



**BOMBAY COLLEGE OF PHARMACY  
(AUTONOMOUS)**

**Detailed Syllabus for M.Pharm Choice Based Credit System (CBCS)  
Examination Scheme & Syllabus  
Semesters I to IV**

**For ALL BRANCHES OF M.PHARM.**

**Effective from academic year 2019-20.**

**Bombay College of Pharmacy- Autonomous  
(Affiliated to University of Mumbai)**

**M. Pharm-Pharmaceutical Chemistry  
Program Outcomes (PO)**

**PO1:** Student should develop an ability to independently carry out research / investigation and development work.

**PO2:** Student should develop an ability to write and present a substantial technical report/document.

**PO3:** Students should be able to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program.

**PO4:** Student should demonstrate a sound understanding of professional and ethical responsibilities in the realm of drug discovery and design.

**PO5:** Student should inculcate lifelong learning abilities for enhancing both advanced technical and non-technical competencies and achieving expertise in the subject matter.

**PO6:** Student should develop inceptiveness and adaptability to the advances in Green Pharmaceutical and Medicinal Chemistry.

**M. Pharm-Pharmaceutics  
Program Outcomes (PO)**

**PO1:** An ability to independently carry out research / investigation and development work.

**PO2:** An ability to write and present a substantial technical report/document.

**PO3:** Students should be able to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor programme.

**PO4:** Students should be aware of modern pharmaceutical tools, software and equipment to analyze problems with existing drug therapy, formulate newer technology and skills in product development solutions and identify risks associated with the solutions for better therapeutic results.

**PO5:** Students should be able to use acquired knowledge to engage in technical communication skills with broad scientific fraternity.

**PO6:** An ability to create an inquisitive as well as ethics conscious mind and an inclination towards research enabling them to work on multidisciplinary, environmentally sustainable, research-oriented tasks for enhanced life-long professional as well as academic competence.

**M. Pharm-Pharmacology  
Program Outcomes (PO)**

**PO1:** An ability to independently carry out research / investigation and development work.

**PO2:** An ability to write and present a substantial technical report/document.

**PO3:** Students should be able to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program.

**PO4:** An ability to demonstrate knowledge of professional and ethical responsibilities in clinical and non-clinical laboratories as required by regulatory bodies/guidelines.

**PO5:** An ability to apply life-long learning skills to enhance advanced technical and non-technical skills in pursuance of being a subject matter expert.

**PO6:** An ability to demonstrate resilience and responsiveness to the changes and evolution in the Pharmaceutical and healthcare environment.

### **M. Pharm-Pharmaceutical Analysis Program Outcomes**

- PO1:** An ability to independently carry out research /investigation and development work.
- PO2:** An ability to write and present a substantial technical report/document
- PO3:** An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program
- PO4:** An ability to demonstrate an integration of theoretical knowledge with practical skills, while also comprehending the influence of environmental science and grasping the principles of sustainable development.
- PO5:** Awareness of ethical considerations in coursework, upholding ethical standards in their academic and research pursuits.
- PO6:** An ability to commit to continuous learning, remain informed about emerging theories and research trends within the field of pharmaceutical analysis.

### **M. Pharm-Pharmacognosy Program Outcomes**

- PO1:** An ability to independently carry out research /investigation and development work.
- PO2:** An ability to write and present a substantial technical report/document
- PO3:** An ability to demonstrate a degree of mastery over the area as per the specialization of the program. The mastery should be at a level higher than the requirements in the appropriate bachelor program

**M.Pharm.Semester I: ALL BRANCHES OF STUDY Total**
**Credits: Semester I – 24**

Subject Code	Subject	Type of course (C/CBS)	Credits	Contact (hrs/wk)	ESE (hrs)	Weightage CIA	Weightage ESE
MPH_C_101_T	Modern Pharm. and Med. Chem.	C	4	3L+1IL	3	15ST+5 A	80
MPH_C_102_T	Modern Pharmaceutics	C	4	3L+1IL	3	15ST+5 A	80
MPH_C_103_T	Modern Pharmacology	C	4	3L+1IL	3	15ST+5 A	80
MPH_C_104_T	Modern Analytical Techniques	C	4	3L+1IL	3	15ST+5 A	80
MPH_C_105_T	Study of Natural Products	C	4	3L+1IL	3	15ST+5 A	80
MPH_C_106_T	Biostatistics and Research Methodology	C	4	3L+1IL	3	15ST+5 A	80

**Legends**

IA Internal Assessment;

ESE End Semester Examination; ST

Sessional Test/s;

A Attendance,

L Lectures;

IL Integrated Learning involving Tutorials, Group Discussions, Assignments, Field Work; P

Practicals, Lab. work, Project;

C Core;

CBS Choice Based Subject; S

Self-study.

In Semester I students of all Branches will take the above 5 subjects, irrespective of their area of specialization in M. Pharm. The Evaluation pattern for every subject will be 20 marks for Continuous Internal Assessment (CIA) and 80 marks for the End Semester Examination. The 20 marks for CIA will be divided into 5 marks for Attendance and 15 marks for a sessional test held mid-semester.

Every student will deliver a Seminar. This will be evaluated at the college level by a Committee consisting of the Principal, HOD and faculty of the Department in which the student will be doing his research work.

**M.Pharm.SemesterII: ALL BRANCHES OF STUDY**
**Total Credits: Semester II – 24**

Subject Code	Subject	Type of course (C/CBS)	Credits	Contact (hrs/wk)	ESE (hr)	Weightage CIA	Weightage ESE
MPH_C_201_S	Seminar	C	4	4 IL	-	100 IA	
MPH_C_2XX_T	Core I	C	4	3L+1IL	3	15ST+5 A	80
MPH_C_2XX_T	Core II	C	4	3L+1IL	3	15ST+5 A	80
MPH_E_2XX_T	Choice Based Subject I	CBS	4	3L+1IL	3	15ST+5 A	80
MPH_E_2XX_T	Choice Based Subject II	CBS	4	3L+1IL	3	15ST+5 A	80
MPH_C_299_L	Experimental Techniques in Pharmaceutical Sciences	C	4	8 P	6	15ST+5 A	80

## Legends

IA Internal Assessment;

ESE End Semester Examination; ST

Sessional Test/s;

A Attendance,

L Lectures;

IL Integrated Learning involving Tutorials, Group Discussions, Assignments, Field Work; P

Practicals, Lab. work, Project;

C Core;

CBS Choice Based Subject; S

Self-study.

In the second semester, all students have to present a seminar. Also, the practical (Experimental Techniques in Pharmaceutical Sciences) is applicable for all branches of specialization. The syllabus for Experimental Techniques in Pharmaceutical Sciences has been prepared for the different branches of specialization – namely Pharmaceutical Chemistry, Pharmaceutics, Pharmacognosy, Pharmaceutical Analysis and Pharmacology. Each Branch of Specialization will also have two Core subjects in the Branch of Specialization and two Choice Based Subjects that may be selected from the List of Choice Based Subjects specified in the Syllabus.

*Syllabus of M.Pharm. (2019-20)*

**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.**

The student will be allotted a Research Supervisor while in Semester I. The Research Supervisor (Guiding Teacher) along with the student may plan the research area to be pursued during Semesters III and IV. The title of the thesis should be communicated to the Chairman of the Board of Studies before the commencement of Sem. III. Request for change in the title of the thesis, at a later time, should have a valid reason and will be considered under the existing rules for title change (minor or major). Any request for change in title should be communicated to the Chairman of the Board of Studies by the student through the Research Guide and forwarded by the Principal.

The student 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 Chairman of the Exam committee at the conclusion of each semester.

Before completing the course, the student 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. A statement that the student has delivered a Colloquium will be mandated before the conduct of the viva-voce examination and such a statement should be part of the thesis.

Students should attend conferences, seminars where they may present their research work and should **publish a review paper** (along with the research supervisor) in any one of the UGC approved research journals before submission of the thesis. Weightage in evaluation of the thesis (vide infra) will be given if the work reported in the thesis has been published in any one of the UGC approved research journals.

There will be no ESE at the end of Semester III. A student 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 announced 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 announced 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 student requiring to keep terms for the next semester and any subsequent semester/s (with payment of all applicable fees) till the student finishes his/her degree.**

At the end of Semester IV the student will submit a thesis to the university. This will jointly be evaluated by the guiding teacher and an external examiner appointed by the Board of Studies. The thesis will be evaluated for a total of 100 marks (**value of 48 credits**), of which 40 marks will be given by the guiding teacher and another 40 marks by the external examiner. The parameters on which the marks will be given are: a) Literature Survey (8 marks) b) Presentation (5 marks) c) Methodology (7 marks) d) Results and Discussion (10 marks) and e) Viva-voce (10 marks). This makes a total of 40 marks to be given by the guiding teacher and another 40 marks will be awarded by the external examiner, which makes a total of 80 marks. The remaining 20 marks is distributed between the review paper (10 marks) and a publication originating from the work published in the thesis (original publication -10 marks). The following table shows how marks are to be awarded for the review paper and the original publication. If at the time of the

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viva-voce examination, the review paper or original publication submitted to a journal has been sent back to the author for corrections/modifications/clarifications etc., marks may still be given by the guiding teacher and the external examiner according to the following table. For journals whose impact factors are not listed in Scopus Index, but nevertheless are journals approved by UGC, a standard 3 marks may be awarded to the student.

<b>Impact factor (IF) of the Journal (as per Scopus Index)</b>	<b>Marks</b>
IF below 1	3
IF above 1 and up to 2	5
IF factor above 2 up to 3	7
IF factor above 3	10

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**

**SEMESTER I****ALL BRANCHES****MPH\_C\_101\_T-Modern Pharmaceutical and Medicinal Chemistry (4h/wk)****Course Objectives:**

1. Learn about identification and modification of lead molecules to increase potency and the therapeutic index and to increase oral bioavailability by understanding the concepts of pharmacophore, privileged structures, me-too or drug-like molecules,
2. Learn about concept of ligand – receptor interaction, types of agonist and antagonists, receptor theories, receptor classifications, and binding assays with the help of topological and stereochemical consideration.
3. To learn the concepts of designing prodrugs and their applications in drug delivery systems. To understand the problems associated with the existing drugs with respect to absorption, distribution, aqueous solubility, site specificity, instability, toxicity, poor patient acceptability. To learn different types of prodrug and design of prodrug.
4. Learn about the Drug Metabolism and its relation to other defense systems, types of Phase I and Phase II Reactions by taking suitable drug examples. To learn the classification and nomenclature of Cytochrome P450s catalytic cycle and mechanism of catalysis. To study CYP substrates, specific probe substrates, specific inhibitors, induction of CYPs and specific inducers. To learn about glucuronosyltransferases, sulfotransferases, glutathione S-transferases, N-acetyl transferases, and FMO.
5. Learn about role of enzymes, enzyme catalyzed reactions and methods for plotting enzyme kinetics data. To learn mechanism of enzyme catalysis and co-enzyme catalysis.

**Course Outcomes (CO):**

1. Understand the principles of identification and modification of lead molecule.
2. Understand classification of the receptors, types of agonist and antagonists and interpret the outcome of ligand receptor interactions.
3. Understand prodrug approach for improving PK/PD properties of drug.
4. Understand Phase I and Phase II metabolic reactions & predict metabolism of NCE'S.
5. Understand basic principles of enzyme kinetics & Graphical handling enzyme kinetic data.

**Course Outcomes**

<b>M. Pharm First Year, Semester I</b>			
<b>MPH_C_101_T Modern Pharmaceutical and Medicinal Chemistry</b>			
<b>Course Code &amp; CO number</b>	<b>At the successful completion of the course, the learners will be able to:</b>	<b>Syllabus Unit no.</b>	<b>Up to Bloom's level</b>
<b>MPH_C_101_T CO1</b>	Understand the principles of identification and modification of lead molecule.	1	2
<b>MPH_C_101_T CO2</b>	Understand classification of the receptors, types of agonist and antagonists and interpret the outcome of ligand receptor interactions.	2	3
<b>MPH_C_101_T CO3</b>	Understand prodrug approach for improving PK/PD properties of drug.	3	3
<b>MPH_C_101_T</b>	Understand Phase I and Phase II metabolic	4	4

<b>CO4</b>	reactions & predict metabolism of NCE'S.		
<b>MPH_C_101_T</b>	Understand basic principles of enzyme kinetics & Graphical handling enzyme kinetic data.	5	4

### Mapping CO with PO

Course code & CO number	PO1	PO2	PO3	PO4	PO5	PO6
<b>MPH_C_101_T</b>	1	0	1	1	2	1
<b>MPH_C_101_T</b>	0	1	2	1	2	0
<b>MPH_C_101_T</b>	1	1	2	2	3	0
<b>MPH_C_101_T</b>	2	2	3	2	3	1
<b>MPH_C_101_T</b>	1	2	3	2	3	0

Unit	Course Content (Topics)	Hours
<b>1</b>	<b>Drug Discovery</b>	<b>5</b>
1.1	Historical perspective	1
1.2	Lead Discovery	1
1.3	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	3
<b>2</b>	<b>Receptors</b>	<b>10</b>
2.1	Basic ligand concepts – agonist, antagonist, partial agonist, inverse agonist, efficiency and potency	1
2.2	Interactions (Forces) involved in drug-receptor complexes	2
2.3	Receptor theories – occupancy theory, rate theory and activation theory	1
2.4	Receptor classification – the four superfamilies	2
2.5	Receptor binding assays – measurement of $K_d$ , $B_{max}$ and $IC_{50}$	2
2.6	Topographical and stereochemical considerations in drug-receptor interactions	2
<b>3</b>	<b>Prodrugs and Drug Delivery Systems</b>	<b>13</b>
3.1	Enzyme activation of drugs, utility of prodrugs – aqueous solubility, absorption and distribution, site specificity, instability, toxicity, poor patient acceptability, formulation problems.	2
3.2	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).	6

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3.1	<i>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.</i>	5
3.2		
<b>4</b>	<b>Drug Metabolism</b>	<b>18</b>
4.1	Introduction to xenobiotic/drug metabolism and its relation to other defense systems (Physical barriers, excretion, immune system).	0.5
4.2	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.	0.5
4.3	Cytochrome P450s: Introduction to the family of enzymes, their classification and nomenclature.	1
4.4	CYP450 catalytic cycle, different types of reactions catalyzed by CYP450 and the mechanisms of catalysis.	4
4.4	Human CYP450 involved in DM, their distribution and properties, typical substrates, specific probe substrates, specific inhibitors, induction of CYPs and specific inducers	2
4.5	Discussion of glucuronosyltransferases, sulfotransferases, glutathione S-transferases, N-acetyl transferases, and FMO [on lines similar to that specified for CYPs as listed above].	4
4.5	<i>Self-study of alcohol/aldehyde dehydrogenases, xanthine and aldehyde oxidase, epoxide hydrolase, esterases, azo and nitro reductases (reactions catalyzed by these enzymes, mechanisms of the reactions, typical substrates/inhibitors/inducers)</i>	6
<b>5</b>	<b>Enzymes</b>	<b>14</b>
5.1	Introduction to enzymes, binding site, specificity of enzyme catalyzed reactions and rate acceleration, Michaelis-Menten kinetics and methods for plotting enzyme kinetic data	4
5.2	Mechanisms of enzyme catalysis – covalent catalysis, acid-base catalysis, electrostatic catalysis, some examples of the mechanisms of enzyme catalysis	2
5.3	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).	4
5.1	<i>Self-study of Hanes plot, Cornish-Eisenthal-Bowden plot</i>	1
5.2	<i>Self-study of roles of coenzymes – biotin, coenzyme A, cyanocobalamin, vitamin K</i>	3
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

1. The Organic Chemistry of Drug Design and Drug Action, Silverman R.B., Academic Press.
2. Textbook of Drug Design and Discovery, Eds. Krosggaard-Larsen P., Liljefors T., Madsen U., Taylor & Francis.
3. Lehninger – Principles of Biochemistry.
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
10. Pharmaceutical Profiling in Drug Discovery for Lead Selection, Borchardt RT, Kerns EH, Lipinski CA, Thakker DR and Wang B, AAPS Press
11. Drug Metabolism – Current Concepts, Ionescu C and Cairn MR, Springer International Edition

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12. Handbook of Drug Metabolism, Woolf TF, Marcel Dekker

**MPH\_C\_102\_T-Modern Pharmaceutics(4h/wk)**
**Objective**

To impart advanced understanding of core concept of Pharmaceutics and to inculcate skill driven knowledge essential for the comprehension of unit operations in pharmaceutical industries.

**Course Outcomes (CO):**

Upon the completion of the course student shall be able to:

1. Understand the relevance of drug degradation pathways and kinetics in predicting solution state and solid-state stability as well as compatibility testing.
2. Comprehend the significance of different preformulation studies, various approaches of solubilization, types of dissolution testing and data analysis of the release profile in formulation development.
3. Recall the regulatory guidelines to assess the role and safety of various pharmaceutical excipients as well as explain the different approaches of risk assessment.
4. Understand the key concepts of optimization techniques and micrometrics in formulation development.

<b>M. Pharm First Year, Semester I</b>			
<b>MPH_C_102_T Modern Pharmaceutics (THEORY-60 hours)</b>			
<i>Course Code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
MPH_C_102_CO1	Understand the relevance of drug degradation pathways and kinetics in predicting solution state and solid-state stability as well as compatibility testing.	1	5
MPH_C_102_CO2	Comprehend the significance of different preformulation studies, various approaches of solubilization, types of dissolution testing and data analysis of the release profile in formulation development.	2	5
MPH_C_102_T CO3	Recall the regulatory guidelines to assess the role and safety of various pharmaceutical excipients as well as explain the different approaches of risk assessment.	3 & 5	5
MPH_C_102_T CO4	Understand the key concepts of optimization techniques and micrometrics in formulation development.	4 & 6	5

Course Code & CO number	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_102_T CO1	1	1	1	2	2	2
MPH_C_102_T CO2	1	1	1	3	2	2
MPH_C_102_T CO3	1	1	1	3	2	2
MPH_C_102_T CO4	1	1	1	3	2	2

Unit	Course Contents (Topics)	Hours
1	<b>Drug Stability:</b>	<b>9</b>
1.1	Importance and need for stability testing	1
1.2	Revision of degradation pathways, kinetics, physical stability	2
1.3	Solution and Solid-state stability, pH stability profiles, v and u graphs, package evaluation, ICH guidelines, statistical aspects in derivation of shelf life.	3
1.2	<i>Self-study- Calculations for shelf life based on degradation kinetics</i>	3
2	<b>Solubilization and Dissolution:</b>	<b>14</b>
2.1	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.	5
2.2	Revision of equations of dissolution and factors affecting dissolution, intrinsic solubility and dissolution rate, validation of testing, different equipment (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-relevant media, BCS classification, IVIVC-study design and interpretation	5
2.3	<i>Self-study- Calculations based on various solubility parameters and equations of dissolution. Pharmacopoeial dissolution apparatus, data treatment of dissolution profiles.</i>	4
3	<b>Excipients and introduction to polymers:</b>	<b>7</b>
3.1	Role of excipients, purity, safety and toxicity with reference to routes of exposure-oral, inhalational, parenteral, others; regulatory aspects, risk assessments, Harmonization of excipient standards like residual solvents class 1,2,3.	2
3.2	Different classes of excipients-surfactants, special lipids, superdisintegrants, gelling agents, colors and flavors, sweetening agents, co-processed excipients.	2
3.3	Definition of polymers, classification; concept of properties used in characterization, methods of polymerization, biocompatibility evaluation, applications	2
3.4	<i>Self-study: sources and brand names of various excipients</i>	1
4	<b>Optimization Techniques:</b>	<b>8</b>
4.1	Definition, Need, Advantages, description of terms such as independent variable, response parameters, response surface, contour plots, polynomial equations	2
4.2	Simplex and factorial designs in optimization	3
4.3	Application of optimization techniques in QbD in product development	1
4.5	<i>Self-study: Placket-Burman design, central composite designs</i>	2

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5	<b>Preformulation:</b>	<b>12</b>
5.1	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	3
5.2	Key Areas in Preformulation research - Bulk Characterization, Solubility Analysis, Stability Analysis, Compatibility with common excipients	4
5.3	Preformulation aspects for Tablets, Injectables, Liquid preparations, Protein & peptide drugs.	3
5.4	<i>Self-study: case study of drug exhibiting various polymorphic forms, drug excipient compatibility</i>	2
6	<b>Powder Technology (Micromeritics):</b>	<b>10</b>
6.1	Revision of following topics: <ul style="list-style-type: none"> <li>• Important definitions &amp; Units</li> <li>• Importance of particle size in pharmaceutical development.</li> <li>• Fundamental &amp; derived properties of powders</li> <li>• Particle size reduction - comminution mechanisms &amp; equipment</li> <li>• Methods of particle size determination (emphasis on basic principles &amp; interpretation of data)</li> </ul>	2
6.2	<b>Comminution</b> - Theory of comminution, milling rate (various mathematical relationships), concept of milling/grinding index, energy for comminution, distribution and limit of comminution	2
6.3	<b>Compaction of powders</b> - 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)	3
6.4	<i>Self-study: case studies on compaction behavior of two excipients</i>	3
	<b>Total</b>	<b>60</b>

**Books (latest edition to be adopted)**

1. Drug Stability Principles and Practices by Carstensen J, Marcel Dekker.
2. Pharmaceutical Stress Testing by Baertschi SW, Taylor and Francis.
3. Pharmaceutical characterisation of Pharmaceutical Solids by Brittain HG, Marcel Dekker.
4. Preformulation in Solid Dosage Form Development by Adeyeye MC, Brittain HG, Informa Healthcare.
5. Dissolution, Bioavailability and Bioequivalence by Abdou HM, Ed A. Gennaro, B. Migdalof, Mack Printing Company.
6. Pharmaceutical Bioequivalence by Welling PG, Francis LST, Dighe SV, Marcel Dekker, Inc.
7. Pharmaceutical Dissolution Testing by Banaker U, Marcel Dekker.
8. Excipient toxicity and safety by Weiner ML, Kotkoski LA.
9. Martin's Physical Pharmacy and Pharmaceutical Sciences, by Sinko PJ, Ed Lea & Feiger, Lippincott Williams & Wilkins.
10. Modern Pharmaceutics by Banker GS, Ed Banker GS & Rhodes CT, Marcel Dekker
11. Pharmaceutical Statistics by Bolton S, Marcel Deckker.
12. The Theory and Practice of Industrial Pharmacy by Lachman L, Lieberman HA, Kanig JL, Varghese Publishing House.
13. Pharmaceutical Dosage Forms: Tablets, Unit Operations and Mechanical Properties Ed Augsburger LL,

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Hoag SW, Informa Healthcare USA, Inc.

14. Techniques of Solubilization of Drugs by Yalkowsky SH, Marcel Dekker.
15. Pharmaceutical Dissolution Testing by Dressman J. Ed Dressman J, Kremmer J, Tylor & Francis
16. Controlled Drug Delivery: Clinical Applications, by Bruk SD, CRC Press Inc.
17. Handbook of Pharmaceutical Granulation Technology by Parikh DM, Informa Healthcare.
18. Pharmaceutical Powder Compaction Technology by Alderborn G, Nystrom C, Marcel Dekker,

**MPH\_C\_103\_T-Modern Pharmacology(4h/wk)**
**Course Objectives:**

This subject is intended to impart fundamental knowledge on molecular level physiological and pathological changes underlying several complex diseases, with an emphasis on the knowledge of apoptosis and immunopharmacology. Additionally, it will focus on the pharmacokinetic and pharmacodynamic aspects of drug in advanced level.

**Course Outcomes (CO):**

M.Pharm First Year, Semester I			
MPH_C_103_T Modern Pharmacology (Theory 4h/wk)			
Course code & CO number	At the successful completion of the course, the learners will be able to:	Syllabus Unit no.	Up to Bloom's level
MPH_C_103_T_CO1	Comprehend pharmacokinetic principles of drug action along with the drug transport mechanisms	1	2 & 3
MPH_C_103_T_CO2	Explain the mechanism of drug actions at cellular and molecular level including the role of channels and factors affecting drug responsiveness, mechanisms of drug dependence and microbial resistance.	2-5	2 & 3
MPH_C_103_T_CO3	Appraise the recent advances in therapy and management of central nervous system, cardiovascular system disorders and diabetes mellitus.	6	2 & 3
MPH_C_103_T_CO4	Understand and remember the concepts of molecular biology, physiological, pathological, pharmacological implications and therapeutic prospects of apoptosis and immunopharmacology	7 & 8	2 & 3

**Mapping CO with PO**

CO	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_206_T_CO1	1	1				
MPH_C_206_T_CO2	1	1				
MPH_C_206_T_CO3	1	1				
MPH_C_206_T_CO4	1	1				

Unit	Course Contents (Topics)	Hours
1		<b>11</b>
1.1	<b>Drug Absorption, distribution, metabolism and excretion.</b>	5
1.2	<ul style="list-style-type: none"> <li>• Mechanisms of transport of drug across membranes.</li> <li>• Transporters involved in drug absorption, distribution and excretion processes.</li> </ul>	3
1.3	<ul style="list-style-type: none"> <li>• -Drug efflux pathways and experimental methods to study drug transport.</li> <li>• Pharmacokinetic factors affecting drug action</li> </ul>	3
2	<b>Mechanism of drug action</b>	<b>11</b>
2.1	Classification of receptors and description of each class with examples.	1
2.2	<ul style="list-style-type: none"> <li>• Signal transduction mechanisms.</li> <li>• Detailed description of signal mediation through cascades after adrenergic, muscarinic, GABAergic, insulin receptor stimulation.</li> </ul>	4
2.3	Regulation of receptors, their involvement in various biological processes including diseases resulting from receptor malfunction and their role in pharmacotherapeutics.	1
2.4	Regulation of intracellular calcium.	2
2.5	Pharmacodynamic interactions in a multicellular context e.g. Vascular wall (interaction of physiological ligands and drugs in pathophysiological setting).	1
2.6	<i>Self-study- Classification and characterization of receptors-IUPHAR (e.g. 5-HT receptors)</i>	2
3	<b>Functions of sodium and potassium channels and therapeutic potential of channel modulators.</b>	<b>3</b>
4	<b>Factors affecting drug responsiveness.</b> <ul style="list-style-type: none"> <li>• Alteration in concentration of drug that reaches receptors.</li> <li>• Variation in concentration of an endogenous receptor ligand.</li> <li>• Alteration in number and function of receptors.</li> <li>• Clinical selectivity: Beneficial vs. toxic effects of drugs.               <ol style="list-style-type: none"> <li>a. Beneficial and toxic effects mediated by the same receptor-effector mechanism.</li> <li>b. Beneficial and toxic effects mediated by identical receptors but in different tissues or by different effector pathways.</li> <li>c. Beneficial and toxic effects mediated by different types of receptors.                   <ul style="list-style-type: none"> <li>• Desensitization, tachyphylaxis.</li> <li>• Drug tolerance.</li> </ul> </li> </ol> </li> </ul>	<b>3</b>
5	<b>Cellular and molecular mechanisms of</b>	<b>4</b>
5.1	Drug dependence (e.g. Morphine).	
5.2	Microbial resistance.	
6	<b>Advances in therapy of</b>	<b>18</b>
6.1	CNS: Depression, Alzheimer's disease, Psychosis, Parkinson's disease, Epilepsy.	5
6.2	CVS: Hypertension, Angina Pectoris, Congestive cardiac failure, Arrhythmia.	5
6.3	Management of Diabetes Mellitus.	2
7	<b>Apoptosis</b>	<b>4</b>

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7.1	Molecular biology, physiological, pharmacological implications and therapeutic prospects.	2
7.2	<i>Self-study-Interaction between cell, growth factors and extracellular matrix.</i>	2
8	<b>Immunopharmacology</b>	<b>6</b>
8.1	Introduction to immunopharmacology, immunomodulators, immunostimulants and immunosuppressants.	4
8.2	<i>Self-study-Autoimmunity</i>	2
	<b>Total</b>	<b>60</b>

**Books (latest edition to be adopted).**

1. Rang and Dale's pharmacology--Elsevier Churchill Livingstone.
2. Lange's Basic and clinical pharmacology, Katzung B.G. Masters S.B., Trevor A.G. Tata McGraw Hill.
3. Goodman 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.

**MPH\_C\_104\_T-Modern Analytical Techniques (4h/wk)**
**Course Objectives:**

Upon completing the following theory topics, learners should be able to:

Comprehend the theoretical concepts, instrumentation, working principles, and applications of modern analytical techniques including multicomponent analysis by UV spectroscopy, FTIR, <sup>1</sup>H-NMR, <sup>13</sup>C-NMR, Mass spectrometry, chromatography, thermoanalytical techniques and Microscopy.

**Course Outcomes (CO):**

<b>M. Pharm First Year, Semester I</b>			
<b>MPH_C_104_T Modern Analytical Techniques (Theory 4 h/ wk)</b>			
<i>Course code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
MPH_C_104_T CO1	Evaluate and justify various methods of multicomponent analysis of drugs using UV-Vis spectroscopy.	1	5
MPH_C_104_T CO2	Describe and assess the relevance and practical usefulness of Chromatography techniques and Hyphenated techniques in pharmaceutical analytical settings.	5, 6, 7	5
MPH_C_104_T CO3	Describe and critically evaluate the underlying theoretical concepts, Instrumentation, working principles, and diverse applications of IR and NMR Spectroscopy & Mass spectrometry.	2, 3, 4	5
MPH_C_104_T CO4	Analyze and interpret spectral data related to I.R, <sup>1</sup> H-NMR, <sup>13</sup> C-NMR and Mass spectral values, DSC spectra, and TGA curves.	2, 3, 4, 8	5
MPH_C_104_T CO5	Analyze the theoretical foundations and review the practical applications of sample preparation techniques, instrumentation, and the underlying principles in Thermoanalytical techniques and Microscopy techniques.	7, 8, 9	5

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**CO-PO Mapping:**

Course code & CO number	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_104_T CO1	2	1	3	3	3	3
MPH_C_104_T CO2	2	1	3	3	3	3
MPH_C_104_T CO3	2	1	3	3	3	3
MPH_C_104_T CO4	2	1	3	3	3	3
MPH_C_104_T CO5	2	1	3	3	3	3

Note: Correlation levels 1, 2 or 3 are defined below:

Slight (Low) Moderate (Medium) Substantial (High) If there is no correlation, put –

Unit	Course contents (Topics)	Hours
1	<b>Multicomponent analysis of drugs using UV-Vis. spectroscopy:</b>	<b>6</b>
1.1	Simultaneous equation method, Absorbance ratio method, Difference spectroscopy, Derivative spectroscopy and Introduction to Ratio derivative spectroscopy,	4
1.2	<i>Self-study-Pharmaceutical applications of above techniques (1.1)</i>	2
2	<b>F.T.I.R spectroscopy:</b>	<b>6</b>
2.1	Construction and working, New sampling techniques.	2
2.2	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).	2
2.3	<i>Self-study-Interpretation of recorded I.R. spectra of drugs and organic compounds.</i>	2
3	<b>NMR spectroscopy:</b>	<b>10</b>
3.1	<b><sup>1</sup>H-NMR:</b> Basic theoretical concepts- ( <i>Self-study-chemical shift, splitting pattern and coupling constant-2 hrs</i> ), Non-first order spectra, methods to make complex spectra simple, FT-NMR.	6
3.2	<b><sup>13</sup>C-NMR:</b> Theory and Principles.	2
3.3	Applications of 2D-NMR (COSY, HETCOR, DEPT and INEPT)	2
4	<b>Mass Spectrometry:</b>	<b>10</b>
4.1	Differentiation techniques-EI, CI, FD, FI, MALDI, API (APPI, APCI, ESI).	4
4.2	Different analyzers-Quadrupole, TOF, QTOF, Ion cyclotron, Ion trap.	2
4.3	Concepts for interpretation of mass spectra-Molecular ion peak, base peak, Isotope abundance, fragmentation pathways- $\alpha$ fission, $\beta$ fission, MacLafferty rearrangement, Retro Diels Alder rearrangement, Tandem mass (MS-MS).	4
5	<b>Terminologies of chromatography:</b> <i>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.</i>	<b>3</b>
6	<b>Advances in chromatography:</b>	<b>11</b>
6.1	HPLC-Ion pair chromatography, Chiral chromatography (chiral stationary phases, use of mobile phase additives, precolumn derivatization, chiral detectors), UPLC, <i>Self-study-Advances in HPLC detectors (1hr).</i>	5

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6.2	Supercritical fluid chromatography-Principle, Instrumentation and pharmaceutical applications.	2
6.3	<i>Self-study-HPTLC-Principles, Instrumentation and applications including fingerprint analysis.</i>	1
6.4	Gas chromatography-Headspace analysis.	1
6.5	Gelelectrophoresis-Principle, Instrumentation and applications.	2
7	<b>Hyphenated techniques:</b>	4
7.1	Interfaces used in and applications-GC-MS, LC-MS, LC-MS-MS	3
7.2	Introduction to LC-NMR and MALDI-TLC.	1
7	<b>Thermoanalytical techniques:</b> Principle, instrumentation and applications including interpretation of data in pharmaceutical cases.	5
7.1	<i>Self-study-DSC and TGA</i>	3
7.2	TMA (Thermomechanical analysis).	1
7.3	<i>Interpretation of DSC and TG curves of suitable compounds/drugs (Self-study)</i>	1
8	<b>Microscopy: Principle, Instrumentation, sample preparation and pharmaceutical applications of -</b> Scanning Electron Microscopy, Transmission Electron Microscopy, Atomic Force Microscopy, Confocal microscopy.	5
	<b>Total</b>	<b>60</b>

**Books (latest edition to be adopted).**

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, CBS Publishers and Distributors.
4. Spectrometric Identification of Organic Compounds by R. M. Silverstein, F. X. Webster, D. J. Kiemle, 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, Lippincott Williams & Wilkins
10. Introduction to Modern Liquid Chromatography by L. R. Snyder, J. J. Kirkland.
11. Chiral separations by Liquid Chromatography and Related Technologies Chromatographic Science Series by Hassan Y., Imran Ali.
12. Static headspace gas chromatography Theory & practice by Bruno Kolb & L. S. Ettre.
13. Encyclopedia of Chromatography, by Jack Cazes
14. Online LC-NMR and Related techniques by Klasu Albert, John Wiley & Sons
15. LC-MS-A Practical Users guide, by Marvin C. McMaster.

**MPH\_C\_105\_T–Study of Natural Products (4 h/wk)**
**Course Objectives: (Paragraph)**

1. To introduce to learners, different natural products, their selection, collection, status in official books and newer methods for authentication and standardization including DNA fingerprinting.
2. To apply the knowledge of phytochemistry in optimization of extraction procedure for different phytoconstituents.
3. To highlight the role of Natural Products in drug discovery and drug development with relevant case studies.
4. To understand and extrapolate the role of natural products as therapeutic agents, prophylactic, nutraceuticals and excipients for NDDS.

**Course Outcomes (CO):**

M. Pharm First Year, Semester I			
MPH_C_105_T	Study of Natural Products	(Theory 4 h/ wk)	
Course code & CO number	At the successful completion of the course, the learners will be able to:	Syllabus Unit no.	Up to Bloom's level
MPH_C_105_T CO1	Understand and apply newer methods for selection, authentication and standardization including DNA fingerprinting of crude drugs	1	3
MPH_C_105_T CO2	Apply the principles underlying extraction in optimization of extraction procedure for different phytochemical classes	2	3
MPH_C_105_T CO3	To interpret the role of Natural Products in drug discovery and drug development with relevant case studies	3	4
MPH_C_105_T CO4	To understand and extrapolate use of natural products as source of therapeutic, prophylactic agents, excipients and nutraceuticals	4, 5 & 6	6
MPH_C_105_T CO5	Understand the status of natural products in official books with examples	7	2

**CO-PO Mapping**

Course Code & CO Number	PO1	PO2	PO3	PO4 (Additional, if required by the department)	PO5 (Additional, if required by the department)	PO6 (Additional, if required by the department)
MPH_C_105_T CO1	1	3	3			
MPH_C_105_T CO2	3	3	3			
MPH_C_105_T CO3	2	3	3			
MPH_C_105_T CO4	3	3	3			
MPH_C_105_T CO5	3	3	3			

Unit	Course Contents (Topics)	Hours
1	<b>Introduction to study and research in herbal drugs:</b>	<b>4</b>
1.1	Different approaches to plants selection, collection and processing for herbal drug research (Random selection, use of ethnobotanical information, use of chemotaxonomical classification etc).	2
1.2	Recent advances in concept of authentication & standardization- significance of chemotaxonomy and DNA fingerprinting with respect to gene expression for secondary metabolites.	2
2	<b>Extraction of phytochemicals</b>	<b>18</b>
2.1	Concept of extraction with respect to activity guided fractionation & isolation of Markers/Biomarkers.	2
2.2	Recent trends in extraction, optimization of extraction, and analysis of the phytochemicals of different classes.	2
2.3	Detailed 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)	9
2.4	<i>Self-study-preparation of flow chart and discussion of physicochemical principles for all large scale extractions</i>	5
3	<b>Natural products in drug discovery and drug development</b>	<b>8</b>
3.1	Role of natural products as lead to the design of new drugs with case history with example e.g., artemisinin, taxane, camptothecin and a few others.	2
3.2	Natural products derived combinatorial libraries and their significance in drug discovery program (HITS and leads).	2
3.3	<i>Self-study-Discussion of lead molecules in drug discovery</i>	4
4	<b>Study of following excipients of natural origin in NDDS with respect to sources, preparation, composition and application</b>	<b>16</b>
4.1	Natural dyes & colorants, sweeteners, flavors and fragrant materials	8
4.2	Kappacarrageenans, galactomannans, glucomannans, cellulose derivatives, lecithin, & alginates.	4
4.3	<i>Self-study-Role of excipients mentioned above, in formulations, with examples</i>	4
5	<b>Application of immunoglobulins from plant sources in diagnosis and therapy.</b>	<b>4</b>
6	<b>Nutraceuticals and their role in healthcare.</b>	<b>4</b>
6.1	Study of following classes of herbs with two or three suitable examples of each: (1) Antioxidants (2) Immunomodulators (3) Antihyperglycemics (4) Hepatoprotectives	4
7	<b>Status of natural products in official Books (latest edition to be adopted)</b>	<b>6</b>
7.1	Introduction to Herbal Pharmacopoeias of different countries	2
7.2	Monographs of natural products in other official Books (latest edition to be adopted).	2
7.3	<i>Self-study-Discussion of monograph of few substances of natural origin</i>	2
	<b>Total</b>	<b>60</b>

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**Books (latest edition to be adopted)**

1. Pharmacognosy Phytochemistry–Medicinal Plants-Jean Brunetton, Lavoisier Publishing, Paris.
2. Textbook of Pharmacognosy-Trease and Evans-14<sup>th</sup> edition. Elsevier science
3. Transgenic Plants-R.Ranjan-Agro Botânica, 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. Cultivation and Processing of Medicinal Plants-Ed. by L.Hornok-John Wiley.
12. Introduction to Flavanoids, Bohr 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, Academic Press, London.
19. Plant Taxonomy and Biosystematics. C.A Stace, Edward Arnold, London.
20. Modern methods of plant analysis K. Paech, Springer-Verlag.
21. Indian Herbal Pharmacopoeia.
22. Indian Pharmacopoeia.
23. Standardization of Botanicals, V. Rajpal, Eastern Publishers, New Delhi.
24. Natural Compounds as Drugs 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 21<sup>st</sup> Century H. Ageta, N. Aimi et al Excerpta Medica, International Congress Series 1157.

**MPH\_C\_106\_T-Biostatistics and Research Methodology (4h/wk)**

Unit	Course Content (Topics)	Hours
	<b>Biostatistics</b>	
1	<b>Collection and Organization of data</b>	<b>8</b>
1.1	Graphical and pictorial presentation of data	1
1.2	Measures of central tendency and dispersion	2
1.3	Variance and standard deviation, relative error, coefficient of variation, precision and accuracy	2
1.4	Sampling techniques: simple random sampling; stratification; estimation of the mean and proportion.	3
2	<b>Probability</b>	<b>6</b>
2.1	Definition. Conditional probability and Bayes' theorem. Probability distributions: binomial, multinomial and Poisson distributions. Normal and lognormal distributions. Use of normal distribution tables.	6
3	<b>Regression</b>	<b>6</b>
3.1	Linear regression and correlation, curvilinear regression, method of least squares, curve fitting, Fiducial limits, probit and logit analysis	6
4	<b>Parametric tests</b>	<b>8</b>
4.1	Testing hypothesis, Types of error. Level of significance. Significant tests and p-value	4
4.2	Tests of significance based on normal distribution, test of significance for correlation coefficients, confidence interval for mean and regression proportion.	4
5	<b>Nonparametric tests</b>	<b>4</b>
5.1	Nonparametric procedures: Chi square goodness of fit test, sign test, Mann-Whitney test; Wilcoxon signed rank test.	4
6	<b>Experimental designs</b>	<b>8</b>
6.1	Randomization, completely randomized, randomized block and Latin square designs, factorial design, crossover and parallel designs	4
6.2	Students should learn use of Minitab/R Software for data summary, correlation, regression analysis, test of hypothesis and experimental design	4
	<b>Total Biostatistics</b>	<b>40</b>
	<b>Research Methodology</b>	
7	<b>Objectives and purpose of Research</b>	<b>2</b>
7.1	Types of research – Educational, clinical, experimental, basic, applied and patent-oriented research	2
8	<b>Literature survey</b>	<b>2</b>
8.1	use of library, Books (latest edition to be adopted) and journals, eJournals, retrieving patents and seeking reprints.	2
9	Methods and tools used in research <ul style="list-style-type: none"> <li>• Qualitative and quantitative studies</li> <li>• Simple data organization, descriptive data analysis</li> <li>• Limitations and sources of errors</li> <li>• Inquiries in form of questionnaire, opinionaire or by interview</li> </ul>	<b>6</b>

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	<ul style="list-style-type: none"> <li>Statistical analysis of data including variance, standard deviation, standard error, mean, student's t test and ANOVA, correlation of data and its interpretation, computer data analysis</li> </ul>	
10	<b>Scientific writing and reporting</b> <ul style="list-style-type: none"> <li>Different types of research papers</li> <li>Title and author names</li> <li>Abstract and keywords</li> <li>Methodology</li> </ul>	3
11	<b>Scientific Presentation</b> <ul style="list-style-type: none"> <li>Importance, types and different skills</li> <li>Content, format of model, introduction and ending</li> <li>Skills for oral presentation and types of visual aids</li> <li>Questionnaire</li> </ul>	3
12	<b>Patents and Trademarks</b> <ul style="list-style-type: none"> <li>The Indian patent system</li> <li>Present status of intellectual property rights (IPR)</li> <li>Product patents and process patent</li> <li>Requirements and preparation of patent proposal</li> <li>Registration of patent in foreign countries</li> </ul>	4
	<b>Total Research Methodology</b>	<b>20</b>
	<b>Total (Biostatistics and Research Methodology)</b>	<b>60</b>

**Books (latest edition to be adopted)**

1. Pharmaceutical Statistics – Practical and Clinical Applications, Bolton S., Marcel Dekker, Inc. N., USA
2. Biostatistics: A Foundation for Analysis in Health Sciences, Wayne W Daniel, John Wiley & Sons, Inc.
3. Introduction to Statistical Analysis, Dixon W. J. and Massey F. J., McGraw Hill, N. Y., USA.
4. Statistical Methods, Snedecor G. W. and Cochran W. G., Iowa State University Press, Ames, Iowa.
5. Research in Education, John W Best and James V Khan, Prentice Hall of India Pvt. Ltd.
6. Effective Business Report Writing, Brown Leland, Prentice Hall Inc. India.
7. Presentation Skills, Michael Hatton, Indian Society for Technical Education, New Delhi.
8. Thesis and Assignment writing, Anderson Jonathan and Durston Berry H, Wiley Eastern Ltd., Bangalore.
9. Writing a Technical Paper, Donald H Menzel, McGraw Hill Book Company, Inc., New York.

**SEMESTER II****MPH\_C\_201\_S SEMINAR**

**Course Objectives:** The purpose of seminar is to upskill students to develop effective scientific communication. The subject will enhance the self-learning ability to gain advanced knowledge of a particular topic while using different database and software

**Course Outcomes (CO):**

<i>Course code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Upto Bloom's level</i>
<b>CO1</b>	Understand the given seminar review topic.	<b>2</b>
<b>CO2</b>	Perform the literature survey using (Pubmed, Google Scholar, Scopus, Web of Science etc) for the given seminar topic.	<b>2,3&amp;4</b>
<b>CO3</b>	Compare and contrast the given data in different reports/ published research papers.	<b>2&amp;3</b>
<b>CO4</b>	Analyze and evaluate the data and facts based on the results obtained in the reported research and review papers and other literature sources related to seminar topic.	<b>2&amp;3</b>
<b>CO5</b>	Create the report on given seminar topic using various ICT and plagiarism checking tools for framing and designing.	<b>2</b>
<b>CO6</b>	Comprehend the use and significance of statistical tools in data analysis, evaluation and presentation while performing literature survey and while drafting the seminar report.	<b>1&amp;3</b>

**Mapping CO with PO**

<b>CO</b>	<b>PO1</b>	<b>PO2</b>	<b>PO3</b>	<b>PO4</b>	<b>PO5</b>	<b>PO6</b>
<b>01</b>	<b>1</b>	<b>1</b>	<b>3</b>		<b>3</b>	
<b>02</b>	<b>1</b>	<b>1</b>	<b>3</b>		<b>3</b>	
<b>03</b>	<b>1</b>	<b>1</b>	<b>3</b>		<b>3</b>	
<b>04</b>	<b>1</b>	<b>1</b>	<b>3</b>		<b>3</b>	
<b>05</b>	<b>1</b>	<b>1</b>	<b>3</b>		<b>3</b>	
<b>06</b>	<b>1</b>	<b>1</b>		<b>3</b>	<b>3</b>	

**MPH\_C\_299\_L-Experimental Techniques in Pharmaceutical Sciences (6h/wk)**

Syllabus for the course Experimental Techniques in Pharmaceutical Sciences for Pharmaceutical Chemistry, Pharmaceutics, Pharmacology, Pharmaceutical Analysis and Pharmacognosy branches is given below.

**A minimum of 8 exercises in the syllabus of a particular branch should be completed.**

**1. Pharmaceutical Chemistry**

**Course Outcome:**

Course Outcome 1: After completing this course, students will be able to accurately measure the logP (partition coefficient) of both a poorly water-soluble and a highly water-soluble drug, demonstrating a comprehensive understanding of drug solubility characteristics.

Course Outcome 2: Students will gain the ability to determine the pKa values of drugs, including weak acids and weak bases, using both potentiometric titration and UV/visible spectroscopy methods, showcasing proficiency in analytical techniques for pharmaceuticals.

Course Outcome 3: Upon course completion, students will be proficient in measuring the V<sub>max</sub> and K<sub>m</sub> values of hydrolase enzymes (e.g., esterases, phosphatases, or lipases) and demonstrate competence in data analysis using Lineweaver-Burk and Eadie-Hofstee methods.

Course Outcome 4: Students will develop the skills to estimate the concentrations of two drugs simultaneously using the simultaneous equation method and the absorbance ratio method, particularly when dealing with combinations of drugs commonly used in fixed-dose combinations.

Course Outcome 5: By the end of the course, students will be capable of synthesizing complex drugs through multistep reactions (at least three steps). They will demonstrate competence in monitoring reactions using TLC, purifying products through column chromatography, and characterizing compounds using IR and NMR spectroscopy while estimating overall reaction yields.

Course Outcome 6: After completing this course, students will be able to synthesize prodrugs of common drugs and study their decomposition kinetics in plasma or serum, particularly through DCC-based coupling to obtain ester prodrugs, illustrating knowledge of drug modification and pharmacokinetics.

Course Outcome 8: Through hands-on experience with physical models, students will learn to construct and interpret models for molecules like glucose, vitamin C, propranolol, and chloramphenicol, enhancing their ability to identify stereocenters and assign correct stereochemistry.

Course Outcome 9: Students will be proficient in performing molecular modeling exercises, including energy minimization, molecular dynamics simulations, docking, 2D/3D-QSAR, structure-based drug design, and pharmacophore mapping, using both commercial and freeware software, highlighting their computational and modeling skills in drug discovery and design.

<b>M. Pharm First Year, Semester II</b>			
<b>MPH_C_299_L Experimental Techniques in Pharmaceutical Sciences</b>			
<i>Course Code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
MPH_C_299_L CO1	Calculate the logP (partition coefficient) of both a poorly water-soluble and a highly water-soluble drug, demonstrating a comprehensive understanding of drug solubility characteristics.	1	3
MPH_C_299_L CO2	Determine the pKa values of drugs, including weak acids and weak bases, using both potentiometric titration and UV/visible spectroscopy methods, showcasing proficiency in analytical techniques for pharmaceuticals.	2	4
MPH_C_299_L CO3	Calculate the Vmax and Km values of hydrolase enzymes (e.g., esterases, phosphatases, or lipases) and demonstrate competence in data analysis using Lineweaver-Burk and Eadie-Hofstee methods.	3	4
MPH_C_299_L CO4	Estimate the concentrations of two drugs simultaneously using the simultaneous equation method and the absorbance ratio method, particularly when dealing with combinations of drugs commonly used in fixed-dose combinations.	4	4
MPH_C_299_L CO5	synthesize complex drugs through multistep reactions (at least three steps). They will demonstrate competence in monitoring reactions using TLC, purifying products through column chromatography, and characterizing compounds using IR and NMR spectroscopy while estimating overall reaction yields.	5	5
MPH_C_299_L CO6	synthesize prodrugs of common drugs and study their decomposition kinetics in plasma or serum, particularly through DCC-based coupling to obtain ester prodrugs, illustrating knowledge of drug modification and pharmacokinetics.	6	5
MPH_C_299_L CO7	Construct and interpret physical models for molecules like glucose, vitamin C, propranolol, and chloramphenicol, enhancing their ability to identify stereocenters and assign correct stereochemistry.	7	4
MPH_C_299_L CO8	Perform molecular modeling exercises, including energy minimization, molecular dynamics simulations, docking, 2D/3D-QSAR, structure-based drug design, and pharmacophore mapping, using both commercial and freeware software, highlighting their computational and modeling skills in drug discovery	8	5

	and design.		
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**CO-PO Mapping:**

Course code & CO number	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_299_L -	2	2	3	1	2	0
MPH_C_299_L -	1	1	3	0	2	0
MPH_C_299_L -	1	2	2	1	2	0
MPH_C_299_L -	1	2	2	1	1	0
MPH_C_299_L -	2	2	2	2	2	3
MPH_C_299_L -	2	1	3	1	3	2
MPH_C_299_L -	1	1	1	1	2	0
MPH_C_299_L -	0	1	1	1	2	0
MPH_C_299_L -	1	2	2	1	2	0

1. Measurement of logP of a poorly water-soluble and a highly water-soluble drug
2. Determination of the pK<sub>a</sub> of a drug (weak acid and weak base) by potentiometric titration and/or by UV/visible spectroscopy
3. Measurement of V<sub>max</sub> and K<sub>m</sub> of a hydrolase enzyme (can use esterase, phosphatase, or lipase) Students should learn to plot data by Lineweaver-Burke and Eadie-Hofstee methods
4. Estimation of two drugs by simultaneous equation method and by absorbance ratio method. (preferably use combinations of drugs that are used as fixed drug combination)
5. Synthesis of some any 2 drugs involving multistep (at least three steps) reactions. (Students should learn to monitor the reaction by TLC, separate the main product from impurities by column chromatography and learn use of IR and <sup>1</sup>H and <sup>13</sup>C NMR to check the structures of the intermediates and the final compounds and estimate overall yield of the reaction).
6. Resolution of racemic mixtures of acidic and basic compounds by formation of diastereomers
7. Synthesis of prodrugs of any one of the common drugs and study of their decomposition (kinetics) in plasma or serum to the parent drug (suggest use of DCC based coupling to obtain ester prodrugs)
8. Establish a RP-HPLC method for the separation of a mixture of two or more compounds (e.g. fixed dose combination drugs, or prodrugs synthesized above or apply to reaction monitoring)
9. Working with physical models- ball and stick or space-filling models. Students should

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learn to construct physical models for glucose, vitamin C, propranolol, chloramphenicol. This will enable students to identify stereocenters and assign correct stereochemistry to them.

10. Demonstration of some molecular modelling exercises like energy minimization, molecular dynamics simulations, docking, 2D/3D-QSAR, structure based drug, pharmacophore mapping etc. using either commercially available programs or freeware.

## 2. Pharmaceutics

### Objectives

To impart to the learner the knowledge of rationale design of drug delivery systems, mathematical approaches for data analysis and apply it to formulation and evaluation of novel drug delivery systems.

### Course Out Comes (COs)

Upon the completion of the course student shall be able to:

- 1) Analyze the drug release data statistically and integrate kinetic models.
- 2) Understand and apply design of experiments in optimizing process or formulation parameters.
- 3) Formulate and evaluate novel drug delivery systems such as orally disintegrating systems, transdermal/ mucoadhesive/ gastroretentive systems/ inhalable microspheres.
- 4) Construct pseudo ternary phase diagram and prepare microemulsion.
- 5) Demonstrate the fabrication and evaluation of vesicular systems, nanoparticles.

<b>M. Pharm First Year, Semester II</b>			
<b>MPH_C_299_L – Experimental Techniques in Pharmaceutical Sciences (Practical 6h/week)</b>			
<b>Course Code &amp; CO number</b>	<b>At the successful completion of the course, the learners will be able to:</b>	<b>Syllabus Unit no.</b>	<b>Up to Bloom's level</b>
MPH_C_299_L CO1	Analyze the drug release data statistically and integrate kinetic models .	1	4
MPH_C_299_L CO2	Understand and apply design of experiments in optimizing process or formulation parameters.	2	4
MPH_C_299_L CO3	Formulate and evaluate novel drug delivery systems such as orally disintegrating systems, transdermal/ mucoadhesive/ gastroretentive systems/ inhalable microspheres.	3-5	4
MPH_C_299_L CO4	Construct pseudo ternary phase diagram and prepare microemulsion.	6	4
MPH_C_299_L CO5	Demonstrate the fabrication and evaluation of vesicular systems and nanoparticles.	7&8	4

<b>Course Code &amp; CO number</b>	<b>PO1</b>	<b>PO2</b>	<b>PO3</b>	<b>PO4</b>	<b>PO5</b>	<b>PO6</b>
MPH_C_299_L CO1	2	2	1	2	2	3
MPH_C_299_L CO2	2	2	1	3	2	3

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MPH_C_299_L CO3	2	2	1	3	2	3
MPH_C_299_L CO4	2	2	1	2	2	3
MPH_C_299_L CO5	2	2	1	3	2	3

1. Study of dissolution profile of IR and ER products. Mathematical treatment of data for release kinetics and  $f_1$  and  $f_2$  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 can be made
8. Design of lipid particulate system (nanosystems with wax can be tried)

### 3. Pharmacognosy and Phytochemistry

#### Course Objectives: (Paragraph)

- 1) To introduce different techniques for extraction of desired phytoconstituents based on their properties
- 2) To apply various analytical techniques for detection and quantification of phytoconstituents in Herbal Drugs.
- 3) To prepare and evaluate herbal formulation such as Churna.
- 4) To carry out bioactivity guided fractionation for a given herb.

#### Course Outcomes (CO):

M. Pharm First Year, Semester II MPH_C_299_P Experimental Techniques in Pharmaceutical Science (Pharmacognosy Laboratory) (Practical 6 h/ wk)			
Course code & CO number	At the successful completion of the course, the learners will be able to:	Experiment no.	Up to Bloom's level
MPH_C_299_P CO1	Design methodologies for extraction of different phytoconstituents such as alkaloids, anthraquinone glycosides, volatile oil, inulin, carotenoids flavonoids as well as mucilage	1,2,3,4,5 &8	6
MPH_C_299_P CO2	Evaluate the extraction efficiency and quality of crude drugs using suitable analytical techniques for detection and quantification of phytoconstituents	1,2,3,4,5 &8	5
MPH_C_299_P CO3	Apply and interpret bio-activity guided	6	3

	fractionation of any herb for antimicrobial or anti-oxidant activity		
MPH_C_299_P CO4	Prepare and evaluate herbal dosage forms such as Churna	7	6

### CO-PO Mapping

Course Code & CO Number	PO1	PO2	PO3	PO4 (Additional, if required by the department)	PO5 (Additional, if required by the department)	PO6 (Additional, if required by the department)
MPH_C_299_P CO1	3	3	3			
MPH_C_299_P CO2	3	3	3			
MPH_C_299_P CO3	3	3	3			
MPH_C_299_P CO4	3	3	3			

1. Extraction and evaluation of Mucilage from suitable sources such as aloes or Leaves of *Annona squamosa* or any other suitable source.
2. Extraction and analysis of alkaloids such as purine alkaloids and Tropane or indole alkaloids from suitable natural sources.
3. Preparation and evaluation of extract of anthraquinone glycosides from *Cassia angustifolia/Cassia fistula* or rhubarb or other suitable source
4. Extraction and analysis of Volatile oil from suitable sources such as clove or eucalyptus or any other.
5. Extraction and detection of inulin from suitable sources such as chicory or Kuth.
6. Activity guided fractionation of any herb for its antimicrobial and/or antioxidant activity.
7. Preparation and evaluation of any herbal 'churna, dosage form (Sitopaladi or Triphala).
8. Extraction and analysis of carotenoid derivatives or flavonoid derivatives from suitable natural sources for each.

### 4. Pharmaceutical Analysis

**Course Objectives:** Upon completing the following practical experiments, learners should be able to: Analyse single and multicomponent formulations using UV-visible spectroscopy techniques, comprehend the practical aspects of analysis and bioanalysis through various chromatographic techniques including HPLC, GC, TLC, preparative TLC, HPTLC and column chromatography, conduct instrument calibration, validate analytical procedures, and elucidate the structures of organic compounds using available spectroscopic data.

<b>M. Pharm (Pharmaceutical Analysis) First Year, Semester II</b>			
<b>MPH_C_299_L - Experimental Techniques in Pharmaceutical Sciences (6 h/wk)</b>			
<i>Course code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
MPH_C_299_L CO1	Analyse, calculate and interpret data obtained through UV Spectrophotometric analysis for pKa determination and quantitative multicomponent evaluation using various methods like simultaneous equation, absorbance ratio, difference spectroscopy and derivative spectroscopy.	1, 3, 8	5
MPH_C_299_L CO2	Apply ICH guidelines to validate developed analytical method by UV spectroscopy and interpret the obtained results.	15	3
MPH_C_299_L CO3	Design and develop analytical and bioanalytical- planar and column chromatographic methods.	6, 7, 10, 11, 12, 16	6
MPH_C_299_L CO4	Assess performance of analytical instruments such as UV spectrophotometer and HPLC through precise calibration experiments.	5, 14 & 17	5
MPH_C_299_L CO5	Analyse and predict structures of organic compounds from reported spectral data ( <sup>1</sup> H NMR, <sup>13</sup> C NMR, Mass, IR, and UV spectra).	2 & 4	6

**CO-PO Mapping:**

Course code & CO number	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_299_L CO1	3	3	3	3	3	3
MPH_C_299_L CO2	3	3	3	3	3	3
MPH_C_299_L CO3	3	3	3	3	3	3
MPH_C_299_L CO4	3	3	3	3	3	3
MPH_C_299_L CO5	3	3	3	3	3	3

1. Determination of  $pK_a$  by U.V. spectroscopy.
2. Sample preparation for I.R. spectroscopy (solid/liquids) and interpretation of IR bands for important functional groups.
3. Assays for drugs in combination by UV derivatives spectroscopy.
4. Structural elucidation workshop: Interpretation of  $^1H$ NMR,  $^{13}C$ NMR, IR and Mass spectrometry of simple compounds (maximum 12 carbon atoms).
5. Standard calibration curve by UV spectroscopy at
  - a.  $\lambda_{max}$
  - b.  $\lambda_{max} + 10$  nm
  - c.  $\lambda_{max} - 10$  nm
6. Determination of response factor by HPLC.
7. Qualitative and Quantitative HPTLC analysis (minimum mixture of 3 compounds).
8. Assay determination by Simultaneous equation, Absorbance ratio and Difference spectroscopy.
9. Determination of Response factor by HPLC analysis of drugs.
10. Preparative TLC analysis.
11. Bioanalysis by HPLC.
12. pH stability evaluation of Aspirin by TLC.
13. Failure investigation/Investigation of 'Out of Specification' report for products and analytical methodology.
14. Qualification of Instruments/Equipment.
15. Validation of analytical method/procedure/process.
16. Separation of components by column chromatography.
17. Calibration of UV spectrophotometer/HPLC column

## 5. Pharmacology

**Course Objectives:** This course will develop the expertise in in-vivo and in vitro assays related to pre-clinical studies of drug screening.

M.Pharm MPH_E_299_T			
First Year, Semester I Pharmacology Practicals			
Course code & CO number	<i>At the successful completion of the course, the learners will be able to:</i>	Syllabus Unit no.	Upto Bloom's level
MPH_E_299_T_CO1	Understand the efficacy and potency of an antagonist for a suitable isolated tissue, and calculate pA <sub>2</sub> values.	1	2
MPH_E_299_T_CO2	Determine and interpret the anti-oxidant effect of a particular therapeutic moiety using antioxidant screening assays like NO levels and SOD activity.	1	2,3&4
MPH_E_299_T_CO3	Comprehend the principle behind behavioural tests of rodents like anti-cataleptic activity, muscle relaxant activity, anti-anxiety activity, etc. and apply them practically	2	2&3
MPH_E_299_T_CO4	Understand and apply the techniques of drug administration and blood withdrawal as well as methods of measuring blood pressure, pulse, etc..	2	2&3
MPH_E_299_T_CO5	Understand the various guidelines (ICH, OECD, AND CCSEA) and apply them in their day-to-day laboratory care and handling of animals.	3	2
MPH_E_299_T_CO6	Comprehend techniques of high throughput screening like cell-based assays, biochemical assays, etc. and various alternative methods of screening pharmaceutical compounds using <i>Drosophila</i> and <i>Zebrafish</i> as pre-clinical models.	3	1&3

### Mapping CO with PO

CO	PO1	PO2	PO3	PO4	PO5	PO6
MPH_E_299_T_CO1	1	1			3	
MPH_E_299_T_CO2	1	1			3	
MPH_E_299_T_CO3	1	1			3	
MPH_E_299_T_CO4	2	1			3	

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MPH_E_299_T_CO5	1	1			3	
MPH_E_299_T_CO6	2	1			3	

- I) Experiments to be performed by students
  - 1) Assay of antagonist using suitable isolated tissue preparation
  - 2) Determination of  $pA_2$  values of antagonists using suitable tissue preparation
  - 3) In vitro antioxidant screening assays (any two) e.g. DPPH, NO, superoxide.
- II) Demonstrations
  - a. Experiments on intact animals to evaluate:
    - 1) Anticatalytic activity
    - 2) Antianxiety activity
    - 3) Anti-inflammatory/analgesic activity
    - 4) Musclerelaxant activity
  - b. Techniques of drug administration and blood withdrawal
  - c. Non-invasive methods of measuring blood pressure, pulse, ECG etc.
- III) Tutorials
  - 1) Care and handling of animals
  - 2) CPCSEA, OECD, ICH guidelines in brief
  - 3) Use of alternative methods of screening (Types of drugs for which these models can be used)
    - Zebrafish
    - Drosophila
  - 4) Techniques for high throughput screening
    - Cell based assays
    - Biochemical assays
    - Radioligand binding assays

**References (latest editions of the following Books (latest editions to be adopted)/CDs to be referred).**

1. ExpharmPro-SimulatedanimalexperimentsinPharmacology, Elsevier
2. Expharm-Stimulatedanimalexperiments, Ravindran
3. H.G.Vogel,Drugdiscoveryandevaluation-PharmacologicalAssays-SpringerVerlog
4. M.N.Ghosh,FundamentalsofExperimentalPharmacology,ScientificBook Agency
5. S.K.Kulkarni,PracticalPharmacologyandClinicalPharmacy,VallabhPublications.
6. CPCSEA,OECD,ICH Guidelines.

**BRANCH: PHARMACEUTICAL CHEMISTRY**  
**SEMESTER II CORE**

**MPH\_C\_202\_T - Advanced Pharmaceutical and Medicinal Chemistry (4h/wk)**

**Course Objectives:**

1. To understand the different types of enzyme inhibitors to determine type of inhibitor and describe how each inhibitor interacts with enzymes. To interpret how this inhibitor affects an enzyme's measured kinetic parameters
2. TO study of the relationships between molecular structure and biological activity, development and evolution of QSAR; the current trends, and pressing challenges for designing drugs using QSAR methodology, study novel and emerging applications of QSAR modeling.
3. To learn 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,  $\alpha$ -helix,  $\beta$ -sheet,  $\beta$ - and  $\gamma$ -turn mimetics.
4. To understand designing of antisense oligonucleotides and small interfering RNAs (siRNAs) with examples.
5. Discuss and emphasize the importance of subjects like Molecular Biology, Genetic engineering and Biotechnology in production of biologicals as drugs.

**Course Outcomes (CO):**

1. Outline the classification of enzyme inhibitors and describe how inhibitors interact with enzymes.
2. Able to interpret how inhibitors affect an enzyme's measured kinetic parameters
3. Understand the basic principles of QSAR development & validation of QSAR models and predictions using QSAR models.
4. Understand the different types of peptidomimetic structures and design mimetics of a given peptide sequence.
5. Understand the concept of antisense oligonucleotides and small interfering RNAs (siRNAs) & their structures.
6. Understand the importance of Molecular Biology, Genetic engineering and Biotechnology in discovery and development.

**Course Outcomes**

<b>M. Pharm First Year, Semester II</b>			
<b>MPH_C_202_T - Advanced Pharmaceutical and Medicinal Chemistry</b>			
<b>Course Code &amp; CO number</b>	<b>At the successful completion of the course, the learners will be able to:</b>	<b>Syllabus Unit no.</b>	<b>Up to Bloom's level</b>
<b>MPH_C_202_T CO1</b>	Outline the classification of enzyme inhibitors and describe how inhibitors interact with enzymes.	1.4	2
<b>MPH_C_202_T CO2</b>	Able to interpret how inhibitors affect an enzyme's measured kinetic parameters	1.5	4
<b>MPH_C_202_T CO3</b>	Understand the basic principles of QSAR development & validation of QSAR models and predictions using QSAR models.	2.2	4
<b>MPH_C_202_T</b>	Understand the different types of peptidomimetic	3.2	4

<b>CO4</b>	structures and design mimetics of a given peptide sequence.		
<b>MPH_C_202_T CO5</b>	Understand the concept of antisense oligonucleotides and small interfering RNAs (siRNAs) & their structures.	4.2	2
<b>MPH_C_202_T CO6</b>	Understand the importance of Molecular Biology, Genetic engineering and Biotechnology in discovery and development.	5	3

### Mapping CO with PO

Course code & CO number	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_202_T	1	1	2	1	2	0
MPH_C_202_T	2	2	2	1	2	0
MPH_C_202_T	2	3	2	2	2	0
MPH_C_202_T	1	2	3	1	3	1
MPH_C_202_T	1	1	2	1	2	0
MPH_C_202_T	3	0	2	3	2	0

Unit	Course Content (Topics)	Hours
1	<b>Enzyme Inhibition</b>	<b>16</b>
1.1	Coverage of basic aspects of enzyme kinetics, catalysis, transition-state theory.	2
1.2	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	1
1.3	Drug synergism, concepts and mechanisms.	1
1.4	Reversible enzyme inhibitors – competitive inhibition, non-competitive inhibition, uncompetitive inhibition with suitable examples. Detection of type of inhibition by suitable plotting methods. Concepts of $IC_{50}$ and $K_i$ .	4
1.5	Slow-tight binding inhibitors, covalent enzyme inhibitors and mechanism-based inhibitors with suitable examples. Concept of $K_{inact}$ and $K_i$ for irreversible inhibitors	4
1.6	<i>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)</i>	4
2	<b>QSAR</b>	<b>14</b>
2.1	Historical Aspects	1
2.2	Electronic Effects - the Hammett equation, lipophilic effects, experimental measurement of lipophilicity, log P and log D, effect of ionization on log P, calculation of log P and log D, Steric effects - the Taft equation	3

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2.3	Hansch Analysis, Free-Wilson method, Topliss operational scheme	2
2.4	Basics of regression analysis - linear and multilinear regression, introduction to PCA, PCR, PLS, ANN and GFA. Correlation coefficients ( $r^2$ and $r^2$ ), F-test, standard error, validation methods like cross-validation by calculation of $q^2$ , boot-strap analysis and randomization. Application domain for predictions using a QSAR model.	6
2.5	Design of training and test sets using factorial design	2
2.5	<i>Self-study – Different types of descriptors reported in literature that account for the steric, electronic and lipophilic effects.</i>	2
3	<b>Peptides and Peptidomimetics</b>	<b>14</b>
3.1	Coverage of peptide structure, biosynthesis of peptides and solid-phase/solution synthesis of peptides.	4
3.2	Design of peptidomimetics by manipulation of the amino acids, modification of the peptide backbone, incorporating conformational constraints locally or globally, $\alpha$ -helix, $\beta$ -sheet, $\beta$ - and $\gamma$ -turn mimetics	4
3.3	<i>Self-study of examples of peptidomimetics for some enzymes and receptors like ACE, CCK, bradykinin</i>	2
4	<b>Antisense therapeutic agents</b>	<b>6</b>
4.1	History and principles	2
4.2	Design of antisense oligonucleotides and small interfering RNAs (siRNAs) with some examples	4
5	<b>Molecular Biology, Genetic Engineering and Biotechnology</b> in production of biologicals as drugs.	<b>6</b>
5.1	<i>Self-study of biotechnology based drugs, vaccines and diagnostic agents with respect to their biological source, their design and the mechanism of their actions</i>	4
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

1. The Organic Chemistry of Drug Design and Drug Action, Silverman R.B., Academic Press.
2. Textbook of Drug Design and Discovery, Eds. Krosggaard-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 Aspect of Peptidomimetics by Maes V., Tourwé D., John Wiley & Sons, Ltd, Chichester, UK.
5. Comprehensive Medicinal Chemistry, Series Ed., Hansch C., Pergamon Press.
6. Burgers Medicinal Chemistry, Drug Discovery and Development, Wiley.

**MPH\_C\_203\_T-Advanced Organic Chemistry (4h/wk)**
**Course Objectives:**

1. To learn the significance and application of catalysts, types of catalyst and catalysis reactions for selective organic compounds
2. To teach the students to analyse a target structure in order to design a synthetic scheme. To acquire the expertise toward synthesis by the manipulation of both activation methods and selectivity control.
3. To learn applications of chiral compounds separation in drug synthesis, chiral auxiliaries, enzymes, chiral solvents, chiral catalysts in asymmetric synthesis
4. To study the new synthetic methods related to the use of non pollution media (green chemistry), green solvents, application of green reagents in normal chemistry reactions.
5. To learn new notions related to combinatorial chemistry by an introduction to liquid and solid phase parallel synthesis using various combinatorial approaches, solid supports, tagging and detagging methods for deconvolution

**Course Outcomes (CO):**

<b>M. Pharm First Year, Semester II</b>			
<b>MPH_C_203_T - Advanced Organic Chemistry</b>			
<i>Course Code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
<b>MPH_C_203_TCO1</b>	Understand chemical catalysis, types of catalysts, and use of catalytic reactions while synthesizing drug intermediates.	2.1, 2.2	3
<b>MPH_C_203_TCO2</b>	Draw the schematic retrosynthetic pathway and analyze the retrosynthetic scheme for any given target molecule.	3.1	4
<b>MPH_C_203_TCO3</b>	Understand the importance of usage of green reagents and solvents for chemical synthesis for pollution free environment and the concepts of atom economy and atom efficiency.	6.2	3
<b>MPH_C_203_TCO4</b>	Apply the principle of combinatorial approach in the drug intermediate synthesis.	5	4
<b>MPH_C_203_TCO5</b>	Able to apply the concepts of chiral auxiliaries, enzymes, chiral solvents, chiral catalysts in asymmetric synthesis.	1.2	4

**Mapping CO with PO**

<b>Course code &amp; CO number</b>	<b>PO1</b>	<b>PO2</b>	<b>PO3</b>	<b>PO4</b>	<b>PO5</b>	<b>PO6</b>
<b>MPH_C_203_T</b>	1	1	2	1	2	1

<b>MPH_C_203_T</b>	2	1	3	1	2	2
<b>MPH_C_203_T</b>	1	1	3	2	3	3
<b>MPH_C_203_T</b>	2	1	2	1	2	0
<b>MPH_C_203_T</b>	1	1	2	2	3	0

Unit	Course Content (Topics)	Hours
1.0	<b>Advanced Stereochemistry</b>	<b>12</b>
1.1	<i>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, exo-endo, syn-anti nomenclature. Stereoselective and stereospecific reactions. Conformational isomerism in acyclic systems. Shape of six membered rings and effect of substituents and reactivity.</i>	2
1.2	Chirality in systems lacking a stereogenic carbon atom	2
1.2.1	Point chirality – tertiary amines and phosphines	1
1.2.2	Axial chirality – allenes, biphenyls and binaphthyls	1
1.2.3	Helical structures – polynucleotides, polyamino acids, biaryls and allenes	1
1.3	Methods for estimating ratios of stereoisomers in a mixture, separation and identification of the individual components by NMR spectroscopy, X-ray crystallography.	1
1.4	Nucleophilic attack on acyclic carbonyl compounds – Cram's rule, Felkin-Ahn rule. Locking effects in nucleophilic reactions at carbonyl groups	2
1.5	Stereochemistry of important reactions leading to formation of alkenes – Wittig and related reactions	2
2.0	<b>Catalysis &amp; Organometallics in Organic Synthesis</b>	<b>12</b>
2.1	Types of catalysis, heterogeneous and homogeneous catalysis, advantages and disadvantages, catalytic cycles	1
2.2	Heterogeneous catalysis – preparation, characterization, kinetics, supported catalysts, catalyst deactivation and regeneration, some examples of heterogeneous catalysis used in synthesis of drugs.	1.5
2.3	Homogeneous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinson catalysts, chiral ligands and chiral induction, Ziegler-Natta catalysts, some examples of homogeneous catalysis used in synthesis of drugs	1.5
2.4	Phase transfer catalysis - theory and applications	1.5
2.5	Introduction, Classification of organometallic compounds based on hapticity and polarity of the M-C bond. Nomenclature and general characters. Synthesis, stability and decomposition pathways.	1.5

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2.6	Transition metal $\pi$ -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.	3
2.7	<i>Self-study - Basic organometallic reactions covering oxidative reactions, migratory reactions, insertions, extrusion, additions, eliminations—their mechanisms and stereochemistry</i>	2
3.0	<b>Synthon Approach and Applications</b>	<b>13</b>
3.1	Retrosynthesis and its advantages, rules for dissection of molecules, meaning of the term, disconnection, FGI, FGA and synthons, guidelines for the order of events	1
3.2	C-X disconnections; C-C disconnections—alcohols and carbonyl compounds; 1,2-, 1,3-, 1,4-, 1,5-, 1,6-difunctionalized compounds	4
3.3	Strategies for synthesis of three, four, five and six-membered rings	3
3.4	Strategies for synthesis of aromatic and saturated heterocycles	3
3.5	<i>Self-study—Strategies for synthesis of saturated heterocycles.</i>	2
4.0	<b>Asymmetric Synthesis</b>	<b>6</b>
4.1	Introduction and need; chiral synthesis using chiral pool, chiral auxiliaries, chiral catalysts	2
4.2	Enzymes, chiral solvents and whole organisms	2
4.3	Analytical methods of determining purity of stereoisomers	1
4.4	<i>Self-study—Applications in industry</i>	1
5.0	<b>Combinatorial Chemistry</b>	<b>11</b>
5.1	Introduction, advantages and planning combinatorial synthesis	1
5.2	Solid phase and solution phase synthesis	5
5.3	Supports, linkers, and tags	1
5.4	Deconvolution and iteration	1
5.5	Parallel synthesis, multi-step—convergent and sequential synthesis	2
5.6	<i>Self-study—Multicomponent reactions</i>	1
6.0	<b>Green Chemistry</b>	<b>5</b>
6.1	History, need and the goals of green chemistry	1
6.2	Basic principles of green chemistry, illustrated with examples to discuss issues of prevention of waste or minimize by-products, atom economy, 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.	3
6.3	<i>Self-study—Reactions carried out using Microwave and ultrasound.</i>	2
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

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 F A and Sundberg R J, 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.

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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 (latest editions to be adopted).
10. Homogenous Transition Metal Catalysis, Masters C., Chapman & Hall.
11. Principles and Practice of Heterogeneous 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.

**BRANCH: PHARMACEUTICS**  
**SEMESTER II CORE**

**MPH\_C\_204\_T-Advanced Pharmaceutics-I(4h/wk)**

**Objectives**

On completion of following theory topics learner should be able to comprehend the concepts involved in designing oral and parenteral sustained release systems; specialized emulsions; gastro-retentive systems; ocular and transdermal systems; and knowledge of pharmaceutical process development.

**Course Outcomes (CO):**

Upon the completion of the course student shall be able to:

1. Understand the key concepts in development of oral and parenteral sustained release systems and their characterization.
2. Summarize phase behaviour, preparation, characterization, bioavailability, and applications of microemulsions, multiple emulsions, self-emulsifying and self-micro emulsifying drug delivery systems.
3. Describe different approaches and evaluation in development of gastro retentive drug delivery systems.
4. Explain the principles involved, designing, and applications of novel systems in development of ocular and transdermal drug delivery systems.
5. Discuss the key elements as per ICH guidelines in pharmaceutical process development and regulatory procedures involved in pharmaceutical product development.

<b>M. Pharm First Year, Semester II</b> <b>MPH_C_204_T Advanced Pharmaceutics I (THEORY-60 hours)</b>			
<b>Course Code &amp; CO number</b>	<b>At the successful completion of the course, the learners will be able to:</b>	<b>Syllabus Unit no.</b>	<b>Up to Bloom's Level</b>
MPH_C_204_T CO1	Understand and recall the key concepts in development of oral and parenteral sustained release systems and their characterization.	1&2	5
MPH_C_204_T CO2	Summarize phase behaviour, preparation, characterization, bioavailability, and applications of microemulsions, multiple emulsions, self-emulsifying and self-micro emulsifying drug delivery systems.	3	4
MPH_C_204_T CO3	Describe different approaches and evaluation of development of gastro retentive drug delivery systems.	4	4
MPH_C_204_T CO4	Explain the principles involved in designing and applications of novel systems in development of ocular and transdermal drug delivery systems.	5&6	5
MPH_C_204_T CO5	Discuss the key elements as per ICH guidelines in pharmaceutical process development and regulatory	7	4

	procedures involved in pharmaceutical product development.		
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Course Code & CO number	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_204_T CO1	1	1	1	3	2	2
MPH_C_204_T CO2	1	1	1	3	2	2
MPH_C_204_T CO3	1	1	1	3	2	2
MPH_C_204_T CO4	1	1	1	3	2	2
MPH_C_204_T CO5	1	1	1	3	2	2

Unit	Course Contents (Topics)	Hours
1	<b>Solids–oral SR system</b>	<b>13</b>
1.1	<i>Self-study-Overview of Single oral unit SR systems.</i>	3
1.2	<i>Self-study-Structure and physiology of GIT.</i>	1
1.3	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.	4
1.4	Multiparticulate systems-pelletization (emphasis on extrusion and spheronization). Orodispersible systems. Pulsatile Drug delivery systems.	5
2	<b>Parenteral SR systems</b>	<b>12</b>
2.1	Need and concept, routes employed	1
2.2	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.	6
2.3	<i>Self-study-Biopharmaceutical aspects, Sterilization &amp; stability issues</i>	2
2.4	Characterization-special emphasis on release studies	1
2.5	Issues related to Safety, Toxicity & Tissue Injury	2
3	<b>Specialized Emulsions</b>	<b>9</b>
3.1	Microemulsions, Multiple emulsions, Self Emulsifying Drug Delivery systems & SMEDDS; Formulation and phase behavior; Preparation & Characterization; Bioavailability Aspects; Applications.	6
3.2	<i>Self-study-Theories of Emulsification, Factors influencing type of emulsion formed.</i>	3
4	<b>Gastro-retentive Drug Delivery Systems</b>	<b>8</b>
4.1	<i>Self-study-Introduction; concept of absorption window; need for GRDDS, gastric motility; principles of Gastro-retention; Factors controlling performance of GRDDS.</i>	3

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4.2	Different Approaches-High density systems, floating systems, muco-adhesive systems, Expandable systems, Magnetic systems, Superporous Hydrogels	4
4.3	Evaluation.	1
5	<b>Ocular drug delivery systems.</b>	7
5.1	<i>Self-study-Structure and physiology of eye; Drug absorption and disposition in the eye.</i>	2
5.2	Methods to prolong ocular drug residence with emphasis on mucoadhesive systems.	1
5.3	Intraocular inserts; Non erodible inserts/ Erodible inserts. Novel ophthalmic drug delivery systems, Nanoparticles, liposomes and prodrugs. Ocular penetration enhancers.	4
6	<b>Transdermal Drug Delivery Systems</b>	7
6.1	<i>Self-study-Structure and physiology of skin.</i>	1
6.2	Principles of skin permeation. Kinetics of skin permeation & penetration enhancers Types (Gels, Patches/films) Pressure sensitive adhesives.	3
6.3	Development & evaluation – <i>in vitro</i> , <i>in vivo</i> .	1
6.4	Iontophoresis.	1
6.5	Recent advances – use of microneedles in transdermal drug delivery.	1
7	<b>Introduction to Pharmaceutical Processing Development. (As per ICH guidelines)</b>	4
7.1	Elements in Pharmaceutical development <ul style="list-style-type: none"> <li>• Target product profile</li> <li>• Critical Quality Attributes.</li> <li>• Linking Material Attributes &amp; process parameters to CQA's Risk Assessment</li> <li>• Design space</li> <li>• Control Strategy</li> <li>• Product Lifecycle management &amp; continual improvement.</li> </ul>	3
7.2	Submission of Pharmaceutical Development and related information in CTD format. <i>Relevant Examples.</i>	1
<b>Total</b>		<b>60</b>

**Books (latest edition to be adopted)**

1. Targeted and Controlled Drug Delivery: Novel Carrier Systems by Vyas SP, Khar RK, CBS Publishers and Distributors.
2. Controlled and Novel Drug Delivery by Jain NK, CBS Publishers and Distributors
3. Controlled Drug Delivery: Fundamentals and Applications by Robinson JR, Lee VHL, Dekker
4. Novel Drug Delivery System by Chien YW, Informa Healthcare.
5. Progress in Controlled and Novel Drug Delivery Systems by Jain NK, CBS Publishers and Distributors
6. Ophthalmic Drug Delivery Systems, Mitra AK, Drugs and Pharmaceutical Sciences Series.
7. Polymeric drug delivery system, Kwon GS, Marcel Dekker.
8. Nanoparticulate Drug Delivery System by Thassu D, Deleers M, Pathak Y, Marcel Dekker.
9. Controlled Drug Delivery- Challenges and Strategies by Park K, American Chemical Society.
10. Colloidal Drug Delivery System by Kreuter J, Marcel Dekker.

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12. [www.ich.org](http://www.ich.org)
13. Pharmaceutical Dosage Forms: Disperse Systems by Lieberman HA, Rieger MM, Banker GS, Marcel Dekker.
14. Pharmaceutical Emulsions and Suspensions by Nielloud F, Marti-Mestres G, Marcel Dekker.
15. Controlled Release Systems Fabrication Technology by Dean STH, CRC Press.
16. Bioadhesive Drug Delivery Systems by Mathiowitz. E, Chickering DE, Lehr CM, Marcel Dekker.
17. Pharmaceutical Skin Penetration Enhancement by Walters. KA, Hadgraft J, Marcel Dekker.
18. Percutaneous Absorption by Bronaugh RL, Maibach HI, Taylor and Francis
19. Transdermal Controlled Systemic Medication by Chien YW, Marcel Dekker
20. Oral Mucosal Drug Delivery by Rathbone MJ, Marcel Dekker.
21. Modified Release Drug Delivery Technology by Rathbone MJ, Hadgraft J, Roberts MS, Lane ME, Informa Healthcare.
22. Pharmaceutical Pelletization Technology, Ghebre-sellassie. I, Marcel Dekker

**MPH\_C\_205\_T-Advanced Pharmaceutics-II(4h/wk)**

**Objectives**

On completion of following theory topics learner should be able to comprehend the concepts involved in targeted systems and knowledge of pulmonary and nasal delivery systems; protein and peptide delivery systems; colloidal drug delivery systems; and brain targeting.

**Course Out Comes (COs)**

Upon the completion of the course student shall be able to:

- 1) Recall and explain active and passive targeting approaches in tumour and cellular targeting.
- 2) Understand the concepts governing design, and evaluation of pulmonary and nasal delivery systems.
- 3) Identify challenges and explain theoretical aspects involved in designing formulations for delivery of proteins and peptides via oral, mucosal, pulmonary, nasal, and parenteral routes.
- 4) Summarize and compare advantages/limitations, constituents and methodology, characterization techniques, and applications of colloidal drug delivery systems like liposomes, niosomes, nanoparticles, polymeric micelles, and solid lipid nanoparticles.
- 5) Compare and contrast the invasive and non-invasive strategies involved in brain targeting..

<b>M. Pharm First Year, Semester II</b>			
<b>MPH_C_205_T Advanced Pharmaceutics – II (THEORY-60 hours)</b>			
<b><i>Course Code &amp; CO number</i></b>	<b><i>At the successful completion of the course, the learners will be able to:</i></b>	<b><i>Syllabus Unit no.</i></b>	<b><i>Up to Bloom's level</i></b>
MPH_C_205_T CO1	Recall and explain active and passive targeting approaches in tumour and cellular targeting.	1	4
MPH_C_205_T CO2	Understand the concepts governing design, and evaluation of pulmonary and nasal delivery systems.	2	4
MPH_C_205_T CO3	Identify challenges and explain theoretical aspects involved in designing formulations for delivery of proteins and peptides via oral, mucosal, pulmonary, nasal, and parenteral routes.	3	4
MPH_C_205_T CO4	Summarize and compare advantages/limitations, constituents and methodology, characterization techniques, and applications of colloidal drug delivery systems like liposomes, niosomes, nanoparticles, polymeric micelles, and solid lipid nanoparticles.	4	4
MPH_C_205_T CO5	Compare and contrast the invasive and non-invasive strategies involved in brain targeting.	5	4

Course Code & CO number	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_205_T CO1	1	1	1	3	2	2
MPH_C_205_T CO2	1	1	1	3	2	2
MPH_C_205_T CO3	1	1	1	3	2	2
MPH_C_205_T CO4	1	1	1	3	2	2
MPH_C_205_T CO5	1	1	1	3	2	2

Unit	Course Contents (Topics)	Hours
1	<b>Targeted systems:- Active and Passive approaches:</b>	<b>6</b>
1.1	Tumour targeting, Molecular targets for cellular targeting, Ligands as delivery and targeting tools, Concept of receptor mediated endocytosis.	3
1.2	<i>Self-study: Concepts and rationale of targeting: active and passive targeting, Cellular biochemistry and molecular events in drug targeting</i>	3
2	<b>Pulmonary and nasal drug delivery systems:</b>	<b>14</b>
2.1	Nasal drug delivery: Nasal administration – dosage forms, Strategies for enhancement in nasal absorption, Animal models for nasal absorption studies, Nasal preparations for systemic effect	4
2.2	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	7.
2.3	<i>Self-study: Anatomy and physiology of the respiratory system, Airway physiology and disposition patterns</i>	3
3	<b>Protein and peptide drug delivery systems:</b>	<b>11</b>
3.1	Physical and chemical stability aspects, protein degradation pathways, techniques of stabilization of proteins and peptides, barrier to transport and approaches to circumvent metabolic barriers.	4
3.2	General protein formulation and delivery system strategies.	1
3.3	Routes for delivery of proteins and peptides with emphasis on oral and mucosal delivery, pulmonary delivery, nasal delivery and parenteral delivery	3
3.4	<i>Self-study: Structure of proteins and peptides, analysis of proteins and peptides.</i>	3
4	<b>Colloidal drug delivery systems:</b>	<b>22</b>
	<b>NOTE</b> that for every colloidal drug delivery system the following aspects to be included: 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. The following drug delivery system to be studied with respect to these aspects –	
4.1	Liposomes	5
4.2	Niosomes	2

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4.3	Nanoparticles	5
4.4	Polymeric micelles	3
4.5	Solid Lipid nanoparticles.	4
4.6	<i>Self-study: An overview colloidal Drug Delivery with respect to Physicochemical &amp; Biopharmaceutical aspects</i>	3
5	<b>Brain targeting:</b>	<b>7</b>
5.1	Introduction, Transport through BBB, Factors affecting drug permeation through BBB	1
5.2	Brain drug delivery strategies: <ul style="list-style-type: none"> <li>• Invasive- Intracerebral implants, Intraventricular infusion, BBB disruption</li> <li>• Non-invasive techniques- Chemical method, Colloidal drug carrier, receptor/ vector mediated approach.</li> <li>• Miscellaneous techniques- Intranasal etc</li> </ul>	3
5.3	<i>Self-study: Blood brain barrier, CSF barrier, limitations in brain uptake of drug, desired physicochemical characteristics of drugs.</i>	3
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

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. 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, 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
9. Thassu D "Nanoparticulate Drug Delivery System" Marcell Dekker Series.
10. Park K, Control Drug Delivery - Challenges and Strategies, CRC, Washington DC
11. MacNally E, Protein Formulation and Delivery
12. Kreuter J, Colloidal Drug Delivery System, Marcell Dekker, Inc New York

**BRANCH: PHARMACOLOGY**  
**SEMESTER II CORE**

**MPH\_C\_206\_T-Advanced Pharmacology (4h/wk)**

**Course Objectives:** This subject is intended to impart advanced knowledge of drug discovery and development, chrono pharmacology, signaling pathways, target identification and the role of transporters.

**Course Outcomes (CO):**

M.Pharm First Year, Semester I			
MPH_C_206_T Advanced Pharmacology (Theory 4h/wk)			
<i>Course code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
MPH_C_206_T_CO1	Explain the various stages of drug discovery and development including techniques of high throughput screening	1 & 2	2
MPH_C_206_T_CO2	Appreciate the importance of toxicity testing and the role of ethical and regulatory requirements for the same	3	2 & 3
MPH_C_206_T_CO3	Reflect on the importance of chrono pharmacology in therapeutics of disease related to GIT and Asthma.	4	2 & 3
MPH_C_206_T_CO4	Review the role of transporter proteins, stem cells and other novel drug targets; impact of inflammation mediators and pro-inflammatory cytokines in mediating inflammation in clinical settings	5-8	2 & 3
MPH_C_206_T_CO5	Comprehend therapeutic potential and signalling pathways of the target site, fundamentals of transporters and their role in pharmacokinetics	6-7	2

**Mapping CO with PO**

CO	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_206_T_CO1	1	2				
MPH_C_206_T_CO2	1	2				
MPH_C_206_T_CO3	1	2				
MPH_C_206_T_CO4	1	2				
MPH_C_206_T_CO5	1	2				

Unit	Course Contents (Topics)	Hours.
1	<b>General aspects of drug discovery and development</b>	<b>2</b>
2	<b>High Throughput Screening</b>	<b>6</b>
2.1	Techniques for High throughput screening. a. Cell based assays b. Biochemical assays. c. Radioligand binding assays.	4
2.2	<i>Self-study-Importance of pharmacokinetic studies in drug development.</i>	2
3	<b>Toxicity Studies</b>	<b>8</b>
3.1	<ul style="list-style-type: none"> <li>• Acute, subacute and chronic toxicity</li> <li>• Safety pharmacology evaluation.</li> <li>• Genetic toxicity, cytotoxicity, toxicogenomics</li> </ul>	5
3.2	<i>Self-study-Schedule Y, OECD, ICH guidelines for toxicity studies by various routes.</i>	3
4	<b>Introduction to Chronopharmacology</b>	<b>8</b>
4.1	<ul style="list-style-type: none"> <li>• Circadian rhythm, Biological Clock, Location, Neuroanatomy and Neurochemistry.</li> <li>• Rhythms and pharmacokinetics.</li> </ul>	5
4.2	<i>Self-study-Rhythms and therapeutic of diseases of GIT and asthma.</i>	3
5	<b>Stem Cells and Therapeutic applications</b>	<b>3</b>
6	<b>Novel drug targets</b>	<b>18</b>
6.1	Physiological functions, pharmacological implications and therapeutic potential of the following target sites: <ul style="list-style-type: none"> <li>• Rhokinase (ROCK).</li> <li>• Phosphoinositide-3-Kinase (PI3K).</li> <li>• Akt (Protein kinase B).</li> <li>• Caspases.</li> <li>• Proteases.</li> <li>• Poly(ADP-ribose) Polymerase (PARP).</li> <li>• Peroxisome proliferator activator receptors (PPAR<math>\alpha</math>, <math>\gamma</math>).</li> </ul>	15
6.2	<i>Self-study-Biological functions of Nitric oxide (NO) and therapeutic potential of nitric oxide modulators.</i>	3
7	<b>Transporter proteins</b>	<b>7</b>
7.1	<ul style="list-style-type: none"> <li>• Classification and biology of ATP binding cassette (ABC) transporters super family, Solute carrier transporter (SLC).</li> <li>• Multidrug resistance proteins (MDR).</li> <li>• Cystic fibrosis transmembrane regulator (CFTR).</li> </ul>	5
7.2	ABC transporters involved in drug absorption, distribution and excretion.	2

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8	<b>Role</b> of Cytokines, Prostaglandins, TNF- $\alpha$ , Bradykinin, Leukotrienes, PAF, Interferons and Adhesion molecules in various immunological and inflammatory disorders	<b>8</b>
	<b>Total</b>	<b>60</b>

**Books (latest edition to be adopted)**

1. Rang and Dale's Pharmacology, Elsevier Churchill Livingstone.
2. Lange's Basic and Clinical Pharmacology, Katzung B.G., Masters S.B., Trevor A.G., Tata McGraw Hill.
3. Goodman 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.

**MPH\_C\_207\_T-Clinical Research Methodology(4h/wk)**

**Basic Course Objectives:** This course will review the concepts that underlie successful clinical research design, ethics, implementation, evaluation, reporting and their significance.

**Course Outcomes(CO):**

M.Pharm First Year, Semester I			
MPH_E_207_T Clinical Research Methodology (Theory 4h/wk)			
<i>Course code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
<b>MPH_E_207_T_C O1</b>	Summarize the processes of drug discovery and development, including various documents required (Investigators Brochure (IB), Protocol and amendments in protocol, Case report form (CRF), Informed consent form (ICF), Content of clinical study report (CSR) along with the regulatory and ethical requirements for conducting clinical trials in accordance with GCP principles and Schedule Y.	<b>1, 2 &amp; 3</b>	<b>2</b>
<b>MPH_E_207_T_C O2</b>	Understand and explain the responsibilities of key players (Sponsor, Investigator, Monitor, Auditor) and the role of Institutional Ethics Committee (IEC)/ Independent Ethics Committee (IdEC)/ Institutional Review Board (IRB) involved in clinical trials	<b>4 &amp; 5</b>	<b>2 &amp; 3</b>
<b>MPH_E_207_T_C O3</b>	Understand and appraise the role of clinical quality assurance and clinical data management.	<b>6 &amp; 7</b>	<b>1 &amp; 2</b>
<b>MPH_E_207_T_C O4</b>	Infer the applications and importance of pharmacoepidemiology in healthcare.	<b>8</b>	<b>2 &amp; 3</b>
<b>MPH_E_207_T_C O5</b>	Comprehend the role of clinical pharmacist in reporting, evaluation, monitoring, prevention, and management of adverse drug reactions and apply them to day-to-day life.	<b>9</b>	<b>2</b>
<b>MPH_E_207_T_C O6</b>	Predict and appraise the applications of Pharmacoeconomics and Outcomes Research in health care and apply them in healthcare management.	<b>10</b>	<b>2 &amp; 3</b>

## Mapping CO with PO

CO	PO1	PO2	PO3	PO4	PO5	PO6
MPH_E_207_T_CO1		1		2	1	
MPH_E_207_T_CO2		1		2	1	
MPH_E_207_T_CO3		1		2	1	
MPH_E_207_T_CO4		1		2	1	
MPH_E_207_T_CO5		1		2	1	
MPH_E_207_T_CO6		1		2	1	

Unit	Course Contents (Topics)	Hours.
1	<b>Clinical trials</b>	<b>14</b>
1.1	Introduction, drug discovery and drug development.	10
1.2	Various phases of clinical trials.	
1.3	Study methodology/designs, Inclusion and Exclusion criteria, objectives and endpoints (efficacy and safety), Methods of allocation, blinding and randomization.	
1.4	Informed consent process.	
1.5	Study monitoring and its importance.	
1.6	Safety monitoring in clinical trials.	
1.7	<i>Self-study-BA/BE studies, Postmarketing studies.</i>	4
2	<b>Documents in clinical study</b> Essential documents in clinical trial- Investigator's Brochure (IB), Protocol and amendments in protocol, Case report form (CRF), Informed consent form (ICF), Content of clinical study report (CSR).	<b>4</b>
3	<b>Ethical guidelines in clinical research</b>	<b>9</b>
3.1	History, ICH-GCP and its principles, Indian GCP (CDSCO Guidelines), ICMR guidelines- Ethical guidelines for Biomedical Research on human subjects 2006, Schedule Y 2005, USFDA guidelines for IND, NDA, ANDA applications.	6
3.2	Self-study: EMEA organization and its functions, EU regulatory guidelines.	3
4	<b>Roles and responsibility</b> of various clinical trial personnel as per ICH-GCP Sponsor, Investigator, Monitor, Auditors	<b>3</b>
5		<b>5</b>
5.1	<b>Institutional Ethics Committee (IEC)/ Independent Ethics Committee (IdEC)/ Institutional Review Board (IRB)</b>	2
5.2	<i>Self-study- Ethical theories, Integrity and Misconduct in clinical research.</i>	3
6	<b>Role of Quality assurance in clinical research</b>	<b>2</b>
7	<b>Clinical Data Management and Report Writing</b>	<b>3</b>
8	<b>Pharmacoepidemiology</b> Types, methods, and factors affecting drug utilization, applications of pharmacoepidemiology in health care and rational use of drugs	<b>5</b>
9	<b>Pharmacovigilance</b>	<b>10</b>

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9.1	Definition, scope and aims of pharmacovigilance, Adverse drug reactions- Classification, mechanism, predisposing factors and causality assessment, Role of clinical pharmacist in reporting, evaluation, monitoring, prevention and management of ADRs.	5
9.2	<i>Self-study: Reporting-CIOMS forms, Periodic safety update reports (PSURs) as per Indian regulatory guidelines.</i>	5
10	<b>Pharmacoeconomics and Outcomes Research</b> Theories and methodologies of Pharmacoeconomics and Outcomes Research. Applications of pharmacoeconomics to pharmacotherapy and managed healthcare.	<b>5</b>
	<b>Total</b>	<b>60</b>

*Syllabus of M.Pharm. (2019-20)*

**Books (latest editions to be adopted)**

1. Rick NG. Drugs from Discovery to Approval, John Wiley & Sons, Inc.
2. Allen Cato, Lynda Sutton. Clinical Drug Trials and Tribulations Second Edition Revised, second edition, Marcel Dekker Inc.
3. Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance, second edition, John Wiley & Sons Ltd.
4. Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc. Publication.
5. Sandy Weinberg. Guidebook for Drug Regulatory Submissions, first edition, A John Wiley & Sons, Inc.
6. Duolao Wang and Ameet Bakhai. Clinical Trials: A Practical Guide to Design, Analysis, and Reporting, Remedica.
7. Giovanna Di Ignazio, Di Giovanna and Haynes, Principals of Clinical Research, Wrightson Biomedical Pub.
8. R K Rondels, S A Varley, C F Webb, Clinical Data management, John Wiley & Sons Inc.
9. Strom BI, Limmel SE. Textbook of Pharmacoepidemiology. Chichester, West Sussex, England: John Wiley & Sons Ltd.
10. Rascati, Karen L. Essentials of Pharmacoeconomics. Philadelphia, Pa.: Lippincott Williams & Wilkins.
11. M. F. Drummond, M. J. Sculpher and G. W. Torrance, Methods for the economic evaluation of health care programmes. Oxford University Press, USA.
- 13 Brenda Waning; Michael Montagne; William W McCloskey, Pharmacoepidemiology: principles and practice, New York: McGraw-Hill.
- 14 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)

**BRANCH: PHARMACEUTICAL ANALYSIS  
SEMESTER II CORE**

**MPH\_C\_208\_T-Analytical Method Development and Validation Techniques (4h/wk)**

**Course Objectives:** Upon completing the following theory topics, learners should be able to:

Comprehend and formulate the analytical method development and validation procedures for drug substances/products stability assays, bioanalysis, and impurity profiling in accordance with the guidelines outlined by ICH, Pharmacopoeias, and CDER guidelines.

**Course Outcomes:**

<b>M. Pharm                      First Year, Semester II</b>			
<b>MPH_C_208_T ANALYTICAL METHOD DEVELOPMENT AND VALIDATION TECHNIQUES (4 h/wk)</b>			
<b><i>Course code &amp; CO number</i></b>	<b><i>At the successful completion of the course, the learners will be able to:</i></b>	<b><i>Syllabus Unit</i></b>	<b><i>Up to Blooms</i></b>

Course Code & CO number	PO1	PO2	PO3	PO4	PO5	<i>n</i>		<i>level</i>
						PO6		
MPH_C_208_T CO1	1	2	3	4	5	1		4
MPH_C_208_TCO1	1	2	3	4	5	3		
MPH_C_208_TCO2 MPH_C_208_T	3	3	3	3	3	3		
MPH_C_208_TCO3	2	1	2	3	3	2-6		6
MPH_C_208_TCO4	2	2	3	3	3			
MPH_C_208_TCO5	2	1	3	3	3			
MPH_C_208_T CO3	Evaluate and justify the selection of detectors, sample preparation methods, quantitation methods, characterisation techniques, stationary phases, and solvents during the analytical method development using HPLC and HPTLC.						2 & 3	5
MPH_C_208_T CO4	Analyze and critically comprehend the ICH & CDER guidelines, pharmacopoeial specifications, for analytical and bioanalytical methods and stability testing.						2-6	4
MPH_C_208_T CO5	Formulate essential stability testing protocols and kinetic studies within the drug/product development process.						6	6

### CO-PO Mapping

Unit	Course Contents (Topics)	Hours
1	<b>Calibration &amp; Validation of analytical instruments:</b> a. HPLC. b. UV-VIS spectrophotometer. c. FTIR. d. Dissolution test apparatus.	4
2	<b>HPLC assay method development for API and drug products:</b>	20
2.1	Preliminary investigations - Nature of sample, its composition and properties. (should also include significance of $K_a$ , partition coefficient and current methods to determine the same), separation goals, sample pretreatment and detection, developing separation.	5
2.2	Basics of separation - Resolution, Resolution as a function of solvent strength, selectivity and column plate number; and sample size effect.	1
2.3	<i>Self-study - Detection - Comparison of sensitivity, selectivity, advantages, disadvantages and applications with respect to detectors such as U.V, Fluorescence, PDA, Refractive Index, Evaporative light scattering detector and electrochemical detectors.</i>	2

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2.4	Sample preparation and pretreatment for solid, liquid, semisolid samples; column switching and pre and post column derivatization.	2
2.5	<i>Self-study-Columns-characteristics of column and column packing and column specifications.</i>	1
2.6	Method development for Reverse-phase, Ion pair and ion exchange chromatography, Gradient elution-principle and development of gradient separation. <i>Self-study-pharmaceutical examples for these methods-(1 hr).</i>	3
2.7	Quantitation analysis-measurement of signals, quantitation methods, sources of errors, procurement, storage and use of reference standards and working standards.	2
2.8	ICH guidelines for analytical method validation (Q2 with latest revision), System suitability testing as per USP, IP.	3
2.9	<i>Self-study-One detailed HPLC analysis of any API by USP or IP (1 hr)</i>	1
3	<b>HPTLC:</b> Method development and validation for fixed dose combination drugs and herbal analysis.	3
4	<b>Impurity profiling:</b>	9
4.1	a. <i>Self-study-Sources of impurities and ICH terminologies-Organic impurities, Inorganic impurities, Residual solvents, Isolation and characterisation methods for impurities (3 hrs).</i> b. Analytical method development and quantitation of impurities.	5
4.2	ICH guidelines-Q3A, Q3B, Q3C with latest revisions.	4
5	<b>Bioanalytical method development and validation:</b>	13
5.1	Steps followed-sample preparation, liquid-liquid extraction, precipitation, solid-phase extraction, sintered column solid phase extraction.	3
5.2	Bioanalytical method validation including full, partial, cross validation, selectivity, accuracy, calibration curve, stability (freeze-thaw and mobile phase), recovery.	4
5.3	CDER and ICH guidelines for bioanalytical method validation.	4
5.4	<i>Self-study-Examples of bioanalytical method development and validation for a specified drug estimated in urine/plasma/serum samples.</i>	2
6	<b>Stability testing:</b>	11
6.1	Drug development cycle and stability testing.	2
6.2	Stress testing of drug substances.	1
6.3	Stability indicating assays (specific and selective), Role of kinetic studies.	3
6.4	Stability testing protocols.	1
6.5	Retest period/Shelf-life determination of drug substances/phytopharmaceuticals/biotechnological products and equipment.	2
6.6	ICH guidelines-Q1 A and Q1 B with latest revisions.	2
	<b>Total</b>	<b>60</b>

**Books (latest edition to be adopted)**

1. Practical HPLC Method Development by L.R. Snyder, John Wiley & Sons
2. Analytical Method Validation and Instrument Performance Verification by Chung Chow Chan, Herman Lam, Y.C. Lee, Xue-Ming Zhang, Wiley Interscience, John Wiley & Sons, Incorp Publications.
3. United States Pharmacopoeia and Indian Pharmacopoeia.
4. Handbook of Isolation and Characterisation of Impurities in Pharmaceuticals by Satinder Ahuja & Karen Mills Alsante, Academic Press, USA.

**Syllabus of M.Pharm. (2019-20)**

5. Handbook of Bioanalysis & Drug Metabolism by Gary Evans, CRC Press,
6. HPLC method development by Satinder Ahuja
7. Sethi's Quantitative Analysis of Pharmaceutical Formulations by P.D. Sethi, CBS Publishers and Distributors, New Delhi.
8. Remington - The Science and Practice of Pharmacy.
9. Validation and Qualification in Analytical Laboratories, Ludwig Huber; Informa Healthcare.
10. Handbook of stability testing in pharmaceutical development - Regulations, Methodologies and Best practices; Editor Kim Huynh-Ba, Springer.
11. J.T. Carstensen, C.T. Rhodes, Drug stability: principles & Practices, Marcel Dekker Inc., New York

**INTERNET REFERENCES:**

1. USFDA (CDER) and ICH guidelines for Bioanalytical method validation.
2. ICH guidelines - Q1A(R), Q3A(R), Q3B, Q3C, Q6A.
3. ICH guidelines for analytical method validation.

**MPH\_C\_209\_T-Spectroscopic Structural Elucidation (4h/wk)**
**Course Objectives**

Upon completing the following theory topics, learners should be able to:

Elucidate the compound structures using spectral data acquired from UV spectroscopy, IR, <sup>1</sup>H-NMR, <sup>13</sup>C-NMR spectroscopy, and Mass spectrometry.

**Course Outcomes:**

<b>M. Pharm First Year, Semester II</b>			
<b>MPH_C_209_T - Spectroscopic Structural Elucidation (4 h/ wk)</b>			
<i>Course code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
MPH_C_209_T CO1	Analyse and determine the $\lambda$ max for dienes, and $\alpha$ , $\beta$ – unsaturated ketones by UV spectroscopy	1	5
MPH_C_209_T CO2	Identify and interpret functional group stretching/bending vibrational frequencies of organic compounds based on IR spectral data.	2	4
MPH_C_209_T CO3	Predict and justify the number of signals, chemical shift, splitting patterns in the <sup>1</sup> H-NMR spectroscopy, and <sup>13</sup> C-NMR spectra of organic compounds.	2	6
MPH_C_209_T CO4	Explain the mass spectral fragmentation patterns for compounds.	4	4
MPH_C_209_T CO5	Synthesise and construct structural deductions from spectral data obtained in UV, IR, NMR spectroscopy, and Mass spectrometry for structural elucidation of organic compounds.	1-5	6

## CO-PO Mapping:

Course code & CO number	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_209_T CO1	1	2	3	3	3	3
MPH_C_209_T CO2	2	2	3	3	3	3
MPH_C_209_T CO3	2	2	3	3	3	3
MPH_C_209_T CO4	1	2	3	3	3	3
MPH_C_209_T CO5	2	3	3	3	3	3

Problems of structural elucidation involving the following techniques:

- UV spectroscopy.
- IR spectroscopy.
- <sup>1</sup>H-NMR spectroscopy.
- <sup>13</sup>C-NMR spectroscopy.
- Mass Spectrometry.

The problems should cover the following aspects:

Unit	Course Contents (Topics)	Hours
1	Calculation of $\lambda_{max}$ for dienes, $\alpha, \beta$ -unsaturated ketones by UV spectroscopy. <i>Self-study-practice problems (1hr)</i>	5
2	Prediction of characteristic IR bands, NMR spectra ( <sup>1</sup> H NMR) – chemical shift, splitting pattern and ratio of proton intensity, ( <sup>13</sup> C NMR) – number of signals, chemical shift and splitting pattern, mass fragmentation patterns. <i>Self-study-practice problems (2hrs)</i>	10
3	Distinguishing compounds using UV/IR/ <sup>1</sup> H NMR/ <sup>13</sup> C NMR and/or Mass spectrometry. <i>Self-study-practice problems (2hrs)</i>	10
4	Interpretation of mass spectra with explanation of fragmentation patterns. <i>Self-study-practice problems (2hrs)</i>	9
5	Problems involving structure elucidation by UV/IR/ <sup>1</sup> H NMR/ <sup>13</sup> C NMR and/or Mass spectrometry, <i>Self-study-practice problems (8 hrs)</i>	26
	<b>Total</b>	<b>60</b>

## Books (latest editions to be adopted)

- 1 Introduction to Spectroscopy by D.L. Pavia, G.M. Lampman & G.S. Kriz, Thomson Brooks/Cole, United States.
- 2 Spectrometric Identification of Organic compounds by Robert M. Silverstein, Francis X. Webster, D.J. Kiemle, John Wiley & Sons.
- 3 Organic Spectroscopy by William Kemp.
- 4 Applications of absorption spectroscopy of organic compounds by John Robert Dyer, Prentice Hall, London.

**BRANCH: PHARMACOGNOSY AND PHYTOCHEMISTRY SEMESTER  
II CORE**

**MPH\_C\_210\_T - Advances in Pharmacognosy and Phytochemistry (4h/wk)**

**Course Objectives: (Paragraph)**

1. To impress the role of factors both intrinsic and extrinsic that impact the type and content of phytoconstituents in herbal drugs.
2. To understand the chemistry, source and uses of various drug substances of plant, animal, terrestrial or marine origin belonging to different therapeutic segments
3. To study the classification, sources and uses of flavonoids and elucidate the structure of simple flavonoids by spectroscopic methods.
4. To introduce the application of plant tissue culture and plant biotechnology for enhancing the plant attributes.

**Course Outcomes (CO):**

M. Pharm First Year, Semester II MPH_C_210_T Advances in Pharmacognosy and Phytochemistry (Theory 4 h/ wk)			
Course code & CO number	At the successful completion of the course, the learners will be able to:	Syllabus Unit no.	Up to Bloom's level
MPH_C_210_T CO1	Understand the factors both intrinsic and extrinsic that impact the type and content of phytoconstituent	1	2
MPH_C_210_T CO2	To understand the chemistry, source and uses of different classes of phytoconstituents of plant, animal, terrestrial or marine origin belonging to different therapeutic segments	2, 4, 5 & 6	2
MPH_C_210_T CO3	Classify, give sources and uses of flavonoids as well as to elucidate the structure of simple flavonoids by spectroscopic methods	3	6
MPH_C_210_T CO4	Apply the basic principles of Plant Biotechnology in enhancing the plant attributes	7	3

**Course PO-mapping**

Course Code & CO Number	PO1	PO2	PO3	PO4 (Additional, if required by the department)	PO5 (Additional, if required by the department)	PO6 (Additional, if required by the department)
MPH_C_210_T CO1	3	3	3			
MPH_C_210_T CO2	3	3	3			
MPH_C_210_T CO3	3	3	3			
MPH_C_210_T CO4	3	3	3			

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Unit	Course Contents (Topics)	Hours
<b>1</b>	<b>Factors affecting occurrence of compounds of natural origin</b>	<b>6</b>
1.1	Discussion of different factors contributing to the variation in the composition and proportion of secondary metabolites.	2
1.2	Concept of variation of phytochemicals with respect to ecotype, phenotype and genotypic variables. Study of phytoalexins, allelochemicals and aflatoxins, natural pesticides (cover the topics with at least two examples of each).	4
1.3	<i>Recent advances and applications of phytoalexins, allelochemicals &amp; aflatoxins.</i>	3
<b>2</b>	<b>Chemistry, sources &amp; uses of following classes of phytochemicals</b> (1) Alkaloids–Opioids & Purines (2) Iridoids (3) Coumarins (4) Xanthenes	<b>8</b>
2.1	<i>Self-study-Update on traditional uses and recent applications of few examples of the above-mentioned classes</i>	5
<b>3</b>	<b>Chemistry, classification, sources, uses and structure-elucidation by spectral methods of flavanoids.</b>	<b>8</b>
3.1	<i>Self-study–Comparative spectral analysis &amp; recent application of different classes of flavanoids.</i>	4
<b>4</b>	<b>Study of following therapeutic classes of agents of plant and animal origin with respect to sources, applications and chemistry (any two examples of each class).</b> (1) Antibacterial (2) Hepatoprotective & Hypolipidemic agent (3) Antivirals	<b>6</b>
<b>5</b>	<b>Marine drugs of different therapeutic classes</b> 1) Anticancer 2) Cardiovascular drugs 3) Antivirals 4) Anthelmintics 5) Marine toxins	<b>6</b>
<b>6</b>	<b>Study of photosensitizers of natural origins such as porphyrins, psoralenes, thiophenes, quinines and their significance in Photodynamic therapy (PDT) and phytotoxicity.</b>	<b>6</b>
6.1	<i>Self-study-Role of PDT in healthcare with examples.</i>	3
<b>7</b>	<b>Introduction to plant tissue culture (PTC) and plant biotechnology.</b>	<b>5</b>
7.1	Genetic engineering in plants for development of plants resistant to pests, viruses, microbes and diseases. Alteration in ripening of fruits. Advantages and disadvantage of BT crops.	3
7.2	Definition, Methodology & application of biotransformation of phytochemicals with suitable examples.	2
	<b>Total</b>	<b>60 hrs</b>

**Books (latest edition to be adopted) (latest edition to be adopted)**

**Syllabus of M.Pharm. (2019-20)**

1. Pharmacognosy Phytochemistry–Medicinal Plants, Jean Bruneton, Lavoisier Publishing, Paris.
2. Textbook of Pharmacognosy, Trease and Evans, Elsevier Science
3. Transgenic Plants, R. Ranjan, Agro Botánica, 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. Cultivation 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- Ciejer, Kadis and Ajl, Academic Press.
17. Antimicrobial in Food, Alfred Larry Branen, P. Michael Davidson Publishing house
18. Chemical plant Taxonomy T. Swain, Academic Press, London.
19. Plant Taxonomy and Biosystematics, C. A. Stace, Edward Arnold, London.
20. Modern methods of plant analysis K. Paech, Springer-Verlag.
21. Indian Herbal Pharmacopoeia.
22. Indian Pharmacopoeia.
23. Standardization of Botanicals, V. Rajpal, 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 21<sup>st</sup> Century H. Ageta, N. Aimi et al Excerpta Medica, International Congress Series 1157.

**MPH\_C\_211\_T-Natural Product Technology (4 h/wk)**
**Course Objectives: (Paragraph)**

1. To understand the significance of regulatory aspects involved in ensuring minimum standard of quality, safety and efficacy of natural products as per international regulatory guidelines.
2. To study principles and intricacies involved in application of pharmaceutical technology to large scale manufacturing of herbal drugs and formulations w.r.t dosage forms, application, safety, quality control, infrastructure and equipment.
3. To apply and compare different chromatographic, spectroscopic and electrophoretic techniques for analysis, assay and determination of extraction efficiency of major phytochemical classes.
4. To highlight the importance of Phytoequivalence in standardization of extracts and formulations as well as to understand the Bioavailability and Pharmacokinetic aspects of herbal drugs.

**Course Outcomes (CO):**

<b>M. Pharm First Year, Semester II</b> <b>MPH_C_211_T Natural Product Technology (Theory 4 h/ wk)</b>			
<i>Course code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no</i>	<i>Up to Bloom's level</i>
MPH_C_211_T CO1	Understand the significance of regulatory aspects involved in ensuring minimum standard of quality, safety and efficacy of Natural Products as per international regulatory guidelines.	1 & 6	2

MPH_C _211_T _CO2	Comprehend and analyse the intricacies involved in application of pharmaceutical technology to large scale manufacturing of herbal drugs and formulations w.r.t dosage forms, application, safety, quality control, infrastructure and equipment.	2 & 4	4
MPH_C _211_T _CO3	Apply and compare different chromatographic, spectroscopic and electrophoretic techniques for analysis, assay and determination of extraction efficiency of major phytochemical classes	3	3
MPH_C _211_T _CO4	Elaborate on importance of Phytoequivalence in standardization of extracts and formulations as well as to understand the Bioavailability and Pharmacokinetic aspects of herbal drugs	5	2

Course Code & CO Number	PO1	PO2	PO3	PO4 (Additional, if required by the department)	PO5 (Additional, if required by the department)	PO6 (Additional, if required by the department)
MPH_C_211_T CO1	3	3	3			
MPH_C_211_T CO2	3	3	3			
MPH_C_211_T CO3	3	3	3			
MPH_C_211_T CO4	3	3	3			

Unit	Course Contents (Topics)	Hours
1	Detailed study of WHO guidelines for quality control of crude drugs	5
2	<b>Study of herbal formulations</b>	12
2.1	Classification and different stages in preparation of herbal formulations for therapeutic and cosmetic applications	5
2.2	Standardization and evaluation of quality control and safety of herbal formulations	5
2.3	Introduction to different Ayurvedic dosage forms	2
2.4	<i>Self-study-Any two marketed herbal formulations with respect to constituents and uses.</i>	4
3	<b>Quantitative assay to determine extraction efficiency</b>	8
3.1	General methods of estimation of alkaloids, terpenoids and flavonoids	4
3.2	Analysis of Rutin, lycopene, curcuminoids, artemisinin, enzymes and lectins by different methods such as UV, HPTLC, GC, gelelectrophoresis etc., determination of percentage purity.	4
3.3	<i>Self-study-Merits &amp; demerits of different methods of estimation of alkaloids, terpenoids &amp; flavanoids.</i>	5
4	<b>Introduction to herbal product-based industry</b>	6
4.1	Types, forms, scope and application of herbal industries	4
4.2	Type of infrastructure involved in making standardized extract and different dosage forms	2
4.3	<i>Self-study-Equipment and machinery used in large scale extraction</i>	3
5	<b>Bioavailability and pharmacokinetic aspect of herbal drugs with examples of well-known documented herbal drugs. Introduction to concept of Phyto equivalence and pharmaceutical equivalence.</b>	6
6	<b>IPR issues related to herbal and natural products. EMEA and ESCOP guidelines for herbal medicinal products. Preparation of DMF for herbal medicines.</b>	8
6.1	<i>Self-study-Any one patent related to natural products.</i>	3
	<b>Total</b>	<b>60 hrs</b>

**Syllabus of M.Pharm. (2019-20)**

**Books (latest edition to be adopted)**

1. Pharmacognosy Phytochemistry–Medicinal Plants, Jean Brunetton, Lavoisier Publishing, Paris.
2. Textbook of Pharmacognosy, Trease and Evans, Elsevier Science
3. Transgenic Plants, R. Ranjan, Agro Botánica, 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. Experimental Phytochemical Methods, J. B. Harbone, Chapman and Hall
11. Cultivation and Processing of Medicinal Plants-Ed. by L. Hornok, John Wiley.
12. Introduction to Flavonoids, 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, Academic Press, London.
19. Plant Taxonomy and Biosystematics, C. A. Stace, Edward Arnold, London.
20. Modern methods of plant analysis K. Paech, Springer-Verlag.
21. Indian Herbal Pharmacopoeia.
22. Indian Pharmacopoeia.
23. Standardization of Botanicals, V. Rajpal, 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 21<sup>st</sup> Century H. Ageta, N. Aimi et al Excerpta Medica, International Congress Series 1157.

**CHOICE BASED SUBJECTS  
SEMESTER II**

ALL THE SUBJECTS THAT ARE THE CORE SUBJECTS OF THE RESPECTIVE BRANCHES OF SPECIALIZATION AND HAVE CODES MPH\_C\_2XX\_T MAY BE CHOSEN AS CHOICE BASED OR ELECTIVE SUBJECTS SO LONG AS THE STUDENT IS PURSUING A DIFFERENT SPECIALIZATION.

IF SUCH A COURSE IS SELECTED AS A CHOICE BASED COURSE THEN THE GIVEN STUDENT SHOULD CLEARLY STATE SO IN THE EXAMINATION FORM (for example if a student whose specialization is pharmaceutical chemistry chooses MPH\_C\_206\_T – Modern Pharmacology as the choice based/elective subject, then the student while filling the exam form should state the course designation as MPH\_E\_206\_T – Modern Pharmacology) AND FOR THAT STUDENT THE SUBJECT WILL APPEAR IN HIS/HER GRADE CARD WITH THE DESIGNATION MPH\_E\_2XX\_T

THE QUESTION PAPERS FOR COURSES, WHETHER THEY ARE CORE OR ELECTIVE, WILL BE THE SAME/IDENTICAL i.e. THE SUBJECTS ARE CONSIDERED DIFFERENT WITH RESPECT TO PAPER SETTING ONLY IF THE ARABIC NUMERALS DIFFER AND THE NAME OF THE SUBJECT DIFFER AND NOT BASED ON ‘C’ OR ‘E’ DESIGNATION

Given below are the syllabi of more choice-based subjects

**MPH\_E\_212\_T-Quality Assurance Systems (4h/wk)**

Unit	Course Contents (Topics)	Hours
1	<b>Regulatory basis for validation:</b> USFDA guidelines (cGMP guidelines, 21 CFR 210-211), EU guidelines, WHO guidelines.	5
2	<b>Terminology and validation overview:</b>	10
2.1	<i>Self-study: Validation versus verification, testing, calibration and qualification.</i>	3
2.2	Concepts of DQ, IQ, OQ and PQ.	3
2.3	Concepts of Prospective validation, retrospective validation, Concurrent and revalidation. Validation Master Plan.	4
3	<b>Validation of Equipment</b>	10
3.1	Dry Powder Mixers	1
3.2	Fluid Bed and Tray dryers	1
3.3	Tablet Compression Machine	2
3.4	<i>Self-study: Dry Heat Sterilization/Tunnels</i>	1
3.5	Autoclaves	2
3.6	Capsule filling machines.	1
3.7	Validation of Integrated lines by media fill test.	2
4	<b>Utilities Validation</b>	7
4.1	Validation of Pharmaceutical Water System & pure steam,	2
4.2	Validation of HAVC system	3
4.3	Validation of Compressed air	2

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5	<b>Cleaning Validation</b> <i>Self-study: Cleaning of Equipment, Cleaning of Facilities.</i>	4
6	<b>Analytical Method Validation:</b> General principles of analytical method validation, Validation of following analytical instruments	<b>06</b>
6.1	HPLC	2
6.2	Dissolution test apparatus	2
6.3	U.V./Visible spectrophotometers	2
7	<b>Process Validation</b>	<b>13</b>
7.1	<i>Self-study: Prospective, concurrent, retrospective &amp; revalidation Self-study</i> Process validation of following formulations	1
7.2	Uncoated/Coated tablets	2
7.3	Hard gelatin capsules	2
7.4	Ampoules & Vials	2
7.5	<i>Self-study: Ointment/Creams</i>	2
7.6	<i>Self-study: Liquid Orals</i>	2
7.7	Transdermal patches (Matrix systems)	2
8	<b>Self-study- Computer system validation in controlling the manufacturing process</b>	2
9	<b>Process Analytical Technologies (PAT) and Quality by Design (QbD) (US FDA)</b>	<b>3</b>
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

1. Validation and Qualification in Analytical Laboratories by Ludwig Huber, Informa Health Care, New York, London.
2. Pharmaceutical Process Validation by R. Nash and Wachter, Marcel Dekker Inc, New York.
3. GMP for Pharmaceuticals by Sidney H. Willing, 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.

**INTERNET REFERENCES:**

1. [www.fda.gov](http://www.fda.gov) (USFDA guidelines for PAT and QbD).
2. [www.ich.org](http://www.ich.org)
3. WHO publications on related topics.
4. EMEA guidelines

**MPH\_E\_213\_T-Pharmaceutical Quality Management (4h/wk)**

Unit	Course Contents (Topics)	Hours
<b>1</b>	<b>Concept of-</b>	<b>8</b>
1.1	Total Quality Management (TQM),	2
1.2	Quality control and quality assurance,	2
1.3	Quality control laboratory responsibilities,	2
1.4	<i>Self-study: Good laboratory practices</i>	2
<b>2</b>	<b>GMP</b>	<b>8</b>
2.1	Organization of pharmaceutical manufacturing unit, production management,	4
2.2	<i>Self-study: Revised schedule M.</i>	4
<b>3</b>	<b>Personnel:</b>	<b>12</b>
3.1	<i>Self-study: Introduction, Human resource development, Qualification Experience and Training, Responsibilities, Personal Hygiene and Gowning.</i>	6
3.2	Location, Plant layout, Lighting, Sewage, Water Handling- Sewage, Refuse and Disposal, Washing and toilet facility, Sanitation, Control of contamination and Environmental controls.	6
<b>4</b>	<b>Materials Management:</b>	<b>8</b>
4.1	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.	6
4.2	Warehousing- Good Warehousing Practices, distribution and records.	2
<b>5</b>	<b>Manufacturing Operations and Control:</b>	<b>8</b>
5.1	<i>Self-study: Sanitation of Manufacturing Premises, Line clearance, Mix-ups and Cross contamination, Processing and holding of Intermediates and Bulk Products</i>	3
5.2	Packaging, I.P.Q.C., Release and storage of Finished Product, Process Deviations and Incidents, Drug product inspection, Yield calculations	3
5.3	Expiry dating, Manufacturing record review and approval.	2
<b>6</b>	<b>Documentation and Records:</b>	<b>6</b>
	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.	
<b>7</b>	<b>Post Operational Activities:</b>	<b>5</b>
7.1	Distribution, Complaints and recalls, evaluation of complaints, Recall procedures, related records and documents.	2
7.2	Outsourcing: Facility audit, Manufacturing, Packaging, Analytical, Clinical and other services outsourcing.	3
<b>8</b>	<b>Site and Plant security:</b>	<b>2</b>
	Security personnel, Entry procedure to site & plant, Internal security, Vehicle parking, Fuel storage, Canteen & cooking, Garden & horticulture.	
<b>9</b>	<b>Audits:</b>	<b>3</b>

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Unit	Course Contents (Topics)	Hours
	Principle of Quality audit, Plant level, Department wise documentation.	
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

1. Quality Assurance of Pharmaceuticals, 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.
5. Quality Assurance Guide by Organization of Pharmaceutical Producers of India.

**MPH\_E\_214\_T–Biopharmaceutics(4h/wk)**

Unit	Course Content (Topics)	Hours
1	<b>Mechanisms of drug release</b>	<b>10</b>
1.1	Diffusion controlled release, chemically controlled release, swelling controlled release of drugs from formulations-Higuchi model and the Power-Law model for drug release and their comparison, discussion of newer mechanistic models described drug release from formulations	6
1.2	<i>Self-study of zero, first, and second order release kinetics and their graphical profiles</i>	4
2	<b>Drug Dissolution</b>	<b>18</b>
2.1	Theories of drug dissolution – Noyes Whitney Diffusion model; Hixon Crowell Model; Interfacial barrier model (Continuous and discrete reaction limited dissolution), concepts of solubility versus dissolution rate, physicochemical factors affecting drug dissolution, pharmaceutical factors affecting drug dissolution, physiological factors affecting drug dissolution, methods for estimation of solubility, methods for determination of dissolution rate	14
2.2	<i>Self-study of experimental method design for solubility and dissolution rate determination</i>	4
3	<b>Drug Absorption</b>	<b>16</b>
3.1	Mechanisms of drug absorption, detailed discussion of the variety of transporters and the role of transporters in the GI tract and liver and their role in drug absorption, physicochemical factors affecting drug absorption, pharmaceutical factors affecting drug absorption, physiological factors affecting drug absorption, gut and hepatic metabolism and their role in determination of bioavailability, in vitro and in vivo methods for estimation of permeability/transport across membranes/absorption, computational methods for prediction of solubility/permeability/absorption	12
3.2	<i>Self-study of the experimental design of methods for determination/prediction of drug transport</i>	4
4	<b>Routes of Drug Administration</b>	<b>11</b>
4.1	Discussion of the different routes of drug administration from the perspective of the nature of the absorption barrier/s, mechanisms of drug release, drug permeability/absorption from the site of administration, drug/pharmaceutical/physiological factors affecting drug dissolution/dissolution rate/absorption from the different routes of drug delivery	8
4.2	<i>Self-study of the advantages and limitations of the different routes of administration and examples of drug administered by these routes</i>	3
5	<b>Discussion of the traditional and high-throughput approaches towards estimation of solubility, dissolution rate and drug absorption and use of this information in a drug discovery and development setting.</b>	<b>5</b>
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

*Syllabus of M.Pharm. (2019-20)*

1. Clinical Pharmacokinetics and Pharmacodynamics-Concepts and Applications, Rowland M and Tozer TN, Walters Kluwer – Lippincott Williams and Wilkins.
2. Applied Biopharmaceutics and Pharmacokinetics, Shargel L and Yu ABC, Appleton and Lange, International Edition
3. Handbook of Basic Pharmacokinetics including clinical applications, Ritschel WA and Kearns GL, APhA,
4. Basic Pharmacokinetics, Jambhekar SS and Breen PJ, Pharmaceutical Press.
5. Biopharmaceutics and Pharmacokinetics, Venkateshwarlu V, Pharma Book Syndicate
6. Drug Bioavailability- Estimation of solubility, permeability, absorption and bioavailability, van der Waterbeemd H, Lennernas H and Artursson P, Wiley VCH.
7. Modelling in Biopharmaceutics, Pharmacokinetics and Pharmacodynamics – Homogenous and Heterogenous approaches, Macheras P and Iliadis A, Springer

**MPH\_E\_215\_T-Pharmacokinetics(4h/wk)****COURSE OBJECTIVES:**

1. Learn the routes of administration, sampling sites and definitions of A,D, M and E.
2. Learn the mathematical equations that describe the plasma concentration versus time relationship of drugs administered as a IV bolus, Multiple IV bolus, IV infusion and an extravascular dose (one compartment model).
3. Learn how to calculate primary and secondary PK parameters from concentration and time data.
4. Learn how urine sampling can be used to analyze IV bolus dose data.
5. Learn how to design a dosage regimen of a drug based on PK principles.

**COURSE OUTCOMES:**

1. Understand the routes of administration, sampling sites and definitions of A,D,M and E.
2. Understand the mathematical equations that describe the plasma concentration versus time relationship of drugs administered as a IV bolus, Multiple IV bolus, IV infusion and an extravascular dose (one compartment model).
3. Understand how to calculate primary and secondary PK parameters from concentration and time data.
4. Understand how urine sampling can be used to analyze IV bolus dose data.
5. Understand how to design a dosage regimen of a drug based on PK principles.

<b>M. Pharm First Year, Semester II</b>			
<b>MPH_E_215_T – Pharmacokinetics</b>			
<i>Course Code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
<b>MPH_E_215_T CO1</b>	Understand the routes of administration, sampling sites and definitions of A,D,M and E.	1	2
<b>MPH_E_215_T CO2</b>	Understand the mathematical equations that describe the plasma concentration versus time relationship of drugs administered as a IV bolus, Multiple IV bolus, IV infusion and an extravascular dose (one compartment model).	2.1	4
<b>MPH_E_215_T CO3</b>	Understand how to calculate primary and secondary PK parameters from concentration and time data.	2.3	5
<b>MPH_E_215_T CO4</b>	Understand how urine sampling can be used to analyze IV bolus dose data.	4	4
<b>MPH_E_215_T CO5</b>	Understand how to design a dosage regimen of a drug based on PK principles.	3	5

**CO-PO Mapping:**

<b>Course code &amp; CO number</b>	<b>PO1</b>	<b>PO2</b>	<b>PO3</b>	<b>PO4</b>	<b>PO5</b>	<b>PO6</b>
<b>MPH_E_215_T</b>	0	1	3	2	3	0

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<b>MPH_E_215_T</b>	1	2	3	2	2	0
<b>MPH_E_215_T</b>	1	2	2	1	3	0
<b>MPH_E_215_T</b>	2	2	3	1	2	0
<b>MPH_E_215_T</b>	2	2	3	2	3	0

<b>Unit</b>	<b>Course Content (Topics)</b>	<b>Hours</b>
1	<b>Introduction to pharmacokinetics</b> and its utility in drug design and dosage regimen design. Definitions of absorption, distribution, metabolism, excretion, elimination. Different approaches for determination of pharmacokinetics of drugs – non-compartmental, physiological, and compartmental modeling. Assumptions involved in the evolution of single and multi-compartment models.	<b>4</b>
2	<b>Discussion</b> (including mathematical description and equations) of the pharmacokinetics of drugs showing one compartment pharmacokinetics following different dosing methods/protocols [blood/plasma/urine sampling]	<b>40</b>
2.1	Discussion (including mathematical description and equations) of the pharmacokinetics of drugs showing one compartment pharmacokinetics following intravenous bolus dosing [blood/plasma/urine sampling]	5
2.1	Discussion (including mathematical description and equations) of the pharmacokinetics of drugs showing one compartment pharmacokinetics following intravenous multiple bolus dosing [blood/plasma]	5
2.2	Discussion (including mathematical description and equations) of the pharmacokinetics of drugs showing one compartment pharmacokinetics following intravenous constant infusion dosing [blood/plasma].	5
2.3	Discussion (including mathematical description and equations) of the pharmacokinetics of drugs showing one compartment pharmacokinetics following extravascular bolus dosing [blood/plasma]. Discussion of the concept of bioavailability (absolute and relative) and bioequivalence.	5
2.4	Discussion (including mathematical description and equations) of the pharmacokinetics of drugs showing one compartment pharmacokinetics following extravascular multiple bolus dosing [blood/plasma].	5
2.5	Discussion of approaches to solve problems related to the analysis of pharmacokinetic study data obtained after different types of dosing. Discussion of approaches to problems solving involving data from bioavailability and bioequivalence studies. Discussion of approaches to dosage regimen design	5
2.6	<i>Self-study of problems and problems solving related to the theoretical concepts outlined above (blood and urine data analysis)</i>	10
3	<b>Discussion of the processes of absorption, distribution and elimination</b> with respect to how these processes impact the values of rate constants for absorption/distribution/elimination and the values of bioavailability, volume of distribution and clearance.	<b>10</b>
4	<b>Introduction to drug transporters</b> and their impact on the pharmacokinetics of drugs and pharmacokinetic drug-drug interactions.	<b>3</b>

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5	<b>Brief introduction to the concept of dose- and time-dependent pharmacokinetics</b> [non-linear pharmacokinetics]and their impact on drug development and clinical use.	<b>3</b>
	<b>Total</b>	<b>60</b>

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**Books (latest edition to be adopted):**

1. Clinical Pharmacokinetics and Pharmacodynamics-Concepts and Applications, Rowland M and Tozer TN, Walters Kluwer – Lippincott Williams and Wilkins.
2. Applied Biopharmaceutics and Pharmacokinetics, Shargel L and Yu ABC, Appleton and Lange, International Edition
3. Handbook of Basic Pharmacokinetics including clinical applications, Ritschel WA and Kearns GL, APhA,
4. Basic Pharmacokinetics, Jambhekar SS and Breen PJ, Pharmaceutical Press.
5. Biopharmaceutics and Pharmacokinetics, Venkateshwarlu V, Pharma Book Syndicate
6. Drug Bioavailability-Estimation of solubility, permeability, absorption and bioavailability, van der Waterbeemd H, Lennernas H and Artursson P, Wiley VCH.
7. Modelling in Biopharmaceutics, Pharmacokinetics and Pharmacodynamics – Homogenous and Heterogenous approaches, Macheras P and Iliadis A, Springer

**MPH\_E\_216\_T-Clinical Pharmacy (4h/wk)**

Unit	Course Content (Topics)	Hours
1	<b>Introduction to Clinical Pharmacy</b>	<b>3</b>
1.1	Scope, Objectives and Goals in Health Care.	
1.2	Practice of Clinical Pharmacy in Hospitals and Community.	
2	<b>Understanding the patient</b>	<b>11</b>
2.1	Pharmacist-Patient Interview, Interview Techniques, communication skills.	8
2.2	Patient oriented medical records (POMR): Medication history and records, habits related to use of OTC medications, foods, allergies and sensitivities.	
2.3	Patient follow-up and discharge interview for hospitalized patients.	
2.4	Pharmacological and Biochemical examinations and their significance.	
2.5	Ethics related to medical record	
2.6	Discharge card	
2.7	<i>Self-study-Supervision of therapeutic success, side effects and adverse effects</i>	3
3	<b>Therapeutic use of medicine</b>	<b>10</b>
3.1	Drug selection and administration. Problems associated with concomitant therapy.	
3.2	Patient sensitivities, allergies. Precautions during use, Diet control.	
3.3	Reasons for non-compliance, Strategies for improving compliance.	
3.4	Use of drugs and concerns in geriatric, pediatric patients and in pregnancy	
3.5	Drug-drug interactions and drug interactions with food, alcohol and tobacco.	
	<b>Therapeutic drug monitoring (TDM)</b>	<b>6</b>
4.1	Introduction, individualization of drug dosage regimen (variability-genetic, age, weight, disease and interacting drugs).	
4.2	Indications for TDM, protocol for TDM.	
4.3	Pharmacokinetic-pharmacodynamic correlation in drug therapy.	
4.4	TDM of drugs used in following disease conditions: cardiovascular diseases, CNS conditions etc.	
5	<b>Drug formulary, drug utilization review (DUR) including rational drug therapy</b>	<b>3</b>
6	<b>Drug Information</b>	<b>4</b>
6.1	Introduction to information resources	
6.2	Drug information Centre (DIC) and Drug information services.	
6.3	Drug literature utilization, selection, evaluation and communication.	
6.4	Role of DIC in ensuring rational use of drugs (RUD).	
7	<b>Standard treatment protocol of selected non communicable diseases/conditions like diabetes, hypertension, stroke, obesity, arthritis, cardiopulmonary dysfunction and fluid and electrolyte imbalance.</b>	<b>10</b>
8	<i>Self-study-General concepts of poisoning and toxicology Critical care management: Common life support systems-Acute and chronic renal failure, cardiac and epileptic attack and respiratory failure.</i>	<b>13</b>

	<b>Total</b>	<b>60</b>
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**Books (latest editions to be adopted):**

1. J.T. Dipiro, R.L. Talbert, G.C. Yee, G.R. Matzke, B.G. Wells, L. Michael Posey (Eds.)
2. Pharmacotherapy: A Pathophysiologic Approach, The McGraw-Hill Companies, Inc.
3. E.T. Herfindal and D.R. Gourley, Text Book of Therapeutics: Drug and Disease Management, Lippincott Williams & Wilkins, USA.
4. T.M. Speight and N.H.G. Holford (Ed.), Avery's Drug Treatment: Principles and Practice of Clinical Pharmacology and Therapeutics, ADIS Press, Sydney, Australia.
5. Dennis L. Kasper, Eugene Braunwald, Anthony S. Fauci, Stephen L. Hauser, Dan L. Longo, J. Larry Jameson, and Kurt J. Isselbacher, (Eds.), Harrison's Principles of Internal Medicine, The McGraw-Hill Companies, Inc.
6. Pharmaceutical Practice - A.J. Winfield, R.M.E. Richards, Churchill Livingstone publication.
7. Drug Interaction Facts, David S. Tatro.

**MPH\_E\_217\_T-Drug Metabolism (4h/wk)**

Unit	Course Content (Topics)	Hours
1	<b>Introduction to xenobiotic/drug metabolism</b>	6
1.1	Introduction to xenobiotic/drug metabolism and its relation to other defense systems (Physical barriers, excretion, immune system).	2
1.2	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.	4
2	<b>Cytochrome P450s:</b> Introduction to the family of enzymes, their classification and nomenclature.	20
2.1	Introduction to the family of enzymes, their classification and nomenclature.	2
2.2	CYP450 catalytic cycle, different types of reactions catalyzed by CYP450 and the mechanisms of catalysis.	8
2.3	Human CYP450 involved in DM, their distribution and properties, typical substrates, specific probe substrates, specific inhibitors, induction of CYPs and specific inducers	7
2.4	Genetic polymorphism in CYP450 expression	3
3	<b>NONP450 enzymes</b>	20
3.1	Introduction to NONP450 enzymes involved in drug metabolism	05
3.2	<i>Self-study of NON P450s - glucuronosyltransferases, sulfotransferases, glutathione S-transferases, N-acetyl transferases, xanthine oxidase, aldehyde oxidase, esterase, epoxide hydrolase, nitro/azoreductases and FMO [on lines similar to that specified for CYPs as listed above].</i>	15
4	<b>Introduction to methods for studying DM.</b> 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}.	5
5	<b>Discussion of types of DM studies</b> – metabolic stability, cross species comparisons, metabolite profiling and identification, reaction phenotyping, CYP inhibition and CYP induction studies.	6
6	<b>Introduction to in silico drug metabolite predictions and associated algorithms.</b>	3
	<b>Total</b>	<b>60</b>

**Books (latest edition to be adopted):**

- Comprehensive Medicinal Chemistry, Series Ed., Hansch C., Pergamon Press.
- Wilson and Gisvold's, Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott-Raven
- Foye's Principles of Medicinal Chemistry, Lippincott Williams and Wilkins.
- 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
- Pharmaceutical Profiling in Drug Discovery for Lead Selection, Borchardt RT, Kerns EH, Lipinski CA, Thakker DR and Wang B, AAPS Press
- Drug Metabolism – Current Concepts, Ionescu C and Cairn MR, Springer International Edition

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- g. Handbook of Drug Metabolism, Woolf TF, Marcel Dekker.

**MPH\_E\_218\_T-BasicMolecularBiology(4h/wk)**

**Course Objectives:** The course will mainly focus on the study of principal molecular events of cell incorporating DNA Replication, Transcription and Translation in prokaryotic as well as eukaryotic organisms and additionally focuses on recombinant DNA technology, proteomics and genomic technologies to study its implications in research, therapeutics and plant tissue culture.

**Course Outcomes(CO):**

M.Pharm First Year, Semester I			
MPH_E_218_T BasicMolecularBiology(Theory4h/wk)			
<i>Course code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
<b>MPH_E_218_T_CO1</b>	Understand about the organization of genome and structure of gene, DNA and RNA.	<b>1 &amp; 2</b>	<b>2</b>
<b>MPH_E_218_T_CO2</b>	Remember and understand about the mechanisms of different cellular processes like DNA replication and repair, transcription, translation, and post-transcriptional and post-translational modifications in both prokaryotes and eukaryotes.	<b>2&amp;3</b>	<b>2&amp;3</b>
<b>MPH_E_218_T_CO3</b>	Understand about rDNA technology and its applications	<b>4</b>	<b>2&amp;3</b>
<b>MPH_E_218_T_CO4</b>	Understand about different techniques to study genomics and proteomics and its implications in research.	<b>4</b>	<b>2&amp;3</b>

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<b>MPH_E_218_T_C O5</b>	Understand the various molecular biology techniques (Western blotting, molecular cloning) and its application in research.	<b>4</b>	<b>2</b>
<b>MPH_E_218_T_C O6</b>	Understand medical molecular biology and relate its applications in cancer and gene therapy and comprehend the concepts of plant tissue culture.	<b>4&amp;5</b>	<b>2&amp;3</b>

**Mapping CO with PO**

CO	PO1	PO2	PO3	PO4	PO5	PO6
<b>MPH_E_218_T_CO1</b>		<b>1</b>		<b>1</b>	<b>1</b>	
<b>MPH_E_218_T_CO2</b>		<b>1</b>		<b>1</b>	<b>1</b>	
<b>MPH_E_218_T_CO3</b>		<b>1</b>		<b>1</b>	<b>1</b>	
<b>MPH_E_218_T_CO4</b>		<b>1</b>		<b>1</b>	<b>1</b>	
<b>MPH_E_218_T_CO5</b>		<b>1</b>		<b>1</b>	<b>1</b>	
<b>MPH_E_218_T_CO6</b>		<b>1</b>		<b>1</b>	<b>1</b>	

Unit	Course Content (Topics)	Hours
<b>1</b>	<b>The beginnings of molecular biology</b>	<b>1</b>
<b>2</b>	<b>DNA Structure and Role of DNA</b>	<b>16</b>
2.1	Organization of the genome, building from nucleotide to chromatin	6
2.2	The genetic code and its relationship to protein structure	2
2.3	DNA replication, Telomere maintenance, mechanisms of DNA repair, DNA recombination	8
<b>3</b>	<b>The versatility of RNA</b>	<b>23</b>
3.1	Transcription and translation in prokaryotes; Transcription and translation in eukaryotes	8
3.2	Epigenetics and monoallelic gene expression	3
3.3	RNA processing and post-transcriptional gene regulation	8
3.4	Mechanisms of translation	4
<b>4</b>	<b>Genetically modified organisms: Use in basic and applied research</b>	<b>14</b>
4.1	Recombinant DNA technology, molecular cloning, & some tools for analyzing gene expression	8
4.2	Genome analysis: DNA typing; Genomics and beyond; Medical molecular biology: applications in Cancer and Gene therapy; Genes and behavior. Proteomics and genomics: Methods for studying gene and protein expression	6
<b>5</b>	<b>Plant tissue culture and animal cell culture</b>	<b>6</b>
	<b>Total</b>	<b>60</b>

**Books (latest edition to be adopted)**

1. Genes IX, Ed Benjamin Lewin. Oxford University Press.
2. Molecular Cell Biology, Lodish H, Berk A, Zipursky S L, Matsudaira P., Baltimore D, Darnell J, Publisher W. H. Freeman.
3. Molecular Biology of the Cell, Alberts Publisher Garland Science.

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4. Watson, J.D. Tania A. Baker, Stephen P. Bell, Alexander Gann, Michael Levine, Richard Losick, Molecular Biology of the Gene, Benjamin Cummings.
5. Molecular Biology in Medicinal Chemistry, Dingemann Th, Steinhilber D and Folkers G, Wiley-VCH, Germany
6. Basic Principles of Gene Manipulation, Primrose SB, Twyman RM and Old RW, Blackwell.
7. Molecular Biology and biotechnology, Walker JM and Rapley R, Royal Society of Chemistry

**MPH\_E\_219\_T-Pharmaceutical Biotechnology (4h/wk)**

Unit	Course Content (Topics)	Hours
<b>1</b>	<b>Production and Control of Biotech derived products</b>	<b>25</b>
1.1	Recombinant DNA products – insulin, growth hormone, erythropoietin, cytokines	5
1.2	Vaccines – attenuated virus, genetic alterations of live virus as a vector of other pathogens (recombinant virus or recombinant vaccinia virus)	7
1.3	Diagnostic proteins – protein A, protein G, antibodies	4
1.4	Quality control testing of biotech products – determining impurities, contamination -viral, bacterial endotoxin, rabbit pyrogen test, sterility, protein identification, fingerprints by electrophoresis, isoelectric focusing, immunogenicity, partial sequence analysis.	9
<b>2</b>	<b>Plant biotech products</b>	<b>10</b>
2.1	Substances produced by plant cell culture	2
2.2	Transgenic plants and their application	4
2.3	Biotransformations with plant cell culture	4
<b>3</b>	<b>Biotech products through fermentation</b>	<b>13</b>
3.1	Fermentation – batch, continuous fermentation	2
3.2	Role of bioengineering in fermentation – geometry of fermentation tanks, design of impellers, agitation systems and environmental conditions of fermentation	3
3.3	Fermentative production of important secondary metabolites – penicillins, amino glycosides, polyene macrolides, macrolides, anthracyclines	3
3.4	Principles of downstream processing of fermentation products	3
3.5	Unit operations and techniques employed in downstream processing of fermentation products, microbial strain selection and preservation methods	3
3.6	Genotype and phenotype variation of characters of microbes	
<b>4</b>	<b>Self-study - Biotransformation</b>	<b>12</b>
4.1	<i>Biotransformation principles and industrial applications in the production of chemicals and drugs</i>	
4.2	<i>Immobilization of enzymes, proteins and their applications – biosensors, enzyme electrodes, immunosensors, optical sensors</i>	
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

1. Biotechnology, H.J. Rehm, G. Reed. Vols 1– 12, A. Pulher, P. Stadler Eds, Weinheim, New York
2. A text book of Biotechnology, H.D. Kumar Affiliated, East–West Press Pvt. Ltd.
3. Genetic Engineering Fundamentals, Karl Kammer, Meyer Virginia, C. Clark.
4. Genes V, Benjamin Lewin, Oxford University Press.
5. Methods in Plant Molecular Biology and Biotechnology, Bernard R Glick, John E Thompson, CRC Press.
6. Genetic and Biochemistry of Antibiotics Production, Leo C Vining, Colin, Stuttard Butterworth, Heinemann.

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7. Biotechnology – Applications and Research, Paul N Chermisnoff, Robert P Ouellett, Technomic Publishing Co. Inc.
8. Transgenic Plants: A production systems for industrial and pharmaceutical proteins, Meran R. L. Owen, Jan Pen, John Wiley and Sons.
9. Biotechnology of antibiotics, William R Strohl, Marcel Dekker.
10. Molecular Biochemistry – Therapeutic applications and strategies, Sunil Maulik and Salil D Patel, John Wiley and Sons, Inc.

**MPH\_E\_220\_T-Models for DDSEvaluation(4h/wk)**

Unit	Course Content(Topics)	Hours
1	Pharmacodynamic models for evaluation of DDS containing drugs of various categories e.g. cardiovascular agents, antidiabetic, anti-inflammatory, antiepileptic, anticancer, hepatoprotectives, analgesics, antistress, antiasthmatic and antitussives.	20
2	In vitro cell culture techniques for evaluation of drug permeation from DDS, including isolation, maintenance of cell lines, culturing monolayers, evaluation of drug transport	8
3	In vitro/ex vivo models for evaluation of drug absorption	5
4	In vitro cytotoxicity evaluation using cell cultures and techniques such as MTT assay, dye uptake etc.	5
5	Toxicity testing – in vitro – In vitro toxicity testing and its application to safety evaluation, general perspectives, in vitro trends and issues, ocular and cutaneous irritation, validation of in vitro toxicity tests – acute, sub-acute and chronic toxicity testing, biochemical basis of toxicity, design of toxicological studies, quality assurance in toxicological studies, toxicity by routes – parenteral, oral, percutaneous and inhalation, target organ toxicity exemplified by hepatotoxicity and cutaneous (dermal) toxicity.	10
	<b>Total</b>	<b>48</b>

**Books (latest edition to be adopted)**

1. Bioassay Techniques for drug development, Atta Ur Rahman, M. Iqbal Choudhar, William J Thomsen.
2. In vitro Methods in Pharmaceutical Research, Eds. J.V. Castell, M.J. Gomer, Lechon, Academic Press
3. In vitro Toxicity Testing, John M Frazier.
4. General and Applied Toxicology, Bryan Ballantyne, T Marris and P. Turner.

**MPH\_E\_221\_T-Rational Drug Design(4h/wk)**

Unit	Course Content(Topics)	Hours
1.0	<b>Molecular Mechanics</b> and the force field. General form of a generic force field, force field parametrization.	<b>5</b>
1.1	<i>Self-study – Comparison between the different force fields in existence at present time</i>	1
2.0	<b>Energy minimization</b>	<b>6</b>
2.1	Steepest descents, conjugate gradients, Newton Raphson method, advantages and limitations of each method	
3.0	<b>Conformational analysis</b>	<b>10</b>
3.1	Systematic search, Monte Carlo simulations, Molecular dynamic simulations, distance geometry, strengths and limitations of each method	

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4.0	<b>Docking</b>	<b>10</b>
4.1	Docking by energy minimization, superimposition, molecular dynamics, Metropolis Monte Carlo, genetic algorithms, build-up approach. Different types of scoring function, e.g. of successful application of docking.	8
4.2	<i>Self-study – Successful applications of docking</i>	2
5.0	<b>de novo ligand design</b>	<b>10</b>
5.1	Classes of de novo ligand design – active site analysis methods, whole-molecule methods, connection methods, random connection and disconnection methods, e.g. of successful application of de novo ligand design	
5.2	Fragment based drug design	2
5.3	<i>Self-study – Successful applications of de novo drug design</i>	2
6.0	<b>Pharmacophore modelling</b>	<b>9</b>
6.1	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.	7
6.2	<i>Self-study – Successful e.g. of pharmacophore maps in drug design</i>	2
7.0	<b>Virtual Screening</b> based on similarity, docking, pharmacophore maps and filters for drug-likeness and ADME	<b>3</b>
8.0	<b>3D-QSAR</b>	<b>6</b>
8.1	CoMFA and CoMSIA, Mention of other 3D-QSAR techniques and introduction to the 4 <sup>th</sup> , 5 <sup>th</sup> and 6 <sup>th</sup> dimension in QSAR.	4
8.2	Self-study – 3D-QSAR method other than CoMFA and CoMSIA	2
	<b>Total</b>	<b>60</b>

**Books (latest edition to be adopted)**

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.

**MPH\_E\_222\_T-Advanced Biochemistry (4h/wk)**

Unit	Course Content (Topics)	Hours
1	<b>Proteins</b>	<b>15</b>
1.1	Structure – primary, secondary, tertiary, quaternary; motifs, structural and functional domains, protein families and macromolecular assemblies	5
1.2	Mechanisms for regulating protein function: Protein-protein interactions, interaction with ligands; Ca <sup>2+</sup> and GTP as modulators, cyclic phosphorylation and dephosphorylation, proteolytic cleavage.	2
1.3	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.	4
1.4	Protein biosynthesis: translation machinery in prokaryotic and eukaryotic systems; comparison of similarities and differences, drug affecting protein biosynthesis and protein function	4
2	<b>DNA and nucleic acids</b>	<b>15</b>

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2.1	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	15
3	<b>Carbohydrates</b>	8
3.1	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	8
4	<b>Lipids</b>	7
4.1	Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipids as secondary messengers and cofactors, biological role of lipids, drug affecting lipid metabolism.	7
5	<b>Self-study of protein superfamilies, N and C terminal sequencing, DNA structures other than B-DNA, DNA sequencing, DNA pyrosequencing, cerebrosides, sphingolipids.</b>	15
	<b>Total</b>	<b>60</b>

**Books (latest edition to be adopted)**

1. Principles of Biochemistry, Lehninger, Nelson D.L., C.B.S Publishers, New Delhi.
2. Biochemistry, Stryer L, W.H. Freymer & Co., New York.
3. Molecular Cell Biology, Lodish H, Darneu J, Scientific American Books (latest edition to be adopted), N.Y.
4. Biochemistry- The chemical reactions of living cells, Vol 1 & 2, Metzler DE, Elsevier Academic Press.
5. Biochemistry, Berg JM, Tymoczko J and Stryer L, W.H. Freeman and Company and Sumanas Inc.
6. Biomacromolecules- Introduction to structure, function and informatics, Stan Tsai C, Wiley-Liss
7. Protein: Structure and Molecular properties, Thomas E Creighton, W.H. Freeman.
8. Physical Biochemistry- Principles and applications, Sheehan D, Wiley-Blackwell

**MPH\_E\_223\_T-Green Chemistry (4h/wk)**

Unit	Course Content (Topics)	Hours
1	<b>Introduction to the concepts of Green Chemistry</b> – history, need, goals, limitations, obstacles and opportunities	5
1.1	<b>Introduction to the principles of Green Chemistry</b> – 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 <i>etc</i> ), energy requirements for reactions, selection of starting materials, renewable starting materials, avoidance of unnecessary derivatization – careful use of blocking/protecting groups	15
1.2	Microwave assisted organic synthesis; photochemical transformations; sonication; solid phase transformations; aqueous phase transformations; enzymatic transformations; etc	8
1.2	<i>Self-study-transformations using ionic liquids, PEG, polymers supported reagents</i>	4

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2	<b>Application</b> of green synthetic reactions, green starting materials, green reagents, green solvents and reaction conditions, green catalysis and examples of green synthesis, green analytical methods	<b>13</b>
2.1	<i>Self-study – Examples of Green synthesis</i>	3
3	<b>Future trends in green chemistry</b> – oxidation reduction reagents and catalysts; biomimetics and multifunctional reagents; combinatorial green chemistry; solventless reactions; non-covalent derivatization; biomass conversion; emission control; biocatalysis	<b>12</b>
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

1. Green Chemistry: Theory and Practice, Anastas P T and Warner J C, Oxford University Press.
2. Green Chemistry: Introductory Text, Lancaster M, R C S London
3. Introduction to Green Chemistry, Ryan M. A., Tinnes M., American Chemical Society (Washington).
4. Handbook of Green Chemistry and Technology, Clarke J and Macquarie D, Blackwell Publishing.
5. Green Chemistry – Green 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.

## MPH\_E\_224\_T-Drug Regulatory Affairs (4h/wk)

No.	Course Contents (Topics)	Hours
1.0	Need for Regulations	1
2.0	<b>Indian Regulations</b>	15
2.1	Introduction to Indian Regulations	1
2.2	Drugs & Cosmetic Act & Rules - Overview and recent amendments	5
2.2.1	• Schedule DI and DII (Registration and Import)	
2.2.2	• Schedule M	
2.2.3	• Schedule Y	
2.2.4	• Central Drug Laboratories	
2.3	ICMR guidelines for ethical considerations in biomedical research on human subjects	1
2.4	BA-BE studies	2
2.5	New drug application	1
2.6	Insurance, Compensation and Indemnification of trial subjects	1
2.7	Expert Referral	1
2.7.1	• IBSC, RCGM	
2.7.2	• ICMR	
2.7.3	• NDAC	
2.7.4	• CBBTDEC	
2.8	WHO GMP Certification, FSC and CoPP procedure	1
2.9	Procedures for obtaining Test license (Form 29 and Form 11); Export NOC	1
2.10	Loan license/Contract manufacturing	1
3.0	<b>US Regulations</b>	6
3.1	Introduction to US Regulations	1
3.2	Hatch Waxman Act and amendments, FDAMA Medicare Modernization Act	
3.3	Introduction to Orange Guide and 21-CFR	1
3.4	Investigational new drug (IND) filing	1
3.5	US Drug Master File (DMF) filing, amendments and annual reports	1
3.6	Abbreviated New Drug Application (ANDA) filing	1
3.7	New Drug Application (NDA) filing	
3.8	Post approval changes	1
4.0	<b>European Regulations</b>	6
4.1	Introduction to European Regulations	1
4.2	Active Substance Master File (ASMF) filing	1
4.3	CEP filing	
4.4	Marketing Authorization and filing procedures	2
4.4.1	• National Procedure	
4.4.3	• Mutual Recognition Procedure (MRP)	
4.4.4	• Decentralized Procedure (DCP)	
4.4.5	• Centralized Procedure (CP)	
4.5	Handling variations	

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4.6	Clinical Trial Regulations in EU	2
<b>5.0</b>	<b>Other applicable Regulations and Guidelines</b>	<b>10</b>
5.1	Overview of ICH guidelines	1
5.2	CTD format of dossier	1
5.3	eCTD filing procedure	
5.4	21-CFR Part 11	1
5.5	Audits and Inspections, FDA 483's – Lessons learnt	1
5.6	Overview of registration process in other geographies	1
5.7	Biological license application (BLA)	1
5.8	Medical Device Registration process	1
5.9	Regulations governing Stem Cell therapeutics	1
5.10	Introduction to Pharmacovigilance and Drug Safety	1
5.11	Orphan Medicinal Products	1
<b>6.0</b>	<b>Intellectual Property Rights (IPR)</b>	<b>4</b>
6.1	Overview of patents from regulatory perspective	
6.2	PCT application & general rules	
6.3	WTO/GATT system	
6.4	TRIPS Agreement	
6.5	Compulsory licensing	
6.6	Patent search, drafting and filing procedure	
6.7	Patent infringement analysis	
6.8	Trademark/copyright filing procedures	
	<b>Total</b>	<b>42</b>

**Books (latest editions to be adopted)**

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-Practices-Development/dp/1574910515>
3. Guide to Drug Regulatory Affairs/Buch, Brigitte Friese.
4. Drugs and Cosmetics Act, 1940 and Rules, 1945.

**Useful links:**

1. <http://www.cdsc.nic.in/>
2. <http://clinicaltrials.gov/>
3. <http://dbt.biosafety.nic.in/>
4. <http://www.emea.europa.eu/>
5. <http://www.ich.org/>
6. <http://www.fda.gov/>

## MPH\_E\_225\_T–Cosmeticology(4h/wk)

Unit	Course Contents(Topics)	Hours
<b>1</b>	<b>General Anatomy and Physiology of skin, hair, nail and tooth:</b>	<b>8</b>
1.1	<i>Self-study: Anatomy and physiology of skin, hair, nail and tooth-emphasis on points with reference to cosmetics.</i>	4
1.2	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.	4
<b>2</b>	<b>General raw materials in cosmetic formulations:</b>	<b>19</b>
2.1	Overview of raw materials- Water, natural & synthetic oils, fats & waxes, inorganic solids, emulsifiers, thickeners, hydrocolloids, polymers, surfactants, antioxidants, humectants, polysiloxanes, preservatives.	2
2.2	Colouring agents used in cosmetics. Quality evaluation of colors, safety, toxicity and regulatory aspects of colors w.r. to cosmetic products	3
2.3	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.	6
2.4	Therapeutic ingredients in various cosmetics like skin products, dentifrices, hair care and nail preparations, and performance evaluation of these activities.	3
2.3	<i>Self-study: Detail of general raw materials (oils, fats, waxes, surfactants, preservatives, polysiloxanes), Historical purview of perfumes, Approved colours as per Indian, European and US specifications</i>	5
<b>3</b>	<b>Application of novel approaches in cosmetic formulations</b>	<b>4</b>
3.1	Concepts of microemulsions, liposomes, niosomes, nanoparticles, iontophoresis, to enhance functional attributes & delivery of cosmeceuticals.	4
<b>4</b>	<b>Herbal cosmetics</b>	<b>6</b>
4.1	Current trends in use of herbal materials in cosmetics.	2
	<i>Self-study: Discussion on aloe vera, henna, tea tree oil, neem in various cosmetic products</i>	4
<b>5</b>	<b>Packaging and labelling of cosmetic products</b>	<b>5</b>
5.1	Packaging materials, speciality packages for cosmetics, labelling requirements for cosmetics	5
<b>6</b>	<b>Quality standards of cosmetic products:</b>	<b>18</b>
6.1	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.	8
6.2	Microbiological quality of cosmetic products.	2
6.3	Safety and toxicity evaluation of cosmetic products	4
6.4	Legal considerations and regulatory procedures of cosmetic products	2

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6.5	<i>Self-study-BIS, European and US specifications about quality standards of cosmetic products</i>	2
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

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, Wiley-Interscience, Wiley India Pvt. Ltd.
3. Poucher's Perfumes, cosmetics & Soaps, Hilda Butler, Kluwer Academic Publishers, Netherlands
4. Cosmetic Technology, Ed. By S.Nanda, A. Nanda and R. Khar, Birla Publications Pvt. Ltd., New Delhi
5. Handbook of Cosmetic Science and Technology, Ed. M. Paye, A.O. Barel, H.I. Maibach, Informa Healthcare USA, Inc.
6. Encyclopedia of Pharmaceutical Technology, James Swarbrick, James C. Boylan, Marcel Dekker Inc.
7. BIS Guidelines for different cosmetic products
7. Drugs & Cosmetics Act & Rules, 1940 (with latest amendments).

**MPH\_E\_226\_T-Polymers in Pharmacy (4h/wk)****Objectives**

On completion of following theory topics learner should be able to comprehend the classification of polymers and the concepts involved in co-polymerization, properties and characterization, methods, biocompatibility aspects, biocompatible polymers, and applications of polymers in pharmacy.

**Course Out Comes (COs)**

Upon the completion of the course student shall be able to:

- 1.) Classify polymers and describe the applications of polymers in pharmacy..
- 2.) Summarize properties, characterization, and methods of polymer synthesis.
- 3.) Explain mechanism of tissue reaction to polymers and describe biocompatibility testing of polymers.
- 4.) Enlist the features, design and evaluation of biocompatible polymers.

<b>M. Pharm First Year, Semester II</b>			
MPH_E_226_T - Polymers in Pharmacy (THEORY-60 hours)			
<i>Course Code &amp; CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Syllabus Unit no.</i>	<i>Up to Bloom's level</i>
MPH_E_226_T CO1	Classify polymers and describe the applications of polymers in pharmacy.	1,2,&3	4
MPH_E_226_T CO2	Summarize properties, characterization, and methods of polymer synthesis.	4 & 5	4
MPH_E_226_T CO3	Explain mechanism of tissue reaction to polymers and describe biocompatibility testing of polymers.	6	4
MPH_E_226_T CO4	Enlist features, design and evaluation of biocompatible polymers.	7&8	3

<i>Course Code &amp; CO number</i>	<i>PO1</i>	<i>PO2</i>	<i>PO3</i>	<i>PO4</i>	<i>PO5</i>	<i>PO6</i>
MPH_E_226_T CO1	1	1	1	2	2	2
MPH_E_226_T CO2	1	1	1	3	2	2
MPH_E_226_T CO3	1	1	1	3	2	2
MPH_E_226_T CO4	1	1	1	3	2	2

<b>Unit</b>	<b>Course Contents (Topics)</b>	<b>Hrs.</b>
1.0	Historical Background, Basic definitions, Applications	1
<b>2.0</b>	<b>Classification of Polymers</b>	<b>7</b>
2.1	Classification based on reaction to temperature and structure/arrangement/architecture-linear, branched, crosslinked.	2

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2.2	Polymerization mechanisms-Addition&step-growth polymerization-Freeradical, cationic, anionic and Ziegler Natta mechanisms	5
<b>3.0</b>	<b>Copolymerization</b>	<b>5</b>
3.1	Theoretical aspects of copolymerization	3
3.2	<i>Self-study-Case studies of any two copolymers</i>	2
<b>4.0</b>	<b>Properties &amp; Characterization of polymers</b>	<b>12</b>
4.1	Factors affecting and Overview	1
4.2	Molecular weight and determination of molecular weight,	2
4.3	Solid state characterization-glass transition temperature, Crystallinity,	3
4.4	Solubility of polymers & Swelling pr, Mechanical properties	3
4.5	<i>Self-study-Case study-any 3 polymers-characteristics &amp; comparison</i>	3
<b>5.0</b>	<b>Methods of Preparation of Polymers</b>	<b>11</b>
5.1	Bulk polymerization, Solution polymerization,	3
5.2	Suspension polymerization, Emulsion polymerization.	3
5.3	Additives in polymers, Fabrication of polymeric devices/systems-casting, extrusion, moulding etc	3
5.4	<i>Self-study-One example polymer for each method</i>	2
<b>6.0</b>	<b>Biocompatibility of Polymers</b>	<b>10</b>
6.1	Safety & Biocompatibility issues-Overview	1
6.2	Reaction of polymer to tissues, effect of body/host system to polymers	2
6.3	Mechanisms of tissue reactions/injury,	2
6.4	Evaluation of biocompatibility of polymers	3
6.5	<i>Self-study-Pharmacopoeial &amp; other tests for toxicity evaluation of polymers</i>	2
<b>7.0</b>	<b>Biocompatible Polymers</b>	<b>10</b>
7.1	General features of biocompatible polymers, enzymatically degradable bonds in polymers	2
7.2	Design of biocompatible polymers & evaluation,	4
7.3	<i>Self-study-some examples-PLGA, cellulose, acrylates, hydrogels.</i>	4
<b>8.0</b>	<b>Applications of polymers in pharmacy.</b>	<b>4</b>
8.1	Overview of applications as thickeners, binders, coating agents, adhesives, as release modifying agents, including smart polymers, elastomers	2
8.2	<i>Self-study: One example each of-adhesive polymer, coating agent, drug release modifier, smart polymer</i>	2
	<b>Total</b>	<b>60</b>

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**Books (latest edition to be adopted)**

1. Fundamental Principles of Polymeric Materials, Rosen SL, Wiley Interscience Publication.
2. Martin's Physical Pharmacy and Pharmaceutical Sciences by Sinko PJ, Ed Lea & Feiger, Lippincott Williams & Wilkins.
3. Controlled Drug Delivery: Fundamentals and Applications, Robinson JR, Lee VHL, Dekker.
4. Biodegradable Polymers as Drug Delivery Systems, Chasin M, Langer R, Marcel Dekker.
5. Controlled and Novel Drug Delivery by Jain NK, CBS Publishers and Distributors.
6. Controlled Drug Delivery: Clinical Applications, by Bruk SD, CRC Press Inc.
7. Polymeric Drug Delivery System by Kwon GS, Marcel Dekker.
8. Aqueous polymeric coating for pharmaceutical dosage forms by McGinity JW, Marcel Dekker

**MPH\_E\_227\_T-Drug Evaluation Techniques(4h/wk)**

**Course Objectives:** The course will impart knowledge of the stages of drug discovery, drug evaluation through high throughput screening assays, target-based drug discovery and alternative screening models like zebrafish, drosophila etc. with the estimation of biological fluids.

**Course Outcomes (CO):**

<b>M.Pharm First Year, Semester I</b>			
<b>MPH_E_227_T Drug Evaluation Techniques (Theory 4h/wk)</b>			
<b>Course code &amp; CO number</b>	<b>At the successful completion of the course, the learners will be able to:</b>	<b>Syllabus Unit no.</b>	<b>Up to Bloom's level</b>
<b>MPH_E_227_T_CO1</b>	Understand and explain the various stages of drug discovery and biological screening including animal models, in vitro-in vivo correlations, animal testing along with their care and maintenance as per OECD, CCSEA and ICH guidelines.	<b>1</b>	<b>2</b>
<b>MPH_E_227_T_CO2</b>	Understand the techniques used in high throughput screening like cell-based assays, biochemical assays, fluorescence-based assays and chemiluminescence based detection assays and relate to their applications in drug discovery and development.	<b>1</b>	<b>2&amp;3</b>
<b>MPH_E_227_T_CO3</b>	Comprehend and appreciate the importance of alternate methods of screening such as Zebrafish and drosophila models including alternate methods to toxicity testing viz. pyrogenicity, in vitro skin and eye irritation tests and apply them in your basic research.	<b>1&amp;4</b>	<b>2&amp;3</b>
<b>MPH_E_227_T_CO4</b>	Understand, discuss and apply the screening & evaluation models and the techniques of drugs/leads for CNS, antidiabetic, immunomodulatory, anti-inflammatory and antioxidant activities.	<b>2</b>	<b>2&amp;3</b>
<b>MPH_E_227_T_CO5</b>	Understand the methods used in target-based drug discovery for anti-tubercular, anti-cancer, anti-HIV and anti-malarial activities and comprehend the importance of target-based drug discovery and use of in vitro screening techniques in drug discovery e.g. Turbidimetric assay, GPIIb-IIIa assays for antiplatelet activity.	<b>2</b>	<b>2</b>
<b>MPH_E_227_T_CO6</b>	Review the methods for estimation of drugs from complex biological fluids eg. Blood, tissue, CSF etc. and imply them in their research.	<b>3</b>	<b>2&amp;3</b>

**Mapping CO with PO**

CO	PO1	PO2	PO3	PO4	PO5	PO6
MPH_E_227_T_CO1	1	1			3	
MPH_E_227_T_CO2	1	1			3	
MPH_E_227_T_CO3	1	1			3	
MPH_E_227_T_CO4	1	1			3	
MPH_E_227_T_CO5	1	1			3	
MPH_E_227_T_CO6	2	1			3	

Unit	Course Contents (Topics)	Hours
1		19
1.1	<b>Basic principles of drug discovery and biological screening</b> <ul style="list-style-type: none"> <li>Correlation between various animal models and human situations</li> <li>Correlation between <i>in vitro</i> and <i>in vivo</i> screens.</li> <li>Care, handling, breeding techniques of lab animals.</li> <li>CPCSEA, OECD, ICH guidelines in brief.</li> </ul>	6
1.2	<b>High throughput screening in drug discovery</b> Techniques for high throughput screening <ul style="list-style-type: none"> <li>Cell based assays</li> <li>Biochemical assays</li> <li>Radioligand binding assays</li> </ul>	6
1.3	<b>Detection methods</b> <ul style="list-style-type: none"> <li>Fluorescence based assay techniques</li> <li>Chemiluminescence based assay techniques.</li> </ul>	3
1.4	<b>Self-study Use of alternative methods of screening</b> <ul style="list-style-type: none"> <li><i>Zebrafish model</i></li> <li><i>Drosophila</i></li> <li><i>Types of drugs for which these models can be used.</i></li> </ul>	4
	<b>Target based drug discovery and <i>in vitro</i> screening techniques for</b>	<b>26</b>
2.1	Anti-platelet activity-Turbidimetric, GPIIb-IIIa assays using platelet aggregometer.	2

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2.2	CNS: <ul style="list-style-type: none"> <li>Alzheimer's disease: <i>in vivo</i> which includes aluminium induced, scopolamine induced memory loss. <i>In vitro</i> includes acetylcholinesterase activity.</li> <li>Parkinson's disease <i>in vivo</i> includes Haloperidol, reserpine, rotenone, MPTP induced models.</li> <li>Antidepressant and anticonvulsants.</li> </ul>	6
2.3	Anti-diabetic: Alloxan, STZ, genetically diabetic animals and various <i>in vitro</i> methods	3
2.4	<ul style="list-style-type: none"> <li>Antitubercular: BACTEC</li> <li>Anticancer: Few <i>in vitro</i> cell lines, models for metastasis</li> <li>Anti-HIV: Various targets involved</li> <li>Antimalarial.</li> </ul>	6
2.5	Immunomodulatory: <i>in vivo</i> and <i>in vitro</i> methods.	2
2.6	Anti-inflammatory: Acute, subacute and chronic models.	2
2.7	<i>Self-study-Antioxidant activity</i>	5
3	<ul style="list-style-type: none"> <li><b>Estimation of drugs</b> from complex media like biological fluids, e.g. blood, tissues, CSF etc.</li> <li><i>Self-study-USFDA guidelines for bioanalysis methods including validation</i></li> </ul>	5 2
4	<ul style="list-style-type: none"> <li><i>In vitro</i> skin irritation and eye irritation tests, <i>In vitro</i> tests for pyrogenicity</li> <li><i>Self-study-Alternative methods for toxicity testing (in vitro)</i></li> </ul>	5
	<b>Total</b>	<b>60</b>

**Books (latest editions to be adopted)**

- H.G. Vogel, Drug discovery and evaluation, Pharmacological Assays, Springer Verlag.
- R.A. Turner, Screening methods in pharmacology, Academic Press.
- D.R. Laurence and A.L. Bacharach, Evaluation of drug activities: Pharmacometrics, Academic Press.
- A. Schwartz, Methods in Pharmacology, Plenum Publishing Corporation.
- Website-- [Altox.org/ttrc/validation-va](http://Altox.org/ttrc/validation-va)

**RESEARCH PROJECT AND THESIS**

**Course Objectives:** This course will impart students with the knowledge to independently carry forward research, starting from creation of hypothesis, planning, experimentation, data analysis, and reporting.

**Course Outcome**

<b>Course code &amp; CO number</b>	<b>At the successful completion of the course, the learners will be able to:</b>	<b>Upto Bloom's level</b>
CO1	Perform the literature survey on the given research problem and where they will be able to compare and contrast the given data in different reports/published papers	3&4

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<b>CO2</b>	Develop skills in handling of different animal species used in preclinical pharmacology and toxicology (Rodents/Zebrafish/Drosophila) or counselling of patients for PV monitoring with follow up (if applicable) under professional guidance.	<b>2&amp;3</b>
<b>CO3</b>	Handled different instruments (UV/HPLC/Stereotaxic apparatus/ELISA/RT-PCR etc) and develop the skills in using the same for research methodologies.	<b>3,4 &amp;5</b>
<b>CO4</b>	Plan and draft the research study protocol of their project, including efficacy and safety end points, including case report form or Individual Case safety report form (if applicable), including inclusion and exclusion criteria, including sample size, including randomization and statistical plan after reviewing the published literature in that area and based on existing knowledge and skills	<b>4,5&amp;6</b>
<b>CO5</b>	Plan and execute the research study with literature survey, performance of experiments, capture of data, analysis, evaluation, interpretation & collation of the data to drafting of synopsis followed by the thesis and apply statistical tests and concepts to the study data viz. sample size, sampling, application of ANOVA, post hoc tests along with the use of statistical software to draw conclusions and inferences along with the presentation of the data in suitable forms and figures.	<b>2,3&amp; 6</b>
<b>CO6</b>	Develop their scientific writing skills while creating thesis, understand publication ethics, plagiarism, ICT tools, and comprehend applications of research outcomes.	<b>1&amp;3</b>

**Mapping CO with PO**

CO	PO1	PO2	PO3	PO4	PO5	PO6
<b>01</b>	<b>1</b>	<b>1</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>3</b>
<b>02</b>	<b>1</b>	<b>1</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>3</b>
<b>03</b>	<b>1</b>	<b>1</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>3</b>
<b>04</b>	<b>1</b>	<b>1</b>	<b>3</b>	<b>2</b>	<b>3</b>	<b>3</b>

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05	1	1	3	2	3	3
06	1	1	3	2	3	3

<i>CO number</i>	<i>At the successful completion of the course, the learners will be able to:</i>	<i>Up to Bloom's level</i>
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Course-  
PO  
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ma

**cology**

CourseCode	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_103_T			1		3	
MPH_C_206_T					3	
MPH_E_207_T				3	2	
MPH_E_218_T			3		3	3
MPH_E_227_T					3	
MPH_E_299_T				3	3	3
Seminar		3				
ResearchProjectand Thesis	3					3

**M. Pharm (Pharmaceutical Analysis)  
Research Project & Thesis in Pharmaceutical Sciences**

**Course Objectives:**

Upon completing the research project, learners should be able to:

Apply the knowledge in the design and execution of experiments, critically assess analytical data and synthesize information from diverse sources, acquire essential skills and principles necessary to make meaningful contributions to the field of pharmaceutical analysis, while upholding the utmost standards of integrity, and cultivate ethical research practices and effective communication.

**Course Outcomes:**

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CO1	Conduct a comprehensive and critical analysis of the existing literature, synthesizing knowledge to identify the research gaps, and emerging trends in the selected research domain.	6
CO2	Utilize advanced research technologies, laboratory instruments/equipment, software, and tools effectively to facilitate the research process, with a concurrent understanding of the environmental science impact and the principles of sustainable development.	3
CO3	Proficiently communicate the research findings in a clear, concise, and engaging manner in writing, ensuring effective dissemination of knowledge.	6
CO4	Create graphs, figures, and visual representations that effectively communicate the research data.	6
CO5	Evaluate methodologies and results using statistical methods to optimize experimental designs, ensuring efficient data collection and analysis.	5
CO6	Understand and execute the principles of research and publication ethics, significance of avoiding plagiarism, during the execution of research project and the creation/publication of thesis, research presentation and/or publication.	6

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**CO-PO Mapping:**

<i>CO number</i>	PO1	PO2	PO3	PO4	PO5	PO6
CO1	3	3	3	3	3	3
CO2	3	3	3	3	3	3
CO3	3	3	3	3	3	3
CO4	3	3	3	3	3	3
CO5	3	3	3	3	3	3
CO6	3	3	3	3	3	3

**Course mapping Pharmaceutical Analysis**

Course code	PO1	PO2	PO3	PO4	PO5	PO6
MPH_C_104_T	2	1	3	3	3	3
MPH_C_208_T	2	2	3	3	3	3
MPH_C_209_T	2	2	3	3	3	3
MPH_C_299_T	3	3	3	3	3	3