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 in receptiveness 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.SemesterI:ALLBRANCHESOFSTUDY Total

Credits: Semester I – 24

SubjectCode	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 andResearch Methodology	C	4	3L+1IL	3	15ST+5 A	80

Legends
IAInternalAssessment;
ESEEndSemesterExamination; ST
Sessional Test/s;
AAttendance,
L Lectures;
ILIntegratedLearninginvolvingTutorials,GroupDiscussions,Assignments,FieldWork; P
Practicals, Lab. work, Project;
CCore;
CBSChoiceBasedSubject; 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 InternalAssessment(CIA)and80marksfortheEndSemesterExamination.The20marksforCIAwillbe divided into 5 marks for Attendance and 15 marks for a sessional test held mid-semester.
EverystudentwilldeliveraSeminar.Thiswillbeevaluatedatthecollegelevelbyacommitteeconsisting ofthePrincipal, HODandfacultyoftheDepartmentinwhichthestudent will bedoinghisresearchwork.

M.Pharm.SemesterII:ALLBRANCHESOFSTUDY

TotalCredits:SemesterII–24

SubjectCode	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	CoreI	C	4	3L+1IL	3	15ST+5 A	80
MPH_C_2XX_T	CoreII	C	4	3L+1IL	3	15ST+5 A	80
MPH_E_2XX_T	ChoiceBased SubjectI	CBS	4	3L+1IL	3	15ST+5 A	80
MPH_E_2XX_T	ChoiceBased SubjectII	CBS	4	3L+1IL	3	15ST+5 A	80
MPH_C_299_L	Experimental Techniquesin Pharmaceutical Sciences	C	4	8 P	6	15ST+5 A	80

Legends
IAInternalAssessment;
ESEEndSemesterExamination; ST
Sessional Test/s;
AAttendance,
L Lectures;
ILIntegratedLearninginvolvingTutorials,GroupDiscussions,Assignments,FieldWork; P
Practicals, Lab. work, Project;
CCore;
CBSChoiceBasedSubject; 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 AnalysisandPharmacology.EachBranchofSpecializationwillalsohavetwoCoresubjectsintheBranch of Specialization and two Choice Based Subjects that may be selected from the List of Choice Based Subjects specified in the Syllabus.

M.Pharm.SemesterIIIandSemesterIV:ALLBRANCHESOF STUDY
TotalCredits:SemesterIII–24(MPH_C_301_D),SemesterIV-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.Thetitle ofthethesisshouldbecommunicatedtothe Chairman ofthe Board of Studies beforethe commencementofSem.III.Requestforchangeinthetitleofthethesis,atalatertime,shouldhaveavalid reason and will be considered under the existing rules for title change (minor or major). Any request for changeintitleshouldbecommunicatedtotheChairmanoftheBoardofStudiesbythestudentthroughthe Research Guide and forwarded by the Principal.

Thestudentisexpectedtoworkaminimumof40hrs/weekinResearchtobeentitledfor24Credits eachinSemesterIIIandIV.TheGuidingTeacher(ResearchSupervisor)willsignastatementtothiseffect 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 andwillbeassessedbesidesothersbytheHeadoftheDepartment,theGuideandthePrincipal.AStatement 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 researchjournalsbeforesubmissionofthethesis.Weightageinevaluationofthethesis(videinfra)willbe 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/RegulatoryAuthority. The time betweensubmissionof synopsis andthesis shouldbeatleast one month.

Anylatesubmissionofsynopsisorthesiswillresultinthestudentrequiringtokeeptermsfor thenextsemesterandanysubsequentsemester/s(withpaymentofallapplicablefees)tillthestudent 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 begivenarea)LiteratureSurvey(8marks)b)Presentation(5marks)c)Methodology(7marks)d)Results andDiscussion(10marks)ande)Viva-voce(10marks).Thismakesatotalof40markstobegivenbythe guidingteacherandanother40markswillbeawardedbytheexternalexaminer,whichmakesatotalof80 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 showshowmarksaretobeawardedforthereviewpaperandtheoriginalpublication.Ifatthetimeofthe

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 teacherand the external examiner accordingto the followingtable.Forjournalswhose impactfactors are not listed in Scopus Index, but nevertheless are journals approved by UGC, a standard 3 marks may be awarded to the student.

Impactfactor(IF)oftheJournal(asperScopusIndex)	**Marks**
IFbelow1	3
IFabove1andupto 2	5
IFfactorabove2upto3	7
IFfactorabove3	10

Thesemarkswillbeallottedtothecoursedesignatedas**MPH_C_301_D+MPH_C_401_Dfora 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

TotalCreditsforM.Pharm:
SemesterI-24+SemesterII-24+SemesterIII- 24+SemesterIV-24=96credits

SEMESTERI

ALLBRANCHES

MPH_C_101_T-ModernPharmaceuticalandMedicinalChemistry(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

M. PharmFirst Year,Semester I **MPH_C_101_TModern Pharmaceutical and Medicinal Chemistry**			
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_101_T CO1	Understand the principles of identification and modification of lead molecule.	1	2
MPH_C_101_T CO2	Understand classification of the receptors, types of agonist and antagonists and interpret the outcome of ligand receptor interactions.	2	3
MPH_C_101_TCO3	Understand prodrug approach for improving PK/PD properties of drug.	3	3
MPH_C_101_T	Understand Phase I and Phase II metabolic	4	4

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

Mapping COwithPO

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

Unit	CourseContent(Topics)	Hours
1	**Drug Discovery**	**5**
1.1	Historicalperspective	1
1.2	Lead Discovery	1
1.3	LeadModification–identificationofthepharmacophore,functionalgroup modification,privilegedstructuresanddrug-likemolecules,modificationstoincrease potencyandthetherapeuticindex,modificationstoincreaseoralbioavailability	3
2	**Receptors**	**10**
2.1	Basicligandconcepts–agonist,antagonist,partialagonist,inverseagonist,efficiency and potency	1
2.2	Interactions(Forces)involvedindrug-receptorcomplexes	2
2.3	Receptortheories–occupancytheory,ratetheoryandactivationtheory	1
2.4	Receptorclassification–thefoursuperfamilies	2
2.5	Receptorbindingassays –measurementofK_d,B_{max}andIC_{50}	2
2.6	Topographicalandstereochemicalconsiderationsindrug–receptorinteractions	2
3	**ProdrugsandDrugDelivery Systems**	**13**
3.1	Enzyme activation of drugs, utility of prodrugs – aqueous solubility, absorption and distribution,sitespecificity,instability,toxicity,poorpatientacceptability, formulationproblems.	2
3.2	Carrier-linked prodrugs – carrier linkages for variousfunctional groups, carrier-linked bipartite prodrugs, macromolecular drug carrier systems, tripartite prodrugs, mutual prodrugs, bioprecursor prodrugs (hydrolytic activation, elimination activation, oxidativeactivation,reductiveactivation,nucleotideactivation,phosphorylation activation,sulfationactivationanddecarboxylationactivation).	6

3.1 3.2	*Self-studyofspecific examplesofdrugs thathave been converted to prodrugs for solvingproblemsrelatedtoADMEandtheirreleasemechanisms.Self-studyof prodrugsinvolvingspecifictissuetargetingorspecificactivationatthetargettissue.*	*5*
4	**Drug Metabolism**	**18**
4.1	Introductiontoxenobiotic/drugmetabolismanditsrelationtootherdefense systems (Physicalbarriers,excretion,immunesystem).	0.5
4.2	Types of reactions (I and II), consequences of drug metabolism (DM) [inactivation, bioactivation,prodrugs],organsofDM,localizationofdrugmetabolizingenzymes, factorsaffectingdrugmetabolism.	0.5
4.3	CytochromeP450s:Introductiontothefamilyofenzymes,theirclassificationand nomenclature.	1
4.4	CYP450catalyticcycle,differenttypesofreactionscatalyzedbyCYP450sandthe mechanismsof catalysis.	4
4.4	HumanCYP450sinvolvedinDM,theirdistributionandproperties,typicalsubstrates, specificprobesubstrates,specificinhibitors,inductionofCYPsandspecificinducers	2
4.5	Discussionofglucuronosyltransferases,sulfotransferases,glutathioneS-transferases, N-acetyl transferases,andFMO [on lines similartothatspecified forCYPsaslisted above].	4
4.5	*Self-studyofalcohol/aldehydedehydrogenases,xanthineandaldehydeoxidase, epoxidehydrolase,esterases,azoandnitroreductases(reactionscatalyzedbethese enzymes, mechanisms of the reactions, typical substrates/inhibitors/inducers)*	*6*
5	**Enzymes**	**14**
5.1	Introduction to enzymes, binding site, specificity of enzyme catalyzed reactions and rateacceleration,MichaelisMentenkineticsandmethodsforplottingenzymekinetic data	4
5.2	Mechanismsofenzymecatalysis–covalentcatalysis,acid-basecatalysis, electrostaticcatalysis,someexamplesofthemechanismsofenzymecatalysis	2
5.3	Coenzyme catalysis – pyridoxal 5'-phosphate (racemases, decarboxylases, aminotransferases), nicotinamide and flavin (two-electron mechanism, one-electron mechanismandhydridetransfers),folicacidandthiamine(onecarbontransfer reactions).	4
5.1	*Self-studyofHanesplot,Cornish-EisenthalBowdenplot*	*1*
5.2	*Self-studyofrolesofcoenzymes–biotin,coenzymeA,cyanocobolamine,vitaminK*	*3*
	Total	**60**

Books(latesteditionstobeadopted)

1. TheOrganicChemistryofDrugDesignandDrugAction,SilvermanR.B.,AcademicPress.
2. Textbook of Drug Design and Discovery, Eds. Krogsgaard-Larsen P., Liljefors T., Madsen U.,Taylor & Francis.
3. Lehninger–PrinicplesofBiochemistry.
4. MedicinalChemistry:AnIntroduction,ThomasG,Wiley.
5. DrugDiscovery–AHistory,SneaderW,JohnWiley&Sons,Ltd.
6. ComprehensiveMedicinalChemistry,SeriesEd.,HanschC.,PergamonPress.
7. WilsonandGisvold's,TextbookofOrganicMedicinalandPharmaceuticalChemistry,Lippincott-Raven
8. Foye'sPrinciplesofMedicinalChemistry,LippincottWilliamsandWilkins.
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. PharmaceuticalProfilinginDrugDiscoveryforLeadSelection,BorchardtRT,KernsEH,Lipinski CA, Thakker DR and Wang B, AAPS Press
11. DrugMetabolism–CurrentConcepts,IonescuCandCairaMR,SpringerInternational Edition

12. HandbookofDrugMetabolism,WoolfTF,MarcelDekker

MPH_C_102_T-ModernPharmaceutics(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.

M. PharmFirst Year,Semester I MPH_C_102_T **Modern Pharmaceutics (THEORY-60 hours)**			
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_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	**CourseContents(Topics)**	**Hours**
1	**Drug Stability:**	**9**
1.1	Importanceandneedforstabilitytesting	1
1.2	Revisionofdegradationpathways,kinetics,physicalstability	2
1.3	SolutionandSolid- statestability,pHstabilityprofiles,vandugraphs,package evaluation,ICHguidelines,statisticalaspectsinderivationofshelflife.	3
1.2	*Self-study-Calculationsforshelflifebasedondegradationkinetics*	*3*
2	**SolubilizationandDissolution:**	**14**
2.1	ImportanceofaqueoussolubilityofdrugsparticularlyNCEs,surfactantsystemsand phasediagrams,polymericsurfactants,cosolvents,complexation,solidstatemanipulations, cyclodextrins, drug derivatization, salt screening.	5
2.2	Revision of equations of dissolution and factors affecting dissolution, intrinsic solubilityand dissolutionrate,validationof testing, different equipment (emphasis on USPapparatus4),DissolutionofTDDS,particulates,gels&ointments,comparisonof profiles by f2 analysis, development of dissolution method, relevance of dissolution testinginANDAs,bio-relevantmedia,BCSclassification,IVIVC-studydesignand interpretation	5
2.3	*Self-study-Calculationsbasedonvarioussolubilityparametersandequationsof dissolution.Pharmacopoeialdissolutionapparatus,datatreatmentofdissolution profiles.*	*4*
3	**Excipientsandintroductiontopolymers:**	**7**
3.1	Roleofexcipients,purity,safetyandtoxicitywithreferencetoroutesofexposure-oral, inhalational,parenteral,others;regulatoryaspects,riskassessments,Harmonizationof excipient standards like residual solvents class 1,2,3.	2
3.2	Differentclassesof excipients-surfactants,special lipids,superdisintegrants, gelling agents,colorsandflavors,sweeteningagents,co-processedexcipients.	2
3.3	Definitionofpolymers,classification;conceptofpropertiesusedincharacterization, methodsofpolymerization,biocompatibilityevaluation,applications	2
3.4	*Self-study:sourcesandbrandnamesofvariousexcipients*	*1*
4	**OptimizationTechniques:**	**8**
4.1	Definition,Need,Advantages,descriptionoftermssuchasindependentvariable, responseparameters,responsesurface,contourplots,polynomialequations	2
4.2	Simplexandfactorialdesignsinoptimization	3
4.3	ApplicationofoptimizationtechniquesinQbDinproduct development	1
4.5	*Self-study:Placket-Burmandesign,centralcompositedesigns*	2

5	**Preformulation:**	**12**
5.1	ScopeofPreformulation-Role&importanceinNewDrugDiscovery&Approval process-Leadoptimization,StepsinDesigningthepreformulationevaluationofa new drug,criticalissuesandproblems/constraints	3
5.2	KeyAreasinPreformulationresearch-BulkCharacterization,SolubilityAnalysis, StabilityAnalysis,Compatibilitywithcommonexcipients	4
5.3	PreformulationaspectsforTablets,Injectables,Liquidpreparations,Protein&peptide drugs.	3
5.4	*Self-study:casestudyofdrugexhibitingvariouspolymorphicforms,drugexcipient compatibility*	*2*
6	**PowderTechnology(Micromeritics):**	**10**
6.1	Revisionoffollowingtopics: • Importantdefinitions&Units • Importanceofparticlesizeinpharmaceuticaldevelopment. • Fundamental&derivedpropertiesof powders • Particlesizereduction–comminutionmechanisms& equipment • Methodsofparticlesizedetermination(emphasisonbasicprinciples&interpretation of data)	2
6.2	**Comminution-**Theoryofcomminution,millingrate(variousmathematical relationships),conceptofmilling/grindingindex,energyforcomminution,distribution and limit of comminution	2
6.3	**Compaction of powders**- definitions of compression & consolidation, deformation mechanisms of matter, steps in compaction of tablets (in detail), theoretical aspects-Force Volume relationships/porosity –pressure equations (Heckel's Law & equation), Granulation of powders –theory, Effect of compaction pressure on various tablet properties,Energyforcompaction&effectoflubricationofgranules,instrumentation oftabletpresses(principles)	3
6.4	*Self-study:casestudiesoncompactionbehavioroftwo excipients*	*3*
	Total	**60**

Books(latesteditionstobeadopted)

1. DrugStabilityPrinciplesandPracticesbyCarstensenJ,MarcelDekker.
2. PharmaceuticalStresstestingbyBaertschiSW,TaylorandFrancis.
3. PharmaceuticalcharacterisationofPharmaceuticalSolidsbyBrittainHG,MarcelDekker.
4. PreformulationinSolidDosageFormDevelopmentbyAdeyeyeMC,BrittainHG,Informa Healthcare.
5. Dissolution,BioavailabilityandBioequivalencebyAbdouHM,EdA.Gennaro,B.Migdalof,Mack Printing Company.
6. PharmaceuticalBioequivalencebyWellingPG,FrancisLST,DigheSV,MarcelDekker, Inc.
7. PharmaceuticalDissolutionTestingbyBanakerU,MarcelDekker.
8. ExcipienttoxicityandsafetybyWeinerML,KotkoskiLA.
9. Martin'sPhysicalPharmacyandPharmaceuticalSciences,bySinkoPJ,EdLea&Feiger,Lippincott Williams & Wilkins.
10. ModernPharmaceuticsbyBankerGS,EdBankerGS&RhodesCT, MarcelDekker
11. PharmaceuticalStatisticsbyBoltonS,MarcelDeckker.
12. TheTheoryandPracticeofIndustrialPharmacybyLachmanL,LiebermanHA,KanigJL, Varghese Publishing House.
13. PharmaceuticalDosageForms:Tablets,UnitOperationsandMechanicalPropertiesEdAugsburger LL,

Hoag SW, Informa Healthcare USA, Inc.

14. TechniquesofSolubilizationofDrugsbyYalkowskySH, Marcel Dekker.
15. PharmaceuticalDissolutionTestingbyDressmanJ.EdDressmanJ,KremmerJ,Tylor&Francis
16. ControlledDrugDelivery:ClinicalApplications,byBrukSD,CRCPressInc.
17. HandbookofPharmaceuticalGranulationTechnologybyParikhDM,Informahealthcare.
18. PharmaceuticalPowderCompactionTechnologybyAlderbornG,NystromC,Marcel Dekker,

MPH_C_103_T-ModernPharmacology(4h/wk)

CourseObjectives:

This subject is intended to impart fundamental knowledge on molecular level physiological andpathological changes underlying several complex diseases, with an emphasis on the knowledge ofapoptosisandimmunopharmacology.Additionally,itwillfocusonthepharmacokineticandpharmacodynamicaspectsof drugin advancedlevel.

CourseOutcomes(CO):

M.Pharm FirstYear,SemesterI **MPH_C_103_T ModernPharmacology(Theory4h/wk)**			
Course code &COnumber	***At the successful completion of the course,thelearners will beable to:***	***Syllabus Unitno.***	***Up toBloom's level***
MPH_C_103_T CO1	Comprehendpharmacokineticprinciplesofdrugaction alongwiththedrugtransport mechanisms	1	2 &3
MPH_C_103_T_ CO2	Explain the mechanism of drug actions at cellular andmolecularlevelincludingtheroleofchannelsandfactors affectingdrugresponsiveness, mechanismsofdrug dependenceandmicrobial resistance.	2-5	2 &3
MPH_C_103_T _CO3	Appraise the recent advances in therapy and management ofcentral nervous system, cardiovascular system disorders anddiabetesmellitus.	6	2 &3
MPH_C_103_T _CO4	Understand and remember the concepts of molecularbiology, physiological, pathological, pharmacologicalimplicationsandtherapeuticprospectsofapoptosisand immunopharmacology	7 &8	2 &3

Mapping COwithPO

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	CourseContents(Topics)	Hours
1		**11**
1.1	**DrugAbsorption,distribution,metabolismandexcretion.**	5
1.2	• Mechanismsoftransportofdrugacross membranes. • Transportersinvolvedindrugabsorption,distributionandexcretionprocesses.	3
1.3	• *-Drugeffluxpathwaysandexperimentalmethodstostudydrugtransport.* • *Pharmacokineticfactorsaffectingdrugaction*	*3*
2	**Mechanismofdrug action**	**11**
2.1	Classificationofreceptorsanddescriptionofeachclasswithexamples.	1
2.2	• Signaltransductionmechanisms. • Detaileddescriptionofsignalmediationthroughcascadesafteradrenergic,muscarinic, GABAergic, insulin receptor stimulation.	4
2.3	Regulationofreceptors,theirinvolvementinvariousbiologicalprocessesincluding diseasesresultingfromreceptormalfunctionandtheirrolein pharmacotherapeutics.	1
2.4	Regulationofintracellularcalcium.	2
2.5	Pharmacodynamicinteractionsinamulticellularcontexte.g.Vascularwall (interactionsofphysiologicalligandsanddrugsinpathophysiologicalsetting).	1
2.6	*Self-study-Classificationandcharacterizationofreceptors-IUPHAR(e.g.5-HT receptors)*	*2*
3	**Functionsofsodiumandpotassiumchannelsandtherapeuticpotentialof channelmodulators.**	**3**
4	**Factorsaffectingdrugresponsiveness.** • Alterationinconcentrationofdrugthatreaches receptors. • Variationinconcentrationofanendogenousreceptorligand. • Alterationinnumberandfunctionofreceptors. • Clinicalselectivity:Beneficialvs.toxiceffectsofdrugs. a. Beneficialandtoxiceffectsmediatedbythesamereceptor-effector mechanism. b. Beneficial and toxic effects mediated by identical receptors but in different tissues or by different effector pathways. c. Beneficialandtoxiceffectsmediatedbydifferenttypesofreceptors. • Desensitization,tachyphylaxis. • Drugtolerance.	**3**
5	**Cellularandmolecularmechanismsof**	**4**
5.1	Drugdependence(e.g.Morphine).	
5.2	Microbialresistance.	
6	**Advancesintherapyof**	**18**
6.1	CNS:Depression,Alzheimer'sdisease,Psychosis,Parkinson'sdisease,Epilepsy.	5
6.2	CVS:Hypertension,AnginaPectoris,Congestivecardiacfailure,Arrhythmia.	5
6.3	ManagementofDiabetesMellitus.	2
7	**Apoptosis**	**4**

7.1	Molecularbiology,physiological,pharmacologicalimplicationsandtherapeutic prospects.	2
7.2	*Self-study–Interactionbetweencell,growthfactorsandextracellularmatrix.*	*2*
8	**Immunopharmacology**	**6**
8.1	Introductiontoimmunopharmacology,immunomodulators,Immunostimulantsand Immunosuppressants.	4
8.2	*Self-study-Autoimmunity*	*2*
	Total	**60**

Books(latesteditionstobeadopted).

1. RangandDale'spharmacology--ElsevierChurchill Livingston.
2. Lange'sBasicandclinicalpharmacology,KatzungB.G.MastersS.B.,TrevorA.G.TataMcGraw Hill.
3. GoodmannandGilman'spharmacologicalbasisoftherapeutics,EditedbyLaurenceBrunton, Bruce Chabner and Bjorn Knollman, McGraw Hill.
4. Pharmacologicalreviews,AnnualreviewsInc.
5. Advancesinpharmacology,AcademicPress.
6. TrendsinPharmacologicalSciences,CellPressElsevierPublication.

MPH_C_104_T-ModernAnalyticalTechniques(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, ^{1}H-NMR, ^{13}C-NMR, Mass spectrometry, chromatography, thermoanalytical techniques and Microscopy.

Course Outcomes (CO):

M. PharmFirst Year,Semester I **MPH_C_104_T Modern Analytical Techniques (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_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	scribe 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	alyze and interpret spectral data related to I.R, ^{1}H-NMR, ^{13}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

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	Coursecontents(Topics)	Hours
1	**MulticomponentanalysisofdrugsusingUV-Vis.spectroscopy:**	**6**
1.1	Simultaneousequationmethod,Absorbanceratiomethod,Differencespectroscopy, DerivativespectroscopyandIntroductiontoRatioderivativespectroscopy,	4
1.2	*Self-study-Pharmaceuticalapplicationsofabovetechniques(1.1)*	*2*
2	**F.T.I.Rspectroscopy:**	**6**
2.1	Constructionandworking,Newersamplingtechniques.	2
2.2	Interpretation of I.R. spectra in mid I.R. region (aliphatic and aromatic compounds forsimplecompoundssuchasamines,alcohols,amides,nitriles,ketones,aldehydes, esters,acids,nitroand anhydrides).	2
2.3	*Self-study-InterpretationofrecordedI.Rspectraofdrugsandorganiccompounds.*	*2*
3	**NMR spectroscopy:**	**10**
3.1	**^{1}H-NMR:** Basic theoretical concepts-*(Self-study-chemical shift, splitting pattern and coupling constant-2 hrs)*, Non-first order spectra, methods to make complex spectra simple, FT-NMR.	6
3.2	**^{13}C-NMR:** Theoryand Principles.	2
3.3	Applicationsof2D-NMR(COSY,HETCOR,DEPTandINEPT)	2
4	**Mass Spectrometry:**	**10**
4.1	Differentionisationtechniques-EI,CI,FD,FI,MALDI,API(APPI,APCI,ESI).	4
4.2	Differentanalyzers-Quadrupole,TOF,QTOF,Ioncyclotron,Iontrap.	2
4.3	Concepts for interpretation of mass spectra-Molecular ion peak, base peak, Isotope abundance,fragmentationpathways-αfission,βfission,MacLaffartyrearrangement, RetroDielsAlderrearrangement,Tandemmass(MS-MS).	4
5	***Terminologiesofchromatography:*** *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.*	***3***
6	**Advancesinchromatography:**	**11**
6.1	HPLC-Ionpairchromatography,Chiralchromatography (chiralstationary phases, useofmobilephaseadditives,precolumnderivatization,chiraldetectors),UPLC, *Self-study-AdvancesinHPLCdetectors(1hr).*	5

6.2	Supercriticalfluidchromatography-Principle,Instrumentationandpharmaceutical applications.	2
6.3	*Self-study-HPTLC-Principles,Instrumentationandapplicationsincluding fingerprintanalysis.*	1
6.4	Gaschromatography-Headspaceanalysis.	1
6.5	Gelelectrophoresis-Principle,Instrumentationandapplications.	2
7	**Hyphenatedtechniques:**	**4**
7.1	Interfacesusedinandapplications-GC-MS,LC-MS,LC-MS-MS	3
7.2	IntroductiontoLC-NMRandMALDI-TLC.	1
7	**Thermoanalyticaltechniques:** Principle,instrumentationandapplicationsincludinginterpretationofdatain pharmaceutical cases.	**5**
7.1	*Self-study-DSCandTGA*	*3*
7.2	TMA(Thermomechanicalanalysis).	1
7.3	*InterpretationofDSCandTGcurvesofsuitablecompounds/drugs(Self-study)*	1
8	**Microscopy: Principle, Instrumentation, sample preparation and pharmaceutical applications of -** ScanningElectronMicroscopy,TransmissionElectronMicroscopy,AtomicForce Microscopy,Confocalmicroscopy.	**5**
	Total	**60**

Books(latesteditionstobeadopted).

1. ChromatographicmethodsbyA.Braithwaite&S.J.Smith,KluwerAcademicpublishers, Netherlands, London, USA.
2. ThermalAnalysisofPharmaceuticalsbyCraig,Informa,CRCPress,IndianReprint.
3. PracticalPharmaceuticalChemistrybyA.H.BeckettandJ.B.Stenlake,CBSPublishersand Distributors.
4. SpectrometricIdentificationofOrganiccompoundsbyR.M.Silverstein,F.X.Webster,D.J. Kiemle, John Wiley & Sons
5. Applicationsofabsorptionspectroscopyoforganiccompoundsby JohnRobertDyer
6. OrganicSpectroscopybyWilliamKemp,PALGRAVE.
7. TextbookofPharmaceuticalAnalysisbyK.A.Connors,WileyIntersciencePublications.
8. IntroductiontoSpectroscopybyD.L.Pavia,G.M.Lampman&G.S.Kriz.
9. Remington:TheScience&PracticeofPharmacy,LippincotWilliams&Wilkins
10. IntroductiontoModernLiquidChromatographybyL.R.Snyder,J.J.Kirkland.
11. ChiralseparationsbyLiquidChromatographyandRelatedTechnologiesChromatographicScience Series by Hassan Y., Imran Ali.
12. StaticheadspacegaschromatographyTheory&practicebyBrunoKolb&L.S. Ettre.
13. EncyclopediaofChromatography,byJackCazes
14. OnlineLC-NMRandRelatedtechniquesbyKlasuAlbert,JohnWiley& Sons
15. LC-MS-APracticalUsersguide,byMarvinC.McMaster.

MPH_C_105_T–StudyofNaturalProducts (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	CourseContents(Topics)	Hours
1	**Introductiontostudyandresearchinherbaldrugs:**	**4**
1.1	Differentapproachestoplantselection,collectionandprocessingforherbaldrug research (Random selection, use of ethnobotanical information, use of chemotaxonomical classification etc).	2
1.2	Recent advances in concept of authentication & standardization- significance ofchemotaxonomyandDNAfingerprintingwithrespecttogeneexpressionfor secondarymetabolites.	2
2	**Extractionof phytochemicals**	**18**
2.1	Conceptsofextractionwithrespecttoactivityguidedfractionation&isolationof Markers/Biomarkers.	2
2.2	Recenttrendsinextraction,optimizationofextraction,andanalysisofthe phytochemicalsofdifferentclasses.	2
2.3	Detaildiscussionoflargescaleextractionofthefollowing:(1)Opiumalkaloids(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	*Self-study-preparationofflowchartanddiscussionofphysicochemicalprinciples foralllargescale extractions*	*5*
3	**Naturalproductsindrugdiscoveryanddrugdevelopment**	**8**
3.1	Roleofnaturalproductsasleadstothedesignofnewdrugswithcasehistorywith examplese.g.,artemisinin,taxane,camptothecinandafewothers.	2
3.2	Naturalproductsderivedcombinatoriallibrariesandtheirsignificanceindrugs discoveryprogram(HITSand leads).	2
3.3	*Self-study-Discussionofleadmoleculesindrugdiscovery*	*4*
4	**StudyoffollowingexcipientsofnaturaloriginNDDSwithrespecttosources, preparation,compositionandapplication**	**16**
4.1	Naturaldyes&colorants,sweeteners,flavorsandfragrant materials	8
4.2	Kappacarrageenans,galactomannans,glucomannans,cellulosederivatives,lecithin, & alginates.	4
4.3	*Self-study-Roleofexcipientsmentionedabove,informulations,withexamples*	*4*
5	**Applicationofimmunoglobulinsfromplantsourcesindiagnosisandtherapy.**	**4**
6	**Nutraceuticalsandtheirroleinhealthcare.**	**4**
6.1	Studyoffollowingclassesofherbswithtwoorthreesuitableexamplesofeach:(1) Antioxidants(2)Immunomodulators(3)Antihyperglycemics(4)Hepatoprotectives	4
7	**Statusof naturalproductsinofficialBooks(latesteditionstobe adopted)**	**6**
7.1	IntroductiontoHerbalPharmacopoeiasofdifferentcountries	2
7.2	MonographsofnaturalproductsinotherofficialBooks(latesteditionstobe adopted).	2
7.3	*Self-study-Discussionofmonographoffewsubstancesofnatural origin*	*2*
	Total	**60**

Books(latesteditionstobeadopted)

1. PharmacognosyPhytochemistry–MedicinalPlants-JeanBrunetton,LavoisierPublishing,Paris.
2. TextbookofPharmacognosy-TreaseandEvans-14th edition.Elsevierscience
3. TransgenicPlants-R.Ranjan-AgroBotanica,New Delhi.
4. TransgenicPlants-AProductionsystemforIndustrialandPharmaceuticalProteins.byMeran Owen, Jan Pen- John Wiley.
5. MedicinalPlant-TheirBioactivity,ScreeningandEvaluation-CSIR.
6. HomeopathicPharmacopoeiaofIndia-PublisherMinistryofHealth.
7. TheAyurvedicFormularyofPartI&II-PublisherMinistryof Health.
8. ChineseMateriaMedica-You-PingZhu-HarwoodAcademicPublishers.
9. IndiaMateriaMedica-NadkarniA.K.–BombayPopular Prakashan.
10. PhytochemicalMethods -J.B.Harbone-Chapmanandhall
11. Cultivation'sandProcessingofMedicinalPlants-Ed.byL.Hornok-JohnWiley.
12. IntroductiontoFlavanoids,BohrnBruceA,HerwoodAcademicPublishers.
13. CultivationandUtilizationofAromaticplants–Ed.ByAtalC.K.andKapurB.M., CSIR.
14. PlantTissueandCellCultureEd.H.E.Street–BlackwellScientificpublications.
15. Aflatoxin-LeoA.Goldblatt-AcademicPressNewYork.
16. MicrobialToxins-Ciejler,KadisandAjl,Academic press.
17. AntimicrobialinFood–AlfredLarryBranen,P.MichaelDavidsonPublishinghouse
18. ChemicalplantTaxonomyT.Swain,AcademicPress,London.
19. PlantTaxonomyandBiosystematics.C.AStace,EdwardArnold, London.
20. ModernmethodsofplantanalysisK.Paech,Springer-Verlag**.**
21. IndianHerbalPharmacopoeia.
22. IndianPharmacopoeia.
23. StandardizationofBotanicals,V.Rajpal,EasternPublishers,NewDelhi.
24. Natural Compounds as Drugs Editor- Frank Petersen, René Amstutz, Die Deutsche Bibliothek,Germany.
25. Quality controlofHerbal Drugs:AnApproach to evaluationofBotanicals, Pulok Mukherjee- Riddhi International
26. ChemicalsfromPlants:PerspectivesonPlantSecondaryProduct,Walton&Braun,Imperial College Press.
27. TowardsNaturalMedicineResearchinthe21stCenturyH. Ageta,N.AimietalExcerptaMedica, International Congress Series 1157.

MPH_C_106_T-BiostatisticsandResearchMethodology(4h/wk)

Unit	CourseContent(Topics)	Hours
	Biostatistics	
1	**CollectionandOrganizationofdata**	**8**
1.1	Graphicalandpictorialpresentationofdata	1
1.2	Measuresofcentraltendencyand dispersion	2
1.3	Varianceandstandarddeviation,relativeerror,coefficientofvariation,precisionand accuracy	2
1.4	Samplingtechniques:simplerandomsampling;stratification;estimationofthemean and proportion.	3
2	**Probability**	**6**
2.1	Definition.ConditionalprobabilityandBayes'theorem.Probabilitydistributions: binomial,multinomialandPoissondistributions. Normalandlognormal distributions. Use of normal distribution tables.	6
3	**Regression**	**6**
3.1	Linearregressionandcorrelation,curvilinearregression,methodofleastsquares, curvefitting,Fiduciallimits,probitandlogitanalysis	6
4	**Parametrictests**	**8**
4.1	Testinghypothesis,Typesoferror.Levelofsignificance.Significancetestsandp-value	4
4.2	Testsofsignificancebasedonnormaldistribution,testofsignificanceforcorrelation coefficients,confidenceintervalformeanandregressionproportion.	4
5	**Nonparametrictests**	**4**
5.1	Nonparametricprocedures:Chisquaregoodnessoffittest,signtest,Mann-Whitney test;Wilcoxonsignedranktest.	4
6	**Experimentaldesigns**	**8**
6.1	Randomization,completelyrandomized,randomizedblockandLatinsquaredesigns, factorialdesign,crossoverandparallel designs	4
6.2	StudentsshouldlearnuseofMinitab/RSoftwarefordatasummary,correlation, regressionanalysis,testofhypothesisandexperimentaldesign	4
	TotalBiostatistics	**40**
	ResearchMethodology	
7	**ObjectivesandpurposeofResearch**	**2**
7.1	Typesofresearch–Educational,clinical,experimental,basic,appliedandpatent-orientedresearch	2
8	**Literaturesurvey**	**2**
8.1	useoflibrary,Books(latesteditionstobeadopted)andjournals,eJournals,retrieving patentsandseekingreprints.	2
9	Methodsandtoolsusedinresearch • Qualitiativeandquantitativestudies • Simpledataorganization,descriptivedataanalysis • Limitationsandsourcesof errs • Inquiriesinformofquestionnaire,opinionaireorbyinterview	**6**

	• Statisticalanalysisofdataincludingvariance,standarddeviation,standard error,mean,student's*t*testandannova,correlationofdataandits interpretation, computer data analysis	
10	**Scientificwritingandreporting** • Differenttypesofresearchpapers • Titleandauthornames • Abstractandkeywords • Methodology	**3**
11	**ScientificPresentation** • Importance,typesanddifferentskills • Content,formatofmodel,introductionandending • Skillsfororalpresentationandtypesofvisualaids • Questionnaire	**3**
12	**PatentsandTrademarks** • TheIndianpatent system • Presentstatusofintellectualpropertyrights(IPR) • Productpatentsandprocesspatent • Requirementsandpreparationofpatentproposal • Registrationofpatentinforeigncountries	**4**
	TotalResearchMethodology	**20**
	Total(BiostatisticsandResearchMethodology)	**60**

Books(latesteditionstobeadopted)

1. PharmaceuticalStatistics–PracticalandClinicalApplications,BoltonS.,MarcelDekker,Inc.N., USA
2. Biostatistics:AFoundationforAnalysisinHealthSciences,WayneWDaniel,JohnWiley&Sons, Inc.
3. IntroductiontoStatisticalAnalysis,DixonW.J.andMasseyF.J.,McGrawHill,N.Y.,USA.
4. StatisticalMethods,SnedecorG.W.andCochranW.G.,IowaStateUniversityPress,Ames,Iowa.
5. ResearchinEducation,JohnWBestandJamesVKhan,PrenticeHallofIndiaPvt.Ltd.
6. EffectiveBusinessReportWriting,BrownLeland,PrenticeHallInc.India.
7. PresentationSkills,MichaelHatton,IndianSocietyforTechnicalEducation,NewDelhi.
8. ThesisandAssignmentwriting,AndersonJonathanandDurstonBerryH,WileyEasternLtd., Bangalore.
9. WritingaTechnicalPaper,DonaldHMenzel,McGrawHillBookCompany, Inc.,NewYork.

SEMESTERII

MPH_C_201_S SEMINAR

CourseObjectives: Thepurposeofseminaristoupskillstudentstodevelopeffectivescientific communication. The subject will enhance the self-learning ability to gain advanced knowledge of aparticulartopic while usingdifferent database and software

CourseOutcomes(CO):

Course code & COnumber	*At the successful completion of the course,thelearners willbeableto:*	*Upto Bloom' slevel*
CO1	Understandthegivenseminar reviewtopic.	**2**
CO2	Performtheliteraturesurveyusing(Pubmed,GoogleScholar,Scopus, WebofScienceetc)forthegivenseminar topic.	**2,3&4**
CO3	Compare and contrast the given data in different reports/ publishedresearchpapers.	**2&3**
CO4	Analyze and evaluate the data and facts based on the results obtained inthereportedresearchandreviewpapersandotherliteraturesources relatedtoseminartopic.	**2&3**
CO5	Createthereport ongivenseminar topicusingvariousICTand plagiarismcheckingtoolsforframinganddesigning.	**2**
CO6	Comprehendtheuseandsignificanceofstatistical toolsindata analysis, evaluation and presentation while performing literature surveyandwhile draftingthe seminarreport.	**1&3**

Mapping COwithPO

CO	PO1	PO2	PO3	PO4	PO5	PO6
01	**1**	**1**	**3**		**3**	
02	**1**	**1**	**3**		**3**	
03	**1**	**1**	**3**		**3**	
04	**1**	**1**	**3**		**3**	
05	**1**	**1**	**3**		**3**	
06	**1**	**1**		**3**	**3**	

MPH_C_299_L-ExperimentalTechniquesinPharmaceuticalSciences(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**of8 exercises inthesyllabusof aparticularbranchshouldbecompleted.

1. PharmaceuticalChemistry

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 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.

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.

M. PharmFirst Year,Semester II **MPH_C_299_LExperimental Techniques in Pharmaceutical Sciences**			
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_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	Performmolecular 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.		

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. Measurementof logP ofapoorlywatersoluble and ahighlywatersolubledrug
2. Determination of the $pK_a$of a drug (weak acid and weak base) bypotentiometric titration and/or by UV/visible spectroscopy
3. Measurement of $V_{max}$and $K_m$of a hydrolase enzyme (can use esterase, phosphatase, or lipase)Studentshouldlearntoplotdatabylinweaver BurkeandEadieHofsteemethods)
4. Estimationoftwodrugsbysimultaneousequationmethodandbyabsorbanceratiomethod. (preferably use combinations of drugs that are used as fixed drug combination)
5. Synthesisofsomeany2drugsinvolvingmultistep(atleastthreesteps)reactions.(Students shouldlearntomonitorthereactionbyTLC,separatethemainproductfromimpuritiesby column chromatography and learn use of IR and ^{1}H and ^{13}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 RPHPLC 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

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

Toimparttothelearnertheknowledgeof rationale design of drug delivery systems, mathematical approaches for data analysisandapplyittoformulation 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.

M. PharmFirst Year,Semester II

MPH_C_299_L – Experimental Techniques in Pharmaceutical Sciences **(Practical 6h/week)**

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_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

Course Code & CO number	***PO1***	***PO2***	***PO3***	***PO4***	***PO5***	***PO6***
MPH_C_299_L CO1	2	2	1	2	2	3
MPH_C_299_L CO2	2	2	1	3	2	3

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. StudyofdissolutionprofileofIRandERproducts.Mathematicaltreatmentofdatafor release kinetics and f1 and f2 analysis.
2. SimpleOptimizationdesign(formulationstudy/pH-stabilitystudy)
3. Designandevaluation of OrallyDisintegratingDrugDeliverySystem
4. Preparationandevaluationofmicrospheresforinhalationsystem
5. Preparationand evaluationoftransdermal/mucoadhesive/gastroretentive system
6. Constructingphasediagramforonesystemof oil,surfactant-cosurf, water
7. Designofonevesicularsystem -niosomes/liposomes systemscanbemade
8. Designoflipidparticulatesystem(nanosystemswithwax canbetried)

3. PharmacognosyandPhytochemistry

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. ExtractionandevaluationofMucilagefromsuitablesourcessuchasaloesorLeavesof *Annona squamosa*oranyothersuitable source.
2. Extractionandanalysisofalkaloidssuchaspurinealkaloidsand Tropaneorindolealkaloids form suitable natural sources.
3. Preparationandevaluationofextractofanthraquinoneglycosidesfrom*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. Extractionanddetectionofinulinfrom suitablesourcessuch aschicoryor Kuth.
6. Activityguided fractionation ofanyherb forits antimicrobial and/orantioxidant activity.
7. Preparationandevaluation ofanyherbal 'churna,dosageform (Situpaladiaor Triphala).
8. Extractionandanalysisofcarotenoidderivativesorflavonoidderivativesfromsuitable natural sources for each.

4. PharmaceuticalAnalysis

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.

Course Outcomes:

M. Pharm (Pharmaceutical Analysis)First Year, Semester II **MPH_C_299_L - Experimental Techniques in Pharmaceutical Sciences (6 h/wk)**			
Course code &CO number	***At the successful completion of the course, the learners will be able to:***	***SyllabusUnit no.***	***Up to Bloom's level***
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 (^{1}H NMR, ^{13}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 derivative spectroscopy.
4. Structural elucidation workshop: Interpretation of ^{1}HNMR, ^{13}CNMR, IR and Mass spectrometry of simple compounds (maximum 12 carbon atoms).
5. Standard calibration curve by UV spectroscopy at
   a. λmax
   b. λmax+10 nm
   c. λmax– 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/Investigations of 'Out of Specification' report for products and analytical methodology.
14. Qualifications 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 relatedtopre-clinicalstudies of drug screening.

M.Pharm FirstYear,SemesterI **MPH_E_299_T PharmacologyPracticals**			
Course code & COnumber	***At the successful completion of the course,thelearners willbeableto:***	***Syllabus Unitno.***	***Upto Bloom's level***
MPH_E_299_T_CO 1	Understandtheefficacyand potencyofanantagonist for a suitableisolatedtissue,andcalculatepA2values.	**1**	**2**
MPH_E_299_T_CO2	Determine and interpret the anti-oxidant effect of aparticulartherapeuticmoietyusingantioxidantscreeningassayslikeNOlevelsandSODactivity.	**1**	**2,3&4**
MPH_E_299_T_CO3	Comprehend the principle behind behavioural tests ofrodentslikeanti-catalepticactivity,musclerelaxantactivity,anti-anxietyactivity,etc.andapplythempractically	**2**	**2&3**
MPH_E_299_T_CO4	Understandandapplythe techniquesofdrugadministration and blood withdrawal as well as methods of easuringbloodpressure, pulse, etc..	**2**	**2&3**
MPH_E_299_T_CO5	Understand the various guidelines (ICH, OECD, ANDCCSEA)and applythemintheir day-to-daylaboratorycare andhandlingofanimals.	**3**	**2**
MPH_E_299_T_CO6	Comprehend techniques of high throughput screening likecell-basedassays, biochemicalassays,etc,andvariousalternativemethodsofscreeningpharmaceuticalcompoundsusingDrosophilaandZebrafishasreclinicalmodels.	**3**	**1&3**

Mapping COwithPO

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	

MPH_E_299_T_CO5	**1**	**1**			**3**	
MPH_E_299_T_CO6	**2**	**1**			**3**	

I) Experimentsto beperformed bystudents

1) Assayof antagonist usingasuitableisolated tissuepreparation
2) Determination of pA_2 values of antagonists using a suitable tissue preparation
3) Invitroantioxidant screeningassays(anytwo)e.g.DPPH, NO, superoxide.

II) Demonstrations

a. Experimentsonintact animalsto evaluate:

1) Anticatalepticactivity
2) Antianxietyactivity
3) Antiinflammatory/analgesicactivity
4) Musclerelaxantactivity

b. Techniquesofdrugadministration andblood withdrawal
c. Non-invasivemethodsofmeasuringbloodpressure, pulse,ECG etc.

III) Tutorials

1) Careand handlingofanimals
2) CPCSEA,OECD,ICHguidelinesinbrief
3) Use of alternative methods of screening (Types of drugs for which these models can be used)
   –Zebrafish
   -Drosophilia
4) Techniquesforhighthroughputscreening
   -Cellbased assays
   -Biochemicalassays
   -Radioligandbindingassays

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:PHARMACEUTICALCHEMISTRY
SEMSTER II CORE

MPH_C_202_T-AdvancedPharmaceuticalandMedicinalChemistry(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, α-helix, β-sheet, β-and γ-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

M. PharmFirst Year,Semester II **MPH_C_202_T - Advanced Pharmaceutical and Medicinal Chemistry**			
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_202_T CO1	Outline the classification of enzyme inhibitors and describe how inhibitors interact with enzymes.	1.4	2
MPH_C_202_T CO2	Able to interpret how inhibitors affect an enzyme's measured kinetic parameters	1.5	4
MPH_C_202_T CO3	Understand the basic principles of QSAR development & validation of QSAR models and predictions using QSAR models.	2.2	4
MPH_C_202_T	Understand the different types of peptidomimetic	3.2	4

CO4	structures and design mimetics of a given peptide sequence.		
MPH_C_202_TCO5	Understand the concept of antisense oligonucleotides and small interfering RNAs (siRNAs) & their structures.	4.2	2
MPH_C_202_TCO6	Understand the importance of Molecular Biology, Genetic engineering and Biotechnology in discovery and development.	5	3

Mapping COwithPO

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	CourseContent(Topics)	Hours
1	**EnzymeInhibition**	**16**
1.1	Coverageofbasicaspectsofenzymekinetics,catalysis,transition-statetheory.	2
1.2	DrugResistancethroughalterationsofdruguptake,overproductionofenzyme, alterationsoftheenzymeactivesite,overproductionofthesubstrateornewpathways for formation of the product	1
1.3	Drugsynergism,conceptsand mechanisms.	1
1.4	Reversible enzyme inhibitors – competitive inhibition, non-competitive inhibition, uncompetitiveinhibitionwithsuitableexamples.Detectionoftypeofinhibitionby suitableplottingmethods.ConceptsofIC_{50}andK_i.	4
1.5	Slow-tightbindinginhibitors,covalentenzymeinhibitorsandmechanism-based inhibitorswithsuitableexamples.Conceptof$K_{inact}$and$K_i$forirreversibleinhibitors	4
1.6	*Self-studyofspecificexamplesofdifferenttypesofinhibitorsandtheirdesign(some exampleslikeCOXinhibitors,ACEinhibitors,RTinhibitors,HIVproteaseinhibitors, aromataseinhibitors,DHFRinhibitors,viralDNApolymeraseinhibitors, thymidylatesynthaseinhibitorsandothers)*	*4*
2	**QSAR**	**14**
2.1	HistoricalAspects	1
2.2	ElectronicEffects-theHammettequation,lipophiliceffects,experimental measurementoflipophilicity,logPandlogD,effectofionizationonlogP,calculation oflogPandlogD,Stericeffects-theTaftequation	3

2.3	HanschAnalysis,Free-Wilsonmethod,Toplissoperationalscheme	2
2.4	Basics of regression analysis - linear and multilinear regression, introduction to PCA,PCR, PLS, ANN and GFA. Correlation coefficients (r2 and r2), F-test, standard error, validation methods like cross-validation by calculation of q2, boot-strap analysis and randomization. Application domain for predictions using a QSAR model.	6
2.5	Designoftrainingandtestsetsusingfactorialdesign	2
2.5	*Self-study –Differenttypesofdescriptorsreportedinliteraturethataccountfor the steric,electronicandlipophiliceffects.*	*2*
3	**PeptidesandPeptidomimetics**	**14**
3.1	Coverageofpeptidestructure,biosynthesisofpeptidesandsolid-phase/solution synthesisof peptides.	4
3.2	Designofpeptidomimeticsbymanipulationoftheaminoacids,modificationofthe peptide backbone, incorporating conformational constraints locally or globally, α-helix, β-sheet, β-and γ-turn mimetics	4
3.3	*Self-studyofexamplesofpeptidomimeticsforsomeenzymesandreceptorslikeACE, CCK,bradykinin*	*2*
4	**Antisensetherapeuticagents**	**6**
4.1	Historyand principles	2
4.2	DesignofantisenseoligonucleotidesandsmallinterferingRNAs(siRNAs)with someexamples	4
5	**MolecularBiology,GeneticengineeringandBiotechnology**inproductionof biologicalsasdrugs.	**6**
5.1	*Self-studyofbiotechnologybaseddrugs,vaccinesanddiagnosticagentswithrespect totheirbiologicalsource,theirdesignandthemechanismoftheiractions*	*4*
	Total	**60**

Books(latesteditionstobeadopted)

1. TheOrganicChemistryofDrugDesignandDrugAction,SilvermanR.B.,AcademicPress.
2. Textbook of Drug Design and Discovery, Eds. Krogsgaard-Larsen P., Liljefors T., Madsen U.,Taylor & Francis.
3. MedicinalChemistry:AnIntroduction,ThomasG,Wiley.
4. PeptideandProteinDesignforBiopharmaceuticalApplications,EdJensenK.J.,Ch.3Aspectsof Peptidomimetics by Maes V., Tourwé D., John Wiley & Sons, Ltd, Chichester, UK.
5. ComprehensiveMedicinalChemistry,SeriesEd.,HanschC.,PergamonPress.
6. BurgersMedicinalChemistry,DrugDiscoveryandDevelopment,Wiley.

MPH_C_203_T-AdvancedOrganicChemistry(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 auxillaries, 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 deconvolutio

Course Outcomes (CO):

M. PharmFirst Year,Semester II **MPH_C_203_T - Advanced Organic Chemistry**			
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_203_TCO1	Understand chemical catalysis, types of catalysts, and use of catalytic reactions while synthesizing drug intermediates.	2.1, 2.2	3
MPH_C_203_TCO2	Draw the schematic retrosynthetic pathway and analyze the retrosynthetic scheme for any given target molecule.	3.1	4
MPH_C_203_TCO3	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
MPH_C_203_TCO4	Apply the principle of combinatorial approach in the drug intermediate synthesis.	5	4
MPH_C_203_TCO5	Able to apply the concepts of chiral auxiliaries, enzymes, chiral solvents, chiral catalysts in asymmetric synthesis.	1.2	4

Mapping COwithPO

Course code & CO number	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
MPH_C_203_T	1	1	2	1	2	1

MPH_C_203_T	2	1	3	1	2	2
MPH_C_203_T	1	1	3	2	3	3
MPH_C_203_T	2	1	2	1	2	0
MPH_C_203_T	1	1	2	2	3	0

Unit	CourseContent(Topics)	Hours
1.0	**AdvancedStereochemistry**	**12**
1.1	*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 isomerismin acyclicsystems. Shapeofsixmemberedringsand effect ofsubstituents and reactivity*.	*2*
1.2	Chiralityinsystemslackingastereogeniccarbonatom	2
1.2.1	Pointchirality–tertiaryaminesand phosphines	1
1.2.2	Axialchirality–allenes,biphenylsandbinaphthyls	1
1.2.3	Helicalstructures–polynucleotides,polyaminoacids,biarylsandallenes	1
1.3	Methodsforestimatingratiosofstereoisomersinamixture,separationand identificationoftheindividualcomponentsbyNMRspectroscopy,X-ray crystallography.	1
1.4	Nucleophilicattackon acycliccarbonylcompounds–Cram'srule,Felkin-Ahnrule. Lockingeffectsinnucleophilicreactionsatcarbonyl groups	2
1.5	Stereochemistry of importantreactionsleading to formationofalkenes– Wittigand relatedreactions	2
2.0	**Catalysis&OrganometallicsinOrganicSynthesis**	**12**
2.1	Typesofcatalysis,heterogeneousandhomogenouscatalysis,advantagesand disadvantages,catalyticcycles	1
2.2	Heterogeneouscatalysis–preparation,characterization,kinetics,supportedcatalysts, catalystdeactivationandregeneration,someexamplesofheterogeneouscatalysis usedinsynthesisofdrugs.	1.5
2.3	Homogenous catalysis, hydrogenation, hydroformylation, hydrocyanation, Wilkinsoncatalysts,chiralligandsandchiralinduction,Ziegler-Nattacatalysts,some examples of homogenous catalysis used in synthesis of drugs	1.5
2.4	Phasetransfercatalysis -theoryandapplications	1.5
2.5	Introduction,Classificationoforganometalliccompoundsbasedonhapticityand polarityoftheM-Cbond.Nomenclatureandgeneralcharacters.Synthesis,stability anddecompositionpathways**.**	1.5

2.6	Transitionmetalπ-complexeswithunsaturatedorganicmolecules,carbonmonoxide, alkenes, alkynes, allyl, dienes, cyclopentadienyl, arene complexes, preparation, properties, nature of bonding and structural features, important reactions relating tonucleophilic attack on ligands and to organic synthesis. Basic organometallicreactionscoveringoxidativereactions,migratoryreactions,insertions,extrusion,additions,eliminations–theirmechanismsandstereochemistry.	3
2.7	*Self-study - Basic organometallic reactions covering oxidative reactions, migratory reactions,insertions,extrusion,additions,eliminations–theirmechanismsandstereochemistry*	2
3.0	**SynthonApproachand Applications**	**13**
3.1	Retrosynthesisanditsadvantages,rulesfordissectionofmolecules,meaningofthe term,disconnection,FGI,FGAandsynthons,guidelinesfortheorderofevents	1
3.2	C-Xdisconnections;C-Cdisconnections–alcoholsandcarbonylcompounds;1,2-, 1,3-,1,4-,1,5-,1,6-difunctionalizedcompounds	4
3.3	Strategiesforsynthesisofthree,four,fiveandsix-memberedrings	3
3.4	Strategiesforsynthesisofaromaticandsaturatedheterocycles	3
3.5	*Self-study–Strategiesforsynthesisofsaturated heterocycles.*	*2*
4.0	**AsymmetricSynthesis**	**6**
4.1	Introductionandneed;chiralsynthesisusingchiralpool,chiralauxiliaries,chiral catalysts	2
4.2	Enzymes,chiralsolventsandwholeorganisms	2
4.3	Analyticalmethodsofdeterminingpurityofstereoisomers	1
4.4	*Self-study-Applicationsinindustry*	*1*
5.0	**CombinatorialChemistry**	**11**
5.1	Introduction,advantagesandplanningcombinatorialsynthesis	1
5.2	Solidphaseandsolutionphase synthesis	5
5.3	Supports,linkers,andtags	1
5.4	Deconvolutionanditeration	1
5.5	Parallelsynthesis,multistep–convergentandsequentialsynthesis	2
5.6	*Self-study–Multicomponentreactions*	*1*
6.0	**Green Chemistry**	**5**
6.1	History,needandthegoalsofgreenchemistry	1
6.2	Basic principles of green chemistry, illustrated with examples to discuss issues of prevention of waste or minimize by-products, atomeconomy, prevent and minimize formation of hazardous or toxic products, design of safer chemical equivalents, selection of appropriate solvents, media, separation agents, improve economy and efficiencyofreactions,byuseofmicrowaves,ultrasoundetc.,anduseofrenewable startingmaterials.	3
6.3	*Self-study–ReactionscarriedoutusingMicrowaveand ultrasound.*	*2*
	Total	**60**

Books(latesteditionstobeadopted)

1. Stereochemistryofcarboncompounds,ElielE,WilenSH,MandenLN, Wiley.
2. StereochemistryofOrganicCompounds,NasipuriD,WileyEastern.
3. AdvancedOrganicChemistry,CareyFAandSundbergRJ,PartAandB, Springer
4. IntroductiontoGreenChemistry,RyanM.A.,TinnesandM.,AmericanChemicalSociety(Washington).
5. Combinatorial Chemistry; Synthesis and Application, Eds., Wilson S. R. Czarnik A. W., Wiley: New York.
6. OrganicChemistry,ClaydenJ,GreevesN,WarrenS,WothersP,OxfordUniversityPress.
7. StereoselectiveSynthesis,AtkinsonRS,JohnWiley&Sons.

8. TheOrganometallicChemistryoftheTransitionMetals,CrabtreeR.H.,JohnWiley
9. Transition Metals in Synthesis of Complex Organic Molecules, Hegedus L., University Science Books (latest editions to be adopted).
10. HomogenousTransitionMetalCatalysis,MastersC.,Chapman&Hall.
11. PrinciplesandPracticeofHeterogenousCatalysis,ThomasJ.M.,ThomasM.J.,John Wiley
12. PrinciplesofAsymmetricSynthesis,GawleyR.E.,AubreyJ,Elsevier.
13. Greene'sProtectiveGroupsinOrganicSynthesis,Wuts,P.G.M.,GreenT.W.,Wiley
14. OrganicSynthesis–TheDisconnectionApproach,Stuart,W.,Wiley.
15. ThelogicofchemicalsynthesisCoreyEJ andChengX-M,JohnWileyandSons.

BRANCH:PHARMACEUTICS
SEMESTER II CORE

MPH_C_204_T-AdvancedPharmaceutics-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.

M. PharmFirst Year,Semester II MPH_C_204_T **Advanced Pharmaceutics I (THEORY-60 hours)**			
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_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.		

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	CourseContents(Topics)	Hours
1	**Solids–oralSR system**	**13**
1.1	*Self-study-OverviewofSingleoralunitSRsystems.*	*3*
1.2	*Self-study-StructureandphysiologyofGIT.*	*1*
1.3	MechanismofRelease&Releasekineticequations. Types–Diffusioncontrolled,Dissolutioncontrolled,Reservoir,Matrix, Osmotic systems, Ion exchange systems Mucosaldrugdeliverysystems-buccal,gingival, sublingual.	4
1.4	Multiparticulate systems-pelletization (emphasis on extrusion and spheronization).Orodispersiblesystems.PulsatileDrugdeliverysystems.	5
2	**ParenteralSRsystems**	**12**
2.1	Needandconcept,routesemployed	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(indetail-concept,propertiesdesired,variousapproaches),prodrugs (chemicalmodifications),infusionpumps.	6
2.3	*Self-study-Biopharmaceuticalaspects,Sterilization&stabilityissues*	*2*
2.4	Characterization-specialemphasisonreleasestudies	1
2.5	IssuesrelatedtoSafety,Toxicity&TissueInjury	2
3	**SpecializedEmulsions**	**9**
3.1	Microemulsions,Multipleemulsions,Self EmulsifyingDrugDeliverysystems &SMEDDS;Formulationandphasebehavior;Preparation&Characterization; BioavailabityAspects;Applications.	6
3.2	*Self-study-TheoriesofEmulsification,Factorsinfluencingtypeofemulsion formed.*	*3*
4	**Gastro-retentiveDrugDeliverySystems**	**8**
4.1	*Self-study–Introduction;conceptofabsorptionwindow;needforGRDDS, gastric motility; principles of Gastro-retention; Factors controlling performance of GRDDS.*	*3*

4.2	DifferentApproaches-Highdensity systems,floating systems,muco-adhesive systems,Expandablesystems,Magneticsystems,SuperporousHydrogels	4
4.3	Evaluation.	1
5	**Oculardrugdeliverysystems.**	**7**
5.1	*Self-study-Structureandphysiologyofeye;Drugabsorptionanddispositionin the eye.*	*2*
5.2	Methodstoprolongoculardrugresidencewithemphasisonmucoadhesive systems.	1
5.3	Intraocularinserts;Nonerodibleinserts/Erodibleinserts. Novelophthalmicdrugdeliverysystems,Nanoparticles,liposomesand prodrugs. Ocular penetration enhancers.	4
6	**TransdermalDrugDeliverySystems**	**7**
6.1	*Self-study-Structureandphysiologyofskin.*	*1*
6.2	Principlesofskinpermeation. Kineticsofskinpermeation&penetrationenhancers Types (Gels, Patches/films) Pressuresensitiveadhesives.	3
6.3	Development&evaluation–*invitro,in vivo.*	1
6.4	Iontophoresis.	1
6.5	Recentadvances–useofmicroneedlesintransdermaldrugdelivery.	1
7	**IntroductiontoPharmaceuticalProcessingDevelopment. (AsperICH guidelines)**	**4**
7.1	ElementsinPharmaceuticaldevelopment • Targetproductprofile • CriticalQualityAttributes. • LinkingMaterialAttributes&processparameterstoCQA'sRisk Assessment • Designspace • ControlStrategy • ProductLifecyclemanagement&continualimprovement.	3
7.2	Submission of Pharmaceutical Development and related information in CTD format. *RelevantExamples*.	1
	Total	**60**

Books(latesteditionstobeadopted)

1. TargetedandControlledDrugDelivery:NovelCarrierSystemsbyVyasSP,KharRK,CBSPublishers and Distributors.
2. ControlledandNovelDrugDeliverybyJainNK,CBSPublishersand Distributors
3. ControlledDrugDelivery:FundamentalsandApplicationsbyRobinsonJR,LeeVHL, Dekker
4. NovelDrugDeliverySystembyChienYW,Informa Healthcare.
5. ProgressinControlledandNovelDrugDeliverySystemsbyJainNK,CBSPublishersandDistributors
6. OphthalmicDrugDeliverySystems,MitraAK,DrugsandPharmaceuticalSciencesSeries.
7. Polymericdrugdeliverysystem,KwonGS,MarcelDekker.
8. NanoparticulateDrugDeliverySystembyThassuD,DeleersM,PathakY,MarcelDekker.
9. ControlledDrugDelivery-ChallengesandStrategiesbyParkK,AmericanChemical Society.
10. ColloidalDrugDeliverySystembyKreuterJ,MarcelDekker.

12. www.ich.org
13. PharmaceuticalDosageForms:DisperseSystemsbyLiebermanHA,RiegerMM,BankerGS,Marcel Dekker.
14. PharmaceuticalEmulsionsandSuspensionsbyNielloudF,Marti-MestresG,Marcel Dekker.
15. ControlledReleaseSystemsFabricationTechnologybyDeanSTH,CRCPress.
16. BioadhesiveDrugDeliverySystemsbyMathiowitz. E,ChickeringDE,LehrCM,Marcel Dekker.
17. PharmaceuticalSkinPenetrationEnhancementbyWalters.KA,HadgraftJ,MarcelDekker.
18. PercutaneousAbsorptionbyBronaughRL,MaibachHI,TaylorandFrancis
19. TransdermalControlledSystemicMedicationbyChienYW,MarcelDekker
20. OralMucosalDrugDeliverybyRathboneMJ,MarcelDekker.
21. Modified Release Drug Delivery Technology by Rathbone MJ, Hadgraft J, Roberts MS, Lane ME, Informa Healthcare.
22. PharmaceuticalPelletizationTechnology,Ghebre-sellassie.I,MarcelDekker

MPH_C_205_T-AdvancedPharmaceutics-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..

M. PharmFirst Year,Semester II MPH_C_205_T Advanced Pharmaceutics – II **(THEORY-60 hours)**			
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_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	CourseContents(Topics)	Hours
1	**Targetedsystems:-ActiveandPassiveapproaches:**	**6**
1.1	Tumourtargeting,Moleculartargetsforcellulartargeting,Ligandsasdeliveryand targetingtools,Conceptofreceptormediatedendocytosis.	3
1.2	*Self-study:Conceptsandrationaleoftargeting:activeandpassivetargeting, Cellularbiochemistryandmolecularevents indrugtargeting*	*3*
2	**Pulmonaryandnasaldrugdeliverysystems:**	**14**
2.1	Nasaldrugdelivery: Nasaladministration–dosageforms,Strategiesforenhancementinnasalabsorption, Animal models for nasal absorption studies, Nasal preparations for systemic effect	4
2.2	Pulmonarydrugdelivery: Factorsaffectingparticledispositioninthelungs,Dosageformsforpulmonarydrug delivery(Nebulizer,Metereddoseinhalers,Drypowder inhalers),Drugtargetingto the respiratory tract, Pulmonary receptor targeting	7.
2.3	*Self-study:Anatomyandphysiologyoftherespiratorysystem,Airwayphysiology anddispositionpatterns*	*3*
3	**Proteinandpeptidedrugdeliverysystems:**	**11**
3.1	Physicalandchemicalstabilityaspects,proteindegradationpathways,techniquesof stabilizationofproteinsandpeptides,barrierstotransportandapproachestocircumvent metabolic barriers.	4
3.2	Generalproteinformulationanddeliverysystemstrategies.	1
3.3	Routesfordeliveryofproteinsandpeptideswithemphasisonoralandmucosal delivery,pulmonarydelivery,nasaldeliveryandparenteraldelivery	3
3.4	*Self-study:Structureofproteinsandpeptides,analysisofproteinsandpeptides.*	*3*
4	**Colloidaldrugdeliverysystems:**	**22**
	NOTE that for every colloidal drug delivery system the following aspects to be included: Introduction,comparisonwithothercolloidaldrugcarriers,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. Thefollowingdrugdeliverysystemtobestudiedwithrespecttheseaspects–	
4.1	Liposomes	5
4.2	Niosomes	2

4.3	Nanoparticles	5
4.4	Polymericmicelles	3
4.5	SolidLipid nanoparticles.	4
4.6	*Self-study:Anoverviewcolloidal DrugDeliverywithrespecttoPhysicochemical& Biopharmaceuticalaspects*	*3*
5	**Braintargeting:**	**7**
5.1	Introduction,TransportthroughBBB,Factorsaffectingdrugpermeationthrough BBB	1
5.2	Braindrugdeliverystrategies: • Invasive-Intracerebralimplants,Intraventricularinfusion,BBBdisruption • Non-invasivetechniques-Chemicalmethod,Colloidaldrugcarrier,receptor/ vector mediated approach. • Miscellaneoustechniques-Intranasaletc	3
5.3	*Self-study:Bloodbrainbarrier,CSFbarrier,limitationsinbrainuptakeofdrug, desiredphysicochemicalcharacteristicsofdrugs.*	*3*
	Total	**60**

Books(latesteditionstobeadopted)

1. Targetedandcontrolleddrugdelivery:NovelcarriersystemsbyS.PVyasandR.KKhar,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. RobinsonJ.RandLee-controlledandnoveldrugdelivery.
4. Controlleddrugdelivery:Conceptsandadvances,S.P.Vyas,R.K.Khar,VallabhPrakashan.
5. Chien -Y. W-Novel DrugDeliverySystem, Drugand pharmaceutical science series, New YorkInc, Marcell Dekker.
6. ControlledandnoveldrugdeliveryeditedbyN.K.Jain,CBSpublishersanddistributors PvtLtd.
7. Advancesinpharmaceuticalsciences –vol-1to5,byH.S.BeanandA.HBeckett.
8. GlenS.Kwon,Polymericdrugdeliverysystem-MarcellDekkerSeries
9. ThassuD"NanoparticulateDrugDeliverySystem"MarcellDekkerSeries.
10. ParkK,ControlDrugDelivery-ChallengesandStrategies,CRC,Washington DC
11. MacNallyE,ProteinFormulationandDelivery
12. KreuterJ,ColloidalDrugDeliverySystem,MarcellDekker,IncNewYork

BRANCH:PHARMACOLOGY
SEMESTER II CORE

MPH_C_206_T-AdvancedPharmacology(4h/wk)

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

CourseOutcomes (CO):

M.Pharm FirstYear,SemesterI **MPH_C_206_T AdvancedPharmacology (Theory4h/wk)**			
Course code & COnumber	***At the successful completion of the course,thelearners willbeableto:***	***Syllabus Unitno.***	***Up toBloom's level***
MPH_C_206_T_CO1	Explainthe variousstagesof drugdiscoveryand developmentincludingtechniquesofhighthroughputs creening	1 &2	2
MPH_C_206_T_CO2	Appreciatetheimportancetoxicitytestingandtheroleof ethicalandregulatoryrequirementsforthesame	3	2&3
MPH_C_206_T_CO3	Reflect on the importance of chronopharmacology intherapeuticsofdiseaserelatedtoGITandAsthma.	4	2&3
MPH_C_206_T_CO4	Reviewtheroleoftransporterproteins,stemcellsandothernove l drug targets; impact of inflammation mediators andproinflammatorycytokinesinmediatinginflammationin clinicalsettings	5-8	2&3
MPH_C_206_T_CO5	Comprehendtherapeuticpotentialandsignallingpathways of the target site, fundamentals of transporters and their roleinpharmacokinetics	6-7	2

Mapping COwithPO

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	CourseContents(Topics)	Hours.
1	**Generalaspectsof drugdiscoveryanddevelopment**	**2**
2	**HighThroughputScreening**	**6**
2.1	TechniquesforHighthroughputscreening. a. Cellbased assays b. Biochemicalassays. c. Radioligandbindingassays.	4
2.2	*Self-study-Importanceofpharmacokineticstudiesindrugdevelopment.*	2
3	ToxicityStudies	**8**
3.1	• Acute,subacuteandchronic toxicity • Safetypharmacologyevaluation. • Genetictoxicity,cytotoxicity,toxicogenomics	5
3.2	*Self-study-ScheduleY,OECD,ICHguidelinesfortoxicitystudiesbyvariousroutes.*	3
4	**IntroductiontoChronopharmacology**	**8**
4.1	• Circadianrhythm,BiologicalClock,Location,NeuroanatomyandNeurochemistry. • Rhythmsandpharmacokinetics.	5
4.2	*Self-study-RhythmsandtherapeuticsofdiseasesofGITandasthma.*	3
5	**StemCellsandTherapeuticapplications**	**3**
6	**Noveldrug targets**	**18**
6.1	Physiological functions, pharmacological implications and therapeutic potential of the following target sites: • Rhokinase(ROCK). • Phosphoinositide-3-Kinase.(PI3K). • Akt(ProteinkinaseB). • Caspases. • Proteases. • Poly(ADPribose)Polymerase(PARP). • Peroxisomeproliferatoractivatorreceptors(PPARα,γ).	15
6.2	*Self-study-BiologicalfunctionsofNitricoxide(NO)andtherapeuticpotentialof nitricoxidemodulators.*	3
7	**Transporterproteins**	**7**
7.1	• ClassificationandbiologyofATPbindingcassette(ABC)transportersuper family, Solute carrier transporter (SLC). • Multidrugresistanceproteins(MDR). • Cysticfibrosistransmembraneregulator(CFTR).	5
7.2	ABCtransportesinvolvedindrugabsorptiondistributionandexcretion.	2

8	**Role** of Cytokines, Prostaglandins, TNF- α, Bradykinin, Leukotrienes, PAF,Interferons andAdhesionmoleculesinvariousimmunologicaland inflammatorydisorders	**8**
	Total	**60**

Books(latesteditionstobeadopted)

1. RangandDale'sPharmacology,ElsevierChurchillLivingston.
2. Lange'sBasicandClinicalPharmacology,KatzungB.G.,MastersS.B.,TrevorA.G.,Tata McGraw Hill.
3. GoodmannandGilman'sPharmacologicalbasisoftherapeutics,EditedbyLaurenceBrunton, Bruce Chabner and Bjorn Knollman, McGraw Hill.
4. Pharmacologicalreviews,AnnualreviewsInc.
5. Advancesinpharmacology,AcademicPress.
6. TrendsinPharmacologicalSciences,CellPressElsevierPublication.

MPH_C_207_T-ClinicalResearchMethodology(4h/wk)

BasicCourse Objectives: This course will review the concepts that underlie successful clinical researchdesign,ethics,implementation, evaluation,reportingand theirsignificance.

CourseOutcomes(CO):

M.Pharm FirstYear,SemesterI **MPH_E_207_T ClinicalResearchMethodology(Theory4h/wk)**			
Course code &CO number	***At the successful completion of the course,thelearners willbeableto:***	***Syllabus Unitno.***	***Up toBloom's level***
MPH_E_207_T_CO1	Summarize the processes of drug discovery anddevelopment,includingvariousdocumentsrequired (Investigators Brochure (IB), Protocol and amendments inprotocol, Case report form (CRF), Informed consent form(ICF), Content of clinical study report (CSR) along with theregulatoryandethical requirementsforconductingclinical trialsinaccordancewithGCPprinciplesandScheduleY.	**1, 2 &3**	**2**
MPH_E_207_T_CO2	Understand and explain the responsibilities of key players(Sponsor, Investigator, Monitor, Auditor) and the role ofInstitutional Ethics Committee (IEC)/ Independent EthicsCommittee(IdEC)/Institutional ReviewBoard(IRB) involvedinclinicaltrials	**4&5**	**2&3**
MPH_E_207_T_CO3	**U**nderstand and appraise the role of clinical qualityassuranceandclinical datamanagement.	**6&7**	**1&2**
MPH_E_207_T_CO4	Infer the applications and importance ofpharmacoepidemiologyinhealthcare.	**8**	**2&3**
MPH_E_207_T_CO5	Comprehendtheroleofclinicalpharmacistinreporting, evaluation,monitoring,prevention,andmanagementofthead verse drugreactionsandapplythemtoday-to-daylife.	**9**	**2**
MPH_E_207_T_CO6	PredictandappraisetheapplicationsofPharmacoeconomics and Outcomes Research in health care and apply them inhealthcaremanagement.	**10**	**2&3**

Mapping COwithPO

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	CourseContents(Topics)	Hours.
1	**Clinicaltrials**	**14**
1.1	Introduction,drugdiscoveryand drugdevelopment.	10
1.2	Variousphasesofclinicaltrials.	
1.3	Studymethodology/designs,InclusionandExclusioncriteria,objectivesand endpoints(efficacyandsafety),Methodsofallocation,blindingandrandomization.	
1.4	Informedconsent process.	
1.5	Studymonitoringandits importance.	
1.6	Safetymonitoringinclinical trials.	
1.7	*Self-study-BA/BEstudies,Postmarketingstudies.*	4
2	**Documentsinclinicalstudy** Essential documents in clinical trial-Investigators Brochure (IB), Protocol and amendments in protocol, Case report form (CRF), Informed consent form (ICF), Content of clinical study report (CSR**).**	**4**
3	**Ethicalguidelinesinclinicalresearch**	**9**
3.1	History,ICH-GCPanditsprinciples,IndianGCP(CDSCOGuidelines),ICMR guidelines-EthicalguidelinesforBiomedicalResearchonhumansubjects2006, ScheduleY2005,USFDAguidelinesforIND,NDA,ANDAapplications.	6
3.2	Self-study:EMEAorganizationanditsfunctions,EUregulatoryguidelines.	3
4	**Rolesandresponsibility**ofvariousclinicaltrialpersonnelasperICH-GCP Sponsor,Investigator,Monitor,Auditors	**3**
5		**5**
5.1	**Institutional Ethics Committee** (IEC)/ Independent Ethics Committee (IdEC)/InstitutionalReviewBoard(IRB)	2
5.2	*Self-study-Ethicaltheories,IntegrityandMisconductinclinicalresearch.*	3
6	**RoleofQualityassurance**inclinicalresearch	**2**
7	**ClinicalDataManagement**andReport Writing	**3**
8	**Pharmacoepidemiology** Types, methods, andfactors affectingdrugutilization, applications of pharmacoepidemiology in health care and rational use of drugs	**5**
9	**Pharmacovigilance**	**10**

9.1	Definition, scope and aims of pharmacovigilance, Adverse drug reactions-Classification, mechanism, predisposing factors and causality assessment, Role of clinicalpharmacistinreporting,evaluation,monitoring,preventionand managementofADRs.	5
9.2	*Self-study:Reporting-CIOMSforms,Periodicsafetyupdatereports(PSURs)asper Indianregulatoryguidelines.*	5
10	**PharmacoeconomicsandOutcomesResearch** TheoriesandmethodologiesofPharmacoeconomicsandOutcomesResearch. Applicationsofpharmacoeconomicstopharmacotherapyandmanagedhealthcare.	**5**
	Total	**60**

Books(latesteditionstobeadopted)

1. RickNG.DrugsfromDiscoverytoApproval,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. ShayneC.Gad.DrugSafetyEvaluation.AJohnWiley&Sons,Inc.Publication.
5. SandyWeinberg.GuidebookforDrugRegulatorySubmissions,firstedition,AJohnWiley&Sons, Inc.
6. DuolaoWangandAmeetBakhaiClinicalTrialsAPracticalGuidetoDesign,Analysis,and Reporting, Remedica.
7. GiovannadiIgnazio,DiGiovannaandHaynes,PrincipalsofClinicalResearch,Wrightson Biomedical Pub.
8. RKRondels,SAVarley,CFWebb,ClinicalData management,JohnWiley&SonsInc.
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 VariousGuidelineslike:

- ICH (International Conference on Harmonisation), GCP for registration of pharmaceuticals for human use. ICH Harmonised Tripartite
- GuidelineforGoodClinicalPractice,E6,1996.
- ICMRGuideline–EthicalGuidelinesforBiomedicalResearchonHumanSubjects.
- IndianGCP–CentralDrugsStandardControlOrganization.GoodClinicalPractices
- Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- PharmacovigilanceProgrammeofIndia(PvPI)

BRANCH:PHARMACEUTICALANALYSIS

SEMESTER II CORE

MPH_C_208_T-AnalyticalMethodDevelopmentandValidationTechniques(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:

M. Pharm First Year, Semester II **MPH_C_208_T ANALYTICAL METHOD DEVELOPMENT AND VALIDATION TECHNIQUES (4 h/wk)**			
Course code &CO number	***At the successful completion of the course, the learners will be able to:***	***Syllabus Unit***	***Up to Bloom's***

							n	***level***
Course Code & CO number	PO1	PO2	PO3	PO4	PO5		PO6	
MPH_C_208_TCO1	2	2	3	3	3		3	
MPH_C_208_TCO2	3	3	3	3	3		3	
MPH_C_208_TCO3	2	1	3	3	3		3	
MPH_C_208_TCO4	2	2	3	3	3		3	
MPH_C_208_TCO5	2	2	3	3	3		3	
MPH_C_208_TCO1	nalyze and critically assess the calibration and validation procedures for analytical instruments including HPLC, UV-Vis spectrophotometer, FTIR and Dissolution test apparatus.					1		4
MPH_C_208_TCO2	rmulate comprehensive strategies for method development and validation for the analysis of active pharmaceutical ingredients, drug products, impurity profiling, biological matrices and stability indicating assay methods using HPLC, as well as for fixed-dose combination drugs & herbals using HPTLC.					2-6		6
MPH_C_208_TCO3	valuate 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_TCO4	nalyze and critically comprehend the ICH & CDER guidelines, pharmacopoeial specifications, for analytical and bioanalytical methods and stability testing.					2-6		4
MPH_C_208_TCO5	rmulate essential stability testing protocols and kinetic studies within the drug/product development process.					6		6

CO-PO Mapping

Unit	CourseContents(Topics)	Hours
1	**Calibration&Validationofanalyticalinstruments:** a. HPLC. b. UV-VISspectrophotometer. c. FTIR. d. Dissolutiontestapparatus.	**4**
2	**HPLCassaymethoddevelopmentforAPIanddrug products:**	**20**
2.1	Preliminaryinvestigations-Natureofsample,itscompositionandproperties.(should alsoincludesignificanceofpK$_a$,partitioncoefficientandcurrentmethodstodetermine thesame),separationgoals,samplepretreatmentanddetection,developingseparation.	5
2.2	Basicsofseparation-Resolution,Resolutionasafunctionof-solventstrength, selectivityandcolumnplatenumber;andsamplesizeeffect.	1
2.3	*Self-study-Detection-Comparison of sensitivity,selectivity, advantages,disadvantages andapplicationswithrespecttodetectorssuchasU.V,Fluorescence,PDA,Refractive Index,Evaporativelightscatteringdetectorandelectrochemicaldetectors.*	2

2.4	Samplepreparationandpretreatmentforsolid,liquid,semisolidsamples;column switchingandpreandpostcolumnderivatization.	2
2.5	*Self-study-Columns-characteristicsofcolumnandcolumnpackingandcolumn specifications.*	*1*
2.6	Method development for Reverse-phase, Ion pair and ion exchange chromatography, Gradientelution-principleanddevelopmentofgradientseparation.*Self-study-pharmaceuticalexamplesforthesemethods-(1 hr).*	3
2.7	Quantitationanalysis-measurementofsignals,quantitationmethods,sourcesoferrors, procurement,storageanduseofreferencestandardsandworkingstandards.	2
2.8	ICHguidelinesforanalyticalmethodvalidation(Q2withlatestrevision),System suitabilitytestingasperUSP,IP.	3
2.9	*Self-study-OnedetailedHPLCanalysisofanyAPIbyUSPorIP (1hr)*	*1*
3	**HPTLC:** Methoddevelopmentandvalidationforfixeddosecombinationdrugsandherbal analysis.	**3**
4	**Impurityprofiling:**	**9**
4.1	a. *Self-study-Sources of impurities and ICH terminologies-Organic impurities, Inorganic impurities, Residual solvents, Isolation and characterisation methods for impurities (3 hrs).* *b.* Analyticalmethoddevelopmentandquantitationofimpurities.	*5*
4.2	ICHguidelines-Q3A,Q3B,Q3Cwithlatestrevisions.	4
5	**Bioanalyticalmethoddevelopmentandvalidation:**	**13**
5.1	Stepsfollowed-samplepreparation,liquid-liquidextraction,precipitation,solid-phase extraction,sinteredcolumnsolidphase extraction.	3
5.2	Bionalyticalmethodvalidationincludingfull,partial,crossvalidation,selectivity, accuracy,calibrationcurve,stability(freeze-thawandmobilephase),recovery.	4
5.3	CDERandICHguidelinesforbioanalyticalmethodvalidation.	4
5.4	*Self-study-Examplesofbioanalyticalmethoddevelopmentandvalidationfora specifieddrugestimatedinurine/plasma/serumsamples.*	*2*
6	**Stabilitytesting:**	**11**
6.1	Drugdevelopmentcycleandstabilitytesting.	2
6.2	Stresstestingofdrugsubstances.	1
6.3	Stabilityindicatingassays(specificandselective),Roleofkineticstudies.	3
6.4	Stabilitytestingprotocols.	1
6.5	Retestperiod/Shelf-lifedeterminationofdrugsubstances/phytopharmaceuticals/ biotechnologicalproductsandequipment.	2
6.6	ICHguidelines-Q1AandQ1Bwithlatest revisions.	2
	Total	**60**

Books(latesteditionstobeadopted)

1. PracticalHPLCMethodDevelopmentbyL.R.Snyder,JohnWiley& 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. UnitedStatesPharmacopoeiaandIndianPharmacopoeia.
4. HandbookofIsolationandCharacterisationofImpuritiesinPharmaceuticalsbySatinderAhuja& Karen Mills Alsante, Academic Press, USA.

5. HandbookofBioanalysis&DrugmetabolismbyGaryEvans,CRCPress,
6. HPLCmethoddevelopmentbySatinderAhuja
7. Sethi's Quantitative Analysis of Pharmaceutical Formulations by P.D. Sethi, CBS Publishers and Distributors, New Delhi.
8. Remington-TheScienceandPracticeofPharmacy.
9. ValidationandQualificationinAnalyticalLaboratories,LudwigHuber;InformaHealthcare.
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,Drugstability: principles&Practices,MarcelDekker Inc.,New York

INTERNETREFERENCES:

1. USFDA(CDER)andICHguidelinesforBioanalyticalmethodvalidation.
2. ICHguidelines-Q1A(R),Q3A(R),Q3B,Q3C,Q6A.
3. ICHguidelinesforanalyticalmethodvalidation.

MPH_C_209_T-SpectroscopicStructuralElucidation(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, ^{1}H-NMR, ^{13}C-NMR spectroscopy, and Mass spectrometry.

Course Outcomes:

M. Pharm First Year, Semester II **MPH_C_209_T - Spectroscopic Structural Elucidation (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_209_T CO1	Analyse and determine the λ max for dienes, and α, β – 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 ^{1}H-NMR spectroscopy, and ^{13}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

Problemsofstructuralelucidationinvolvingthefollowingtechniques:

- UVspectroscopy.
- IRspectroscopy.
- ^{1}H-NMRspectroscopy.
- ^{13}C-NMRspectroscopy.
- Mass Spectrometry.

Theproblemsshouldcoverthefollowingaspects:

Unit	**CourseContents(Topics)**	**Hours**
1	Calculationofλmaxfordienes,α,β–unsaturatedketonesbyUV spectroscopy.*Self-study-practiceproblems(1hr)*	5
2	PredictionofcharacteristicIRbands,NMRspectra(^{1}HNMR)–chemical shift,splittingpatternandratioofprotonintensity,(^{13}CNMR)-numberof signals,chemicalshiftandsplittingpattern,massfragmentationpatterns. *Self-study-practiceproblems(2hrs)*	10
3	DistinguishingcompoundsusingUV/IR/^{1}HNMR/^{13}CNMRand/or Massspectrometry.*Self-study-practiceproblems(2hrs)*	10
4	Interpretationofmassspectrawithexplanationoffragmentationpatterns. *Self-study-practiceproblems(2hrs)*	9
5	Problemsinvolvingstructureelucidationby-UV/IR/^{1}HNMR/^{13}CNMR and/orMassspectrometry,*Self-study-practiceproblems(8 hrs)*	26
	Total	**60**

Books(latesteditionstobeadopted)

1 IntroductiontoSpectroscopybyD.L.Pavia,G.M.Lampman&G.S.Kriz,ThomsonBrooks/Cole, United States.

2 SpectrometricIdentificationofOrganic compoundsbyRobert.M.Silverstein,Francis.X.Webster, D.J.Kiemle,JohnWiley&Sons.

3 OrganicSpectroscopybyWilliamKemp.

4 Applicationsofabsorptionspectroscopyoforganiccompoundsby JohnRobertDyer,PrenticeHall, London.

BRANCH:PHARMACOGNOSYANDPHYTOCHEMISTRY SEMESTER II CORE

MPH_C_210_T-AdvancesinPharmacognosyandPhytochemistry(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 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			

Unit	CourseContents(Topics)	Hours
1	**Factorsaffectingoccurrenceofcompoundsofnaturalorigin**	**6**
1.1	Discussionofdifferentfactorscontributingtothevariationinthecomposition andproportionofsecondarymetabolites.	2
1.2	Concept of variation of phytochemicals with respect to ecotype, phenotype and genotypic variables. Study of phytoalexins, allelochemicals and aflatoxins,naturalpesticides(coverthetopicswithatleasttwoexamplesof each).	4
1.3	*Recentadvancesandapplicationsofphytoalexins,allelochemicals& aflatoxins.*	*3*
2	**Chemistry,sources&usesoffollowingclassesofphytochemicals** (1)Alkaloids–Opioids&Purines(2)Iridoids(3)Coumarins(4)Xanthones	**8**
2.1	*Self-study-Updateontraditionalusesandrecentapplicationsoffew examplesoftheabove-mentionedclasses*	*5*
3	**Chemistry,classification,sources,usesandstructure-elucidationby spectralmethodsof flavanoids.**	**8**
3.1	*Self-study–Comparativespectralanalysis& recentapplicationofdifferent classesof flavanoids.*	*4*
4	**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).** (1) Antibacterial (2) Hepatoprotective&Hypolipidemicagent (3) Antivirals	**6**
5	**Marinedrugsofdifferenttherapeuticclasses** 1)Anticancer2)Cardiovasculardrugs3)Antivirals4)Anthelmintics5) Marine toxins	**6**
6	**Studyofphotosensitizersofnaturaloriginsuchasporphyrins,psoralenes,thio phenes,quininesandtheirsignificanceinPhotodynamic therapy(PDT)andphytotoxicity.**	**6**
6.1	*Self-study-RoleofPDTinhealthcarewithexamples.*	*3*
7	**Introductiontoplanttissueculture(PTC)andplantbiotechnology**.	**5**
7.1	Geneticengineeringinplantsfordevelopmentofplantsresistanttopests, viruses, microbes and diseases. Alteration in ripening of fruits. Advantages and disadvantage of BT crops.	3
7.2	Definition, Methodology & application of biotransformation of phytochemicalswithsuitableexamples.	2
	Total	**60 hrs**

Books(latesteditionstobeadopted)(latesteditionstobe adopted)

1. PharmacognosyPhytochemistry–MedicinalPlants,JeanBrunetton,LavoisierPublishing,Paris.
2. TextbookofPharmacognosy,TreaseandEvans,Elsevierscience
3. TransgenicPlants,R.Ranjan,AgroBotanica,NewDelhi.
4. TransgenicPlants-AProductionsystemforIndustrialandPharmaceuticalProteins,byMeran Owen, Jan Pen, John Wiley.
5. MedicinalPlant,TheirBioactivity,ScreeningandEvaluation,CSIR.
6. HomeopathicPharmacopoeiaofIndia,PublisherMinistryofHealth.
7. TheAyurvedicFormularyofPartI&II,PublisherMinistryofHealth.
8. ChineseMateriaMedica,You-PingZhu,HarwoodAcademicPublishers.
9. IndiaMateriaMedica,NadkarniA.K.,BombayPopularPrakashan.
10. PhytochemicalMethods,J.B.Harbone,Chapmanandhall
11. Cultivation'sandProcessingofMedicinalPlants-Ed.byL.Hornok,JohnWiley.
12. IntroductiontoFlavanoids,BohrnBruceA.,HerwoodAcademicPublishers.
13. CultivationandUtilizationofAromaticplants,Ed.ByAtalC.K.andKapurB.M.,CSIR.
14. PlantTissueandCellCultureEd.H.E.Street,BlackwellScientificpublications.
15. Aflatoxin,LeoA.GoldBlatt-AcademicPressNewYork.
16. MicrobialToxins-Ciejler,KadisandAjl,AcademicPress.
17. AntimicrobialinFood,AlfredLarryBranen,P.MichaelDavidsonPublishinghouse
18. ChemicalplantTaxonomyT.Swain,AcademicPress,London.
19. PlantTaxonomyandBiosystematics,C.AStace,EdwardArnold, London.
20. ModernmethodsofplantanalysisK.Paech,Springer-Verlag.
21. IndianHerbalPharmacopoeia.
22. IndianPharmacopoeia.
23. StandardizationofBotanicals,V.Rajpal,EasternPublishers,NewDelhi.
24. Natural Compounds as Drugs, Vols. I & II, Editor Frank Petersen, René Amstutz, Die Deutsche Bibliothek, Germany.
25. QualitycontrolofHerbalDrugs:AnApproachtoevaluationofBotanicals,PulokMukherjee, Riddhi International
26. ChemicalsfromPlants:PerspectivesonPlantSecondaryProduct,Walton&Braun,Imperial College Press.
27. TowardsNaturalMedicineResearchinthe21st CenturyH. Ageta,N.AimietalExcerptaMedica, International Congress Series 1157.

MPH_C_211_T-NaturalProductTechnology(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):

M. Pharm First Year, Semester II **MPH_C_211_T Natural Product Technology (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_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_TCO2	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_TCO3	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_TCO4	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	**CourseContents(Topics)**	**Hours**
1	DetailedstudyofWHOguidelinesforqualitycontrolofcrude drugs	**5**
2	**Studyofherbalformulations**	**12**
2.1	Classificationanddifferentstagesinpreparationofherbalformulationsfor therapeuticandcosmeticapplications	5
2.2	Standardizationandevaluationofqualitycontrolandsafetyofherbal formulations	5
2.3	IntroductiontodifferentAyurvedicdosage forms	2
2.4	*Self-study-Anytwomarketed herbalformulationswithrespecttoconstituents and uses.*	*4*
3	**Quantitativeassaystodetermineextractionefficiency**	**8**
3.1	Generalmethodsofestimationofalkaloids,terpenoidsandflavonoids	4
3.2	Analysis of Rutin, lycopene, curcuminoids, artemisinin, enzymes and lectins by differentmethodsuchasUV,HPTLC,GC,gelelectrophoresisetc.,determination ofpercentagepurity.	4
3.3	*Self-study-Merits&demeritsofdifferentmethodsofestimationofalkaloids, terpenoids&flavanoids.*	*5*
4	**Introductiontoherbalproduct-basedindustry**	**6**
4.1	Types,forms,scopeandapplicationofherbalindustries	4
4.2	Typeofinfrastructureinvolvedinmakingstandardizedextractanddifferent dosagesforms	2
4.3	*Self-study–Equipmentandmachineryusedinlargescale extraction*	*3*
5	**Bioavailabilityandpharmacokineticaspectofherbaldrugswithexamplesof well-knowndocumentedherbaldrugs.IntroductiontoconceptofPhyto equivalence and pharmaceutical equivalence.**	**6**
6	**IPRissuesrelatedtoherbalandnaturalproducts.EMEAandESCOP guidelines for herbal medicinal products. Preparation ofDMF for herbalmedicines.**	**8**
6.1	*Self-study–Anyonepatentrelatedtonaturalproducts.*	*3*
	Total	**60 hrs**

Books(latesteditionstobeadopted)

1. PharmacognosyPhytochemistry–MedicinalPlants,JeanBrunetton,LavoisierPublishing,Paris.
2. TextbookofPharmacognosy,TreaseandEvans,Elsevierscience
3. TransgenicPlants,R.Ranjan,AgroBotanica,NewDelhi.
4. Transgenic Plants -A Production system for Industrial and Pharmaceutical Proteins, by Meran Owen, Jan Pen, John Wiley.
5. MedicinalPlant,TheirBioactivity,ScreeningandEvaluation,CSIR.
6. HomeopathicPharmacopoeiaofIndia,PublisherMinistryofHealth.
7. TheAyurvedicFormularyofPartI&II,PublisherMinistryofHealth.
8. ChineseMateriaMedica,You-PingZhu,HarwoodAcademicPublishers.
9. IndiaMateriaMedica,NadkarniA.K.,BombayPopularPrakashan.
10. Experimental PhytochemicalMethods,J.B.Harbone,Chapmanandhall
11. Cultivation'sandProcessingofMedicinalPlants-Ed.byL.Hornok,JohnWiley.
12. IntroductiontoFlavanoids,BohrnBruceA.,HerwoodAcademicPublishers.
13. CultivationandUtilizationofAromaticplants,Ed.ByAtalC.K.andKapurB.M.,CSIR.
14. PlantTissueandCellCultureEd.H.E.Street,BlackwellScientificpublications.
15. Aflatoxin-LeoA.GoldBlatt-AcademicPressNewYork.
16. MicrobialToxins,Ciejler,KadisandAjl,Academic Press.
17. AntimicrobialinFood,AlfredLarryBranen,P.MichaelDavidsonPublishinghouse
18. ChemicalplantTaxonomyT.Swain,AcademicPress,London.
19. PlantTaxonomyandBiosystematics,C.AStace,EdwardArnold, London.
20. ModernmethodsofplantanalysisK.Paech,Springer-Verlag.
21. IndianHerbalPharmacopoeia.
22. IndianPharmacopoeia.
23. StandardizationofBotanicals,V.Rajpal,EasternPublishers,NewDelhi.
24. NaturalCompoundsasDrugs–Vols.I &II,Editor-FrankPetersen,RenéAmstutz,DieDeutsche 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. TowardsNaturalMedicineResearch inthe21stCentury H.Ageta,N.AimietalExcerpta Medica, International Congress Series 1157.

CHOICEBASEDSUBJECTS
SEMESTER II

ALLTHESUBJECTSTHATARETHECORESUBJECTSOF THERESPECTIVEBRANCHES OF SPECIALIZATION AND HAVE CODES MPH_C_2XX_T MAY BE CHOSEN AS CHOICE BASEDORELECTIVESUBJECTSSOLONGASTHESTUDENTISPURSUINGADIFFERENT SPECIALIZATION.
IF SUCH A COURSE IS SELECTED AS A CHOICE BASED COURSE THEN THE GIVEN STUDENTSHOULDCLEARLYSTATESOINTHEEXAMINATIONFORM(forexampleifa 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 WITHRESPECTTOPAPERSETTINGONLYIFTHEARABICNUMERALSDIFFERandTHE NAME OF THE SUBJECT DIFFER AND NOT BASED ON 'C' OR 'E' DESIGNATION

Givenbelowarethesyllabiofmorechoice-basedsubjects

MPH_E_212_T-QualityAssuranceSystems(4h/wk)

Unit	CourseContents(Topics)	Hours
1	**Regulatorybasisforvalidation:** USFDAguidelines(cGMPguidelines,21CFR 210-211),EUguidelines,WHOguidelines.	**5**
2	**Terminologyandvalidationoverview:**	**10**
2.1	*Self-study:Validationversusverification,testing,calibrationandqualification.*	*3*
2.2	ConceptsofDQ,IQ,OQand PQ.	3
2.3	ConceptsofProspectivevalidation,retrospectivevalidation,Concurrentand revalidation.ValidationMasterPlan.	4
3	**ValidationofEquipment**	**10**
3.1	DryPowderMixers	1
3.2	FluidBedandTraydryers	1
3.3	TabletCompressionMachine	2
3.4	*Self-study:DryHeatSterilization/Tunnels*	*1*
3.5	Autoclaves	2
3.6	Capsulefillingmachines.	1
3.7	ValidationofIntegratedlinesbymediafilltest.	2
4	**UtilitiesValidation**	**7**
4.1	ValidationofPharmaceuticalWaterSystem&puresteam,	2
4.2	ValidationofHAVCsystem	3
4.3	ValidationofCompressedair	2

5	**CleaningValidation** *Self-study:CleaningofEquipment,CleaningofFacilities.*	*4*
6	**AnalyticalMethodValidation:**Generalprinciplesofanalyticalmethod validation,Validationoffollowinganalytical Instruments	**06**
6.1	HPLC	2
6.2	Dissolutiontestapparatus	2
6.3	U.V./Visiblespectrophotometers	2
7	**ProcessValidation**	**13**
7.1	*Self-study:Prospective,concurrent,retrospective&revalidationSelf-study*	1
	Processvalidationoffollowingformulations	
7.2	Uncoated/Coatedtablets	2
7.3	Hardgelatincapsules	2
7.4	Ampoules&Vials	2
7.5	*Self-study:Ointment/Creams*	*2*
7.6	*Self-study:LiquidOrals*	*2*
7.7	Transdermalpatches(Matrixsystems)	2
8	***Self-study-Computersystemvalidationincontrollingthemanufacturingprocess***	*2*
9	**ProcessAnalyticalTechnologies(PAT)andQualitybyDesign(QbD)(US FDA)**	**3**
	Total	**60**

Books(latesteditionstobeadopted)

1. Validation and Qualification in Analytical Laboratories by Ludwig Huber, Informa Health Care, New York, London.
2. PharmaceuticalProcessValidationbyR.NashandWachter,MarcelDekkerInc,NewYork.
3. GMPforPharmaceuticalsbySidneyH.Willing,MarcelDeckerSeries,NewYork.
4. UnitedStatesPharmacopoeia&IndianPharmacopoeia.
5. ValidationofPharmaceuticalprocess,F.J.CarletonandJ.Agalloco,MarcelDekkerInc.

INTERNETREFERENCES:

1. www.fda.gov(USFDAguidelinesforPATandQbD).
2. www.ich.org
3. WHOpublicationsonrelatedtopics.
4. EMEA guidelines

MPH_E_213_T-PharmaceuticalQualityManagement(4h/wk)

Unit	CourseContents(Topics)	Hours
1	**Conceptof-**	**8**
1.1	TotalQualityManagement(TQM),	2
1.2	Qualitycontrolandqualityassurance,	2
1.3	Qualitycontrollaboratoryresponsibilities,	2
1.4	*Self-study:Goodlaboratorypractices*	2
2	**GMP**	**8**
2.1	Organizationofpharmaceuticalmanufacturingunit,productionmanagement,	4
2.2	*Self-study:Revisedschedule M.*	4
3	**Personnel:**	**12**
3.1	*Self-study: Introduction, Human resource development, Qualification ExperienceandTraining,Responsibilities,PersonalHygieneandGowning.*	6
3.2	Location,Plantlayout,Lighting,Sewage,WaterHandling-Sewage,Refugeand Disposal, Washing and toiletfacility,Sanitation,Controlsofcontaminationand Environmentalcontrols.	6
4	**MaterialsManagement:**	**8**
4.1	API's,rawmaterials&packagingmaterials,Purchasespecifications,Selection of vendors, Intermediates & Finished products, Rejected and Recovered materials,Recalledproducts,Reagents&culturemedia,Referencestandards, Wastematerials.	6
4.2	Warehousing-GoodWarehousingPractices,distributionandrecords.	2
5	**ManufacturingOperationsandControl:**	**8**
5.1	*Self-study:SanitationofManufacturingPremises,Lineclearance,Mix-upsand Crosscontamination,ProcessingandholdingofIntermediatesandBulk Products*	3
5.2	Packaging,I.P.Q.C.,ReleaseandstorageofFinishedProduct,Process DeviationsandIncidents,Drugproductinspection,Yieldcalculations	3
5.3	Expirydating,Manufacturingrecordreviewandapproval.	2
6	**DocumentationandRecords:** 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.	**6**
7	**PostOperational Activities:**	**5**
7.1	Distribution,Complaintsandrecalls,evaluationofcomplaints,Recall procedures,relatedrecordsanddocuments.	2
7.2	Outsourcing:Facilityaudit,Manufacturing,Packaging,Analytical,Clinicaland otherservicesoutsourcing.	3
8	**SiteandPlant security:** Securitypersonnel,Entryprocedurestosite&plant,Internalsecurity,Vehicle parking, Fuel storage, Canteen & cooking, Garden & horticulture.	**2**
9	**Audits:**	**3**

Unit	CourseContents(Topics)	Hours
	PrincipleofQualityaudit,Plantlevel,Departmentwisedocumentation.	
	Total	**60**

Books(latesteditionstobeadopted)

1. QualityAssuranceofPharmaceuticals,WorldHealthOrganization,Geneva.
2. S.H.Willing,GoodManufacturingPracticesforPharmaceuticals;AplanfortotalQualitycontrol, Latest Edition, Marcel Dekker.
3. RegulatoryguidelinesrelatedtoGMPby
    a. 21CodeofFederalRegulation,Parts210,211&58(USFDAguidelines)
    b. EU,MHRA,UKGuidelinesonGMP
    c. ScheduleMofDrug&CosmeticsAct.
4. QualityPlanning&AnalysisbyJ.M.JuranandF.M.Gryna,TataMcgrawHill,India.
5. QualityAssuranceGuidebyOrganizationofPharmaceuticalProducersofIndia.

MPH_E_214_T–Biopharmaceutics(4h/wk)

Unit	CourseContent(Topics)	Hours
1	**Mechanismsofdrugrelease**	**10**
1.1	Diffusion controlled release, chemically controlled release, swelling controlled releaseofdrugsfromformulations-HiguchimodelandthePower-Lawmodelfor drugreleaseandtheircomparison,discussionofnewermechanisticmodels describeddrugreleasefromformulations	6
1.2	*Self-studyofzero,first,andsecondorderreleasekineticsandtheirgraphical profiles*	*4*
2	**Drug Dissolution**	**18**
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,physiologicalfactorsaffectingdrugdissolution,,methodsfor estimationofsolubility,methodsfordeterminationofdissolution rate	14
2.2	*Self-studyofexpermimentalmethoddesignforsolubilityanddissolutionrate determination*	*4*
3	**Drug Absorption**	**16**
3.1	Mechanismsofdrugabsorption,detaileddiscussionofthevarietyoftransporters and therole of transporters in the GI tract and liver and their role in drug absorption,physicochemical factors affecting drug absorption, pharmaceutical factorsaffectingdrugabsorption,physiologicalfactorsaffectingdrugabsorption, gut and hepatic metabolism and their role in determination of bioavailability, invitro and invivo methods for estimation of permeability/transport across membranes/absorption,computationalmethodsforpredictionof solubility/permeability/absorption	12
3.2	*Self-studyoftheexperimentaldesignofmethodsfor determination/prediction of drug transport*	*4*
4	**RoutesofDrug Administration**	**11**
4.1	Discussionofthedifferentroutesofdrugadministrationfortheperspectiveofthe nature of the absorption barrier/s, mechanisms of drug release, drug permeability/absorption from the site of administration, drug/pharmaceutical/physiologicalfactorsaffecting drugdissolution/dissolution rate/absorptionfromthedifferentroutesofdrugdelivery	8
4.2	*Self-studyoftheadvantagesandlimitationofthedifferentroutesof administrationandexamplesofdrugadministeredbytheseroutes*	*3*
5	**Discussionofthetraditionalandhigh-throughputapproachestowards estimationof solubility,dissolutionrate anddrugabsorptionanduseof this information in a drug discovery and development setting.**	**5**
	Total	**60**

Books(latesteditionstobeadopted)

1. Clinical Pharmacokinetics and Pharmacodynamics-Concepts and Applications, Rowland M and Tozer TN, Walters Kluwer – Lippincott Williams and Wilkins.
2. Applied Biopharmaeutics and Pharmacokinetics, Shargel L and Yu ABC, Appleton and Lange,International Edition
3. HandbookofBasicPharmacokineticsincludingclinicalapplications,RitschelWAandKearnsGL, APhA,
4. BasicPharmacokinetics,JambhekarSSandBreenPJ,PharmaceuticalPress.
5. BiopharmaceuticsandPharmacokinetics,VenkateshwarluV,PharmaBookSyndicate
6. DrugBioavailability-Estimtionofsolubility,permeability,absorptionandbioavailability,vander Waterbeemd H, Lennernas H and Artursson P, Wiley VCH.
7. ModellinginBiopharmaceutics,PharmacokineticsandPharmacodynamics–Homogenousand 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 form 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 form 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.

M. PharmFirst Year,Semester II **MPH_E_215_T – Pharmacokinetics**			
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_E_215_T CO1	Understand the routes of administration, sampling sites and definitions of A,D,M and E.	1	2
MPH_E_215_T CO2	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
MPH_E_215_T CO3	Understand how to calculate primary and secondary PK parameters form concentration and time data.	2.3	5
MPH_E_215_T CO4	Understand how urine sampling can be used to analyze IV bolus dose data.	4	4
MPH_E_215_T CO5	Understand how to design a dosage regimen of a drug based on PK principles.	3	5

CO-PO Mapping:

Course code & CO number	**PO1**	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
MPH_E_215_T	0	1	3	2	3	0

MPH_E_215_T	1	2	3	2	2	0
MPH_E_215_T	1	2	2	1	3	0
MPH_E_215_T	2	2	3	1	2	0
MPH_E_215_T	2	2	3	2	3	0

Unit	CourseContent(Topics)	Hours
1	**Introduction to pharmacokinetics** and its utility in drug design and dosage regimen design.Definitions of absorption, distribution, metabolism, excretion, elimination.Differentapproachesfordeterminationofpharmacokineticsofdrugs – non-compartmental,physiological,andcompartmentalmodeling.Assumptions involvedintheevolutionofsingleandmulti-compartment models.	**4**
2	**Discussion** (including mathematical description and equations) of the pharmacokineticsofdrugsshowingonecompartmentpharmacokineticsfollowing differentdosingmethods/protocols[blood/plasma/urinesampling]	**40**
2.1	Discussion (including mathematical description and equations) of the pharmacokineticsofdrugsshowingonecompartmentpharmacokineticsfollowing intravenousbolusdosing[blood/plasma/urinesampling]	5
2.1	Discussion (including mathematical description and equations) of the pharmacokineticsofdrugsshowingonecompartmentpharmacokineticsfollowing intravenousmultiplebolusdosing[blood/plasma]	5
2.2	Discussion (including mathematical description and equations) of the pharmacokineticsofdrugsshowingonecompartmentpharmacokineticsfollowing intravenousconstantinfusiondosing[blood/plasma].	5
2.3	Discussion (including mathematical description and equations) of the pharmacokinetics of drugs showing one compartment pharmacokinetics following extravascularbolusdosing[blood/plasma].Discussionoftheconceptsof bioavailability(absoluteandrelative)andbioequivalence.	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 approachestoproblemsolvinginvolvingdatafrombioavailabilityand bioequivalencestudies.Discussionofapproachestodosageregimendesign	5
2.6	*Self-studyofproblemsandproblemsolvingrelatedtothetheoreticalconcepts outlinedabove(bloodandurinedataanalysis)*	*10*
3	**Discussion of the processes of absorption, distribution and elimination** with respect to how these processes impact the values of rate constants for absorption/distribution/eliminationandthevaluesofbioavailability,volumeof distributionandclearance.	**10**
4	**Introductiontodrugtransporters**andtheirimpactonthepharmacokineticsof drugsandpharmacokineticdrug-druginteractions.	**3**

5	**Brief introduction to the concept of dose- and time-dependent pharmacokinetics**[non-linearpharmacokinetics]andtheirimpactondrug developmentandclinicaluse.	**3**
	Total	**60**

Books(latesteditionstobeadopted):

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. HandbookofBasicPharmacokineticsincludingclinicalapplications,RitschelWAandKearnsGL, APhA,
4. BasicPharmacokinetics,JambhekarSSandBreenPJ,PharmaceuticalPress.
5. BiopharmaceuticsandPharmacokinetics,VenkateshwarluV,PharmaBookSyndicate
6. DrugBioavailability-Estimtionofsolubility,permeability,absorptionandbioavailability,vander Waterbeemd H, Lennernas H and Artursson P, Wiley VCH.
7. ModellinginBiopharmaceutics,PharmacokineticsandPharmacodynamics–Homogenousand Heterogenous approaches, Macheras P and Iliadis A, Springer

MPH_E_216_T-ClinicalPharmacy(4h/wk)

Unit	CourseContent(Topics)	Hours
1	**IntroductiontoClinicalPharmacy**	**3**
1.1	Scope,ObjectivesandGoalsinHealthCare.	
1.2	PracticeofClinicalPharmacyinHospitalsandCommunity.	
2	**Understandingthepatient**	**11**
2.1	Pharmacist–PatientInterview,InterviewTechniques,communicationskills.	8
2.2	Patientorientedmedicalrecords(POMR):Medicationhistoryandrecords,habits relatedtouseofOTCmedications,foods,allergiesandsensitivities.	
2.3	Patientfollow-upanddischargeinterviewforhospitalized patients.	
2.4	PharmacologicalandBiochemicalexaminationsandtheir significance.	
2.5	Ethicsrelatedtomedicalrecord	
2.6	Dischargecard	
2.7	*Self-study-Supervisionoftherapeuticsuccess,sideeffectsandadverseeffects*	3
3	**Therapeuticuseofmedicine**	**10**
3.1	Drugselectionandadministration.Problemsassociatedwithconcomitanttherapy.	
3.2	Patientsensitivities,allergies.Precautionsduringuse,Dietcontrol.	
3.3	Reasonsfornon-compliance,Strategiesforimprovingcompliance.	
3.4	Useofdrugsandconcernsingeriatric, pediatricpatientsandin pregnancy	
3.5	Drug-druginteractionsanddruginteractionswithfood,alcoholandtobacco.	
	Therapeuticdrugmonitoring(TDM)	**6**
4.1	Introduction,individualizationofdrugdosageregimen(variability-genetic,age, weight,diseaseandinteractingdrugs).	
4.2	IndicationsforTDM,protocolforTDM.	
4.3	Pharmacokinetic-pharmacodynamiccorrelationindrugtherapy.	
4.4	TDMofdrugsusedinfollowingdiseaseconditions:cardiovasculardiseases,CNS conditionsetc.	
5	**Drugformulary,drugutilizationreview(DUR)includingrationaldrug therapy**	**3**
6	**Drug Information**	**4**
6.1	Introductiontoinformationresources	
6.2	DruginformationCentre(DIC)andDruginformationservices.	
6.3	Drugliteratureutilization,selection,evaluationandcommunication.	
6.4	RoleofDICinensuringrationaluseofdrugs (RUD).	
7	**Standard treatment protocol of selected non communicable diseases/conditionslikediabetes,hypertension,stroke,obesity,arthritis, cardiopulmonarydysfunctionandfluidandelectrolyteimbalance.**	**10**
8	*Self-study-Generalconceptsofpoisoningandtoxicology Critical care management: Commonlifesupportsystems-Acuteandchronicrenalfailure,cardiacand epilepticattackandrespiratoryfailure.*	***13***

	Total	**60**

Books(latesteditionstobeadopted):

1. J.T.Dipiro,R.L.Talbert,G.C.Yee,G.R.Matzke,B.G.Wells,L.MichaelPosey(Eds.)
2. Pharmacotherapy:APathophysiologicApproach,TheMcGrawHillCompanies, Inc.
3. E.T. Herfindal and D.R Gourley, Text Book of Therapeutics: Drug and Disease Management, Lippincott Williams & Wilkins, USA.
4. T.M.SpeightandNHGHolford(Ed.),Avery'sDrugTreatment:PrincipalsandPracticeofClinical 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. PharmaceuticalPractice-A.JWinfield,R.M.E.Richards,ChurchillLivingstonepublication.
7. DrugInteractionFacts,DavidS.Tatro.

MPH_E_217_T-DrugMetabolism(4h/wk)

Unit	CourseContent(Topics)	Hours
1	**Introductiontoxenobiotic/drugmetabolism**	**6**
1.1	Introductiontoxenobiotic/drugmetabolismanditsrelationtootherdefense systems(Physicalbarriers,excretion,immunesystem).	2
1.2	Typesofreactions(IandII),consequencesofdrugmetabolism(DM) [inactivation,bioactivation,prodrugs],organsofDM,localizationofdrug metabolizingenzymes,factorsaffectingdrugmetabolism.	4
2	**CytochromeP450s**:Introductiontothefamilyofenzymes,theirclassification and nomenclature.	**20**
2.1	Introductiontothefamilyofenzymes,theirclassificationandnomenclature.	2
2.2	CYP450catalyticcycle,differenttypesofreactionscatalyzedbyCYP450sand themechanismsof catalysis.	8
2.3	HumanCYP450sinvolvedinDM,theirdistributionandproperties,typical substrates, specificprobe substrates, specific inhibitors,induction ofCYPs and specificinducers	7
2.4	GeneticpolymorphisminCYP450expression	3
3	**NONP450enzymes**	**20**
3.1	IntroductiontoNONP450enzymesinvolvedindrugmetabolism	05
3.2	*Self-study of NON P450s - glucuronosyltransferases, sulfotransferases, glutathione S-transferases, N-acetyl transferases, xanthine oxidase, aldehyde oxidase,esterase,epoxidehydrolase,nitro/azoreducatasesandFMO[on lines similartothatspecifiedforCYPsaslisted above].*	*15*
4	**Introduction to methodsfor studying DM**. Discussion of in vitro and in vivo tools, along with their advantages and limitations {recombinant enzymes, subcellularfractions,hepatocytes,liverslices,perfusedliverandwholeanimal studies}.	**5**
5	**DiscussionoftypesofDMstudies**–metabolicstability,crossspecies comparisons,metaboliteprofilingandidentification,reactionphenotyping,CYP inhibitionandCYPinduction studies.	**6**
6	**Introductionto*insilico*drugmetabolitepredictionsandassociated algorithms**.	**3**
	Total	**60**

Books(latesteditionstobeadopted):

a. ComprehensiveMedicinalChemistry,SeriesEd.,HanschC.,PergamonPress.
b. WilsonandGisvold's,TextbookofOrganicMedicinalandPharmaceuticalChemistry,Lippincott-Raven
c. Foye'sPrinciplesofMedicinalChemistry,LippincottWilliamsandWilkins.
d. 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
e. PharmaceuticalProfilinginDrugDiscoveryforLeadSelection,BorchardtRT,KernsEH,Lipinski CA, Thakker DR and Wang B, AAPS Press
f. DrugMetabolism–CurrentConcepts,IonescuCandCairaMR,SpringerInternational Edition

g. HandbookofDrugMetabolism,WoolfTF,MarcelDekker.

MPH_E_218_T-BasicMolecularBiology(4h/wk)

Course Objectives: The course will mainly focus on the study of principal molecular events of cellincorporating DNA Replication, Transcription and Translation in prokaryotic as well as eukaryoticorganismsandadditionallyfocusesonrecombinant DNAtechnology,proteomicsandgenomic technologiestostudyitsimplicationsinresearch,therapeuticsandplant tissueculture.

CourseOutcomes(CO):

M.Pharm FirstYear,SemesterI **MPH_E_218_T BasicMolecularBiology(Theory4h/wk)**			
Course code & COnumber	***At the successful completion of the course,thelearners willbeableto:***	***Syllabusuni tno.***	***Up toBloom's level***
MPH_E_218_T_CO 1	Understandabouttheorganizationofgenomeandstructure ofgene,DNAand RNA.	**1 & 2**	**2**
MPH_E_218_T_CO2	Rememberandunderstandaboutthe mechanismsof differentcellularprocesseslikeDNAreplicationandrepair,transcription, translation, and post-transcriptional and post-translational modificationsinbothprokaryotesand eukaryotes.	**2&3**	**2&3**
MPH_E_218_T_CO3	UnderstandaboutrDNAtechnologyanditsapplications	**4**	**2&3**
MPH_E_218_T_CO4	Understand about different techniques to study genomicsandproteomicsanditsimplications inresearch.	**4**	**2&3**

MPH_E_218_T_CO5	Understandthevariousmolecular biologytechniques (Western blotting, molecular cloning) and its application inresearch.	**4**	**2**
MPH_E_218_T_CO6	Understandmedical molecularbiologyandrelateits applications in cancer and gene therapy and comprehend theconceptsof planttissueculture.	**4&5**	**2&3**

Mapping COwithPO

CO	PO1	PO2	PO3	PO4	PO5	PO6
MPH_E_218_T_CO1		**1**		**1**	**1**	
MPH_E_218_T_CO2		**1**		**1**	**1**	
MPH_E_218_T_CO3		**1**		**1**	**1**	
MPH_E_218_T_CO4		**1**		**1**	**1**	
MPH_E_218_T_CO5		**1**		**1**	**1**	
MPH_E_218_T_CO6		**1**		**1**	**1**	

Unit	CourseContent(Topics)	Hours
1	**Thebeginningsofmolecularbiology**	**1**
2	**DNAStructureandRoleof DNA**	**16**
2.1	Organizationofthegenome,buildingfromnucleotidesto chromatin	6
2.2	Thegeneticcodeanditsrelationshiptoprotein structure	2
2.3	DNAreplication,Telomeremaintenance,mechanismsofDNArepair,DNA recombination	8
3	**TheversatilityofRNA**	**23**
3.1	Transcriptionandtranslationinprokaryotes;Transcriptionandtranslationin eukaryotes	8
3.2	Epigeneticsandmonoallelicgeneexpression	3
3.3	RNAprocessingandpost-transcriptionalgeneregulation	8
3.4	Mechanismsoftranslation	4
4	**Geneticallymodifiedorganisms:Useinbasicandappliedresearch**	**14**
4.1	RecombinantDNAtechnology,molecularcloning,&sometoolsforanalyzing geneexpression	8
4.2	Genomeanalysis:DNAtyping;Genomicsandbeyond;Medicalmolecular biology:applicationsinCancerandGenetherapy;Genesandbehavior. Proteomicsandgenomics:Methodsforstudyinggeneandprotein expression	6
5	**Planttissuecultureandanimalcellculture**	**6**
	Total	**60**

Books(latesteditionstobeadopted)

1. GenesIX,EdBenjaminLewin.OxfordUniversityPress.
2. Molecular Cell Biology, Lodish H, Berk A, Zipursky S L, Matsudaira P., Baltimore D, Darnell J, Publisher W. H. Freeman.
3. MolecularBiologyoftheCell,AlbertsPublisherGarlandScience.

4. Watson,J.D.TaniaA.Baker,StephenP.Bell,AlexanderGann,MichaelLevine,RichardLosick, Molecular Biology of the Gene, Benjamin Cummings.
5. Molecular Biology in Medicinal Chemistry, Dingemann Th, Steinhilber D and Folkers G, Wiley-VCH, Germany
6. BasicPrinciplesofGeneManipulation,PrimroseSB,TwymanRMandOldRW,Blackwell.
7. MolecularBiologyandbiotechnology,WalkerJMandRapleyR,RoyalSocietyofChemistry

MPH_E_219_T-PharmaceuticalBiotechnology(4h/wk)

Unit	CourseContent(Topics)	Hours
1	**ProductionandControlofBiotechderivedproducts**	**25**
1.1	RecombinantDNAproducts–insulin,growthhormone,erythropoietin,cytokines	5
1.2	Vaccines–attenuatedvirus,geneticalterationsoflivevirusasavectorofother pathogens(recombinantvirusorrecombinantvacciniavirus)	7
1.3	Diagnosticproteins–proteinA,proteinG,antibodies	4
1.4	Qualitycontroltestingofbiotechproducts–determiningimpurities,contamination -viral, bacterial endotoxin, rabbit pyrogen test, sterility, protein identification, fingerprints by electrophoresis, isoelectric focusing, immunogenicity, partial sequence analysis.	9
2	**Plantbiotech products**	**10**
2.1	Substancesproducedbyplantcellculture	2
2.2	Transgenicplantsandtheirapplication	4
2.3	Biotransformationswithplantcellculture	4
3	**Biotechproductsthroughfermentation**	**13**
3.1	Fermentation–batch,continuousfermentation	2
3.2	Roleofbioengineeringinfermentation–geometryoffermentationtanks,design ofimpellers,agitationsystemsandenvironmentalconditionsoffermentation	3
3.3	Fermentativeproductionofimportantsecondarymetabolites–penicillins,amino glycosidespolyenemacrolides,macrolides,anthracyclines	3
3.4	Principlesofdownstreamprocessingoffermentationproducts	3
3.5	Unitoperationsandtechniquesemployedinndownstreamprocessingof fermentationproducts,microbialstrainselectionandpreservationmethods	3
3.6	Genotypeandphenotypevariationofcharactersofmicrobes	
4	***Self-study-Biotransformation***	***12***
4.1	*Biotransformationprinciplesandindustrialapplicationsintheproductionof chemicalsand drugs*	
4.2	*Immobilizationofenzymes,proteinsandtheirapplications–biosensors,enzyme electrodes,immunosensors,opticalsensors*	
	Total	**60**

Books(latesteditionstobeadopted)

1. Biotechnology,H.J.Rechm,G.Reed. Vols1– 12, A.Pulher, P.StadlerEds, Weinhelm,New York
2. AtextbookofBiotechnology,H.D.KumarAffiliated,East–WestPressPvt.Ltd.
3. GeneticEngineeringFundamentals,KarlKammer,MeyerVirginia,C.Clark.
4. GenesV,BenjaminLewin,OxfordUniversityPress.
5. MethodsinPlantMolecularBiologyandBiotechnology,BernardRGlick,JohnEThompson,CRC Press.
6. GeneticandBiochemistryof Antiobiotics Production,Leo CVining, Colin, Stuttard Butterworth, Heinemann.

7. Biotechnology – Applications and Research, Paul N Chermisinoff, 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. Biotehnologyofantibiotics,WilliamRStrohl,MarcelDekker.
10. MolecularBiochemistry–Therapeuticapplicationsandstrategies,SunilMaulikandSalilDPatel, John Wiley and Sons, Inc.

MPH_E_220_T-ModelsforDDSEvaluation(4h/wk)

Unit	CourseContent(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	InvitrocellculturetechniquesforevaluationofdrugpermeationfromDDS, includingisolation,maintenanceofcelllines,culturingmonolayers,evaluationof drugtransport	8
3	Invitro/exvivomodelsforevaluationofdrugabsorption	5
4	InvitrocytotoxicityevaluationusingcellculturesandtechniquessuchasMTT assay,dyeuptakeetc.	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,validationofinvitrotoxicitytests–acute,sub-acuteandchronictoxicity testing, biochemical basis of toxicity, design of toxicological studies, quality assurance in toxicological studies, toxicity by routes – parenteral, oral, percutaneousandinhalation,targetorgantoxicityexemplifiedbyhepatotoxicity andcutaneous(dermal)toxicity.	10
	Total	**48**

Books(latesteditionstobeadopted)

1. BioassayTechniquesfordrugdevelopment,AttaUrRahman,M.IqbalChoudhar,WilliamJ Thomsen.
2. In vitro Methods in Pharmaceutical Research, Eds.J.V. Castell, M.J. Gomer, Lechon, Academic Press
3. InvitroToxicityTesting,JohnMFrazier.
4. GeneralandAppliedToxicology,BryanBallantyne,TMarrsandP.Turner.

MPH_E_221_T-RationalDrugDesign(4h/wk)

Unit	CourseContent(Topics)	Hours
1.0	**MolecularMechanics**andtheforcefield.Generalformofagenericforcefield, forcefieldparametrization.	**5**
1.1	*Self-study–Comparisonbetweenthedifferentforcefieldsinexistenceatpresent time*	1
2.0	**Energyminimization**	**6**
2.1	Steepestdescents,conjugategradients,NewtonRaphsonmethod,advantagesand limitationsofeachmethod	
3.0	**Conformationalanalysis**	**10**
3.1	Systematicsearch,MonteCarlosimulations,Moleculardynamicssimulations, distancegeometry,strengthsandlimitationsofeachmethod	

4.0	**Docking**	**10**
4.1	Docking by energy minimization, superimposition, molecular dynamics, MetropolisMonteCarlo,geneticalgorithms,build-upapproach.Differenttypesof scoringfunction,e.gsofsuccessfulapplicationofdocking.	8
4.2	*Self-study–Successfulapplicationsofdocking*	*2*
5.0	***denovo*liganddesign**	**10**
5.1	Classes of de novo ligand design – active site analysis methods, whole-molecule methods,connectionmethods,randomconnectionanddisconnectionmethods,e.gs ofsuccessfulapplicationof*denovo*ligand design	
5.2	Fragmentbaseddrugdesign	2
5.3	*Self-study–Successfulapplicationsofdenovodrug design*	*2*
6.0	**Pharmacophoremodelling**	**9**
6.1	Techniques of developing a pharmacophore map covering both ligand based and receptorbasedapproaches,incorporatingadditionalgeometricfeaturesintoa3D pharmacophore,useofapharmacophoremodelindrugdesign.	7
6.2	*Self-study-Successfule.g.ofpharmacophoremapsindrug design*	*2*
7.0	**VirtualScreening**basedonsimilarity,docking,pharmacophoremapsandfilters fordrug-likenessandADME	**3**
8.0	**3D-QSAR**	**6**
8.1	CoMFAandCoMSIA,Mentionofother3D-QSARtechniquesandintroductionto the4th,5thand6thdimensioninQSAR.	4
8.2	Self-study–3D-QSARmethodsotherthanCoMFAand CoMSIA	2
	Total	**60**

Books(latesteditionstobeadopted)

1. MolecularModelling–PrinciplesandApplications,LeachA.R.,PrenticeHall.
2. PracticalApplicationofComputer-AidedDrugDesign,Ed.CharifsonP.,MarcelDekkerInc.
3. 3DQSARinDrugDesign:Theory,MethodsandApplications,Ed.KubinyiH.,LedienESCOM.
4. MolecularModelingandSimulation-AnInterdisciplinaryGuide,SchlickT.,Springer.

MPH_E_222_T-AdvancedBiochemistry(4h/wk)

Unit	CourseContent(Topics)	Hours
1	**Proteins**	**15**
1.1	Structure–primary,secondary,tertiary,quaternary;motifs,structuraland functionaldomains,proteinfamiliesandmacromolecularassemblies	5
1.2	Mechanismsforregulatingproteinfunction:Protein-proteininteractions, interactionwithligands;Ca^{2+}andGTPasmodulators,cyclicphosphorylation anddephosphorylation,proteolyticcleavage.	2
1.3	Purificationandcharacterizationofproteins:electrophoresis,ultracentrifugation and liquid chromatography, use of biological assays, use of radioisotopes; MS, X-raycrystallography,NMRandhomologymodellingtodeterminestructures; aminoacidanalysis;cleavageofpeptides;proteinsequencing.	4
1.4	Proteinbiosynthesis:translationmachineryinprokaryoticandeukaryoticsystems;co mparisonofsimilaritiesanddifferences,drugaffectingprotein biosynthesisandproteinfunction	4
2	**DNAandnucleicacids**	**15**

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, drugaffectingnucleotidebiosynthesis,RNAandDNAbiosynthesisandRNA andDNA function	15
3	**Carbohydrates**	**8**
3.1	Mono,diandpolysaccharidesandtheirnomenclature,stereochemistry,typesof linkages;conjugatesofcarbohydrateswithothermolecules–glycoproteins, glycolipids, proteoglycans, lipopolysaccharides and their biological roles	8
4	**Lipids**	**7**
4.1	Classification, nomenclature, stereochemistry, storage lipids, membrane lipids, lipidsassecondarymessengersandcofactors,biologicalroleoflipids,drug affectinglipid metabolism.	7
5	***Self-studyofproteinsuperfamilies,NandCterminalsequencing,DNA structuresotherthanB-DNA,DNAsequencing,DNApyrosequencing, cerebrosides,sphingolipids.***	***15***
	Total	**60**

Books(latesteditionstobeadopted)

1. PrinciplesofBiochemistry,Lehninger,NelsonD.L.,C.B.SPublishers,NewDelhi.
2. Biochemistry,StryerL,W.H.Freyment &Co.,New York.
3. MolecularCellBiology,LodishH,DarneuJ,ScientificAmericanBooks(latesteditionstobe adopted), N.Y.
4. Biochemistry- The chemical reactions of living cells, Vol 1 &2, Metzler DE, Elsevier Academic Press.
5. Biochemistry,BergJM,TymoczkoJLandStryerL,WHFreemanandCompanyandSumanasInc.
6. Biomacromolecules-Introductiontostructure,functionandinformatics,StanTsaiC,Wiley-Liss
7. Protein:StructureandMolecularproperties,ThomasECreighton,W.H. Freeman.
8. PhysicalBiochemistry-Principlesandapplications,SheehanD,Wiley-Blackwell

MPH_E_223_T-GreenChemistry(4h/wk)

Unit	CourseContent(Topics)	Hours
1	**IntroductiontotheconceptsofGreenChemistry**–history,need,goals, limitations,obstaclesandopportunities	**5**
1.1	**Introduction to the principles of Green Chemistry** – prevention of waste/by products,maximumincorporationofthematerialsusedintheprocessintothefinal product (atom economy), green metrics, prevention/minimization of hazaradous/toxic products, designingsafer chemicals –basic approaches,selection of appropriate auxiliary substances (solvents, separation agents *etc*), energy requirements for reactions, selection of starting materials, renewable starting materials,avoidanceofunnecessaryderivatization–carefuluseof blocking/protectinggroups	**15**
1.2	Microwaveassisted organic synthesis;photochemicaltransformations; sonication; solid phase transformations; aqueous phase transformations; enzymatic transformations; etc	**8**
1.2	*Self-study-transformationsusingionicliquids,PEG,polymersupportedreagents*	*4*

2	**Application** of green synthetic reactions, green starting materials, green reagents, greensolventsandreactionconditions,greencatalysisandexamplesofgreen synthesis,greenanalyticalmethods	**13**
2.1	*Self-study–ExamplesofGreensynthesis*	*3*
3	**Future trends in green chemistry** – oxidation reduction reagents and catalysts; biomimetics and multifunctional reagents; combinatorial green chemistry; solventlessreactions;non-covalentderivatization;biomassconversion;emission control;biocatalysis	**12**
	Total	**60**

Books(latesteditionstobeadopted)

1. GreenChemistry:TheoryandPractice,AnastasPTandWarnerJC,OxfordUniversityPress.
2. GreenChemistry:IntroductoryText,LancasterM,RCSLondon
3. IntroductiontoGreenChemistry,RyanM.A.,TinnesM.,AmericanChemicalSociety (Washington).
4. HandbookofGreenChemistryandTechnology,ClarkeJandMacquarieD,BlackwellPublishing.
5. GreenChemistry–Greeneralternativetosyntheticorganictransformations,AhluwaliaVK, Narosa Publications, New Delhi.
6. OrganicSynthesis–SpecialTechniques,AhluwaliaVKandAggarwalR,NarosaPublications.

MPH_E_224_T-DrugRegulatoryAffairs(4h/wk)

No.	CourseContents(Topics)	Hours
1.0	Needfor Regulations	1
2.0	**Indian Regulations**	15
2.1	IntroductiontoIndianRegulations	1
2.2	Drugs&CosmeticAct&Rules -Overviewandrecentamendments	5
2.2.1	• ScheduleDIandDII(RegistrationandImport)	
2.2.2	• ScheduleM	
2.2.3	• ScheduleY	
2.2.4	• CentralDrugLaboratories	
2.3	ICMRguidelinesforethicalconsiderationsinbiomedicalresearchonhuman subjects	1
2.4	BA–BE studies	2
2.5	Newdrug application	1
2.6	Insurance,CompensationandIndemnificationoftrialsubjects	1
2.7	ExpertReferral	1
2.7.1	• IBSC,RCGM	
2.7.2	• ICMR	
2.7.3	• NDAC	
2.7.4	• CBBTDEC	
2.8	WHOGMPCertification,FSCandCoPP procedure	1
2.9	ProceduresforobtainingTestlicense(Form29andForm11);ExportNOC	1
2.10	Loanlicense/Contractmanufacturing	1
3.0	**US Regulations**	**6**
3.1	IntroductiontoUSRegulations	1
3.2	HatchWaxmanActandamendments,FDAMedicareModernizationAct	
3.3	IntroductiontoOrangeGuideand21-CFR	1
3.4	Investigationalnewdrug(IND)filing	1
3.5	USDrugMasterFile(DMF)filing,amendmentsandannual reports	1
3.6	AbbreviatedNewDrugApplication(ANDA)filing	1
3.7	NewDrugApplication(NDA)filing	
3.8	Postapprovalchanges	1
4.0	**EuropeanRegulations**	**6**
4.1	IntroductiontoEuropeanRegulations	1
4.2	ActiveSubstanceMasterFile(ASMF)filing	1
4.3	CEP filing	
4.4	MarketingAuthorizationandfilingprocedures	2
4.4.1	• NationalProcedure	
4.4.3	• MutualRecognitionProcedure(MRP)	
4.4.4	• DecentralizedProcedure(DCP)	
4.4.5	• CentralizedProcedure(CP)	
4.5	Handlingvariations	

4.6	ClinicalTrialRegulationsinEU	2
5.0	**OtherapplicableRegulationsandGuidelines**	**10**
5.1	OverviewofICHguidelines	1
5.2	CTDformatof dossier	1
5.3	eCTDfilingprocedure	
5.4	21-CFRPart11	1
5.5	AuditsandInspections,FDA483's–Lessonslearnt	1
5.6	Overviewofregistrationprocessinothergeographies	1
5.7	Biologicallicenseapplication(BLA)	1
5.8	MedicalDeviceRegistrationprocess	1
5.9	RegulationsgoverningStemCelltherapeutics	1
5.10	IntroductiontoPharmacovigilanceandDrugSafety	1
5.11	OrphanMedicinalProducts	1
6.0	**IntellectualPropertyRights(IPR)**	**4**
6.1	Overviewofpatentsfromregulatoryperspective	
6.2	PCTapplication&generalrules	
6.3	WTO/GATT system	
6.4	TRIPSAgreement	
6.5	Compulsorylicensing	
6.6	Patentsearch,draftingandfilingprocedure	
6.7	Patentinfringementanalysis	
6.8	Trademark/copyrightfilingprocedures	
	Total	**42**

Books(latesteditionstobeadopted)

1. GoodDrugRegulatoryPractices:ARegulatoryAffairsQualityManual(GoodDrugDevelopment Series, Vol 1, Helene I. Dumitriu
2. http://www.amazon.com/Good-Drug-Regulatory-Practices-Development/dp/1574910515
3. GuidetoDrugRegulatoryAffairs/Buch, BrigitteFriese.
4. DrugsandCosmeticsAct,1940andRules, 1945.

Usefullinks:

1. http://www.cdsco.nic.in/
2. http://clinicaltrials.gov/
3. http://dbtbiosafety.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	CourseContents(Topics)	Hours
1	**GeneralAnatomyandPhysiologyofskin,hair,nailandtooth:**	**8**
1.1	*Self-study:Anatomyandphysiologyofskin,hair,nailandtooth-emphasisonpoints withreferenceto cosmetics.*	4
1.2	Problems associated with normal functioning of skin, aged skin, dry skin, sensitive skin,acne,pigmentationdisorders.Commonhairproblems-hairloss, manageability problems,splitends,shineandlusterdisorders;nailproblems;toothproblems.	4
2	Generalrawmaterialsincosmeticformulations**:**	**19**
2.1	Overviewofrawmaterials-Water,natural&syntheticoils,fats&waxes,inorganic solids,emulsifiers,thickeners,hydrocolloids,polymers,surfactants,antioxidants, humectants, polysiloxanes, preservatives.	2
2.2	Colouringagentsusedincosmetics.Qualityevaluationofcolors,safety,toxicityand regulatoryaspectsofcolorsw.r.tcosmeticproducts	3
2.3	Perfumes in cosmetics: raw materials in perfumery, developing a perfume composition, current trendsincludingemulsified and solid perfumery, analytical and separation techniques of perfumes, sensory analysis, safety and toxicological evaluationofperfumes,manufacturingandpackagingofperfumes,legislationand regulationsforperfumesincosmetics.	6
2.4	Therapeuticingredientsinvariouscosmeticslikeskinproducts,dentifrices,haircare andnailpreparations,andperformanceevaluationoftheseactivities.	3
2.3	*Self-study:Detailsofgeneralrawmaterials(oils,fats,waxes,surfactants, preservatives, polysiloxanes), Historical purview of perfumes, Approved colours as per Indian, European and US specifications*	*5*
3	**Applicationofnovelapproachesincosmeticformulations**	**4**
3.1	Conceptsofmicroemulsions,liposomes,niosomes,nanoparticles,iontophoresis,to enhancefunctionalattributes&deliveryofcosmeceuticals.	4
4	**Herbal cosmetics**	**6**
4.1	Currenttrendsinuseofherbalmaterialsin cosmetics.	2
	Self-study:Discussiononaleovera,henna,teatreeoil,neeminvariouscosmetic products	*4*
5	**Packagingandlabellingofcosmeticproducts**	**5**
5.1	Packagingmaterials,specialtypackagesforcosmetics,labellingrequirementsfor cosmetics	5
6	**Qualitystandardsofcosmeticproducts:**	**18**
6.1	BISguidelinesforqualityoffinishedproductsforcosmetics,qualitycontrol,textural analysis,performanceandpsychometricevaluationofvariouscosmeticproductssuch ascreams,gels,powders,lipstick,naillacquer,shampoo,sunscreenproducts, dentifrices.	8
6.2	Microbiologicalqualityofcosmeticproducts.	2
6.3	Safetyandtoxicityevaluationofcosmeticproducts	4
6.4	Legalconsiderationsandregulatoryproceduresofcosmeticproducts	2

6.5	*Self-study-BIS,EuropeanandUS specificationsabout qualitystandardsof cosmetic products*	*2*
	Total	**60**

Books(latesteditionstobeadopted)

1. Harry'sCosmeticology,EditedbyJ.B.WilkinsonandR.J.Moore,LongmanScientific& Technical Publishers
2. CosmeticsScienceandTechnology,EditedbyM.S.Balsam,E.Sagarin,S.D.Gerhon,S.J.Strianse and M.M. Rieger, Wiley-Interscience, Wiley India Pvt. Ltd.
3. Poucher'sPerfumes,cosmetics&Soaps,HildaButler,KlewerAcademicPublishers,Netherlands
4. Cosmetic Technology, Ed. By S.Nanda, A. Nanda and R. Khar, Birla Publications Pvt. Ltd., New Delhi
5. HandbookofCosmeticScienceandTechnology,Ed.M.Paye,A.O.Barel,H.I.Maibach,Informa Healthcare USA, Inc.
6. Encyclopedia of PharmaceuticalTechnology, James Swarbrick,James C. Boylan, Marcel Dekker Inc.
7. BISGuidelinesfordifferentcosmeticproducts
7. Drugs&CosmeticsAct&Rules,1940(withlatestamendments).

MPH_E_226_T-PolymersinPharmacy (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.

M. PharmFirst Year,Semester II

MPH_E_226_T - Polymers in Pharmacy **(THEORY-60 hours)**

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_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

Course Code & CO number	***PO1***	***PO2***	***PO3***	***PO4***	***PO5***	***PO6***
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

Unit	**CourseContents(Topics)**	**Hrs.**
1.0	HistoricalBackground,Basicdefinitions,Applications	**1**
2.0	**ClassificationofPolymers**	**7**
2.1	Classification based on reaction to temperature and structure/arrangement/architecture-linear,branched,crosslinked.	2

2.2	Polymerizationmechanisms-Addition&step-growthpolymerization-Freeradical, cationic,anionicandZieglerNattamechanisms	5
3.0	**Copolymerization**	**5**
3.1	Theoreticalaspectsofcopolymerization	3
3.2	*Self-study-Casestudiesofanytwocopolymers*	2
4.0	**Properties&Characterizationofpolymers**	**12**
4.1	FactorsaffectingandOverview	1
4.2	Molecularweightanddeterminationofmolecularweight,	2
4.3	Solidstatecharacterization-glasstransitiontemperature,Crystallinity,	3
4.4	Solubilityofpolymers&Swellingpr,Mechanicalproperties	3
4.5	*Self-study-Casestudy-any3polymers–characteristics&comparison*	3
5.0	**MethodsofPreparationofPolymers**	**11**
5.1	Bulkpolymerization,Solutionpolymerization,	3
5.2	Suspensionpolymerization,Emulsionpolymerization.	3
5.3	Additivesinpolymers,Fabricationofpolymericdevices/systems-casting, extrusion,moulding etc	3
5.4	*Self-study-Oneexamplepolymerforeach method*	2
6.0	**BiocompatibilityofPolymers**	**10**
6.1	Safety&Biocompatibilityissues-Overview	1
6.2	Reactionofpolymertotissues,effectofbody/hostsystemstopolymers	2
6.3	Mechanismsoftissuereactions/injury,	2
6.4	Evaluationofbiocompatibilityofpolymers	3
6.5	*Self-study-Pharmacopoeial &othertestsfortoxicityevaluationofpolymers*	2
7.0	**BiocompatiblePolymers**	**10**
7.1	Generalfeaturesofbiocompatiblepolymers,enzymaticallydegradablebondsin polymers	2
7.2	Designofbiocompatiblepolymers&evaluation,	4
7.3	*Self-study-someexamples-PLGA,cellulosics,acrylates,hydrogels.*	4
8.0	**Applicationsofpolymersinpharmacy**.	**4**
8.1	Overviewofapplicationsasthickeners,binders,coatingagents,adhesives,as releasemodifyingagents,includingsmartpolymers,elastomers	2
8.2	*Self-study:Oneexampleeachof–adhesivepolymer,coatingagent,drugrelease modifier,smart polymer*	2
	Total	**60**

Books(latesteditionstobeadopted)

1. FundamentalPrinciplesofPolymericMaterials,RosenSL,WileyIntersciencePublication.
2. Martin'sPhysicalPharmacyandPharmaceuticalSciencesbySinkoPJ,EdLea&Feiger,Lippincott Williams & Wilkins.
3. ControlledDrugDelivery:FundamentalsandApplications,RobinsonJR,LeeVHL,Dekker.
4. BiodegradablePolymersasDrugDeliverySystems,ChasinM,LangerR,MarcelDekker.
5. ControlledandNovelDrugDeliverybyJainNK,CBSPublishersand Distributors.
6. ControlledDrugDelivery:ClinicalApplications,byBrukSD,CRCPressInc.
7. PolymericDrugDeliverySystembyKwonGS,Marcel Dekker.
8. AqueouspolymericcoatingforpharmaceuticaldosageformsbyMcGinityJW,Marcel Dekker

MPH_E_227_T-DrugEvaluationTechniques(4h/wk)

CourseObjectives: Thecoursewillimpartknowledgeofthestagesofdrugdiscovery,drugevaluationthroughhighthroughputscreeningassays,target-baseddrugdiscoveryandalternativescreeningmodelslikezebrafish, drosophila etc.withestimation ofbiologicalfluids.

CourseOutcomes(CO):

M.Pharm FirstYear,SemesterI **MPH_E_277_T DrugEvaluationTechniques(Theory4h/wk)**			
Course code & COnumber	***At the successful completion of the course,thelearners willbeableto:***	***Syllabus Unitno.***	***Up toBloom 'slevel***
MPH_E_227_T_CO1	Understand and explain the various stages of drug discoveryand biological screening including animal models, in vitro-invivocorrelations,animaltestingalongwiththeircareand maintenanceasperOECD,CCSEAandICHguidelines.	**1**	**2**
MPH_E_227_T_CO2	Understand the techniques used in high throughputscreeninglikecell-basedassays,biochemicalassays, fluorescence-basedassaysandchemiluminescencebaseddetection assays and relate to their applications in drugdiscoveryanddevelopment.	**1**	**2&3**
MPH_E_227_T_CO3	Comprehend and appreciate the importance of alternatemethods of screening such as Zebrafish and drosophilamodels including alternate methods to toxicity testing viz.pyrogenicity,invitroskinandeyeirritationtestsandapply theminyour basicresearch.	**1&4**	**2&3**
MPH_E_227_T_CO4	Understand, discuss and apply the screening & evaluationmodelsandthetechniquesof drugs/leadsforCNS, antidiabetic,immunomodulatory,anti-inflammatoryand antioxidantactivities.	**2**	**2&3**
MPH_E_227_T_CO5	**U**nderstand the methods used in target-based drug discoveryforanti-tubercular,anti-cancer,anti-HIVandanti-malarial activities and comprehend the importanceof target-baseddrug discovery and use of in vitro screening techniques indrugdiscoveryeg.Turbidimetricassay,GPIIB-IIIAassays forantiplateletactivity.	**2**	**2**
MPH_E_227_T_CO6	Review the methods for estimation of drugs from complexbiological fluids eg. Blood, tissue, CSF etc. and imply themintheirresearch.	**3**	**2&3**

Mapping COwithPO

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_277_T_CO6	**2**	**1**			**3**	

Unit	CourseContents(Topics)	Hours
1		**19**
1.1	**Basicprinciplesofdrugdiscoveryandbiological screening** • Correlationbetweenvariousanimalmodelsandhumansituations • Correlationbetween*invitro*and*invivo*screens. • Care,handling,breedingtechniquesoflabanimals. • CPCSEA,OECD,ICHguidelinesinbrief.	6
1.2	**Highthroughputscreeningindrug discovery** Techniquesforhighthroughput screening • Cellbased assays • Biochemicalassays • Radioligandbindingassays	6
1.3	**Detectionmethods** • Fluorescencebasedassaytechniques • Chemiluminescencebasedassaytechniques.	3
1.4	***Self-studyUseofalternativemethodsofscreening*** • *Zebrafish model* • *Drosophila* *Typesofdrugsforwhichthesemodelscanbeused.*	4
	Targetbaseddrugdiscoveryandinvitroscreeningtechniquesfor	**26**
2.1	Anti-plateletactivity-Turbidimetric,GPIIB–IIIAassaysusingplatelet aggregometer.	2

2.2	CNS: • Alzheimer's disease: *in vivo* which includes aluminium induced, scopolamine induced memory loss. In vitro includes acetylcholinesterase activity. • Parkinson's disease *in vivo* includes Haloperidol, reserpine, rotenone, MPTP induced models. • Antidepressantandanticonvulsants.	6
2.3	Anti-diabetic:Alloxan,STZ,geneticallydiabeticanimalsandvariousinvitro methods	3
2.4	• Antitubercular:BACTEC • Anticancer:Few*invitro*celllines,modelsfor metastasis • Anti-HIV:Varioustargetsinvolved • Antimalarial.	6
2.5	Immunomodulatory:*invivo*and*invitro*methods.	2
2.6	Anti-inflammatory:Acute,subacuteandchronicmodels.	2
2.7	*Self-study-Antioxidantactivity*	5
3	• **Estimation of drugs** from complex media like biological fluids, e.g. blood, tissues, CSF etc. • *Self-study-USFDAguidelinesforbioanalysismethodsincludingvalidation*	5 2
4	• *Invitro*skinirritationandeyeirritationtests,*Invitro*testsforpyrogenicity • Self-study-Alternativemethodsfortoxicitytesting(*invitro*)	**5**
	Total	**60**

Books(latesteditionstobeadopted)

1. H.G.Vogel,Drugdiscoveryandevaluation,PharmacologicalAssays,SpringerVerlog.
2. R.A.Turner,Screeningmethodsinpharmacology,AcademicPress.
3. D.R. Laurence and A.L. Bacharach, Evaluation of drug activities: Pharmacometrics, AcademicPress.
4. A.Schwartz,MethodsinPharmacology,PlenumPublishingCorporation.
5. Website--Altox.org/ttrc/validation-va

RESEARCHPROJECTANDTHESIS

Course Objectives: This course will impart students with the knowledge to independently carryforward research, starting from creation of hypothesis, planning, experimentation, data analysis, andreporting.

CourseOutcome

Course code & COnumber	***At the successful completion of the course,thelearners willbeableto:***	***Upto Bloom' slevel***
CO1	Perform the literature survey on the given research problemandweretheywillbeableto compareandcontrastthegivendataindifferentreports/published papers	**3&4**

CO2	Develop skills in handling of different animal species usedinpreclinicalpharmacologyand toxicology (Rodents/Zebrafish/Drosophila)orcounsellingofpatients forPVmonitoringwithfollowup(ifapplicable)underprofessional guidance.	**2&3**
CO3	Handledifferentinstruments(UV/HPLC/Stereotaxic apparatus/ELISA/RT-PCR etc) and develop the skills inusingthesame forresearchmethodologies.	**3,4 &5**
CO4	Plan and draft the research study protocol of their project,including efficacy and safety end points, including casereportformor Individual Case safetyreportform(if applicable), including inclusion and exclusion criteria,includingsamplesize,includingrandomization and statisticalplanafterreviewingthepublishedliteratureinthat areaandbasedonexistingknowledge andskills	**4,5&6**
CO5	Planandexecutetheresearchstudywithliteraturesurvey,performanceofexperiments,captureofdata,analysis, evaluation, interpretation & collation of the data to draftingof synopsis followed by the thesis and apply statistical testsandconceptstothestudydataviz.samplesize,sampling, applicationofANOVA,post hoctestsalongwiththeuseof statisticalsoftwaretodrawconclusionsandinferencesalong	**2,3& 6**
	withthepresentationofthedatainsuitableformsand figures.	
CO6	Developtheirscientificwritingskillswhilecreatingthesis,understandpublicationethics,plagiarism, ICT tools,and comprehendapplicationsofresearchoutcomes.	**1&3**

Mapping COwithPO

CO	PO1	PO2	PO3	PO4	PO5	PO6
01	**1**	**1**	**3**	**2**	**3**	**3**
02	**1**	**1**	**3**	**2**	**3**	**3**
03	**1**	**1**	**3**	**2**	**3**	**3**
04	**1**	**1**	**3**	**2**	**3**	**3**

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

CO number	*At the successful completion of the course, the learners will be able to:*	*Up to Bloom's level*

Course-PO Mapping Pharmacology

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:

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

CO-PO Mapping:

CO number	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