosynthetic analysis of bexarotene an anticancer agent as a case study.
- Unit II:** Functional group interconversions, general methods of synthesis of 4-7 membered rings, and disconnection approach. Applications of synthetic strategies to Synthesis complex molecules: synthesis of Taxol, Estrone, Penicillin, and Prostaglandins on the basis of disconnection and direct associative approaches.
- Unit III:** **Use of protecting groups in multi-step synthesis:** Different protection and deprotection methods. Protection and deprotection of the following functional groups: hydroxyl, carbonyl, amino and carboxyl with applications.
- Unit IV: Syntheses of natural products/bioactive/drug molecules (Case Studies).**
- a) Woodward synthesis of Reserpine from benzoquinone
  - b) Corey synthesis of Longifoline from resorcinol
  - c) Gilbert-Stork synthesis of Griseofulvin from phloroglucinol
  - d) E. Wenkert's synthesis of  $\beta$ -vetivone from acetone
  - e) A.V.Ramarao synthesis of 4-demethoxydaunomycin from ethyl acetoacetate.
- Unit V: Green Chemistry:** Introduction, basic principles of green chemistry, designing a green synthesis: Green starting materials, green reagents, green solvents and reaction conditions, green catalysts. Microwave assisted synthesis: reactions in water, reactions in organic solvents, solvent free reactions. Ultrasound assisted reactions. Comparison of traditional processes versus green processes in the syntheses of Ibuprofen, p-bromotoluene and benzimidazole.
- Unit VI: Combinatorial synthesis & Click Chemistry:** Introduction, Basic ideas and concepts of Combinatorial Chemistry, method of synthesis, solution phase synthesis, solid phase synthesis, combinatorial library design and high throughput screening. Introduction to click chemistry, process chemistry and type of reactions and applications.
- Books Recommended:**
1. G. S. Zweifel and M. H. Nantz, Modern Organic Synthesis-An Introduction, W. H. Freeman and Company, 2006.
  2. A. Carey and R. J. Sundberg, Advanced Organic Chemistry, Part B, Fifth Edition, 2007.

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3. E. J. Corey and X. M. Cheng, The Logics of Chemical Synthesis, Wiley, 1989.
4. K. C. Nicolaou, Classics in Total Synthesis, Vol 1, 2 and 3.
5. S. Warren and P. Wyatt, Organic Synthesis: The Disconnection Approach, 2nd edition, Wiley, 2008.
6. J. H. Fuhrhop, G. Li, Organic Synthesis: Concepts and Methods, 3rd edition, VCH, 1994.
7. W. Carruthers, Some Methods of Organic Synthesis, Cambridge University Press.
8. H. O. House, Modern Synthetic Reactions, Benjamin-Cummings Publishing Co. 1972.
9. Graham L. Patrick, an Introduction to Drug Synthesis, Oxford University Press.
10. Peter G. M. Wuts and Theodora W. Greene, Greene's Protective Groups in Organic Synthesis 4th Edition, Wiley, 2007.

**PYM-PC 710P Laboratory Practicals-2**

**Credits: 9, Contact Hrs: 18**

**Laboratory practicals based on the subjects mentioned in the syllabus.**

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**M.PHARM. THIRD SEMESTER**

S. No.	Subject Code	C/GE/DSE	Subject Name	Hrs/week	Credits
1.	PYM-PC 801T	GE	Research Methodology and Biostatistics	3	3
2.	PYM-PC 803T	C	Drug Regulatory Affairs and Quality Assurance	3	3
3.	PYM-PC 805	DSE	Research Project Phase-I	-	12
			Research Project Phase-I Presentation	-	2
6.	PYM-PC 807	C	Comprehensive viva-voce	-	4
			Total		<b>24</b>

\*C=Core course, F=Foundation course, AEC=Ability enhancement course, SEC=Skill enhancement course, GE= Generic Elective, DSE= Discipline Specific Elective

**M.PHARM. FOURTH SEMESTER**

S. No.	Subject Code	C/GE/DSE	Subject Name	Hrs/week	Credits
1.	PYM-PC 802	DSE	Research Project Phase-II	-	18
			Research Project Phase-II Presentation	-	2
2.	PYM-PC 804	C	Comprehensive viva-voce	-	4
			Total		<b>24</b>

\*C=Core course, F=Foundation course, AEC=Ability enhancement course, SEC=Skill enhancement course, GE= Generic Elective, DSE= Discipline Specific Elective

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Devi Ahilya Vishwavidyalaya

School of Pharmacy

M. Pharm. III Sem. (Pharmaceutical Chemistry)

RESEARCH METHODOLOGY

- Unit I** General Principles of Research: Meaning and importance of research, Objectives of research, types of research, research methods vs. methodology, research process: formulating hypothesis and development of research plan, literature survey, internet as a medium of research, research design process.
- Unit II** Experimental design and analysis: Sampling techniques, sampling theory, various steps in sampling, collection of data-types and methods, analysis of data.
- Unit III** Technical Writing: Scientific writing, writing research paper and review articles, plagiarism, poster preparation and its presentation, writing a dissertation.
- Unit IV** Overview of biostatistics: Difference between parametric and non-parametric statistics, Univariate and multivariate analysis, Confidence interval, Errors, Levels of significance, Hypothesis testing, descriptive statistics: measures of central tendency and dispersal, Histograms, Probability distributions (Binomial, Poisson and Normal), sampling distribution, Kurtosis and Skewness.
- Unit V** Comparing means of two or more groups: Student's t-test, paired t-test, Mann-Whitney U-test, Wilcoxon signed-rank, One-way and two-way analysis of variance (ANOVA), Critical Difference (CD), Least Significant Difference (LSD), Kruskal-Wallis one-way ANOVA by ranks, Friedman two-way ANOVA by ranks,  $\chi^2$  test
- Unit VI** Regression and Correlation: Standard errors of regression coefficients, Comparing two regression lines, Pearson Product-Moment Correlation Coefficient, Spearman Rank Correlation Coefficient, Power and sampling size in correlation and regression.

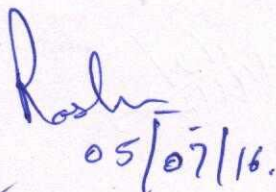
Books Recommended:

1. Kothari, C.R. Research Methodology Methods and Techniques, New Age International Publication.
2. Panneerselvam, R., Research Methodology, PHI learning Pvt. Ltd., New Delhi
3. Poonia, V.S and Poonia, M., Research Methodology and Statistical Methods, Vishvabharti

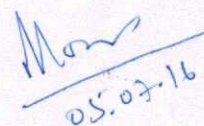
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Publications, New Delhi.

4. Dharmapalan, B., Scientific Research Methodology, Narosa Publishing House, New Delhi.
5. Bolton, S. and Bon, C., Pharmaceutical Statistics, Informa Healthcare, New York.
6. Daniel, W.W., Biostatistics, John Wiley and Sons, New York.
7. Mahajan, B.K., Methods in Biostatistics, Jaypee Brothers, New Delhi.
8. Wermuth, C.G., The Practice of Medicinal Chemistry, Academic Press, USA.

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<b>PYM-PC 803T: DRUG REGULATORY AFFAIRS &amp; QUALITY ASSURANCE</b> <b>Credits: 3, Contact Hrs: 3</b>	
<b>Unit I:</b>	Intellectual Property Rights: Introduction, Types of IPR, Importance of IPR Patent: Patent System, Patentable subject matter, Non patentable subject matter, Criteria for getting a patent, Different Types of Patents Applications and Patent Specifications, Filing and Processing of Application for Patents, Infringement of Patents, Patent co-operation Treaty, Indian Patent Act.
<b>Unit II:</b>	Salient features, rules of Drug & Cosmetic Act and USFDA. WHO guideline and their relevance: WHO certification scheme on the quality of pharmaceutical products Q7A Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients M4. Good Laboratory Practice, ISO 9000 and ISO 14000 series.
<b>Unit III:</b>	Preparation of document for New Drug Approval and Export Registration. Requirements for registration of products into India, USA and European Union Markets. Common Technical Document (CTD). Development and informational content for Investigational New Drugs Application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Supplemental New Drug Application (SNDA), Chemistry, Manufacturing and controls (CMC) Post Approval Changes (PAC) including Scale Up Post approval changes (SUPAC) and Bulk active chemical Post approval changes (BACPAC). Post marketing surveillance, Introduction to Pharmacovigilance.
<b>Unit IV:</b>	Basic concept and scope of Quality Control and Quality Assurance systems, Quality audit and quality management systems. Source and Control of Quality variation of Raw materials, Containers, Closures, Personnel, Environmental and equipments along with clean in place, sterilize in place, methods (TP & STP) for equipments , In process quality control tests for various dosage forms sterile and non sterile.
<b>Unit V:</b>	Concepts in Validation, Process validation and its Application Validation of pharmaceutical operations involved in the production of pharmaceutical products e.g. mixing, drying, filtration etc. Validation of sterilization methods. Qualification and calibration of manufacturing and analytical equipments.
<b>Unit VI:</b>	Statistical quality control, types of sample, types of sampling, concept of acceptance sampling, acceptance sampling plans, sampling risks, the operating characteristic curves, quality control charts. Regulatory drug analysis, analytical method validation. ICH guidelines on analytical method validation.
<b>Books Recommended:</b> <ol style="list-style-type: none"> <li>1. Common Technical documents (ICH guidelines), www.ich.org</li> <li>2. Code of Federal Regulations., www.fda.gov</li> <li>3. The Drug and Cosmetics Act and Rules and its Latest amendments.</li> <li>4. The Patent Act 1970 and its Latest amendments. www.patentoffice.nic.in</li> <li>5. WHO GMP guidelines, www.who.int</li> <li>6. Potdhar, M.A. Pharmaceutical Quality Assurance, 2nd edition, Nirali Prakashan.</li> <li>7. Nash, R.A. and Wachter A.H., "Pharmaceutical Process Validation" Marcel Dekker, Inc., New York</li> <li>8. Bolton, S.H. "Pharmaceutical Statistics"</li> <li>9. Banker, G.S. and Rhodes, C.T. "Modern Pharmaceutics" Marcel Dekker, Inc., New York.</li> </ol>	

10. Careleton, F.J. and Agallow, J.P. "Validation of Aseptic Pharmaceutical Processes" Marcel Dekker, Inc., New York.
11. Garfeild "Quality Assurance Principles of Analytical Laboratories"
12. Lachmann and Libermann, Theory and Practice of Industrial Pharmacy. Third edition, Varghese Publishing House.
13. Remington's Pharmaceutical Sciences. Vol.I-II, 21<sup>st</sup> Edition.

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