Syllabus Appendix / Curriculum Book

Program: Masters of Pharmacy
Choice Based Credit System (CBCS) 2016
Duration: 2 Years / 4 Semesters

VIVEKANANAD EDUCATION SOCIETY'S COLLEGE OF PHARMACY

Hashu Advani Memorial Complex, Behind Collectors Colony, Chembur(E),Mumbai-400074

TABLE OF CONTENTS

Semester - I

<table>
<tr><th colspan="5">Course: Modern Pharmaceutical and Medicinal Chemistry (CBCS)</th></tr>
<tr><td colspan="2">Course Code: MPH_C_101_T</td><td colspan="2">First Year M. Pharm</td><td>Semester: I</td></tr>
<tr><td colspan="2">Type of course: Theory</td><td colspan="2">Contact Hours: 4 Hours/week (4L + 1T)</td><td>Total Contact Hours: 60</td></tr>
<tr><td colspan="2">Course assessment Methods:</td><td colspan="2">Continuous mode of assessment</td><td>Semester-end assessment</td></tr>
<tr><td colspan="2">Assessment Tool*:</td><td>Theory Sessional Exam</td><td>Attendance</td><td>End semester Examination</td></tr>
<tr><td colspan="2">Max. Marks:</td><td>15</td><td>5</td><td>80</td></tr>
<tr><td colspan="2">Pre-requisites:</td><td colspan="3">Before undertaking the course, students should have knowledge of the following:
1. Basics of proteins specifically receptors and enzymes
2. Basics of ADME properties and drug delivery systems</td></tr>
<tr><td colspan="2">Course Objectives:</td><td colspan="3">After completion of course students will be able to know:
● 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</td></tr>
<tr><td colspan="2">Course Outcomes: Upon completion of the course the student shall be able to:</td><td colspan="2">PO Mapped</td><td>PSO mapped</td></tr>
<tr><td>CO1</td><td>Recall the concept of protein folding, receptors and their types, SAR, mechanism of action of certain class of drugs, enzyme kinetics and principles of enzyme inhibitors</td><td colspan="2">1, 2, 3, 7, 8, 11</td><td>1, 2, 3</td></tr>
<tr><td>CO2</td><td>Explain and illustrate the principles and applications of medicinal chemistry to impart knowledge about recent advances in the field of medicinal chemistry at the molecular level including different techniques for the rational drug design.</td><td colspan="2">1, 2, 3, 4, 6, 7, 11</td><td>1, 2, 3</td></tr>
<tr><td>CO3</td><td>Application of the gained knowledge in basic research of rational design of enzyme inhibitors along with their metabolic profile and stereochemistry.</td><td colspan="2">1, 2, 4, 6, 7, 8, 11</td><td>1, 2, 3</td></tr>
<tr><td>CO4</td><td>Evaluating and interpreting the role of chirality in selective and specific therapeutic agents to realize that stereo-selectivity is a prerequisite for drug evolution.</td><td colspan="2">1, 2, 3, 4, 5, 10, 11</td><td>1, 2, 3</td></tr>
<tr><td colspan="5">Topics covered:</td></tr>
</table>

Unit I:	**Drug Discovery**	**Hours: 5**

- Historical perspective
- Lead Discovery
- Lead Modification – identification of the pharmacophore, functional group modification, privileged structures and drug-like molecules, modifications to increase potency and the therapeutic index, modifications to increase oral bioavailability

Unit II:	**Receptors**	**Hours: 10**

- Basic ligand concepts – agonist, antagonist, partial agonist, inverse agonist, efficiency and potency
- Interactions (Forces) involved in drug-receptor complexes
- Receptor theories – occupancy theory, rate theory and activation theory
- Receptor classification – the four superfamilies
- Receptor binding assays- measurement of Kd, Bmax and IC50
- Topographical and stereochemical considerations in drug –receptor interactions

Unit III:	**Prodrugs and Drug Delivery Systems**	**Hours: 13**

- Enzyme activation of drugs, utility of prodrugs – aqueous solubility, absorption and distribution, site specificity, instability, toxicity, poor patient acceptability, formulation problems.
- Carrier-linked prodrugs – carrier linkages for various functional groups, carrier-linked bipartite prodrugs, macromolecular drug carrier systems, tripartite prodrugs, mutual prodrugs, bioprecursor prodrugs (hydrolytic activation, elimination activation, oxidative activation, reductive activation, nucleotide activation, phosphorylation activation, sulfation activation and decarboxylation activation).
- Self study of specific examples of drugs that have been converted to prodrugs for solving problems related to ADME and their release mechanisms.
- Self study of prodrugs involving specific tissue targeting or specific activation at the target tissue.

Unit IV:	**Drug Metabolism**	**Hours: 18**

- Introduction to xenobiotic/drug metabolism and its relation to other defence systems (Physical barriers, excretion, immune system).
- Types of reactions (I and II), consequences of drug metabolism (DM) [inactivation, bioactivation, prodrugs], organs of DM, localization of drug metabolizing enzymes, factors affecting drug metabolism.
- Cytochrome P450s: Introduction to the family of enzymes, their classification and nomenclature.
- CYP450 catalytic cycle, different types of reactions catalyzed by CYP450s and the mechanisms of catalysis.
- Human CYP450s involved in DM, their distribution and properties, typical substrates, specific probe substrates, specific inhibitors, induction of CYPs and specific inducers.
- Discussion of glucuronosyltransferases, sulfotransferases, glutathione S-transferases, N-acetyl transferases, and FMO [on lines similar to that specified for CYPs as listed above].
- Self study of alcohol/aldehyde dehydrogenases, xanthine and aldehyde oxidase, epoxide hydrolase, esterases, azo and nitro reductases (reactions catalyzed be these enzymes, mechanisms of the reactions, typical substrates/inhibitors/inducers)

Unit V:	**Enzymes**	**Hours: 14**

- Introduction to enzymes, binding site, specificity of enzyme catalyzed reactions and rate acceleration, Michaelis Menten kinetics and methods for plotting enzyme kinetic data.
- Mechanisms of enzyme catalysis – covalent catalysis, acid-base catalysis, electrostatic catalysis, some examples of the mechanisms of enzyme catalysis
- Coenzyme catalysis– pyridoxal 5'-phosphate (racemases, decarboxylases,

aminotransferases), nicotinamide and flavin (two-electron mechanism, one-electron mechanism and hydride transfers), folic acid and thiamine (one carbon transfer reactions). ● Self study of Hanes plot, Cornish-Eisenthal Bowden plot. ● Self study of roles of coenzymes – biotin, coenzyme A, cyanocobalamin, vitamin K.	
Reference material:	**Books:** 1. The Organic Chemistry of Drug Design and Drug Action, Silverman R. B., Academic Press. 2. Textbook of Drug Design and Discovery, Eds. Krogsgaard-Larsen P., Liljefors T., Madsen U., Taylor & Francis. 3. Lehninger – Principles of Biochemistry, 4th edition. 4. Medicinal Chemistry: An Introduction, Thomas G, Wiley. 5. Drug Discovery – A History, Sneader W, John Wiley & Sons, Ltd. 6. Comprehensive Medicinal Chemistry, Series Ed., Hansch C., Pergamon Press. 7. Wilson and Gisvold's, Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott-Raven 8. Foye's Principles of Medicinal Chemistry, Lippincott Williams and Wilkins. 9. Drug Metabolizing Enzymes-Cytochrome P450 and Other Drug Metabolizing Enzymes in Drug Discovery and Development, Lee JS, Obach SR and Fisher MB, Marcel Dekker, Fontis India, 2003 10. Pharmaceutical Profiling in Drug Discovery for Lead Selection, Borchardt RT, Kerns EH, Lipinski CA, Thakker DR and Wang B, AAPS Press, 2004 11. Drug Metabolism – Current Concepts, Ionescu C and Caira MR, Springer International Edition 12. Handbook of Drug Metabolism, Woolf TF, Marcel Dekker, 1999.

Course: Modern Pharmaceutics (CBCS, 2016-17)				
Course Code: MPH_C_102_T	**First Year M. Pharm**			**Semester: I**
Type of course: Theory	**Contact Hours: 4 Hours/week (3L + 1LT)**			**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**			**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	Total Internal Assessment	End semester Examination
Max. Marks:	**15**	**5**	**20**	**80**
Pre-requisites:	Basic knowledge about pre-formulation, validation, GMP and scale-up techniques.			
Course Objectives:	Upon completion of the course, student shall be able to understand: 1. The elements of pre-formulation studies. 2. Various aspects of excipients and introduction to polymers 3. Optimization techniques & Micromeritics 4. Stability Testing, sterilization process & packaging of dosage forms			

Course Outcomes: The learner should be able to:		**PO Mapped**	**PSO Mapped**
CO1	Understand the concepts of pre-formulation, micromeritics, tablet compression, optimization.	1, 3, 4, 6, 7	1, 2, 3
CO2	Apply the preformulation and excipient knowledge for proper design of safe, efficacious, stable and quality formulations.	1, 2, 3, 4, 6, 7, 8, 10, 11	1, 2, 3
CO3	Investigate various aspects of solubility, dissolution and stability	1, 2, 3, 4, 6, 7, 8, 11	1, 2, 3
CO4	Analyze the formulation parameters, apply optimization techniques and devise suitable formulation composition.	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	1, 2, 3

Topics covered:

Unit I	**Drug Stability**	**Hours: 9**

- Importance and need for stability testing
- Revision of degradation pathways, kinetics, physical stability
- Solution and Solid state stability, pH stability profiles, v and u graphs, package evaluation, ICH guidelines, statistical aspects in derivation of shelf life.

Self study- Calculations for shelf life based on degradation kinetics

Unit II	**Solubilization and Dissolution**	**Hours: 14**
▪ Importance of aqueous solubility of drugs, particularly NCEs, surfactant systems and phase diagrams, polymeric surfactants, cosolvents, complexation, solid state manipulations, cyclodextrins, drug derivatization, salt screening. ▪ Revision of equations of dissolution and factors affecting dissolution, intrinsic solubility and dissolution rate, validation of testing, different equipments (emphasis on USP apparatus 4), Dissolution of TDDS, particulates, gels & ointments, comparison of profiles by f2 analysis, development of dissolution method, relevance of dissolution testing in ANDAs , bio-relevent media, BCS classification, IVIVC- study design and interpretation ▪ Self study- Calculations based on various solubility parameters and equations of dissolution. Pharmacopoeial dissolution apparatus, data treatment of dissolution profiles.		
Unit III	**Excipients and introduction to polymers**	**Hours: 7**
▪ Role of excipients, purity, safety and toxicity with reference to routes of exposureoral, inhalational, parenteral, others; regulatory aspects, risk assessments, Harmonization of excipient standards like residual solvents class 1,2,3. ▪ Different classes of excipients - surfactants, special lipids, superdisintegrants, gelling agents, colours and flavours, sweetening agents, co-processed excipients. ▪ Definition of polymers, classification; concept of properties used in characterisation, methods of polymerisation, biocompatibility evaluation, applications. ▪ Self study: sources and brand names of various excipients		
Unit III:	**Optimisation Techniques**	**Hours: 8**
▪ Definition, Need, Advantages, description of terms such as independent variable, response parameters, response surface, contour plots, polynomial equations. ▪ Simplex and factorial designs in optimisation ▪ Application of optimisation techniques in QbD in product development ▪ Self study: Placket-Burman design, central composite designs		
Unit IV:	**Preformulation**	**Hours: 12**
▪ Scope of Preformulation-Role & importance in New Drug Discovery & Approval process-Lead optimization, Steps in Designing the preformulation evaluation of a new drug, critical issues and problems/constraints ▪ Key Areas in Preformulation research- Bulk Characterization, Solubility Analysis, Stability Analysis, Compatibility with common excipients ▪ Preformulation aspects for Tablets, Injectables, Liquid preparations, Protein & peptide drugs. ▪ Self study: case study of drug exhibiting various polymorphic forms, drug excipient compatibility		
Unit V:	**Powder Technology (Micromeritics)**	**Hours: 10**
Revision of following topics: ▪ Important definitions & Units ▪ Importance of particle size in pharmaceutical development. ▪ Fundamental & derived properties of powders ▪ Particle size reduction –comminution mechanisms & equipment ▪ Methods of particle size determination (emphasis on basic principles & interpretation of data)		
	Comminution	

▪ Theory of comminution, milling rate (various mathematical relationships), concept of milling/grinding index, energy for comminution, distribution and limit of comminution	
	Compaction of powders
▪ Definitions of compression & consolidation, deformation mechanisms of matter, steps in compaction of tablets (in detail), ▪ Theoretical aspects- Force Volume relationships/porosity –pressure equations (Heckel's Law & equation), Granulation of powders –theory, ▪ Effect of compaction pressure on various tablet properties, Energy for compaction & effect of lubrication of granules, instrumentation of tablet presses (principles) ▪ Self study: case studies on compaction behaviour of two excipients	
Reference material:	**Books** 1. Drug Stability Principles and Practices by Carstensen J, Marcel Dekker, 3rdedn, Vol 107, 1990. 2. Pharmaceutical Stress testing by Baertschi SW, Taylor and Francis, Vol 153, 2005. 3. Pharmaceutical characterisation of Pharmaceutical Solids by Brittain HG, Marcel Dekker, Vol 70, 1995 4. Preformulation in Solid Dosage Form Development by Adeyeye MC, Brittain HG, Informa Healthcare, Vol 178, 2008. 5. Dissolution, Bioavailability and Bioequivalence by Abdou HM, Ed A. Gennaro, B. Migdalof, Mack Printing Company,1st edn, 1989. 6. Pharmaceutical Bioequivalence by Welling PG, Francis LST, Dighe SV, Marcel Dekker, Inc., Vol. 48, 1991. 7. Pharmaceutical Dissolution Testing by Banaker U, Marcel Dekker, Vol 49, 1992. 8. Excipient toxicity and safety by Weiner M L, Kotkoski LA , Vol 103, Marcel Dekker, 1999. 9. Martin's Physical Pharmacy and Pharmaceutical Sciences, by Sinko PJ, Ed Lea & Feiger, Lippincott Williams & Wilkins, 6thedn, 2010. 10. Modern Pharmaceutics by Banker GS, Ed Banker GS & Rhodes CT, Marcel Dekker, 4th edn, Vol 121, 2003. 11. Pharmaceutical Statistics by Bolton S, Marcel Deckker, 3rdedn, Vol 80, 1997.

Course: Modern Pharmacology (CBCS Revised 2019)			
Course Code: MPH_C_103_T	**First Year M. Pharm**		**Semester: I**
Type of course: Theory	**Contact Hours: 4 Hours/week (3L + 1T)**		**Total Contact Hours:**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	**15**	**5**	**80**
Pre-requisites:	Learner should be aware of Pathophysiology and conventional pharmacotherapy of CNS, CVS, and Diabetes Mellitus. Learner should know basic concepts of pharmacokinetics, pharmacodynamics and immunology. Learner should be aware of pharmacology of antimicrobial agents.		
Course Objectives:	The course aims to impart knowledge about advances in following therapeutic areas: CNS, CVS and Diabetes Mellitus. The course aims to impart knowledge of pharmacokinetics and pharmacodynamics. Also covers the mechanism of dependence and tolerance, Apoptosis, immunopharmacotherapy.		

	Course Outcomes: Upon completion of the current course the learner would be able to:	**PO Mapped**	**PSO mapped**
CO1	Explain the mechanisms of drug transport and concepts of Pharmacokinetics, pharmacodynamics.	1, 3, 6, 8, 9	QA 3, PSO1, PSO2, PSO3, PC 3
CO2	Explain the factors affecting drug responsiveness, mechanisms of drug dependence and microbial resistance and apoptosis.	1,3,4, 6, 7, 8, 9	QA 3, PSO1, PSO2, PSO3, PC 3
CO3	Explain Immunopharmacology and advances in the pharmacotherapy of CNS, CVS and Diabetes Mellitus.	1,3,4, 6, 8, 9	QA 3, PSO1, PSO2, PSO3, PC 3

Topics covered:

Unit I:	**Pharmacokinetics**	**11**

Drug Absorption, distribution, metabolism and excretion.

- Mechanisms of transport of drug across membranes.

Transporters involved in drug absorption, distribution and excretion processes.

- Self study-Drug efflux pathways and experimental methods to study drug transport.

Pharmacokinetic factors affecting drug action

Unit II:	**Mechanism of drug action**	**11**

- Classification of receptors and description of each class with examples.
- Signal transduction mechanisms.
- Detailed description of signal mediation through cascades after adrenergic, muscarinic, GABAergic, insulin receptor stimulation.
- Regulation of receptors, their involvement in various biological processes including diseases resulting from receptor malfunction and their role in pharmacotherapeutics.
- Regulation of intracellular calcium.
- Pharmacodynamic interactions in a multicellular context e.g. Vascular wall (interactions of physiological ligands and drugs in pathophysiological setting).
- Self study- Classification and characterization of receptors-IUPHAR (Eg. 5-HT receptors)

Unit III:	**Functions of sodium and potassium channels and therapeutic potential of channel modulators.**	**Hours: 3**
Unit IV:	**Factors affecting drug responsiveness.**	**Hours: 3**

- Alteration in concentration of drug that reaches receptors.
- Variation in concentration of an endogenous receptor ligand.
- Alteration in number and function of receptors.
- Clinical selectivity: Beneficial vs. toxic effects of drugs.
  a. Beneficial and toxic effects mediated by the same receptor - effector mechanism.
  b. Beneficial and toxic effects mediated by identical receptors but in different tissues or by different effector pathways.
  c. Beneficial and toxic effects mediated by different types of receptors.
- Desensitization, tachyphylaxis.
- Drug tolerance.

Unit V:	**Cellular and molecular mechanisms of**	**Hours: 4**

- Drug dependence (Eg. Morphine).
- Microbial resistance.

Unit VI:	**Advances in therapy of**	**Hours: 18**

- CNS: Depression, Alzheimer's disease, Psychosis, Parkinson's disease, Epilepsy.
- CVS: Hypertension, Angina Pectoris, Congestive cardiac failure, Arrhythmia.
- Management of Diabetes Mellitus.

Unit VII:	**Apoptosis**	**Hours: 4**

- Molecular biology, physiological, pharmacological implications and therapeutic prospects.
- Self study – Interaction between cell, growth factors and extracellular matrix.

Unit VIII:	**Immunopharmacology**	**Hours: 6**

- Introduction to immunopharmacology, immunomodulators, Immunostimulants and Immunosuppressants.
- Self study-Autoimmunity

Reference material:	**Books** 1. Rang and Dale's pharmacology-- Elsevier Churchill Livingston. 2. Lange's Basic and clinical pharmacology, Katzung B.G. Masters S.B., Trevor A.G. Tata McGraw Hill.

	3. Goodmann and Gilman's pharmacological basis of therapeutics, Edited by Laurence Brunton, Bruce Chabner and Bjorn Knollman, McGraw Hill. 4. Pharmacological reviews, Annual reviews Inc. 5. Advances in pharmacology, Academic Press. **6.** Trends in Pharmacological Sciences, Cell Press Elsevier Publication.

<table>
<tr><td colspan="5">Course: Modern Analytical Techniques (CBCS)</td></tr>
<tr><td>Course Code:

MPH_C_104_T</td><td colspan="2">First Year M. Pharm</td><td colspan="2">Semester: I</td></tr>
<tr><td>Type of course: Theory</td><td colspan="2">Contact Hours: 4 Hours/week (3L + 1T)</td><td colspan="2">Total Contact Hours: 60</td></tr>
<tr><td>Course assessment Methods:</td><td colspan="2">Continuous mode of assessment</td><td colspan="2">Semester-end assessment</td></tr>
<tr><td>Assessment Tool*:</td><td>Theory Sessional Exam</td><td>Attendance</td><td colspan="2">End semester Examination</td></tr>
<tr><td>Max. Marks:</td><td>15</td><td>5</td><td colspan="2">80</td></tr>
<tr><td>Pre-requisites:</td><td colspan="4">Before undertaking the course, students should have knowledge of the following:

1. Liquid-liquid extraction- Partition coefficient, molecular diffusion, mass transfer
2. Adsorption, adsorption isotherms, quantum theory, difference between protons, neutrons and electrons
3. Carbocation stability, fission and rearrangements.
4. Difference between protons, neutrons and electrons</td></tr>
<tr><td>Course Objectives:</td><td colspan="4">After completion of course students will be able to know:

● Chemicals and Excipients
● The analysis of various drugs in single and combination dosage forms
● Theoretical and practical skills of the instruments</td></tr>
<tr><td colspan="2">Course Outcomes: Upon completion of the course the student shall be able to:</td><td colspan="2">PO Mapped</td><td>PSO mapped</td></tr>
<tr><td>CO1</td><td>Recall with examples the terminologies associated with spectroscopy, chromatography, X-ray diffraction, electrophoresis, potentiometry and thermal analysis</td><td colspan="2">1, 2, 3, 8, 11</td><td>1, 2, 3</td></tr>
<tr><td>CO2</td><td>Explain and illustrate the theory, instrumentation and applications of various techniques involved in spectroscopy, chromatography, X-ray diffraction, electrophoresis, potentiometry and thermal analysis</td><td colspan="2">1, 2, 3, 4, 6, 8, 11</td><td>1, 2, 3</td></tr>
</table>

CO3	Apply the knowledge gained to calculate concentration by UV-visible spectroscopy, predict the IR frequencies, number of signals in NMR and fragmentation pattern in MS for simple organic compounds	2, 3, 4, 11	1, 2, 3
CO4	Predict the spectroscopic behavior of molecules	2, 3, 4, 8, 11	1, 2, 3

Topics covered:

Unit 1: Multicomponent analysis of drugs using UV- Vis. spectroscopy: 6 — **Hours: 6**

- Simultaneous equation method, Absorbance ratio method, Difference spectroscopy, Derivative spectroscopy and Introduction to Ratio derivative spectroscopy,
- Self-study-Pharmaceutical applications of above techniques (1.1)

Unit 2: F.T.I.R spectroscopy: — **Hours: 6**

- Construction and working, newer sampling techniques.
- Interpretation of I.R. spectra in mid I.R. region (aliphatic and aromatic compounds for simple compounds such as amines, alcohols, amides, nitriles, ketones, aldehydes, esters, acids, nitro and anhydrides).
- Self-study-Interpretation of recorded I.R spectra of drugs and organic compounds.

Unit 3: NMR spectroscopy: — **Hours: 10**

- 1H- NMR: Basic theoretical concepts-(Self-study-chemical shift, splitting pattern and coupling constant-2 hrs), non-first order spectra, methods to make complex spectra simple, FT-NMR.
- 13C-NMR: Theory and Principle.
- Applications of 2D-NMR (only COSY and HETCOR)

Unit 4: Mass Spectrometry: — **Hours: 10**

- Different ionization techniques-EI, CI, FD, FI, MALDI, API (APPI, APCI, ESI).
- Different analysers-Quadrupole, TOF, QTOF, Ion cyclotron, Ion trap.
- Concepts for interpretation of mass spectra-Molecular ion peak, base peak, Isotope abundance, fragmentation pathways-α fission, β fission, MacLaffarty rearrangement, Retro Diels Alder rearrangement, Tandem mass (MS-MS).

Unit 5: Terminologies of chromatography: — **Hours: 3**

Self-study-Theoretical plate, HETP, Plate theory, Rate theory, Van Deemter equation, Isocratic elution, Gradient elution, capacity factor, selectivity factor, Resolution, tailing factor, asymmetry factor.

Unit 6: Advances in chromatography: — **Hours: 11**

- HPLC-Ion pair chromatography, Chiral chromatography (Chiral stationary phases, use of mobile phase additives, precolumn derivatization, chiral detectors), UPLC, Self-Study-Advances in HPLC detectors (1 hr)
- Supercritical Fluid Chromatography-Principle, Instrumentation and pharmaceutical applications.
- Self-study-HPTLC-Principles, Instrumentation and applications including fingerprint

analysis.

- Gas chromatography-Headspace analysis.
- Gel electrophoresis-Principle, Instrumentation and applications

Unit 7: Hyphenated techniques:	**Hours: 4**

- Interfaces used in and applications-MS, LC-MS, LC-MS-MS
- Introduction to LC-NMR and MALDI-TLC.

Unit 8: Thermoanalytical techniques:	**Hours: 5**

- Principle, instrumentation and applications including interpretation of data in pharmacy for: Self-study-DSC and TGA
- TMA (Thermo mechanical analysis)
- Interpretation of DSC and TG curves of suitable compounds/drugs (Self-study)

Unit 9: Microscopy: Principle, Instrumentation, sample preparation and pharmaceutical applications of	**Hours: 5**

Scanning Electron Microscopy, Transmission Electron Microscopy, Atomic Force Microscopy, Confocal microscopy.

Reference material:

Books:

1. Chromatographic methods by A.Braithwaite & S.J.Smith, Kluwer Academic publishers, Netherlands, London, USA.
2. Thermal Analysis of Pharmaceuticals by Craig, Informa, CRC Press, Indian Reprint.
3. Practical Pharmaceutical Chemistry by A.H.Beckett and J.B.Stenlake, fourth edition, part two, CBS Publishers and Distributors.
4. Spectrometric Identification of Organic compounds by R.M.Silverstein, F.X.Webster,D.J.Kiemle , Latest edition, John Wiley & Sons
5. Applications of absorption spectroscopy of organic compounds by John Robert Dyer
6. Organic Spectroscopy by William Kemp, PALGRAVE.
7. Textbook of Pharmaceutical Analysis by K.A.Connors, Wiley Interscience Publications.
8. Introduction to Spectroscopy by D.L.Pavia, G.M.Lampman & G.S.Kriz.
9. Remington: The Science & Practice of Pharmacy, 20th edition, Vol. 1, Lippincot Williams & Wilkins
10. Introduction to Modern Liquid Chromatography by L.R.Snyder, J.J.Kirkland 3rd edition.
11. Chiral separations by Liquid Chromatography and Related Technologies Chromatographic Science Series by Hassan Y., Imran Ali, Vol. 90.
12. Static head space gas chromatography Theory & practice by Bruno Kolb & L.S.Ettre.
13. Encyclopedia of Chromatography, by Jack Cazes, 3rd edition, Vol.1,2 & 3.
14. Online LC-NMR and Related techniques by Klasu Albert, John Wiley & Sons
15. LC-MS- A Practical Users guide, by Marvin C. McMaster.

Course: Study of Natural Products (CBCS)			
Course Code: MPH_C_105_T	**First Year M. Pharm**		**Semester: I**
Type of course: Theory	**Contact Hours: 4 Hours/week (3L + 1T)**		**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	**15**	**5**	80
Pre-requisites:	Basic knowledge of biological sources of various medicinal plants		
Course Objectives:	After completion of the course students will be able to understand extraction of phytochemcials and understand the significance of herbal drugs in drug discovery and development		

Course Outcomes: Upon completion of the course the student shall be able to:		**PO Mapped**	**PSO mapped**
CO1	Define and summarize phytochemicals and herbal drugs used in drug discovery, nutraceuticals, immunoglobulins and related applications	1, 2, 3, 8, 11	1, 2, 3
CO2	Explain the use of herbal drugs as excipients, in utraceuticals, as immunoglobulins and related applications	1, 2, 3, 4, 6, 8, 11	1, 2, 3
CO3	Apply the knowledge gained to isolate phytochemicals from herbal drugs and carry out standardization	2, 3, 4, 11	1, 2, 3
CO4	Summarize the information of various herbs from Herbal Pharmacopoeia	2, 3, 4, 8, 11	1, 2, 3

Topics covered:

Unit 1: Introduction to study and research in herbal drugs:	**Hours: 4**

- Different approaches to plant selection, collection and processing for 2 herbal drug research (Random selection, use of ethnobotanical information, Use of chemotaxonomical classification etc.).

● Recent advances in concept of authentication & standardization - significance of chemotaxonomy and DNA finger-printing with respect to gene expression for secondary metabolites.	
Unit 2: Extraction of phytochemicals	**Hours: 18**
● Concepts of extraction with respect to activity guided fractionation & isolation of Markers/Biomarkers. ● Recent trends in extraction, optimization of extraction, and analysis of the phytochemicals of different classes. ● Detail discussion of large-scale extraction of the following: (1) Opium alkaloids (2) Piperine (3) Sennosides (4) Caffeine (5) Cinchona alkaloids (6) Rutin (7) Lemon grass oil (8) Patchouli oil (9) Steroids (Diosgenin from all sources) ● Self-study- preparation of flow chart and discussion of physicochemical principles for all large-scale extractions	
Unit 3: Natural products in drug discovery and drug development	**Hours: 8**
● Role of natural products as leads to the design of new drugs with case history with examples e.g., artemisinin, taxane, camptothecin and a few others. ● Natural products derived combinatorial libraries and their significance in drugs discovery programme (HITS and leads). ● Self-study- Discussion of lead molecules in drug discovery	
Unit 4: Study of following excipients of natural origin in NDDS with respect to sources, preparation, composition and application	**Hours: 16**
● Natural dyes & colorants, sweeteners, flavours and fragrant materials ● Kappa carrageenans, galactomannans, glucomannans, cellulose derivatives, lecithin, & alginates. ● Self-study- Role of excipients mentioned above, in formulations, with examples	
Unit 5: Application of immunoglobulins from plant sources in diagnosis and therapy	**Hours: 4**
Unit 6: Nutraceuticals and their role in health care.	**Hours: 4**
Study of following classes of herbs with two or three suitable examples of each: (1) Antioxidants (2) Immunomodulators (3) Antihyperglycemics (4) Hepatoprotectives	
Unit 7: Status of natural products in official books	**Hours: 6**
● Introduction to Herbal Pharmacopoeias of different countries ● Monographs of natural products in other official books ● Self-study-Discussion of monograph of few substances of natural origin	
Reference material:	**Books:** 1. Pharmacognosy Phytochemistry – Medicinal Plants- Jean Brunetton, Lavoisier Publishing, Paris. 2. Text book of Pharmacognosy- Trease and Evans- 14th edition. Elsevier science 3. Transgenic Plants- R. Ranjan- Agro Botanica, New Delhi. 4. Transgenic Plants-A Production system for Industrial and Pharmaceutical Proteins. By Meran Owen, Jan Pen- John Wiley. 5. Medicinal Plant-Their Bioactivity, Screening and Evaluation- CSIR.

6. Homeopathic Pharmacopoeia of India- Publisher Ministry of Health.
7. The Ayurvedic Formulary of Part I & II- Publisher Ministry of Health.
8. Chinese Materia Medica-You-Ping Zhu- Harwood Academic Publishers.
9. India Materia Medica- Nadkarni A.K. –Bombay Popular Prakashan.
10. Phytochemical Methods - J.B.Harbone - Chapman and hall
11. Cultivations and Processing of Medicinal Plants-Ed. by L. Hornok-John Wiley.
12. Introduction to Flavanoids-Bohrn Bruce A. – Herwood Academic Publishers.
13. Cultivation and Utilization of Aromatic plants – Ed. By Atal C. K. and Kapur B.M.-CSIR.
14. Plant Tissue and Cell Culture Ed. H.E. Street – Blackwell Scientific publications.
15. Aflatoxin- Leo A. Goldblatt- Academic Press New York.
16. Microbial Toxins- Ciejler, Kadis and Ajl- Academic press.
17. Antimicrobial in Food – Alfred larry Branen, P. Michael Davidson Publishing house
18. Chemical plant Taxonomy T. Swain, 1963. Academic Press, London.
19. Plant Taxonomy and Biosystematics .C.A Stace, 1985. Edward Arnold, London.
20. Modern methods of plant analysis K. Paech, 1956., Springer-Verlag.
21. Indian Herbal Pharmacopoeia, Vol. 1&2, RRL, IDMA, 1998, 2000.
22. Indian Pharmacopoeia, 2010.
23. Standardization of Botanicals,V. Rajpal, 2002. Eastern Publishers, New Delhi.
24. Natural Compounds as Drugs – Vols. I & II, Editor- Frank Petersen, René Amstutz, Die Deutsche Bibliothek, Germany.
25. Quality control of Herbal Drugs: An Approach to evaluation of Botanicals, Pulok Mukherjee - Riddhi International
26. Chemicals from Plants: Perspectives on Plant Secondary Product, Walton & Braun, Imperial College Press.
27. Towards Natural Medicine Research in the 21st Century H. Ageta, N. Aimi et al Excerpta Medica, International Congress Series 1157.

Semester - II

<table>
<tr><td colspan="5">Course: Biostatistics & Research Methodology (CBCS)</td></tr>
<tr><td>Course Code:
MPH_C_201_T</td><td colspan="3">First Year M. Pharm</td><td>Semester: II</td></tr>
<tr><td>Type of course: Theory</td><td colspan="3">Contact Hours: 4 Hours/week (3L + 1T)</td><td>Total Contact Hours: 60</td></tr>
<tr><td>Course assessment Methods:</td><td colspan="2">Continuous mode of assessment</td><td colspan="2">Semester-end assessment</td></tr>
<tr><td>Assessment Tool*:</td><td>Theory Sessional Exam</td><td colspan="2">Attendance</td><td>End semester Examination</td></tr>
<tr><td>Max. Marks:</td><td>15</td><td colspan="2">5</td><td>80</td></tr>
<tr><td>Pre-requisites:</td><td colspan="4">Students must be aware about the following:
Importance of research
Basic terminologies like hypothesis, aim, objectives, rationale in research</td></tr>
<tr><td>Course Objectives:</td><td colspan="4">This Course aims to:
To train students in general research methodologies like objectives, study design, review of literature, randomization, types of studies
To train students in Biostatistics to enable them to statistically evaluate their research data
To train students in the basic concepts of medical research including informed consent, , concepts like autonomy, beneficence and non-maleficence, as well as about the declaration of Helsinki and other guidelines like ICH GCP, Nuremberg code which govern ethical conduct of clinical trials.
To train students on the CPCSEA guidelines for animal handling and animal house facilities including the transport, storage and care of animals. As well as about the basic procedures to be followed to ensure the efficient management of animal house facility at the site</td></tr>
<tr><td colspan="2">Course Outcomes: Upon completion of the course the student shall be able to:</td><td colspan="2">PO Mapped</td><td>PSO mapped</td></tr>
<tr><td>CO1</td><td>Students will be able to explain basic research methodologies like objectives study design, review of literature, randomization, types of studies</td><td colspan="2">1,2,6,7,8,9,10,11</td><td>1,2,3</td></tr>
<tr><td>CO2</td><td>Students will be able to explain, analyze the data and apply the</td><td colspan="2">1,2,3,6,7,8,9,</td><td>1,2,3</td></tr>
</table>

	statistical principles in the evaluation of the research data	10,11	
CO3	Students will be able to explain the basic concepts of medical research including informed consent, , concepts like autonomy, beneficence and non-maleficence, as well as about the declaration of Helsinki and other guidelines like ICH GCP, Nuremberg code which govern ethical conduct of clinical trials	1,2,3,6,7,8,9, 10,11	1,2,3
CO4	Students will be able to explain the basic facilities in animal handling and animal house facilities like transport, storage and care of animals. As well as about the basic procedures to be followed to ensure the efficient management of animal house facility at the site.	1,2,3,6,7,8,9, 10,11	1,2,3

Topics covered:

Biostatistics

Unit 1: Collection and Organization of data	**Hours: 8**

- Graphical and pictorial presentation of data
- Measures of central tendency and dispersion
- Variance and standard deviation, relative error, coefficient of variation, precision and accuracy
- Sampling techniques: simple random sampling; stratification; estimation of the mean and proportion.

Unit 2: Probability	**Hours: 6**

- Definition. Conditional probability and Bayes' theorem. Probability distributions: binomial, multinomial and Poisson distributions. Normal and lognormal distributions. Use of normal distribution tables.

Unit 3: Regression	**Hours: 6**

- Linear regression and correlation, curvilinear regression, method of least squares, curve fitting, Fiducial limits, probit and logit analysis

Unit 4: Parametric tests	**Hours: 8**

- Testing hypothesis, Types of error. Level of significance. Significance tests and p-value
- Tests of significance based on normal distribution, test of significance for correlation coefficients, confidence interval for mean and regression proportion

Unit 5: Nonparametric tests	**Hours: 4**

- Nonparametric procedures: Chi square goodness of fit test, sign test, MannWhitney test; Wilcoxon signed rank test

Unit 6: Experimental designs	**Hours: 8**

● Randomization, completely randomized, randomized block and Latin square designs, factorial design, cross over and parallel designs ● Students should learn use of Minitab / R Software for data summary, correlation, regression analysis, test of hypothesis and experimental design	
Research Methodology	
Unit 7: Objectives and purpose of Research	**Hours: 2**
● Types of research – Educational, clinical, experimental, basic, applied and patent-oriented research	
Unit 8: Literature survey	**Hours: 2**
Use of library, books and journals, eJournals, retrieving patents and seeking reprints	
Unit 9: Methods and tools used in research	**Hours: 6**
● Qualitiative and quantitative studies ● Simple data organization, descriptive data analysis ● Limitations and sources of errs ● Inquiries in form of questionnaire, opinionaire or by interview ● Statistical analysis of data including variance, standard deviation, standard error, mean, student's t test and annova, correlation of data and its interpretation, computer data analysis	
Unit 10: Scientific writing and reporting	**Hours:3**
● Different types of research papers ● Title and author names ● Abstract and key words ● Methodology	
Unit 11: Scientific Presentation	**Hours:3**
● Importance, types and different skills ● Content, format of model, introduction and ending ● Skills for oral presentation and types of visual aids ● Questionnaire	
Unit 12: Patents and Trade marks	**Hours:4**
● The Indian patent system ● Present status of intellectual property rights (IPR) ● Product patents and process patent ● Requirements and preparation of patent proposal ● Registration of patent in foreign countries	
Reference material:	**Books:** 16. Chromatographic methods by A.Braithwaite & S.J.Smith, Kluwer Academic publishers, Netherlands, London, USA. 17. Thermal Analysis of Pharmaceuticals by Craig, Informa, CRC Press, Indian Reprint. 18. Practical Pharmaceutical Chemistry by A.H.Beckett and J.B.Stenlake, fourth edition, part two, CBS Publishers and Distributors. 19. Spectrometric Identification of Organic compounds by R.M.Silverstein,

	F.X.Webster,D.J.Kiemle , Latest edition, John Wiley & Sons 20. Applications of absorption spectroscopy of organic compounds by John Robert Dyer 21. Organic Spectroscopy by William Kemp, PALGRAVE. 22. Textbook of Pharmaceutical Analysis by K.A.Connors, Wiley Interscience Publications. 23. Introduction to Spectroscopy by D.L.Pavia, G.M.Lampman & G.S.Kriz. 24. Remington: The Science & Practice of Pharmacy, 20th edition, Vol. 1, Lippincot Williams & Wilkins 25. Introduction to Modern Liquid Chromatography by L.R.Snyder, J.J.Kirkland 3rd edition. 26. Chiral separations by Liquid Chromatography and Related Technologies Chromatographic Science Series by Hassan Y., Imran Ali, Vol. 90. 27. Static head space gas chromatography Theory & practice by Bruno Kolb & L.S.Ettre. 28. Encyclopedia of Chromatography, by Jack Cazes, 3rd edition, Vol.1,2 & 3. 29. Online LC-NMR and Related techniques by Klasu Albert, John Wiley & Sons 30. LC-MS- A Practical Users guide, by Marvin C. McMaster.

<table>
<tr><td colspan="5">Course: Advanced Pharmaceutical and Medicinal Chemistry (CBCS)</td></tr>
<tr><td>Course Code:

MPH_C_202_T</td><td colspan="2">First Year M. Pharm</td><td colspan="2">Semester: II</td></tr>
<tr><td>Type of course: Theory</td><td colspan="2">Contact Hours: 4 Hours/week (4L + 1T)</td><td colspan="2">Total Contact Hours: 60</td></tr>
<tr><td>Course assessment Methods:</td><td colspan="2">Continuous mode of assessment</td><td colspan="2">Semester-end assessment</td></tr>
<tr><td>Assessment Tool*:</td><td>Theory Sessional Exam</td><td>Attendance</td><td colspan="2">End semester Examination</td></tr>
<tr><td>Max. Marks:</td><td>15</td><td>5</td><td colspan="2">80</td></tr>
<tr><td>Pre-requisites:</td><td colspan="4">Before undertaking the course, students should have knowledge of the following:

1. Basics of enzymes as drug targets

2. Basics of parameters of drug molecules responsible for steric, lipophilic and electronic factors.

3. Biotechnological aspects in vaccine development.</td></tr>
<tr><td>Course Objectives:</td><td colspan="4">After completion of course students will be able to know:

● Various strategies to design and develop new drug like molecules for biological targets

● Statistical methods used in QSAR analysis and importance of statistical parameters

● Therapeutic values of Peptidomimetics

● Production of antisense agents

● Use of biotechnology in association with molecular biology and genetic engineering in production of drugs.</td></tr>
<tr><td colspan="3">Course Outcomes: Upon completion of the course the student shall be able to:</td><td>PO Mapped</td><td>PSO mapped</td></tr>
</table>

CO1	Recall and relate the concept of enzyme kinetics and principles of enzyme inhibitors with the new advancements in medicinal chemistry with respect to synergism, biological activity of the molecule. Finding peptide synthesis and RNA structure to develop potential agents.	1, 2, 3,4, 6, 8, 9, 11	1, 2, 3
CO2	Classify the type of enzyme inhibitors and interpret their nature of inhibition from the various plots of enzyme kinetics to explain and understand their molecular mechanism of inhibition and establish the relation with their IC50 and Ki values.	1, 2, 4, 5, 6, 8, 9, 11	1, 2, 3
CO3	Identify and make use of descriptors of molecules to develop an equation to quantitatively establish the structure activity relationship.	1, 2, 3, 4, 7, 8, 9, 10, 11	1, 2, 3
CO4	Apply the acquired knowledge in design of covalently and non-covalently binding enzyme inhibitors, peptidomimetics, antisense agents and biologicals based on converged fields of chemistry and biology.	1, 2, 3, 4, 6, 7, 9, 11	1, 2, 3

Topics covered:

Unit I:	**Enzyme Inhibition**	**Hours: 16**

- Coverage of basic aspects of enzyme kinetics, catalysis, transition-state theory.
- Drug Resistance through alterations of drug uptake, overproduction of enzyme, alterations of the enzyme active site, overproduction of the substrate or new pathways for formation of the product
- Drug synergism, concepts and mechanisms.
- Reversible enzyme inhibitors – competitive inhibition, non-competitive inhibition, uncompetitive inhibition with suitable examples. Detection of type of inhibition by suitable plotting methods. Concepts of IC50 and Ki.
- Slow-tight binding inhibitors, covalent enzyme inhibitors and mechanism-based inhibitors with suitable examples. Concept of Kinact and Ki for irreversible inhibitors
- Self-study of specific examples of different types of inhibitors and their design (some examples like COX inhibitors, ACE inhibitors, RT inhibitors, HIV protease inhibitors, aromatase inhibitors, DHFR inhibitors, viral DNA polymerase inhibitors, thymidylate synthase inhibitors and others).

Unit II:	**QSAR**	**Hours: 14**

- Historical Aspects
- Electronic Effects- the Hammett equation, lipophilic effects, experimental measurement of lipophilicity, logP and logD, effect of ionization on logP, calculation of logP and logD, Steric effects- the Taft equation
- Hansch Analysis, Free-Wilson method, Topliss operational scheme
- Basics of regression analysis - linear and multilinear regression, introduction to PCA, PCR, PLS, ANN and GFA. Correlation coefficients (r2 and r2 pred), F-test, standard

<table>
<tr><td colspan="3">error, validation methods like cross-validation by calculation of q2, boot-strap analysis and randomization. Application domain for predictions using a QSAR model.
● Design of training and test sets using factorial design
● Self-Study – Different types of descriptors reported in literature that account for the steric, electronic and lipophilic effects.</td></tr>
<tr><td>Unit III:</td><td>Peptides and Peptidomimetics</td><td>Hours: 14</td></tr>
<tr><td colspan="3">● Coverage of peptide structure, biosynthesis of peptides and solid-phase/solution synthesis of peptides.
● Design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally, α-helix, β-sheet, β-and γ-turn mimetics
● Self-study of examples of peptidomimetics for some enzymes and receptors like ACE, CCK, bradykinin
● Self-study of examples of peptidomimetics for some enzymes and receptors like ACE, CCK, bradykinin</td></tr>
<tr><td>Unit IV:</td><td>Antisense therapeutic agents</td><td>Hours: 6</td></tr>
<tr><td colspan="3">● History and principles
● Design of antisense oligonucleotides and small interfering RNAs (siRNAs) with some examples</td></tr>
<tr><td>Unit V:</td><td>Molecular Biology, Genetic engineering and Biotechnology</td><td>Hours: 6</td></tr>
<tr><td colspan="3">● Molecular Biology, Genetic engineering and Biotechnology in production of biologicals as drugs.
● Self-study of biotechnology-based drugs, vaccines and diagnostic agents with respect to their biological source, their design and the mechanism of their actions</td></tr>
<tr><td>Reference material:</td><td colspan="2">Books:

1. The Organic Chemistry of Drug Design and Drug Action, Silverman R. B., Academic Press.
2. Textbook of Drug Design and Discovery, Eds. Krogsgaard-Larsen P., Liljefors T., Madsen U., Taylor & Francis.
3. Medicinal Chemistry: An Introduction, Thomas G, Wiley.
4. Peptide and Protein Design for Biopharmaceutical Applications, Ed Jensen K. J., Ch. 3 Aspects of Peptidomimetics by Maes V., Tourwé D., John Wiley & Sons, Ltd, Chichester, UK.
5. Comprehensive Medicinal Chemistry, Series Ed., Hansch C., Pergamon Press.
6. Burger's Medicinal Chemistry, Drug Discovery and Development, Wiley.</td></tr>
</table>

Course:Advanced Organic Chemistry (CBCS 2016)				
Course Code: MPH_C_203_T	**First Year M. Pharm**		**Semester: II**	
Type of course: Theory	**Contact Hours: 4 Hours/week (3L + 1T)**			**Total Contact Hours:60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**	
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination	
Max. Marks:	**15**	**5**	**80**	
Pre-requisites:	Students should recollect basic reactions of organic chemistry and should have understanding of how to write reaction mechanism stepwise. Student should possess knowledge related to basic concepts of stereochemistry and biological significance of chiral medicinal drugs. Students should have through understanding of conventional synthetic methods for organic compound.			
Course Objectives:	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. To understand concepts of synthon approach			

Course Outcomes: Upon completion of the current course the learner would be able to:		**PO Mapped**	**PSO mapped**
CO1	Learn and apply advanced concepts of stereochemisty	1,3,4,8,10,11	1,2
CO2	Understand and explain basic concepts of Catalysis, its types and different reactions of organometallic compounds.	1,3,4,8,10,11	1,2,3
CO3	Understand the restrosynthetic methods and apply the knowledge of reactions covered for predicting retrosynthetic pathways of newer drugs	1,3,4,8,10,11	1,2
CO4	Apply and integrate acquired concepts of asymmetric synthesis in synthesis of chiral medicinal compounds.	1,3,4,8,10,11	1,2,3
CO5	Understand the merits and techniques involved in combinatorial synthesis	1,3,4,8,10,11	1,2,3
CO6	Understand various greener chemistry approaches and compare them against conventional methods of synthesis	1,3,4,8,10,11	1,2,3

Topics covered:		
Unit I:	**Advanced Stereochemistry**	**12**

- *Self Study - Coverage of the basic concepts in stereochemistry –optical activity, specific rotation, racemates and resolution of racemates, the Cahn-Ingold-Prelog sequence rule, meso compounds, pseudo asymmetric centres, pro-R, pro-S, axes of symmetry, Fischers D and L notation, cis-trans isomerism, exoendo, syn-anti nomenclature. Stereoselective and stereospecific reactions. Conformational isomerism in acyclic systems. Shape of six membered rings and effect of substituents and reactivity*.
- Chirality in systems lacking a stereogenic carbon atom
- Point chirality – tertiary amines and phosphines
- Axial chirality – allenes, biphenyls and binaphthyls
- Helical structures – polynucleotides, polyamino acids, biaryls and Allenes
- Methods for estimating ratios of stereoisomers in a mixture,separation and identification of the individual components by NMR spectroscopy, X-ray crystallography
- Nucleophilic attack on acyclic carbonyl compounds – Cram's rule, Felkin-Ahn rule. Locking effects in nucleophilic reactions at carbonyl groups Stereochemistry of important reactions leading to formation of alkenes – Wittig and related reactions

Unit II:	**Catalysis & Organometallics in Organic Synthesis**	**12**

- Types of catalysis, heterogeneous and homogenous catalysis, advantages and disadvantages, catalytic cycles
- Heterogeneous catalysis – preparation, characterization, kinetics,
- supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.
- Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogenous catalysis used in synthesis of drugs
- Phase transfer catalysis - theory and applications
- Introduction, Classification of organometallic compounds based on hapticity and polarity of the M-C bond. Nomenclature and general characters. Synthesis, stability and decomposition pathways**.**
- Transition metal π-complexes with unsaturated organic molecules,carbon monoxide, alkenes, alkynes, allyl, dienes, cyclopentadienyl, arene complexes, preparation, properties, nature of bonding and structural features, important reactions relating to nucleophilic attack on ligands and to organic synthesis. Basic organometallic reactions covering oxidative reactions, migratory reactions, insertions, extrusion, additions, eliminations – their mechanisms and stereochemistry.
- *Self Study - Basic organometallic reactions covering oxidative*
- *reactions, migratory reactions, insertions, extrusion, additions,*
- *eliminations – their mechanisms and stereochemistry*

Unit III:	**Synthon Approach and Applications**	**Hours: 13**

- Retrosynthesis and its advantages, rules for dissection of molecules, meaning of the term, disconnection, FGI, FGA and synthons, guidelines for the order of events
- C-X disconnections; C-C disconnections – alcohols and carbonyl compounds; 1,2-, 1,3-, 1,4-, 1,5-, 1,6-difunctionalized compounds
- Strategies for synthesis of three, four, five and six-membered rings
- Strategies for synthesis of aromatic and saturated heterocycles
- *Self Study – Strategies for synthesis of saturated heterocycles.*

Unit IV:	**Asymmetric Synthesis**	**Hours: 6**
● Introduction and need; chiral synthesis using chiral pool, chiral auxiliaries, chiral catalysts ● Enzymes, chiral solvents and whole organisms ● Analytical methods of determining purity of stereoisomers ● *Self Study - Applications in industry*		
Unit V:	**Combinatorial Chemistry**	**Hours: 11**
● Introduction, advantages and planning combinatorial synthesis ● Solid phase and solution phase synthesis ● Supports, linkers, and tags ● Deconvolution and iteration ● Parallel synthesis, multistep – convergent and sequential synthesis. ● *Self Study – Multicomponent reactions*		
Unit VI:	**Green Chemistry**	**Hours: 5**
● History, need and the goals of green chemistry ● Basic principles of green chemistry, illustrated with examples to discuss issues of prevention of waste or minimize by-products, atomeconomy, prevent and minimize formation of hazardous or toxic products, design of safer chemical equivalents, selection of appropriate solvents, media, separation agents, improve economy and efficiency of reactions, by use of microwaves, ultrasound etc and use of renewable starting materials. ● *Self Study – Reactions carried out using Microwave and ultrasound.*		
Reference material:	**Books** 1. Stereochemistry of carbon compounds, Eliel E, Wilen S H, Manden L N, Wiley. 2. Stereochemistry of Organic Compounds, Nasipuri D, Wiley Eastern. 3. Advanced Organic Chemistry, Carey FA and Sundberg RJ, Part A and B, Springer 4. Introduction to Green Chemistry, Ryan M. A., Tinnesand M., American Chemical Society (Washington). 5. Combinatorial Chemistry; Synthesis and Application, Eds., Wilson S. R. Czarnik A. W.Wiley: New York. 6. Organic Chemistry, Clayden J, Greeves N, Warren S, Wothers P, Oxford University Press. 7. Stereoselective Synthesis, Atkinson R S, John Wiley & Sons. 8. The Organometallic Chemistry of the Transition Metals, Crabtree R. H., John Wiley 9. Transition Metals in Synthesis of Complex Organic Molecules, Hegedus L., University Science Books. 10. Homogenous Transition Metal Catalysis, Masters C., Chapman & Hall. 11. Principles and Practice of Heterogenous Catalysis, Thomas J. M., Thomas M. J., John Wiley 12. Principles of Asymmetric Synthesis, Gawley R. E., Aubrey J, Elsevier. 13. Greene's Protective Groups in Organic Synthesis, Wuts, P. G. M., Green T. W., Wiley 14. Organic Synthesis – The Disconnection Approach, Stuart, W., Wiley. 15. The logic of chemical synthesis, Corey E J and Cheng X-M, John Wiley and Sons.	

Course: Advanced Pharmaceutics I (CBCS Revised 2016)					
Course Code: MPH_C_204_T	**First Year M. Pharm**			**Semester: I**	
Type of course: Theory	**Contact Hours: 4 Hours/week (4L)**			**Total Contact Hours: 60**	
Course assessment Methods:	**Continuous mode of assessment**				**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	Three Academic Activities	Teacher - Student interaction	End semester Examination
Max. Marks:	**15**	**4**	**3**	**3**	75
Pre-requisites:	Should have knowledge of recent advances in new drug delivery systems and pharmaceutical market trend.				
Course Objectives:	The course aims to impart a higher level of theoretical up to date knowledge in design, development and evaluation of advanced drug delivery systems.				

Course Outcomes Upon completion of the course, the students will be able to		**PO Mapped**	**PSO mapped**
CO1	Understand the recent advances in tablet technology. Will acquire insight to oral controlled release drug delivery system and machinery used for the same.	1,3,5,6,9,11	1, 3
CO2	Familiarize with the recent advances in particulate drug delivery systems, provide an insight to formulation and evaluation of small volume and large volume Parenterals and study the recent advances in injectable controlled release and long acting formulations	1,3,5,6,9,11	1,3
CO3	Will be introduced to specialized pharmaceutical disperse phase systems.	1,3,5,6,9,11	1,3
CO4	Understand the recent advances in gastro retentive oral drug delivery systems, concepts and various types of oral controlled release drug delivery system and evaluation methods for the same.	1,3,5,6,9,11	1,3
CO5	Acquire knowledge on site specific drug delivery systems to increase therapeutic efficacy of drug with minimum side-effects. Understand physiology of eye and develop advancements in ocular controlled drug delivery systems.	1,3,5,6,9,11	1,3
CO6	Acquire knowledge on site specific drug delivery systems to increase therapeutic efficacy of drug with minimum side-effects. Understand in detail biochemistry and anatomy of skin, recent developments in transdermal drug delivery systems and evaluate TDDS as per regulatory guidelines. Perceive knowledge on Quality by design to obtain safe, effective and reproducible formulations (as per ICH guidelines)	1,3,5,6,9,11	1,2,3

Topics covered:		
Unit I:	**Solids – oral SR system**	**Hours: 13**
▪ Overview of Single oral unit SR systems, Structure and physiology of GIT, Mechanism of Release & Release kinetic equations. Types – Diffusion controlled, Dissolution controlled, Reservoir, Matrix, Osmotic systems, Ion exchange systems Mucosal drug delivery systems-buccal, gingival, sublingual. Multiparticulate systems-pelletization (emphasis on extrusion and spheronization). Orodispersible systems. Pulsatile Drug delivery systems.		
Unit II:	**Parenteral SR systems**	**Hours: 12**
▪ Need and concept, routes employed, Approaches- aqueous systems (complexation, use of polymers), aqueous suspensions (depot injections, microspheres, magnetic microspheres), Oily solutions & suspensions, Emulsions (Microemulsions, multiple emulsions,), Implants (in detail-concept, properties desired, various approaches), prodrugs (chemical modifications), infusion pumps, Biopharmaceutical aspects, Sterilization & stability issues, Characterization wrt on release studies, Issues related to Safety, Toxicity & Tissue Injury		
Unit III:	**Specialized Emulsions**	**Hours: 9**
▪ Microemulsions, Multiple emulsions, Self Emulsifying Drug Delivery systems & SMEDDS; Formulation and phase behaviour; Preparation & Characterization; Bioavailabity Aspects; Applications, Theories of Emulsification, Factors influencing type of emulsion formed.		
Unit IV:	**Gastro-retentive Drug Delivery Systems**	**Hours: 8**
● Introduction; concept of absorption window; need for GRDDS, gastric motility; principles of Gastro-retention; Factors controlling performance of GRDDS. Different Approaches- High density systems, floating systems, mucoadhesive systems, Expandable systems, Magnetic systems, Superporous Hydrogels, Evaluation.		
Unit V:	**Ocular drug delivery systems.**	**Hours: 7**
● Structure and physiology of eye; Drug absorption and disposition in the eye. Methods to prolong ocular drug residence with emphasis on mucoadhesive systems. Intraocular inserts; Nonerodible inserts / Erodible inserts. Novel ophthalmic drug delivery systems, Nanoparticles , liposomes and prodrugs. Ocular penetration enhancers.		
Unit VI:	**Transdermal Drug Delivery Systems**	**Hours: 7**
● Structure and physiology of skin. Principles of skin permeation. Kinetics of skin permeation & penetration enhancers. Types (Gels, Patches/films), Pressure sensitive adhesives, Development & evaluation – in vitro, in vivo. Iontophoresis, Recent advances –use of microneedles in transdermal drug delivery.		
Unit VI:	**Introduction to Pharmaceutical Processing Development.**	**Hours: 4**
● Elements in Pharmaceutical development- Target product profile, Critical Quality Attributes., Linking Material Attributes & process parameters to CQA's Risk Assessment Design space, Control Strategy, Product Lifecycle management & continual improvement. Submission of Pharmaceutical Development and related information in CTD format.		
Reference material:	1. Targeted and Controlled Drug Delivery: Novel Carrier Systems by Vyas SP, Khar RK, CBS Publishers and Distributors, 1stedn, 2002. 2. Controlled and Novel Drug Delivery by Jain NK, CBS Publishers and Distributors, 2008. 3. Controlled Drug Delivery: Fundamentals and Applications by Robinson JR, Lee VHL, Dekker, 2 ndedn, Vol 29, 1987. 4. Novel Drug Delivery System by Chien YW, 2ndedn, Vol 50, Informa Healthcare,	

	2003. 5. Progress in Controlled and Novel Drug Delivery Systems by Jain NK, CBS Publishers and Distributors; 2004. 6. Ophthalmic Drug Delivery Systems, Mitra AK, 2nd edn., Drugs and Pharmaceutical Sciences Series, Vol. 130, Marcel Dekker, 2003. 7. Polymeric drug delivery system, Kwon GS, Marcel Dekker, Vol 148, 2005. 8. Nanoparticulate Drug Delivery System by Thassu D, Deleers M, Pathak Y, Marcel Dekker, Vol 166, 2007. 9. Controlled Drug Delivery- Challenges and Strategies by Park K, American Chemical Society, 1997. 10. Colloidal Drug Delivery System by Kreuter J, Marcel Dekker Vol 66, 1994. 11. www.ich.org 12. Pharmaceutical Dosage Forms: Disperse Systems by Lieberman HA, Rieger MM, Banker GS, Marcel Dekker, Vol 3, 2nd edn, 2005. 13. Pharmaceutical Emulsions and Suspensions by Nielloud F, Marti- Mestres G, Marcel Dekker, Vol 105, 2000. 14. Controlled Release Systems Fabrication Technology by Dean STH, CRC Press, Vol 1, 1988. 15. Bioadhesive Drug Delivery Systems by Mathiowitz.E , Chickering DE , Lehr CM, Marcel Dekker Vol 98 ,1999. 16. Pharmaceutical Skin Penetration Enhancement by Walters. K A, Hadgraft J, Marcel Dekker, Vol 59, 1993. 17. Percutaneous Absorption by Bronaugh RL, Maibach HI, Taylor and Francis, 3rd edn, Vol 97, 2005. 18. Transdermal Controlled Systemic Medication by Chien YW, Marcel Dekker, Vol. 31, 1987. 19. Oral Mucosal Drug Delivery by Rathbone MJ, Marcel Dekker, Vol 74, 1996. 20. Modified Release Drug Delivery Technology by Rathbone MJ, Hadgraft J, Roberts MS, Lane ME, Informa Healthcare, 2nd edn, Vol 183(1), 2008. 21. Pharmaceutical Pelletization Technology, Ghebre-sellassie. I, , Marcel Dekker, Vol. 37

Course: Advanced Pharmaceutics II (CBCS Revised 2016)					
Course Code: MPH_C_205_T	**First Year M. Pharm**			**Semester: I**	
Type of course: Theory	**Contact Hours: 4 Hours/week (4L)**			**Total Contact Hours: 60**	
Course assessment Methods:	**Continuous mode of assessment**				**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	Three Academic Activities	Teacher - Student interaction	End semester Examination
Max. Marks:	**15**	**4**	**3**	**3**	75

Pre-requisites:	Should have knowledge of recent advances in new drug delivery systems and pharmaceutical market trend.
Course Objectives:	The course aims to impart a higher level of theoretical up to date knowledge in design, development and evaluation of advanced drug delivery systems.

Course Outcomes Upon completion of the course, the students will be able to		**PO Mapped**	**PSO mapped**
CO1	Understand site specific drug delivery systems to increase therapeutic efficacy of drug with minimum side-effects. Will know specialized pharmaceutical dispersed systems and recent advances in particulate drug delivery systems.	1,3,5,6,9,11	1, 3
CO2	Understand anatomy and physiology of nasal mucosa and lungs. Have knowledge on recent developments in nasal and pulmonary drug delivery systems and its applications.	1,3,5,6,9,11	1,3
CO3	Understand the structural complexity and challenges to peptides and protein delivery of drugs and develop recent developments in peptide based drug delivery systems.	1,3,5,6,9,11	1,3
CO4	Gain knowledge on recent advances in particulate drug delivery systems.	1,3,5,6,9,11	1,3
CO5	Acquire knowledge on site specific drug delivery systems to increase therapeutic efficacy of drug with minimum side-effects. Understand physiology of brain, its barriers and develop advancements in brain controlled drug delivery systems.	1,3,5,6,9,11	1,3

Topics covered:

Unit I:	Targeted systems:-Active and Passive approaches:	**Hours: 6**

- Concepts and rationale of targeting: active and passive targeting, Cellular biochemistry and molecular events in drug targeting. Tumour targeting, Molecular targets for cellular targeting, Ligands as delivery and targeting tools, Concept of receptor mediated endocytosis

Unit II:	Pulmonary and nasal drug delivery systems:	**Hours: 14**

- Anatomy and physiology of the respiratory system, Airway physiology and disposition patterns
- Nasal drug delivery: Nasal administration – dosage forms, Strategies for enhancement in nasal absorption, Animal models for nasal absorption studies, Nasal preparations for systemic effect

- Pulmonary drug delivery : Factors affecting particle disposition in the lungs, Dosage forms for pulmonary drug delivery (Nebulizer, Metered dose inhalers, Dry powder inhalers), Drug targeting to the respiratory tract, Pulmonary receptor targeting

Unit III:	Protein and peptide drug delivery systems:	**Hours: 11**

- Structure of proteins and peptides, analysis of proteins and peptidesPhysical and chemical stability aspects, protein degradation pathways, techniques of stabilization of proteins and peptides, barriers to transport and approaches to circumvent metabolic barriers. General protein formulation and delivery system strategies. Routes for delivery of proteins and peptides with emphasis on oral and mucosal delivery, pulmonary delivery, nasal delivery and parenteral delivery

Unit IV:	Colloidal drug delivery systems:	**Hours: 22**

- Introduction, comparison with other colloidal drug carriers, Advantages/limitations, constituents and mechanism of formation, method of preparation and drug loading, characterisation and evaluation, stability, long circulating / modified form of colloidal drug carrier, bio distribution and application. An overview colloidal Drug Delivery with respect to Physicochemical& Biopharmaceutical aspects. Liposomes, Niosomes, Nanoparticles, SLNs, Polymeric micelles

Unit V:	Brain targeting:	**Hours: 7**

- Introduction, Blood brain barrier, CSF barrier, limitations in brain uptake of drug, desired physicochemical characteristics of drugs. Transport through BBB, Factors affecting drug permeation through BBB, Brain drug delivery strategies: Invasive- Intracerebral implants, Intraventricular infusion, BBB disruption, Non-invasive techniques- Chemical method, Colloidal drug carrier, receptor/ vector mediated approach. Miscellaneous techniques- Intranasal etc

Reference material:

1. Targeted and controlled drug delivery: Novel carrier systems- by S. P Vyas and R. K Khar, CBS publishers and distributors pvt Ltd.
2. Advances in controlled and novel drug delivery edited by N.K.Jain, CBS publishers and distributors pvt Ltd.
3. Robinson J.R and Lee- controlled and novel drug delivery.
4. Controlled drug delivery: Concepts and advances, S.P.Vyas, R.K. Khar, Vallabh Prakashan.
5. Chien- Y. W- Novel Drug Delivery System, Drug and pharmaceutical science series, Vol 14, New York Inc, Marcell Dekker.
6. Controlled and novel drug delivery edited by N. K .Jain, CBS publishers and distributors pvt Ltd.
7. Advances in pharmaceutical sciences – vol-1 to 5, by H. S. Bean and A. H Beckett.
8. Glen S. Kwon, Polymeric drug delivery system- Marcell Dekker Series , Vol 148, P.No.533-560
9. Thassu D "Nanoparticulate Drug Delivery System" Vol 166, Marcell Dekker Series 2007.
10. Park K, Control Drug Delivery- Challenges and Strategies, CRC, Washington DC 1997
11. MacNally E "Protein Formulation and Delivery" 2nd edition, Vol75, 2008 12. Kreuter J, Colloidal Drug Delivery System, Vol.66, Marcell Dekker, Inc New York,1994

Course: Quality Assurance System (CBCS)			
Course Code: **MPH_C_212_T**	**First Year M. Pharm**		**Semester: II**
Type of course: Theory	**Contact Hours: 4 Hours/week (3L + 1T)**		**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	**15**	**5**	80
Pre-requisites:	Basic understanding of validation and how it can be applied to industry and thus improve the quality of the products.		
Course Objectives:	Upon completion of this course, it is expected that students will be able to Understand the concepts of calibration, qualification and validation, the qualification of various equipment and instruments, Process validation of different dosage forms, Validation of analytical method for estimation of drugs, Cleaning validation of equipment employed in the manufacture of pharmaceuticals.		

Course Outcomes: Upon completion of the course the student shall be able to:		**PO Mapped**	**PSO mapped**
CO1	Understand the concept of validation, qualification and calibration	1,2,3,4,8, 11	1
CO2	Describe procedure for qualification of instruments and equipment	1.2.3.4	1
CO3	Summarize the parameters of ICH guidelines for analytical method validation.	1, 11	3
CO4	Comprehend the concept of process validation of different dosage forms	1,2,3,4,5, 6,7,8	1
CO5	Gain knowledge of the process of cleaning validation	1,2,3,4,8, 10	2
CO6	Correlate the knowledge of IPR with respect to pharmaceutical products	1,2,3,4,7, 8,11	3

Topics covered:

Unit 1: Regulatory basis for validation	**Hours: 5**
• US FDA guidelines (cGMP guidelines, 21 CFR 210-211), EU guidelines, WHO guidelines.	
Unit 2: Terminology and validation overview	**Hours: 10**
• Self-Study: Validation versus verification, testing, calibration and qualification. • Concepts of DQ, IQ, OQ and PQ • Concepts of Prospective validation, retrospective validation, Concurrent and revalidation. Validation Master Plan.	
Unit 3: Validation of Equipment	**Hours: 10**
• Dry Powder Mixers • Fluid Bed and Tray dryers • Tablet Compression Machine • Self-study: Dry Heat Sterilization/Tunnels • Autoclaves • Capsule filling machines • Validation of Integrated lines by media fill test	
Unit 4: Utilities Validation	**Hours: 7**
• Validation of Pharmaceutical Water System & pure steam • Validation of HAVC system • Validation of Compressed air	
Unit 5: Cleaning Validation	**Hours: 4**
• Self-study: Cleaning of Equipment, Cleaning of Facilities	
Unit 6: Analytical Method Validation	**Hours: 6**
• General principles of analytical method validation, Validation of following analytical Instruments: HPLC, Dissolution test apparatus, U.V./Visible spectrophotometers	
Unit 7: Process Validation	**Hours: 13**
• Self-study: Prospective, concurrent, retrospective & revalidation Self-study • Process validation of following formulations: Uncoated / Coated tablets, Hard gelatin Capsules, Ampoules & Vials, Self-study: Ointment/Creams, Self-study: Liquid Orals, Transdermal patches (Matrix systems)	
Unit 8: Self-Study-Computer system validation in controlling the manufacturing process.	**Hours: 2**
Unit 9: Process Analytical Technologies (PAT) and Quality by Design (QbD) (US FDA)	**Hours: 3**
Reference material:	**Books:** 1. Validation and Qualification in Analytical Laboratories by Ludwig Huber, Second edition (2007), Informa Health Care, New York, London. 2. Pharmaceutical Process Validation by R.Nash and Wachter, Volume 129, Latest edition, Marcel Dekker Inc, New York. 3. GMP for Pharmaceuticals by Sidney H. Willing, Fifth edition, Marcel Decker Series, New York.

	4. United States Pharmacopoeia & Indian Pharmacopoeia. 5. Validation of Pharmaceutical process, F. J. Carleton and J. Agalloco, Marcel Dekker Inc.

Course: Pharmaceutical Quality Management (CBCS)				
Course Code: MPH_C_213_T	**First Year M. Pharm**		**Semester: II**	
Type of course: Theory	**Contact Hours: 4 Hours/week (3L + 1T)**		**Total Contact Hours: 60**	
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**	
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination	
Max. Marks:	**15**	**5**	80	
Pre-requisites:	Basic knowledge of pharmaceutical manufacturing planning, processes and industry.			
Course Objectives:	Upon completion of the course, it is expected that students will be able to understand- 1. The importance of quality 2. ISO management systems 3. Tools for quality improvement 4. Analysis of issues in quality 5. Quality evaluation of pharmaceuticals 6. Stability testing of drug and drug substances 7. Statistical approaches for quality			

Course Outcomes: Upon completion of the course the student shall be able to:		**PO Mapped**	**PSO mapped**
CO1	Understand the concept of quality, strategic quality management and define different terms involved in quality management systems.	1,2,5,6	1,3
CO2	Understand the concept of statistical process control (SPC) and explain the principles involved in SPC like process capability, control chart analysis and process control.	2,3,4,5,11	1,3
CO3	Recognize the importance of customer, different concepts required to achieve customer satisfaction and desired quality the development of quality culture and define and comprehend the different terms, types and process involved in benchmarking.	3,6,8,9,10	3
CO4	Comprehend principles involved in pharmaceutical quality management like six sigma, ISO, WHO-GMP and CFR-21.	2,3,4,5,6,7,10	1,2

CO5	Apply ICH guidelines for drug stability, risk management and quality by design.	1,2,3,5,8,9	1,3

Topics covered:

Unit 1: Concept of-	**Hours: 8**
● Total Quality Management (TQM), Quality control and quality assurance, Quality control laboratory responsibilities. Self-study: Good laboratory practices	
Unit 2: GMP	**Hours: 8**
● Organization of pharmaceutical manufacturing unit, production management, ● Self-study: Revised schedule M	
Unit 3: Personnel:	**Hours: 12**
● Self-study: Introduction, Human resource development, Qualification Experience and Training, Responsibility, Personl Hygiene & Grooming. ● Location, Plant layout, Lighting, Sewage, Water Handling-Sewage, Refuge and Disposal, Washing and toilet facility, Sanitation, Controls of contamination and Environmental controlsties, Personal Hygiene and Gowning	
Unit 4: Materials Management:	**Hours: 8**
● API's, raw materials & packaging materials, Purchase specifications, Selection of vendors, Intermediates & Finished products, Rejected and Recovered materials, Recalled products, Reagents & culture media, Reference standards, Waste materials ● Warehousing- Good Warehousing Practices, distribution and records	
Unit 5: Manufacturing Operations and Control:	**Hours: 8**
● Self-study: Sanitation of Manufacturing Premises, Line clearance, Mix-ups and Cross contamination, Processing and holding of Intermediates and Bulk Products ● Packaging, I.P.Q.C., Release and storage of Finished Product, Process Deviations and Incidents, Drug product inspection, Yield calculations ● Expiry dating, Manufacturing record review and approval	
Unit 6: Documentation and Records:	**Hours: 6**
● In-process and Product Release Specifications, Master production and control record, Batch production and control record, Standard Operating Procedures (SOP), Change Control, Site master file	
Unit 7: Post Operational Activities:	**Hours: 5**
● Distribution, Complaints and recalls, evaluation of complaints, Recall procedures, related records and documents ● Outsourcing: Facility audit, Manufacturing, Packaging, Analytical, Clinical and other services outsourcing.	
Unit 8: Site and Plant security:	**Hours: 2**
● Security personnel, Entry procedures to site & plant, Internal security, Vehicle parking, Fuel storage, Canteen & cooking, Garden & horticulture	
Unit 9: Audits:	**Hours: 3**
● **Principle of Quality audit, Plant level, Department wise documentation**	

Reference material:	**Books:** **1.** Quality Assurance of Pharmaceuticals, Vol. 2, Updated Edition, World Health Organization, Geneva. **2.** S.H. Willing, Good Manufacturing Practices for Pharmaceuticals; A plan for total Quality control, Latest Edition, Marcel Dekker. 3. Regulatory guidelines related to GMP by: a. 21 Code of Federal Regulation, Parts 210, 211&58 (USFDA guidelines) b. EU, MHRA, UK Guidelines on GMP c. Schedule M of Drug & Cosmetics Act. 4. Quality Planning & Analysis by J. M. Juran and F. M. Gryna, Tata Mcgraw Hill, India. Quality Assurance Guide by Organization of Pharmaceutical Producers of India.

Course: Drug Metabolism (CBCS)			
Course Code: **MPH_C_217_T**	**First Year M. Pharm**		**Semester: II**
Type of course: Theory	**Contact Hours: 4 Hours/week (4L + 1T)**		**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	**15**	**5**	80
Pre-requisites:	• Basic knowledge of anatomy and physiology of liver and kidney • Concept of ADME		
Course Objectives:	Upon completion of the course the student will be able to predict the metabolic pathway for simple organic molecules/drugs		

Course Outcomes: Upon completion of the course the student shall be able to:		**PO Mapped**	**PSO mapped**
CO1	Recall the concept of drug metabolism, types of drug metabolism and in silico drug metabolism prediction	1, 2, 3, 7, 8, 11	1, 2, 3
CO2	Explain and illustrate the mechanism for metabolism of drugs through primary and secondary pathways	1, 2, 3, 4, 6, 7, 11	1, 2, 3
CO3	Application of the gained knowledge in basic studies on metabolism and metabolic profiling	1, 2, 4, 6, 7, 8, 11	1, 2, 3

Topics covered:

Unit 1:	**Introduction to xenobiotic/drug metabolism**	**Hours: 6**

- Introduction to xenobiotic/drug metabolism and its relation to other 2 defense systems (Physical barriers, excretion, immune system).
- Types of reactions (I and II), consequences of drug metabolism (DM) [inactivation, bioactivation, prodrugs], organs of DM, localization of drug metabolizing enzymes, factors affecting drug metabolism

Unit 2:	**Cytochrome P450s**	**Hours: 20**

- Introduction to the family of enzymes, their classification and nomenclature
- Introduction to the family of enzymes, their classification and nomenclature

● CYP450 catalytic cycle, different types of reactions catalyzed by CYP450s and the mechanisms of catalysis ● Human CYP450s involved in DM, their distribution and properties, typical substrates, specific probe substrates, specific inhibitors, induction of CYPs and specific inducers ● Genetic polymorphism in CYP450 expression		
Unit 3:	**NON P450 enzymes**	**Hours: 20**
● Introduction to NON P450 enzymes involved in drug metabolism ● Self-study of NON P450s - glucuronosyltransferases, sulfotransferases, glutathione S-transferases, N-acetyl transferases, xanthine oxidase, aldehyde oxidase, esterase, epoxide hydrolase, nitro/azo reducatases and FMO [on lines similar to that specified for CYPs as listed above]		
Unit 4:	**Introduction to methods for studying DM**	**Hours: 5**
● Discussion of in vitro and in vivo tools, along with their advantages and limitations {recombinant enzymes, subcellular fractions, hepatocytes, liver slices, perfused liver and whole animal studies}		
Unit 5:	**Discussion of types of DM studies**	**Hours: 6**
Metabolic stability, cross species comparisons, metabolite profiling and identification, reaction phenotyping, CYP inhibition and CYP induction studies.		
Unit 6:	**Introduction to in silico drug metabolite predictions and associated algorithms.**	**Hours: 3**
Reference material:	**Books:** 1. Rick NG. Drugs From Discovery to Approval, second edition, John Wiley & Sons, Inc 2004. 2. Allen Cato, Lynda Sutton, Clinical Drug Trials and Tribulations Second Edition Revised, second edition, Marcel Dekker Inc; 2nd Revised edition March 26, 2002. 3. Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance, second edition, John Wiley & Sons Ltd,2002. 4. Shayne C. Gad, Drug Safety Evaluatio, A John Wiley & Sons, Inc. Publication, 2000. 5. Sandy Weinberg. Guidebook For Drug Regulatory Submissions, first edition, A John Wiley & Sons, Inc. 2009. 6. Duolao Wang and Ameet Bakhai Clinical Trials A Practical Guide to Design, Analysis, and Reporting, Remedica 2006. 7. Giovanna di Ignazio, Di Giovanna and Haynes, Principals of Clinical Research, Wrightson Biomedical Pub., 2001 8. R K Rondels, S A Varley, C F Webb, Clinical Datamanagement, Second Edition, John Wiley & Sons Inc, January 1997. 9. Strom BI, Limmel SE. Textbook of Pharmacoepidemiology. Chichester, West Sussex, England: John Wiley & Sons Ltd; 2006. 10. Rascati, Karen L. Essentials Of Pharmacoeconomics. Philadelphia, Pa.: Lippincott Williams & Wilkins, 2009. 11. M. F. Drummond, M. J. Sculpher and G. W. Torrance, Methods for the economic evaluation of health care programmes. Oxford University Press, USA,	

	2005. 12. Brenda Waning; Michael Montagne; William W McCloskey, Pharmacoepidemiology: principles and practice, New York : McGraw-Hill, 2001 13. Various Guidelines like: ● ICH (International Conference on Harmonisation), GCP for registration of ● pharmaceuticals for human use. ICH Harmonised Tripartite ● Guideline for Good Clinical Practice, E6, 1996. ● ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects. ● Indian GCP – Central Drugs Standard Control Organization. Good Clinical Practices ● Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001. ● Pharmacovigilance Programme of India (PvPI)

Course: Experimental Techniques in Pharmaceutical Sciences (CBCS, 2016)				
Course Code: MPH_C_299_L	**First Year M. Pharm**			**Semester: I**
Type of course: Practical	**Contact Hours: 6 Hours/week**			**Total Contact Hours: 48**
Course assessment Methods:	**Continuous mode of assessment**			**Semester-end assessment**
Assessment Tool*:	**Theory Sessional Exam**	**Attendance**	**Total Internal Assessment**	**End semester Examination**
Max. Marks:	**15**	**5**	**20**	**80**
Pre-requisites:	Have practical knowledge in preparation of novel pharmaceutical products, concepts *in vitro* and *in vivo* studies.			
Course Objectives:	The course aims to impart a higher level of practical up to date knowledge in pharmaceutical product development, statistical models, bioavailability studies and cosmetic preparations.			

COURSE OUTCOMES		**PO Mapped**	**PSO Mapped**
CO1	Design novel drug delivery systems and evaluate them.	1, 3, 4, 6, 7	1, 2, 3
CO2	Apply the preformulation and excipient knowledge for proper design of safe, efficacious, stable and quality formulations.	1, 2, 3, 4, 6, 7, 8, 10, 11	1, 2, 3
CO3	Investigate various aspects of dissolution and its mathematical treatment.	1, 2, 3, 4, 6, 7, 8, 11	1, 2, 3
CO4	Analyze the formulation parameters, apply optimization techniques and devise suitable formulation composition.	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	1, 2, 3

TOPICS

1. Study of dissolution profile of IR and ER products. Mathematical treatment of data for release Kinetics and f1 and f2 analysis.
2. Simple Optimization design (formulation study/pH-stability study)
3. Design and evaluation of Orally Disintegrating Drug Delivery System
4. Preparation and evaluation of microspheres for inhalation system
5. Preparation and evaluation of transdermal/mucoadhesive/gastroretentive system
6. Constructing phase diagram for one system of oil, surfactant- cosurf, water
7. Design of one vesicular system - niosomes/liposomes systems
8. 8. Design of lipid particulate system (nanosystems with wax can be tried)

Reference material:	No separate books specified for practicals

Course: Rational Drug Design (CBCS)			
Course Code: **MPH_E_221_T**	**First Year M. Pharm**		**Semester: II**
Type of course: Theory	**Contact Hours: 4 Hours/week (4L + 1T)**		**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	**15**	**5**	80
Pre-requisites:	Before undertaking the course, students should have knowledge of the following: 1. Basics of Protein 3D structure, computer applications 2. Basics of organic chemistry related to bond characteristics.		
Course Objectives:	After completion of course students will be able to know: ● Role of Computer Aided Drug Design (CADD) in rational drug discovery ● Different CADD techniques and their applications. ● Various strategies to design and develop new drug like molecules ● Working with molecular softwares to design new drug molecules ● The *in-silico* virtual screening protocols		

Course Outcomes: Upon completion of the course the student shall be able to:		**PO Mapped**	**PSO mapped**
CO1	Recall and relate the different structures of protein along with the structure activity relationship of existing studied drugs and their interactions with the protein residues.	1, 2, 3, 4, 7, 8, 11	1, 2, 3
CO2	Classify and explain the different techniques to calculate the potential and kinetic energies of the system using Quantum and Molecular Mechanics, energy minimization and molecular	1, 2, 3, 4, 5, 8, 9, 11	1, 2, 3

	conformational space search in the binding cavity of protein.		
CO3	Make use of the minimal energy conformation of protein and ligand to construct and develop a model based on desired techniques like molecular docking, 3D-QSAR, pharmacophore modelling, homology modelling, molecular dynamics, etc.	1, 2, 4, 5, 6, 8, 9, 11	1, 2, 3
CO4	Analyze the results obtained based on the characteristics of different interactions (docking), equations (QSAR), binding energy (dynamics) and interpret the molecular mechanism of how a drug act in a particular manner to be either inhibiting or stimulating the enzyme/receptor.	1, 2, 3, 4, 5, 7, 8, 9, 11	1, 2, 3

Topics covered:

Unit I:	**Molecular Mechanics**	**Hours: 5**

- Molecular Mechanics and the forcefield. General form of a generic force field, force field parameterization.
- Self-Study – Comparison between the different force fields in existence at present time.

Unit II:	**Energy minimization**	**Hours: 6**

- Steepest descents, conjugate gradients, Newton Raphson method, advantages and limitations of each method

Unit III:	**Conformational analysis**	**Hours: 10**

- Systematic search, Monte Carlo simulations, Molecular dynamics simulations, distance geometry, strengths and limitations of each method.

Unit IV:	**Docking**	**Hours: 10**

- Docking by energy minimization, superimposition, molecular dynamics, Metropolis Monte Carlo, genetic algorithms, build-up approach. Different types of scoring function, e.gs of successful application of docking.
- Self-Study – Successful applications of docking.

Unit V:	**de novo ligand design**	**Hours: 10**

- Classes of de novo ligand design – active site analysis methods, whole-molecule methods, connection methods, random connection and disconnection methods, e.gs of successful application of de novo ligand design.

● Fragment based drug design ● Self-Study – Successful applications of de novo drug design.		
Unit VI:	**Pharmacophore modelling**	**Hours: 9**
● Techniques of developing a pharmacophore map covering both ligand based and receptor based approaches, incorporating additional geometric features into a 3D pharmacophore, use of a pharmacophore model in drug design. ● Self-study - Successful e.g. of pharmacophore maps in drug design.		
Unit VII:	**Virtual Screening**	**Hours: 3**
● Virtual Screening based on similarity, docking, pharmacophore maps and filters for drug-likeness and ADME.		
Unit VIII:	**3D-QSAR**	**Hours: 6**
● CoMFA and CoMSIA. Mention of other 3D-QSAR techniques and introduction to the 4th, 5th and 6th dimension in QSAR. ● Self-Study – 3D-QSAR methods other than CoMFA and CoMSIA.		
Reference material:	**Books:** 1. Molecular Modelling – Principles and Applications, Leach A. R., Prentice Hall. 2. Practical Application of Computer-Aided Drug Design, Ed. Charifson P., Marcel Dekker Inc. 3. 3D QSAR in Drug Design: Theory, Methods and Applications, Ed. Kubinyi H., Ledien ESCOM. 4. Molecular Modeling and Simulation -An Interdisciplinary Guide, Schlick T., Springer.	

Course: Advanced Biochemistry (CBCS)			
Course Code: **MPH_E_222_T**	**First Year M. Pharm**		**Semester: II**
Type of course: Theory	**Contact Hours: 4 Hours/week (4L + 1T)**		**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	**15**	**5**	80
Pre-requisites:	Before undertaking the course, students should have knowledge of the following: 1. Basics of chemical processes associated with living cells. 2. Basics of biochemical pathways with enzymes.		
Course Objectives:	After completion of course students will be able to know: ● Emphasizing on genetic organization of mammalian genome and hetero & autocatalytic functions of DNA. ● Understand the catalytic role of enzymes, importance of enzyme inhibitors in design of new drugs, therapeutic and diagnostic applications of enzymes. ● Understand the metabolism of nutrient molecules in physiological and pathological conditions. ● Understand the genetic organization of the mammalian genome and functions of DNA in the synthesis of RNAs and proteins.		

Course Outcomes: Upon completion of the course the student shall be able to:		**PO Mapped**	**PSO mapped**
CO1	Recall the protein subfamilies along with defining the terminologies like metabolism, nucleic acid, enzymes, cofactors, biomolecules, etc.	1, 2, 3, 4, 7, 8, 11	1, 2, 3
CO2	Classify and nomenclature of lipids, carbohydrates and nucleic acids, purification, characterization and synthesis of proteins.	1, 2, 3, 4, 5, 8, 9, 11	1, 2, 3

CO3	Apply the knowledge gained in understanding the effects of drugs on lipid metabolism, protein function, nucleic acid biosynthesis, carbohydrates linkages to improve the pharmacokinetic properties of certain drugs	1, 2, 3, 4, 5, 8, 9, 11	1, 2, 3

Topics covered:

Unit I:	**Proteins**	**Hours: 15**

- Structure – primary, secondary, tertiary, quaternary; motifs, structural and functional domains, protein families and macromolecular assemblies.
- Mechanisms for regulating protein function: Protein-protein interactions, interaction with ligands; Ca2+ and GTP as modulators, cyclic phosphorylation and dephosphorylation, proteolytic cleavage.
- Purification and characterization of proteins: electrophoresis, ultracentrifugation and liquid chromatography, use of biological assays, use of radioisotopes; MS, X-ray crystallography, NMR and homology modelling to determine structures; amino acid analysis; cleavage of peptides; protein sequencing.
- Protein biosynthesis: translation machinery in prokaryotic and eukaryotic systems; comparison of similarities and differences, drug affecting protein biosynthesis and protein function.

Unit II:	**DNA and nucleic acids**	**Hours: 15**

- DNA, RNA structure, nomenclature, double helix, conformations, higher order packing and architecture of DNA, transcription and replication of DNA – mechanisms in prokaryotic and eukaryotic systems, DNA repair mechanisms, drug affecting nucleotide biosynthesis, RNA and DNA biosynthesis and RNA and DNA function.

Unit III:	**Carbohydrates**	**Hours: 8**

- Mono, di and polysaccharides and their nomenclature, stereochemistry, types of linkages; conjugates of carbohydrates with other molecules– glycoproteins, glycolipids, proteoglycans, lipopolysaccharides and their biological roles.

Unit IV:	**Lipids**	**Hours: 7**

- Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipids as secondary messengers and cofactors, biological role of lipids, drug affecting lipid metabolism.

Unit V:	**Self-study topics**	**Hours: 15**

- Self-study of protein superfamilies, N and C terminal sequencing, DNA structures other than B-DNA, DNA sequencing, DNA pyrosequencing, cerebrosides, sphingolipids.

Reference material:

Books:

- Principles of Biochemistry, Lehninger, Nelson D.L., C.B.S Publishers, New Delhi.
- Biochemistry, Stryer L, W. H. Freeman & Co., New York.
- Molecular Cell Biology, Lodish H, Darneu J, Scientific American Books, N.Y.
- Biochemistry- The chemical reactions of living cells, Vol 1 &2, Metzler DE, Elsevier Academic Press.

	● Biochemistry, Berg JM, Tymoczko JL and Stryer L, WH Freeman and Company and Sumanas Inc. ● Biomacromolecules- Introduction to structure, function and informatics, Stan Tsai C, Wiley-Liss. ● Protein: Structure and Molecular properties, Thomas E Creighton, W. H. Freeman. ● Physical Biochemistry- Principles and applications, Sheehan D, Wiley-Blackwell.

Course: Green Chemistry (CBCS)			
Course Code: **MPH_E_223_T**	**First Year M. Pharm**		**Semester: II**
Type of course: Theory	**Contact Hours: 4 Hours/week (4L + 1T)**		**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	**15**	**5**	80
Pre-requisites:	Before undertaking the course, students should have knowledge of the following: 1. Basics of organic chemistry reactions, like rearrangement reactions. 2. Catalysts and use of catalysts in the reaction, nature and role of solvent used in synthesis.		
Course Objectives:	After completion of course students will be able to know: ● To introduce the learner with principles of green chemistry. ● To study the source, disposal and prevention of chemical waste. ● To learn basic level environmental management systems. ● To learn and select various kinds of catalysis with respect to industrial case studies.		

Course Outcomes: Upon completion of the course the student shall be able to:		**PO Mapped**	**PSO mapped**
CO1	Know the terms involved in green chemistry and know various guidelines of the environmental management system.	1, 2, 3, 4, 8, 9, 10, 11	1, 2, 3
CO2	Understand the concept and techniques of waste management and illustrate the twelve principles of green chemistry. Make use of the microwave concept in the synthetic reactions.	1, 2, 3, 4, 5, 6, 8, 9, 10, 11	1, 2, 3
CO3	Outline type of catalysis and their uses, safe solvents, water as reaction solvent.	1, 2, 3, 4, 5, 7, 8, 10, 11	1, 2, 3

CO4	Learn greener process designing and future prospects to be applied in their research areas.	1, 2, 3, 4, 5, 7, 8, 10, 11	1, 2, 3

Topics covered:

Unit I:	**Introduction to the concepts of Green Chemistry**
● History, need, goals, limitations, obstacles and opportunities.	**Hours: 5**
● Introduction to the principles of Green Chemistry- Prevention of waste/by products, maximum incorporation of the materials used in the process into the final product (atom economy), green metrics, prevention/minimization of hazardous/toxic products, designing safer chemicals –basic approaches, selection of appropriate auxiliary substances (solvents, separation agents etc), energy requirements for reactions, selection of starting materials, renewable starting materials, avoidance of unnecessary derivatization – careful use of blocking/protecting groups.	**Hours: 15**
● Microwave assisted organic synthesis; photochemical transformations; sonication; solid phase transformations; aqueous phase transformations; enzymatic transformations; etc.	**Hours: 8**
● Self-Study - transformations using ionic liquids, PEG, polymer supported reagents.	**Hours: 4**
Unit II:	**Applications**
● Application of green synthetic reactions, green starting materials, green reagents, green solvents and reaction conditions, green catalysis and examples of green synthesis, green analytical methods.	**Hours: 13**
● Self-Study – Examples of Green synthesis	**Hours: 3**
Unit III:	**Future trends in green chemistry**
● Oxidation reduction reagents and catalysts; biomimetics and multifunctional reagents; combinatorial green chemistry; solventless reactions; non-covalent derivatization; biomass conversion; emission control; biocatalysis	**Hours: 12**

Reference material:

Books:

1. Green Chemistry: Theory and Practice, Anastas P T and Warner J C, Oxford University Press.
2. Green Chemistry: Introductory Text, Lancaster M, RCS London
3. Introduction to Green Chemistry, Ryan M. A., Tinnesand M., American Chemical Society (Washington).
4. Handbook of Green Chemistry and Technology, Clarke J and Macquarrie D, Blackwell Publishing.
5. Green Chemistry – Greener alternative to synthetic organic transformations, Ahluwalia V K, Narosa Publications, New Delhi.
6. Organic Synthesis – Special Techniques, Ahluwalia V K and Aggarwal R, Narosa Publications.

Course: Drug Regulatory Affairs (CBCS)				
Course Code: **MPH_E_224_T**	**First Year M. Pharm**		**Semester: II**	
Type of course: Theory	**Contact Hours: 4 Hours/week (3L + 1T)**		**Total Contact Hours: 60**	
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**	
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination	
Max. Marks:	**15**	**5**	80	
Pre-requisites:	Have foundational knowledge in pharmaceutical science, pharmaceutical management and communication skills.			
Course Objectives:	The course aims to impart a higher level of theoretical up to date knowledge in international regulatory affairs and clinical trial studies related to pharmaceutical product development.			

Course Outcomes: Upon completion of the course the student shall be able to:		**PO Mapped**	**PSO mapped**
CO1	Understand the concepts of innovator and generic drugs, drug development process and the Regulatory guidance and guidelines for filing and approval process.	1,2,4,6,7,9,11	1, 2
CO2	Develop and submit the dossiers in CTD/ eCTD formats and the post approval regulatory requirements for actives and drug products	1,2,3,4,7,8,10	1,2
CO3	Understand the requirements in the clinical trials settings and pharmacovigilance activities	1,2,3,4,5,6,7, 8,9,10,11	1,2,3
CO4	To correlate the theoretical knowledge with professional and practical need of pharmaceutical industry.	1,2,3,4,5,6,7, 8,10,11	3

Topics covered:		
Unit 1:	**Need for Regulations**	**Hours: 1**
Unit 2:	**Indian Regulations**	**Hours: 15**

1. Introduction to Indian Regulations
2. Drugs & Cosmetic Act & Rules - Overview and recent amendments
- Schedule DI and DII (Registration and Import)
- Schedule M
- Schedule Y
- Central Drug Laboratories
3. ICMR guidelines for ethical considerations in biomedical research on human subjects
4. BA – BE studies
5. New drug application
6. Insurance, Compensation and Indemnification of trial subjects Expert Referral
   - IBSC, RCGM
   - ICMR
   - NDAC
   - CBBTDEC
7. WHO GMP Certification, FSC and CoPP procedure
8. Procedures for obtaining Test license (Form 29 and Form 11); Export NOC
9. Loan license / Contract manufacturing

Unit 3:	**US Regulations**	**Hours: 6**

- Introduction to US Regulations
- Hatch Waxman Act and amendments, FDA Medicare Modernization Act
- Introduction to Orange Guide and 21-CFR
- Investigational new drug (IND) filing
- US Drug Master File (DMF) filing, amendments and annual reports
- Abbreviated New Drug Application (ANDA) filing
- New Drug Application (NDA) filing
- Post approval changes

Unit 4:	**European Regulations**	**Hours: 6**

1. Introduction to European Regulations
2. Active Substance Master File (ASMF) filing
3. CEP filing
4. Marketing Authorization and filing procedures
- National Procedure
- Mutual Recognition Procedure (MRP)
- Decentralized Procedure (DCP)
- Centralized Procedure (CP)
5. Handling variations
6. Clinical Trial Regulations in EU

Unit 5:	**Other applicable Regulations and Guidelines**	**Hours: 10**

- Overview of ICH guidelines
- CTD format of dossier
- eCTD filing procedure
- 21- CFR Part 11
- Audits and Inspections, FDA 483's – Lessons learnt
- Overview of registration process in other geographies
- Biological license application (BLA)
- Medical Device Registration process

<table>
<tr><td colspan="3">

- Regulations governing Stem Cell therapeutics
- Introduction to Pharmacovigilance and Drug Safety
- Orphan Medicinal Products

</td></tr>
<tr><td>Unit 6:</td><td>Intellectual Property Rights (IPR)</td><td>Hours: 4</td></tr>
<tr><td colspan="3">

- Overview of patents from regulatory perspective
- PCT application & general rules
- WTO / GATT system
- TRIPS Agreement
- Compulsory licensing
- Patent search, drafting and filing procedure
- Patent infringement analysis
- Trademark/ copyright filing procedures

</td></tr>
<tr><td>Reference material:</td><td colspan="2">Books:

1. Good Drug Regulatory Practices: A Regulatory Affairs Quality Manual (Good Drug
Development Series, Vol 1, Helene I. Dumitriu
2.http://www.amazon.com/Good-Drug-Regulatory-PracticesDevelopment/dp/1574910515
3. Guide to Drug Regulatory Affairs / Buch, Brigitte Friese.
4. Drugs and Cosmetics Act, 1940 and Rules, 1945.

Useful links:
5. http://www.cdsco.nic.in/
6. http://clinicaltrials.gov/
7. http://dbtbiosafety.nic.in/
8. http://www.emea.europa.eu/
9. http://www.ich.org/
10. http://www.fda.gov/</td></tr>
</table>

Course: Cosmeticology (CBCS Revised 2016)			
Course Code: MPHE_225 _T	**First Year M. Pharm**		**Semester: II**
Type of course: Theory	**Contact Hours: 4 Hours/week (4L)**		**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	15	**5**	**80**
Pre-requisites:	Have basic knowledge of formulation technology and understanding of functional role of excipients.		
Course Objectives:	The course will enable learners to take up cosmetic science as career option.		

Course Outcomes Upon completion of the course, the students will be able to		**PO Mapped**	**PSO mapped**
CO1	Describe the role and functional performance of cosmetic excipients , therapeutics ingredients and perfumes in the formulation of cosmetics for skin, hair, nails and oral care.	1,2,3,4,6,7,9,10,11	1, 2,3
CO2	Understand the quality evaluation and regulations for the use of colors in cosmetics	1,2,3,4,6,7,9,10,11	1,2,3
CO3	Formulate and evaluate cosmetics for skin care and hair care as well as dental and oral care	1,2,3,4,5,6,7,8,10,11	1,2,3
CO4	Design and evaluate herbal cosmetics for skin care, hair care and oral care	1,2,3,4,5,6,7,8,10,11	123
CO5	Utilize novel approaches of formulation technologies in delivery of functional ingredients to skin, hair nails and oral cavity.	1,2,3,4,6,7,9,10,11	123
CO6	Understand the packaging and labeling requirements and quality standards of cosmetic products related to safety, toxicity and microbiological standards in accordance with BIS, EU and US requirements	1,2,3,4,6,7,9,10,11	1,2,3

Topics covered:

Unit I:	**General Anatomy and Physiology of skin,hair, nail and tooth:**	**Hours: 8**

- Anatomy and physiology of skin, hair, nail and tooth-emphasis on points with reference to cosmetics.
- Problems associated with normal functioning of skin, aged skin, dry skin, sensitive skin, acne, pigmentation disorders.
- Common hair problems - hair loss, manageability problems, split ends, shine and luster disorders; nail problems;
- tooth problems.

Unit II:	**General raw materials in cosmetic formulations:**	**Hours: 19**

- Overview of raw materials-Water, natural & synthetic oils, fats& waxes, inorganic solids, emulsifiers, thickeners, hydrocolloids, polymers, surfactants, antioxidants, humectants, polysiloxanes, preservatives
- Colouring agents used in cosmetics. Quality evaluation of colors, safety, toxicity and regulatory aspects of colors w.r.t. cosmetic products
- Perfumes in cosmetics: raw materials in perfumery, developing a perfume
- composition, current trends including emulsified and solid perfumery, analytical and separation techniques of perfumes, sensory analysis, safety and toxicological evaluation of perfumes, manufacturing and packaging of perfumes, legislation and regulations for perfumes in cosmetics
- Therapeutic ingredients in various cosmetics like skin products, dentifrices, hair care and nail preparations, and performance evaluation of these activities.
- Details of general raw materials (oils, fats, waxes, surfactants, preservatives, polysiloxanes), Historical purview of perfumes, Approved colours as per Indian, European and US specifications

Unit III:	**Application of novel approaches in cosmetic formulations**	**Hours: 4**

- Concepts of microemulsions, liposomes, niosomes, nanoparticles, iontophoresis, to enhance functional attributes & delivery of cosmeceuticals.

Unit IV:	**Herbal cosmetics**	**Hours: 2**

- Current trends in use of herbal materials in cosmetics.
- Discussion on aleo vera, henna, tea tree oil, neem in various cosmetic products

Unit V:	**Packaging and labelling of cosmetic products**	**Hours: 5**

- Packaging materials, speciality packages for cosmetics, labelling requirements for cosmetics

Unit VI:	**Quality standards of cosmetic products**	**Hours: 18**

- BIS guidelines for quality of finished products for cosmetics, quality control, textural analysis, performance and psychometric evaluation of various cosmetic products such as creams, gels, powders, lipstick, nail lacquer, shampoo, sunscreen products, dentifrices.
- Microbiological quality of cosmetic products
- Safety and toxicity evaluation of cosmetic products
- Legal considerations and regulatory procedures of cosmetic products
- BIS, European and US specifications about quality standards of
- cosmetic products

Reference material:	1. Harry's Cosmeticology Edited by J.B. Wilkinson and R. J. Moore, Longman Scientific & Technical Publishers 2. Cosmetics Science and Technology, Edited by M.S. Balsam, E. Sagarin, S.D. Gerhon, S.J.Strianse and M.M.Rieger, Volumes 1,2 and 3.Wiley-Interscience, Wiley India Pvt. Ltd.,2008 3. Poucher's Perfumes, cosmetics & Soaps, 10th Ed, Editor- Hilda Butler, Klewer Academic Publishers, Netherlands, 2000 4. Cosmetic Technology, Ed. By S.Nanda, A. Nanda and R. Khar, Birla Publications Pvt. Ltd., New Delhi, 2007 5. Handbook of Cosmetic Science and Technology, edited by M. Paye, A.O.Barel, H. I. Maibach, Informa Healthcare USA,Inc. 2007. 6. Encyclopedia of Pharmaceutical Technology, Vol. 6, Eds. James Swarbrick, James C. Boylan, Marcel Dekker Inc., 1992 7. BIS Guidelines for different cosmetic products 8. Drugs & Cosmetics Act & Rules, 1940 (with latest amendments).

Course: Polymers in Pharmacy (CBCS Revised 2016)			
Course Code: MPHE_226_T	**First Year M. Pharm**		**Semester: II**
Type of course: Theory	**Contact Hours: 4 Hours/week (4L)**		**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	15	**5**	**80**

Pre-requisites:	Have a fundamental understanding of polymers and physical properties of substances like rheology, and thermal behavior.
Course Objectives:	The course aims and equipping the learners with the knowledge of polymers and being able to justify the use of right polymer in the formulation.

Course Outcomes Upon completion of the course, the students will be able to		**PO Mapped**	**PSO mapped**
CO1	Study the classification and preparation methods of synthetic polymers	1,2,3,4,6,7,9,10,11	1, 2,3
CO2	Study the characterization of polymers rheologically and thermally.	1,2,3,4,6,7,9,10,11	1,2,3
CO3	Know about biocompatibility of polymers and understanding the properties of biocompatible polymers are.	1,2,3,4,5,6,7,8,10,11	1,2,3
CO4	Explain why polymers are used in drug delivery applications	1,2,3,4,6,7,8,9,10,11	123

Topics covered:

Unit I:	Historical Background, Basic definitions, Applications	**Hours: 1**
Unit II:	**Classification of Polymers:**	**Hours: 7**

- Classification based on reaction to temperature and structure/arrangement/architecture - linear, branched, cross-linked.
- Polymerization mechanisms- Addition & step-growth polymerization-Free radical, cationic, anionic and Ziegler Natta mechanisms

Unit III:	**Copolymerization**	**Hours: 5**

- Theoretical aspects of copolymerization
- Self study- Case studies of any two copolymers

Unit IV:	**Properties & Characterization of polymers**	**Hours: 12**

● Factors affecting and Overview, Molecular weight and determination of molecular weight. ● Solid state characterization- glass transition temperature, Crystallinity. ● Solubility of polymers & Swelling proreties, Mechanical properties ● Case study-any 3 polymers – characteristics & comparison		
Unit V:	**Methods of Preparation of Polymers**	**Hours: 11**
● Bulk polymerization, Solution polymerization, ● Suspension polymerization, Emulsion polymerization. ● Additives in polymers, Fabrication of polymeric devices/systems- casting, extrusion, moulding etc ● One example polymer for each method		
Unit VI:	**Biocompatibility of Polymers**	**Hours: 10**
● Safety & Biocompatibility issues- Overview ● Reaction of polymer to tissues, effect of body/host systems to polymers ● Mechanisms of tissue reactions/injury, ● Evaluation of biocompatibility of polymers ● Pharmacopoeial & other tests for toxicity evaluation of polymers		
Unit VII:	**Biocompatible Polymers**	**Hours: 10**
● General features of biocompatible polymers, enzymatically degradable bonds in polymers ● Design of biocompatible polymers & evaluation, ● Some examples-PLGA, cellulosics, acrylates, hydrogels.		
Unit VII:	**Applications of polymers in pharmacy.**	**Hours: 4**
● Overview of applications as thickeners, binders, coating agents, adhesives, as release modifying agents, including smart polymers, elastomers ● One example each of – adhesive polymer, coating agent, drug release modifier, smart polymer		
Reference material:	1. Fundamental Principles of Polymeric Materials by Rosen SL, Wiley-Interscience Publication, 2nd edn, 1993. 2. Martin's Physical Pharmacy and Pharmaceutical Sciences by Sinko PJ, Ed Lea & Feiger, Lippincott Williams & Wilkins, 6th edn, 2010. 3. Controlled Drug Delivery: Fundamentals and Applications, Robinson JR, Lee VHL, Dekker, 2nd edn, Vol 29, 1987. 4. Biodegradable Polymers as Drug Delivery Systems, Chasin M, Langer R, Marcel Dekker, Vol 45, 1990. 5. Controlled and Novel Drug Delivery by Jain NK, CBS Publishers and Distributors, 2008. 6. Controlled Drug Delivery: Clinical Applications, by Bruk SD, CRC Press Inc., Vol 2, 1983. 7. Polymeric Drug Delivery System by Kwon GS, Marcel Dekker, Vol 148, 2005. 8. Aqueous polymeric coating for pharmaceutical dosage forms by McGinity J W , Marcel Dekker, Vol 79.	

Course: Drug Evaluation Techniques (CBCS)			
Course Code: **MPH_E_227_T**	**First Year M. Pharm**		**Semester: II**
Type of course: Theory	**Contact Hours: 4 Hours/week (3L + 1T)**		**Total Contact Hours: 60**
Course assessment Methods:	**Continuous mode of assessment**		**Semester-end assessment**
Assessment Tool*:	Theory Sessional Exam	Attendance	End semester Examination
Max. Marks:	**15**	**5**	80
Pre-requisites:			
Course Objectives:			

Course Outcomes: Upon completion of the course the student shall be able to:		**PO Mapped**	**PSO mapped**
CO1	Recall with examples the terminologies associated with in vitro methods available for targeted drug delivery systems	1, 2, 3, 8, 11	1, 2, 3
CO2	Explain and illustrate the various evaluation techniques available for targeted drug delivery systems, basic principles of drug discovery and estimation of drug from complex media	1, 2, 3, 4, 6, 8, 11	1, 2, 3
CO3	Apply the knowledge gained to perform in vitro assays and screening methods for different drugs and novel drug delivery systems	2, 3, 4, 11	1, 2, 3

Topics covered:

Unit 1:	**Hours: 19**

1. Basic principles of drug discovery and biological screening
   - Correlation between various animal models and human situations.
   - Correlation between in vitro and in vivo screens.
   - Care, handling, breeding techniques of lab animals.
   - CPCSEA, OECD, ICH guidelines in brief
2. High throughput screening in drug discovery
3. Techniques for high throughput screening.

- Cell based assays
- Biochemical assays.
- Radio ligand binding assays

4. Detection methods
   - Fluorescence based assay techniques
   - Chemiluminescence based assay techniques
5. Self-study Use of alternative methods of screening:
6. Zebrafish model
7. Drosophila Types of drugs for which these models can be used

Unit 2: Target based drug discovery and in vitro screening techniques for	**Hours: 26**

1. Anti-platelet activity- Turbidimetric, GP IIB – IIIA assays using platelet aggregometer

CNS:

- Alzheimer's disease: in vivo which includes aluminum induced, scopolamine induced memory loss. In vitro includes acetylcholenesterase activity.
- Parkinson's disease: in vivo includes Haloperidol, reserpine, rotenone, MPTP induced models.
- Anti-depressant and anti-convulsants

2. Anti-diabetic: Alloxan, STZ, genetically diabetic animals and various in vitro methods
   - Anti-tubercular: BACTEC
   - Anticancer: Few in vitro cell lines, models for metastasis.
   - Anti-HIV: Various targets involved
   - Anti-malarial
3. Immunomodulatory: in vivo and in vitro methods.
4. Anti-inflammatory: Acute, subacute and chronic models.
5. Self-study-Antioxidant activity

Unit 3: Estimation of drugs	**Hours: 5**

- Estimation of drugs from complex media like biological fluids Eg. blood, tissues, CSF etc.
- Self-study-US FDA guidelines for bio analysis methods including validation.

Unit 4:	**Hours: 5**

- -In vitro skin irritation and eye irritation tests
  -In vitro tests for pyrogenicity
- Self-study-Alternative methods for toxicity testing (in vitro)

Reference material:	**Books:** 1. H.G. Vogel, Drug discovery and evaluation- Pharmacological Assays-Springer Verlog. 2. R.A.Turner, Screening methods in pharmacology- Academic Press. 3. D.R.Laurence and A.L.Bacharach- Evaluation of drug activities: Pharmacometrics. Academic Press. 4. A. Schwartz, Methods in Pharmacology- Plenum Publishing Corporation. 5. Website--Altox.org/ttrc/validation-va

Semester – III and IV

M. Pharm. Semester III and Semester IV: ALL BRANCHES OF STUDY
Total Credits: Semester III – 24 (MPH_C_301_D), Semester IV-24 (MPH_C_401_D)

Research work related to the title of the thesis that has been registered with the University.

The learner should be allotted a Research Guide in Semester I. The Guiding Teacher (Research Supervisor) along with the learner may plan the Research area to be pursued during Semesters III and IV. The title of the thesis should be communicated to the University before the commencement of Sem. III. Title change request if any, at a later time, should have a valid reason and will be considered under the existing rules of the University for title change (minor or major). Any request for change in title should be communicated to the University by the learner through the Research Guide and the Principal of the College/Institute. The learner is expected to work a minimum of 40 hrs/week in Research to be entitled for 24 Credits each in Semester III and IV. The Guiding Teacher (Research Supervisor) will sign a statement to this effect at the conclusion of Semesters III and IV, which may be communicated to the Controller of Examinations at the conclusion of each semester. Before completing the course, the learner will be required to give a Colloquium on the research work carried out by him/her during Semesters III and IV. The Colloquium will follow an open structure and will be assessed besides others by the Head of the Department, the Guide and the Principal of the College. A Statement that the learner has delivered a Colloquium must be sent to the University and will be mandated before the conduct of the viva-voce examination by the University.

Learners should be encouraged to attend conferences, seminars where they may present their research work, and to publish the findings of their research.

There will be no ESE at the end of Semester III. A learner will be permitted to submit his/her synopsis no earlier than 20 months (after 20 months) from the beginning of the M. Pharm program as instructed by the Government/Regulatory Authority for the respective year, BUT will have to submit the final thesis by the end of 24 months from the beginning of the M. Pharm program as instructed by the Government/Regulatory Authority. The time between submission of synopsis and thesis should be at least one month.

Any late submission of synopsis or thesis will result in the learner requiring to keep terms for the next semester and any subsequent semester/s till the learner finishes his/her degree.

At the end of Semester IV the learner will submit a thesis to the university. This will jointly be evaluated by the guiding teacher and an external examiner appointed by the university from academia or from the pharmaceutical industry. The evaluation will be for a total of 100 marks (**value of 48 credits**), of which 50 marks will be given by the guiding teacher and 50 marks by the external examiner. The parameters on which the marks will be given are: a. Literature Survey (10 marks) b. Presentation (8 marks) c. Methodology (7 marks) d. Results and Discussion (10 marks) and e. Viva-voce (15 marks). This makes a total of 50 marks each to be given by the guiding teacher and by the external examiner separately. These marks will be allotted to the course designated as **MPH_C_301_D + MPH_C_401_D for a total value of 48 credits**.

The submission of synopsis and the holding of the viva voce examination shall be done independent of the fact whether the student has successfully cleared semester I and Semester II. However, the result of the viva voce of M. Pharm. Examination will be declared only if the student has successfully cleared Semester I and Semester II examinations

Total Credits for M. Pharm:

Semester I -24 + Semester II -24 + Semester III - 24 + Semester IV - 24 = 96 credits