KAKATIYA UNIVERSITY, WARANGAL

SYLLUBUS FOR MASTER OF PHARMACY
(M.PHARM)
TWO YEARS COURSE
From the academic year 2023-2024 onwards

FACULTY OF PHARMACEUTICAL SCIENCES,
KAKATIYA UNIVERSITY NAAC A+ Grade, WARANGAL

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CHAPTER–I: REGULATIONS

1. ShortTitleandCommencement

These regulations shall be called as "The Revised Regulations for the Master of Pharmacy (M.Pharm.)Degree Program - Credit Based Semester System (CBSS) of the Pharmacy Council ofIndia,NewDelhi".TheyshallcomeintoeffectfromtheAcademicYear20203-24.Theregulations framed are subject tomodifications from time to time by the authorities of theKakatiya University.

2. Minimumqualificationforadmission

APassinthefollowingexaminations

a) B.PharmDegreeexaminationofanIndianuniversityestablishedbylawinIndiafroma

ninstitutionapprovedbyPharmacyCouncilofIndiaandhasscorednotlessthan55 %ofthemaximummarks(aggregate of 4years of B.Pharm.)

b) Every student, selected for admission to post graduate pharmacy program in any PCIapprovedinstitutionshould haveobtainedregistrationwiththeStatePharmacyCouncilorshould obtain the same within one month from the date of his/her admission, failing which theadmissionofthecandidateshallbecancelled.

Note: It is mandatory to submit a migration certificate obtained from the respective universitywhere the candidate hadpassedhis/herqualifyingdegree (B.Pharm.)

3. Durationoftheprogram

The program of study for M.Pharm. shall extend over a period of four semesters (two academicyears). The curricula and syllabi for the program shall be prescribed from time to time byPhamacyCouncilofIndia,NewDelhi.

4. Mediumofinstructionandexaminations

MediumofinstructionandexaminationshallbeinEnglish.

5. Workingdaysineachsemester

Eachsemestershallconsistofnotlessthan90workingdays.Theoddsemestersshallbeconductedfromth emonthofJune/JulytoNovember/Decemberandtheevensemestersshallbeconductedfromthemonthof December/JanuarytoMay/Juneineverycalendaryear.

6. Attendance and progress

Acandidate isrequiredto put inat least 75%attendance in individualcoursesconsidering theory andpractical separately.The candidate shall complete the prescribedcourse satisfactorily tobeeligible toappearfortherespective examinations.

7. Program/Coursecreditstructure

As per the philosophyof Credit Based Semester System, certain quantumof academic work viz.theoryclasses, practicalclasses, seminars, assignments, etc. are measured interms ofcredits. Onsatisfactorycompletionofthe courses, a candidate earns credits. The amount ofcredit associatedwith a course is dependent upon the number of hours of instruction per week in that course.Similarly the credit associated with any of the other academic, co/extra- curricular activities isdependent upon the quantum of work expected to be put in for each of these activities perweek/peractivity.

CreditassignmentTheoryand

Laboratorycourses

Courses are broadly classified as Theoryand Practical. Theorycourses consist of lecture (L) andPractical(P)coursesconsistofhoursspentinthelaboratory.Credits(C)foracourseisdependent on the number of hours of instruction per week in that course, and is obtained byusingamultiplierof one(1)forlectureandamultiplierofhalf (1/2)forpractical (laboratory)hours.Thus, for example, a theorycourse having four lectures per week throughout the semestercarries a credit of 4. Similarly, a practical having four laboratory hours per week throughoutsemestercarries acreditof2.

Thecontacthoursofseminars,assignmentsandresearchworkshallbetreatedasthatofpracticalcoursesf or the purpose of calculating credits. i.e., the contact hours shall be multiplied by 1/2. Similarly,thecontacthoursofjournalclub,researchworkpresentationsanddiscussionswiththesupervi sorshallbeconsideredas theorycourseandmultipliedby1.

Minimumcreditrequirements

Theminimumcreditpoints requiredforthe awardofM. Pharm. degree is 95. However based onthe credit points earned by the students under the head of co-curricular activities, a student shallearn a maximum of 100 credit points. These credits are divided into Theory courses, Practical,Seminars,Assignments,Researchwork,Discussionswiththesupervisor,JournalclubandCo-Curricular activities over the durationoffour semesters. The credits are distributed semester-wiseasshown inTable 14.Coursesgenerallyprogressinsequence,buildingcompetenciesand

their positioning indicates certain academic maturity on the part of the learners. Learners areexpectedtofollow the semester-wiseschedule ofcoursesgiveninthe syllabus.

8. Academicwork

A regular record of attendance both in Theory, Practical, Seminar, Assignment, Journal club,Discussion with thesupervisor,Researchwork presentation and Dissertation shall be maintainedbythedepartment/teachingstaffofrespectivecourses.

9. Courseofstudy

ThespecializationsinM.PharmprogramisgiveninTable1.

Table–1:ListofM.Pharm.SpecializationsandtheirCode

S.No.	Specialization	Code
1.	Pharmaceutics	MPH
2.	IndustrialPharmacy	MIP
3.	PharmaceuticalChemistry	MPC
4.	PharmaceuticalAnalysis	MPA
5.	PharmaceuticalQualityAssurance	MQA
6.	PharmaceuticalRegulatoryAffairs	MRA
7.	PharmacyPractice	MPP
8.	Pharmacology	MPL
9.	Pharmacognosy	MPG

The courseofstudy for M.Pharmspecializations shall include Semester wise Theory& Practical asgiven in Table – 2 to 11. The number of hours to be devoted to each theory and practical courseinanysemestershallnotbelessthanthatshowninTable–2to11.

Table–2:CourseofstudyforM.Pharm.(Pharmaceutics)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPH101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPH102T	DrugDeliverySystems	4	4	4	100
MPH103T	ModernPharmaceutics	4	4	4	100
MPH104T	IPRandRegulatoryAffairs	4	4	4	100
MPH105P	Modern PharmaceuticalAnalyticalTechniquesPractical	6	3	6	100
MPH106P	Pharmaceutics-IPractical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MPH201T	Advanced Biopharmaceutics& Pharmacokinetics	4	4	4	100
MPH202T	MolecularPharmaceutics (Nanotechnology&Targeted DrugDeliverySystems)	4	4	4	100
MPH203T	PharmaceuticalProduction Technology	4	4	4	100
MPH204T	Cosmetic andCosmeceuticals	4	4	4	100
MPH205P	AdvancedBioPharmaceuticsand PharmaocokineticsPractical	6	3	6	100
MPH206P	Pharmaceutics-IIPractical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–3:CourseofstudyforM.Pharm.(IndustrialPharmacy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MIP101T	ModernPharmaceuticalAnalyticalTechniques	4	4	4	100
MIP102T	PharmaceuticalFormulationDevelopment	4	4	4	100
MIP103T	Noveldrugdeliverysystems	4	4	4	100
MIP104T	IPRandRegulatoryAffairs	4	4	4	100
MIP105P	PharmaceuticalAnalyticalTechniques PracticalI	6	3	6	100
MIP106P	IndustrialPharmacy-IPracticalII	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MIP201T	AdvancedBiopharmaceuticsandPharmacokinetics	4	4	4	100
MIP202T	ScaleupandTechnologyTransfer	4	4	4	100
MIP203T	PharmaceuticalProductionTechnology	4	4	4	100
MIP204T	EntrepreneurshipManagement	4	4	4	100
MIP205P	AdvancedBioPharmaceuticsandPharmaocokineticsPractical	6	3	6	100
MIP206P	IndustrialPharmacyPractical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–4:CourseofstudyforM.Pharm.(PharmaceuticalChemistry)

CourseCode	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPC101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPC1012T	Advanced Organic Chemistry-I	4	4	4	100
MPC103T	Advanced Medicinal Chemistry-I	4	4	4	100
MPC104T	ChemistryofNaturalProducts	4	4	4	100
MPC105P	ChemistryofNaturalProductsPractical	6	3	6	100
MPC106P	AdvancedMedicinal Chemistry–IPractical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MPC201T	SpectroscopicIdentificationofOrganic compounds	4	4	4	100
MPC202T	Advanced Organic Chemistry-II	4	4	4	100
MPC203T	AdvancedmedicinalChemistry-II	4	4	4	100
MPC204T	ComputerAidedDrugDesign	4	4	4	100
MPC205P	AdvancedOrganicChemistryPractical	6	3	6	100
MPC206P	AdvancedMedicinalChemistry-II Practical	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–5:CourseofstudyforM.Pharm.(PharmaceuticalAnalysis)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPA101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPA102T	Advanced Pharmaceutical Analysis-I	4	4	4	100
MPA103T	PharmaceuticalValidation	4	4	4	100
MPA104T	FoodAnalysis	4	4	4	100
MPA105P	ModernPharmaceutical AnalyticalTechniques	6	3	6	100
MPA106P	AdvancedPharmaceuticalAnalysis-I	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MPA201T	AdvancedInstrumental Analysis	4	4	4	100
MPA202T	ModernBio-Analytical Techniques	4	4	4	100
MPA203T	QualityControland QualityAssurance	4	4	4	100
MPA204T	AdvancedPharmaceuticalAnalysis-II	4	4	4	100
MPA205P	AdvancedInstrumentalAnalysis	6	3	6	100
MPA206P	AdvancedPharmaceuticalAnalysis-II	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–6:CourseofstudyforM.Pharm.(PharmaceuticalQualityAssurance)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MQA101T	Modern Pharmaceutical AnalyticalTechniques	4	4	4	100
MQA102T	QualityManagement System	4	4	4	100
MQA103T	QualityControlandQuality Assurance	4	4	4	100
MQA104T	ProductDevelopmentand TechnologyTransfer	4	4	4	100
MQA105P	ModernPharmaceuticalAnalytical techniques	6	3	6	100
MQA106P	QualityAsssuranceandQualityControl	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MQA201T	Hazards and Safety Management	4	4	4	100
MQA202T	PharmaceuticalValidation	4	4	4	100
MQA203T	Auditsand Regulatory Compliance	4	4	4	100
MQA204T	Pharmaceutical ManufacturingTechnology	4	4	4	100
MQA205P	PharmaceuticalValidation	6	3	6	100
MQA206P	PharmaceuticalManufacturingTechnology	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–7:CourseofstudyforM.Pharm.(RegulatoryAffairs)

Course Code	Course	Credit Hours	Credit Points	Hrs./ wk	Marks
SemesterI					
MRA 101T	GoodRegulatoryPractices	4	4	4	100
MRA 102T	Documentationand RegulatoryWriting	4	4	4	100
MRA 103T	ClinicalResearch Regulations	4	4	4	100
MRA 104T	RegulationsandLegislationforDrugs& Cosmetics,MedicalDevices,Biologicals & Herbals, and Food &NutraceuticalsInIndia andIntellectual PropertyRights	4	4	4	100
MRA 105P	RegulatoryAffairsPracticalI	6	3	6	100
MRA 106P	RegulatoryAffairsPracticalII	6	3	6	100
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700
SemesterII					
MRA 201T	RegulatoryAspectsofDrugs &Cosmetics	4	4	4	100
MRA 202T	RegulatoryAspectsofHerbal &Biologicals	4	4	4	100
MRA 203T	Regulatory Aspectsof MedicalDevices	4	4	4	100
MRA 204T	RegulatoryAspectsofFood &Nutraceuticals	4	4	4	100
MRA 205P	RegulatoryAffairsPracticalIII	6	3	6	100
MRA 206P	RegulatoryAffairsPracticalIV	6	3	6	100
	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–8:CourseofstudyforM.Pharm.(PharmacyPractice)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPP 101T	ClinicalPharmacyPractice	4	4	4	100
MPP 102T	Pharmacotherapeutics-I	4	4	4	100
MPP 103T	Hospital&Community Pharmacy	4	4	4	100
MPP 104T	ClinicalResearch	4	4	4	100
MPP 105P	PharmacyPracticePracticalI	6	3	6	100
MPP 106P	PharmacyPracticePracticalII	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MPP 201T	PrinciplesofQualityUseof Medicines	4	4	4	100
MPP 102T	PharmacotherapeuticsII	4	4	4	100
MPP 203T	ClinicalPharmacokineticsand TherapeuticDrugMonitoring	4	4	4	100
MPP 204T	Pharmacoepidemiology Pharmacoeconomics	4	4	4	100
MPP 205P	PharmacyPracticePracticalIII	6	3	6	100
MPP 206P	PharmacyPracticePracticalIV	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–9:Courseofstudyfor(Pharmacology)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPL 101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPL 102T	AdvancedPharmacology-I	4	4	4	100
MPL103T	PharmacologicalandToxicologicalScreeningMethods-I	4	4	4	100
MPL 104T	CellularandMolecular Pharmacology	4	4	4	100
MPL 105P	PharmacologyPracticalI	6	3	6	100
MPL 106P	PharmacologyPracticalII	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MPL 201T	AdvancedPharmacologyII	4	4	4	100
MPL202T	PharmacologicalandToxicologicalScreeningMethods-II	4	4	4	100
MPL 203T	PrinciplesofDrugDiscovery	4	4	4	100
MPL 204T	ClinicalResearchandPharmacovigilence	4	4	4	100
MPL 205P	PharmacologyPracticalIII	6	3	6	100
MPL 206P	PharmacologyPracticalIV	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–10:CourseofstudyforM.Pharm.(Pharmacognosy)

Course Code	Course	Credit Hours	Credit Points	Hrs./wk	Marks
SemesterI					
MPG101T	ModernPharmaceutical AnalyticalTechniques	4	4	4	100
MPG102T	AdvancedPharmacognosy-1	4	4	4	100
MPG103T	Phytochemistry	4	4	4	100
MPG104T	IndustrialPharmacognostical Technology	4	4	4	100
MPG105P	AdvancedPharmacognosy-I	6	3	6	100
MPG106P	Phytochemistry	6	3	6	100
-	Seminar/Assignment	7	4	7	100
Total		35	26	35	700
SemesterII					
MPG201T	AdvancedPharmacognosy-II	4	4	4	100
MPG202T	IndianSystemofMedicine	4	4	4	100
MPG203T	Herbalcosmetics	4	4	4	100
MPG204T	ClinicalResearchandPharmacovigilence	4	4	4	100
MPG205P	AdvancedPharmacognosy-II	6	3	6	100
MPG206P	HerbalCosmetics	6	3	6	100
-	Seminar/Assignment	7	4	7	100
	Total	35	26	35	700

Table–11:CourseofstudyforM.Pharm.IIISemester(CommonforAllSpecializations)

CourseCode	Course	CreditHours	CreditPoints
MRM301T	ResearchMethodologyand Biostatistics	4	4
-	Journalclub	1	1
-	Discussion/Presentation (ProposalPresentation)	2	2
-	ResearchWork	28	14
Total		35	21

Table–12:CourseofstudyforM.Pharm.IVSemester(CommonforAllSpecializations)

Course Code	Course	CreditHours	CreditPoints
-	JournalClub	1	1
-	ResearchWork	31	16
-	Discussion/FinalPresentation	3	3
Total		35	20

Table–13:Semesterwisecreditsdistribution

Semester	CreditPoints
I	26
II	26
III	21
IV	20
Co-curricularActivities(AttendingConference,Scientific PresentationsandOtherScholarlyActivities)	Minimum=02Maximum=07*
TotalCreditPoints	Minimum=95 Maximum=100

*CreditPointsforCo-curricularActivities

TableNo-14GuidelinesforAwardingCreditPointsforCo-CurricularAwards

NameoftheActivity	MaximumCredit PointsEligible/ Activity
ParticipationinNationalLevel Seminar/Conference/Workshop/Symposium/TrainingPrograms (relatedtothespecializationofthestudent)	01
ParticipationininternationalLevelSeminar/Conference/Workshop/Symposium/TrainingPrograms(relatedtothespecializationofthe student)	02
AcademicAward/ResearchAwardfromState Level/NationalAgencies	01
AcademicAward/ResearchAwardfromInternational Agencies	02
Research/ReviewPublicationinNationalJournals (IndexedinScopus/WebofScience)	01
Research/ReviewPublicationinInternationalJournals (IndexedinScopus/WebofScience)	02

Journal: TheEditorialBoardOutsideIndia

*Thecreditpointsassignedforextracurricularandorco-curricularactivitiesshall begivenbythePrincipalsofthecollegesandthesameshallbesubmitted totheUniversity.Thecriteriato acquirethiscreditpointshallbedefined bytheUniversityfromtimetotime.

1. **ProgramCommittee**

1. TheM. Pharm. programmeshallhaveaProgrammeCommitteeconstitutedbytheHeadoftheinstitutioninco nsultationwithalltheHeadsofthe departments.

2. ThecompositionoftheProgrammeCommitteeshallbeasfollows:

A teacher at the cadre of Professor shall be the Chairperson; One Teacher from each M.Pharmspecialization and four student representatives (two fromeach academic year), nominated bytheHeadoftheinstitution.

3. DutiesoftheProgrammeCommittee:

i. Periodicallyreviewingtheprogressoftheclasses.
ii. Discussingtheproblemsconcerningcurriculum,syllabusandtheconductofclasses.
iii. Discussingwiththecourseteachersonthenatureandscopeofassessmentforthecourseandthesa meshallbeannouncedto thestudentsatthebeginningofrespectivesemesters.
iv. CommunicatingitsrecommendationtotheHeadoftheinstitutiononacademicmatters.
v. TheProgrammeCommitteeshallmeetatleasttwiceinasemesterpreferablyattheendofeachses sionalexamandbefore theendsemesterexam.

2. **Examinations/Assessments**

Theschemesforinternalassessment andendsemesterexaminationsaregiveninTable – 16.Endsemesterexaminations

The End Semester Examinations for each theory and practical course through semesters I to IVshall be conducted by the respective university and the marks/grades shall be submitted to theuniversity.

Note:IneachsemesterSeminar-50marksandAssignment-50marks(NonUniversityexam/Internalassessment)

TableNo:16-SchemesforInternalAssessmentandEndSemester(Pharmaceutics-MPH)

CourseCode	Course	InternalAssessment			EndSemester Exams		TotalMarks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPH101T	ModernPharmaceuticalAnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPH102T	DrugDelivery System	25	1.30Hr	25	75	3Hrs	100
MPH103T	ModernPharmaceutics	25	1.30Hr	25	75	3Hrs	100
MPH 104T	IPRandRegulatory Affair	25	1.30Hr	25	75	3Hrs	100
MPH 105P	ModernPharmaceutical Analyticaltechniques	25	3Hrs	25	75	4Hrs	100
MPH 106P	Pharmaceutics-I	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-		3Hrs	100
Total							700
SEMESTERII							
MPH 201T	AdvancedBiopharmaceutics&Pharmacokinetics	25	1.30Hr	25	75	3Hrs	100
MPH 202T	MolecularPharmaceutics(NanoTechandTargetedDDS)	25	1.30Hr	25	75	3Hrs	100
MPH 203T	PharmaceuticalProductionTechnology	25	1.30Hr	25	75	3Hrs	100
MPH 204T	Cosmeticand Cosmeceutic Als	25	1.30Hr	25	75	3Hrs	100
MPH 205P	PharmaceuticsPracticalIII	25	3Hrs	25	75	4Hrs	100
MPH 206P	PharmaceuticsPracticalIV	25	3Hrs	25	75	4Hrs	100
	Seminar /Assignment	100				3Hrs	100
Total							700

TableNo:17-SchemesforInternalAssessmentandEndSemester(IndustrialPharmacy-MIP)

Course Code	Course	InternalAssessment			EndSemesterExams		TotalMarks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MIP101T	ModernPharmaceutical AnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MIP102T	PharmaceuticalFormulationDevelopment	25	1.30Hr	25	75	3 Hrs	100
MIP103T	NovelDrugDeliverySystems	25	1.30Hr	25	75	3 Hrs	100
MIP104T	IntellectualPropertyRightsand RegulatoryAffairs	25	1.30Hr	25	75	3 Hrs	100
MIP105P	PharmaceuticalAnalyticalTechniques	25	3Hrs	25	75	4Hr	100
MIP106P	Industrialpharmacy-I	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
Semester-II							
Total							700
MIP201T	AdvancedBiopharmaceutics Pharmacokinetics	25	1.30Hr	25	75	3 Hrs	100
MIP202T	ScaleupandTechnologyTransfer	25	1.30Hr	25	75	3 Hrs	100
MIP203T	PharmaceuticalProductionTechnology	25	1.30Hr	25	75	3 Hrs	100
MIP204T	EntrepreneurshipManagement	25	1.30Hr	25	75	3 Hrs	100
MIP205P	AdvancedBiopharmaceutics Pharmacokinetics	25	3hrs	25	75	4hrs	100
MIP206P	IndustrialPharmacy-II	25	3hrs	25	75	4hrs	100
-	Seminar /Assignment	100	-	-		3Hrs	100
Total							700

TableNo:18-SchemesforInternalAssessmentandEndSemester(PharmaceuticalChemistry-MPC)

CourseCode	Course	InternalAssessment			EndSemester Exams		Total Marks
		SessionalExams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPC101T	ModernPharmaceuticalanalytical Techniques	25	1.30Hr	25	75	3Hrs	100
MPC102T	AdvancedOrganic Chemistry-I	25	1.30Hr	25	75	3Hrs	100
MPC103T	AdvancedMedicinal Chemistry-I	25	1.30Hr	25	75	3Hrs	100
MPC104T	ChemistryofNaturalProducts	25	1.30Hr	25	75	3Hrs	100
MPC105P	ChemistryOfNaturalProducts	25	3Hrs	25	75	4Hrs	100
MPC106P	AdvancedMedicinalChemistry-I	25	3hrs	25	75	4Hrs	100
-	Seminar /Assignment	100				3Hrs	100
Total							700
SEMESTERII							
MPC201T	SpectroscopicIdentificationofOrganiccompounds	25	1.30Hr	25	75	3 Hrs	100
MPC202T	AdvancedOrganic Chemistry-II	25	1.30Hr	25	75	3 Hrs	100
MPC203T	ComputerAidedDrugDeisgn	25	1.30Hr	25	75	3Hrs	100
MPC204T	AdvancedMedicinalChemistry&ScreeningMethods	25	1.30Hr	25	75	3Hrs	100
MPC205P	AdvancedOrganicChemistry	25	3hrs	25	75	4hrs	100
MPC206P	AdvancedMedicinalChemistry-II	25	3hrs	25	75	4hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700

TableNo:19-SchemesforInternalAssessmentandEndSemester(Pharmaceutical Analysis-MPA)

CourseCode	Course	InternalAssessment			EndSemester Exams		Total Marks
		Continuous Mode	Sessional Exams	Total	Marks	Duration	
			Marks / Duration				
SEMESTERI							
MPA101T	ModernPharmaceuticalAnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPA102T	AdvancedPharmaceuticalAnalysis-I	25	1.30Hr	25	75	3Hrs	100
MPA103T	PharmaceutiCalValidation	25	1.30Hr	25	75	3Hrs	100
MPA104T	FoodAnalysis	25	1.30Hr	25	75	3Hrs	100
MPA105P	ModernPharmaceuticalAnalyticalTechniques	25	3Hrs	25	75	4Hrs	100
MPA106P	PharmaceutiCalAnalysis-I	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MPA201T	AdvancedInstrumentalAnalysis	25	1.30Hr	25	75	3Hrs	100
MPA202T	ModernBio-AnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPA203T	QualityControlandQualityAssurance	25	1.30Hr	25	75	3Hrs	100
MPA204T	AdvancedPharmaceutical Analysis-II	25	1.30Hr	25	75	3Hrs	100
MPA205P	AdvancedInstrumentalAnalysis-I	25	3Hrs	25	75	4Hrs	100
MPA206P	AdvancedPharmaceutical Analysis-II	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700

TableNo:20-SchemesforInternalAssessmentandEndSemester(PharmaceuticalQuality Assurance-MQA)

Course Code	Course	InternalAssessment			EndSemester Exams		Total Marks
		Sessional Exams		Total	Marks	Duration	
		Marks	DurationOn				
SEMESTERI							
MQA101T	ModernPharmaceuticalAnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MQA102T	QualityManagementSystem	25	1.30Hr	25	75	3Hrs	100
MQA103T	QualityControland QualityAssurance	25	1.30Hr	25	75	3Hrs	100
MQA104T	ProductDevelopmentand TechnologyTransfer	25	1.30Hr	25	75	3Hrs	100
MQA105P	PharmaceuticalQualityAssurancePracticalI	25	3Hrs	25	75	4Hrs	100
MQA106P	PharmaceuticalQualityAssurancePractical -II	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MQA201T	HazardsandSafetyManagement	25	1.30Hr	25	75	3Hrs	100
MQA202T	PharmaceuticalValidation	25	1.30Hr	25	75	3Hrs	100
MQA203T	Audits RegulatoryCompliance	25	1.30Hr	25	75	3Hrs	100
MQA204T	PharmaceuticalManufacturingTechnology	25	1.30Hr	25	75	3Hrs	100
MQA205P	PharmaceuticalQuality AssurancePracticalIII	25	3Hrs	25	75	4Hrs	100
MQA206P	PharmaceuticalQualityAssurancePracticalIV	25	3Hrs	25	75	4Hrs	100
	Seminar/Assignment	100				3Hrs	100
Total							700

TableNo:21-SchemesforInternalAssessmentandEndSemester(Pharmaceutical RegulatoryAffairs-MPA)

CourseCode	Course	InternalAssessment			EndSemester Exams		Total Marks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MRA101T	GoodPharmaceuticalPractices	25	1.30Hr	25	75	3Hrs	100
MRA102T	DocumentationandRegulatoryWriting	25	1.30Hr	25	75	3Hrs	100
MRA103T	ClinicalResearchRegulations	25	1.30Hr	25	75	3Hrs	100
MRA104T	RegulationsandLegislation Drugs&Cosmetics,MedicalDevices,Biologicals & Herbals, and Food&NutraceuticalsInIndiaandIntellectualPropertyRights	25	1.30Hr	25	75	3Hrs	100
MRA105T	PharmaceuticalRegulatory AffairsPracticalI	25	3Hrs	25	75	3Hrs	100
MRA106T	PharmaceuticalRegulatory AffairsPracticalII	25	3Hrs	25	75	3Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
Semester-II							
MRA201T	RegulatoryAspectsofDrugs & Cosmetics	25	1.30Hr	25	75	3Hrs	100
MRA202T	RegulatoryAspectsof Herbal&Biologicals	25	1.30Hr	25	75	3Hrs	100
MRA203T	RegulatoryAspectsofMedicalDevices	25	1.30Hr	25	75	3Hrs	100
MRA204T	RegulatoryAspectsofFood& Nutraceuticals	25	1.30Hr	25	75	3Hrs	100
MRA205P	PharmaceuticalRegulatoryAffairs PracticalIII	25	3Hrs	25	75	4Hrs	100
MRA206P	PharmaceuticalRegulatoryAffairs PracticalIV	25	3Hrs	25	75	4Hrs	100
	Seminar /Assignment	100				3Hrs	100
	Total						700

TableNo:22-SchemesforInternalAssessmentandEndSemester(PharmacyPractice-MPP)

Course Code	Course	InternalAssessment			End Semester Exams		TotalMarks
		SessionalExams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPP101T	ClinicalPharmacyPractice	25	1.30Hr	25	75	3Hrs	100
MPP102T	Pharmacotherapeutics-I	25	1.30Hr	25	75	3Hrs	100
MPP103T	Hospital&CommunityPharmacy	25	1.30Hr	25	75	3Hrs	100
MPP104T	ClinicalResearch	25	1.30Hr	25	75	3Hrs	100
MPP105P	PharmacyPractice-IPractical-II	25	3 Hrs	25	75	4Hrs	100
MPP106P	PharmacyPractice-IIPractical-II	25	3Hrs	25	75	4Hrs	100
-	Seminar/Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MPP201T	PrinciplesofQualityUseof Medicines	25	1.30Hr	25	75	3Hrs	100
MPP202T	PharmacotherapeuticsII	25	1.30Hr	25	75	3Hrs	100
MPP203T	ClinicalPharmacokineticsand Therapeutic DrugMonitoring	25	1.30Hr	25	75	3Hrs	100
MPP204T	Pharmacoepidemiology& Pharmacoeconomics	25	1.30Hr	25	75	3Hrs	100
MPP205P	PharmacyPractice-IPractical-III	25	3Hrs	25	75	4Hrs	100
MPP206P	PharmacyPractice-IIPractical-IV	25	3Hrs	25	75	4Hrs	100
-	Seminar/Assignment -	100	-	-	-	3Hrs	100
Total							700

TableNo:23-SchemesforInternalAssessmentandEndSemester(Pharmacology-MPL)

Course Code	Course	InternalAssessment			EndSemester Exams		TotalMarks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPL101T	ModernPharmaceuticalAnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPL102T	AdvancedPharmacology-I	25	1.30Hr	25	75	3Hrs	100
MPL103T	PharmacologicalandToxicologicalScreening Methods-I	25	1.30Hr	25	75	3Hrs	100
MPL104T	CellularandMolecular Pharmacology	25	1.30Hr	25	75	3Hrs	100
MPL105P	Pharmacology-I	25	3Hrs	25	75	4Hrs	100
MPL106P	Pharmacology-II	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment -	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MPL201T	AdvancedPharmacologyII	25	1.30Hr	25	75	3Hrs	100
MPL102T	Pharmacologicaland ToxicologicalScreening Methods-II	25	1.30Hr	25	75	3Hrs	100
MPL203T	PrinciplesofDrugDiscovery	25	1.30Hr	25	75	3Hrs	100
MPL204T	Clinicalresearchand pharmacovigilance	25	1.30Hr	25	75	3Hrs	100
MPL205P	Pharmacology-III	25	3Hrs	25	75	4Hrs	100
MPL206P	Pharmacology-IV	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700

TableNo:24-SchemesforInternalAssessmentandEndSemester(Pharmacognosy-MPG)

Course Code	Course	InternalAssessment			EndSemester Exams		TotalMarks
		Sessional Exams		Total	Marks	Duration	
		Marks	Duration				
SEMESTERI							
MPG101T	ModernPharmaceutical AnalyticalTechniques	25	1.30Hr	25	75	3Hrs	100
MPG102T	AdvancedPharmacognosy-1	25	1.30Hr	25	75	3Hrs	100
MPG103T	Phytochemistry	25	1.30Hr	25	75	3Hrs	100
MPG104T	IndustrialPharmacognostical Technology	25	1.30Hr	25	75	3Hrs	100
MPG105P	AdvancedPharmacognosy-I	25	3Hrs	25	75	4Hrs	100
MPG106P	Phytochemistry	25	3Hrs	25	75	4Hrs	100
-	Seminar /Assignment	100	-	-	-	3Hrs	100
Total							700
SEMESTERII							
MPG201T	AdvancedPharmacognosy-II	25	1.30Hr	25	75	3Hrs	100
MPG102T	IndianSystemofMedicine	25	1.30Hr	25	75	3Hrs	100
MPG203T	Herbalcosmetics	25	1.30Hr	25	75	3Hrs	100
MPG204T	ClinicalResearchand Pharmacovigilence	25	1.30Hr	25	75	3Hrs	100
MPG205P	AdvancedPharmacognosy-II	25	3Hrs	25	75	4Hrs	100
MPG206P	HerbalCosmetics	25	3Hrs	25	75	4Hrs	100
-	Seminar/Assignment -	100	-	-	-	3Hrs	100
Total							700

Tables–25:Schemesforinternalassessmentsandendsemesterexaminations(SemesterIII&IV)

Course Code	Course		InternalAssessment			EndSemester Exams		Total Marks
			SessionalExams		Total	Marks	Duration	
			Marks	Duration				
SEMESTERIII								
MRM301T	Research Methodologyand Biostatistics		25	1.30Hr	25	75	3Hrs	100
-	Journalclub		-	-	25	-	-	25
-	Discussion/ Presentation (Proposal Presentation)		-	-	50	-	-	50
-	Researchwork		-	-	-	250	4Hr	250
Total								425
SEMESTERIV								
-	Journalclub	-	-	-	25	-	-	25
-	Discussion/ Presentation (Proposal Presentation)	-	-	-	75	-	-	75
-	Researchworkand Colloquium	-	-	-	-	400	4Hr	400
Total								500

11.2.1.Sessional Exams

Two sessional exams shall be conducted for each theory / practical course as per the schedulefixedbythecollege(s).Theschemeofquestionpaperfortheoryandpracticalsessionalexaminations is given in the table. The average marks of two sessional exams shall be computedforinternalassessmentas pertherequirementsgivenintables.

12. PromotionandAwardofgrades

A studentshallbe declared PASSand eligibleforgetting gradein a course of M.Pharm.programme if he/she secures at least 50% marks in that particular course including internalassessment

13. CarryForwardofMarks

Incaseastudentfailstosecuretheminimum50%inanyTheoryorPracticalcourseasspecifiedin 12, then he/she shall reappearfor the end semester examination of that course. Howeverhis/her marks of the Internal Assessment shall be carried over and he/she shall be entitled forgrade obtainedbyhim/heronpassing.

14. ImprovementofInternalAssessment

A student shall have the opportunity to improve his/her performance only once in the sessionalexam component of theinternal assessment. The re-conduct of the sessional exam shall becompleted before the commencementofnextendsemestertheoryexaminations.

15. Re–ExaminationofEndSemesterExaminations

Reexaminationofendsemesterexaminationshallbeconductedaspertheschedulegivenintable 28.Theexactdatesofexaminationsshallbenotifiedfromtimetotime.

Table–26:Tentativescheduleofendsemesterexaminations

Semester	For RegularCandidates	ForFailedCandidates
IandIII	November/ December	May/June
IIandIV	May/June	November/December

16. AllowedtoKeepTerms (ATKT):

No student shall be admitted to any examination unless he/she fulfills the norms given in 6.ATKTrules areapplicable asfollows:

A student shall be eligible to get his/her CGPA upon successful completion of the courses off toIV semesters.

Note: Grade AB should be considered as failed and treated as one head for deciding ATKT. Suchrulesarealsoapplicableforthosestudentswhofailtoregisterforexamination(s)of any course in any semester.

17. GradingofPerformance

Lettergradesandgradepointsallocations:

Basedontheperformances,eachstudentshallbeawardedafinallettergradeattheendofthesemesterforeachcourse.Thelettergradesandtheir correspondinggradepointsaregiveninTable–28.

Table–27:LettergradesandgradepointsequivalenttoPercentageofmarksandperformances

Percentageof MarksObtained	LetterGrade	GradePoint	Performance
90.00–100	O	10	Outstanding
80.00–89.99	A	9	Excellent
70.00–79.99	B	8	Good
60.00–69.99	C	7	Fair
50.00–59.99	D	6	Average
Lessthan50	F	0	Fail
Absent	AB	0	Fail

AlearnerwhoremainsabsentforanyendsemesterexaminationshallbeassignedalettergradeofABand a correspondinggrade pointofzero.He/she shouldreappearforthe saidevaluation/examinationinduecourse.

18. TheSemesterGradePointAverage(SGPA):

The performance of a student in a semester is indicated by a number called 'Semester GradePoint Average'(SGPA). TheSGPAistheweightedaverageofthegradepointsobtainedinallthe coursesby the student during the semester. Forexample, if a studenttakes five courses (Theory/Practical)ina semester withcreditsC1, C2, C3and C4 andthe student'sgrade points in these courses are G1,G2,G3andG4,respectively,andthenstudents'SGPAisequalto:

$$SGPA=\frac{C_1G_1+C_2G_2+C_3G_3+C_4G_4}{C_1+C_2+C_3+C_4}$$

The SGPA is calculated to two decimal points. It shouldbe noted that, the SGPA for anysemestershall takeintoconsideration the F and ABSgrade awarded in thatsemester. ForexampleifalearnerhasaForABS gradeincourse4,theSGPAshallthen becomputed as:

$$SGPA=\frac{C_1G_1+C_2G_2+C_3G_3+C_4*ZERO}{C_1+C_2+C_3+C_4}$$

19. CumulativeGradePointAverage(CGPA):

The CGPA is calculated with the SGPA of all the IV semesters to two decimal points and isindicated in final grade report card/final transcript showing the grades of all IV semesters andtheir courses. The CGPA shall reflect the failed statusin case of F grade(s), till the course(s)is/arepassed. When the course(s) is/are passedby obtaining a pass grade on subsequent examination(s)the CGPA shall onlyreflect the new grade and not the fail grades earned earlier. The CGPA iscalculatedas:

$$CGPA=\frac{C_1S_1+C_2S_2+C_3S_3+C_4S_4}{C_1+C_2+C_3+C_4}$$

whereC1, C2, C3,….isthetotalnumberofcreditsforsemesterI,II,III,…. and$S_1,S_2,S_3,\ldots$isthe SGPAofsemesterI,II,III,…..

20. DeclarationofClass

TheclassshallbeawardedonthebasisofCGPAasfollows:FirstClasswithDistinction=CGPAof. 7.5andabove

FirstClass =CGPAof6.00to 7.49

SecondClass=CGPA of 5.00to5.99

21. ProjectWork

Allthestudentsshallundertakeaproject under thesupervisionofateacher inSemester IIItoIV andsubmitareport.4copiesoftheprojectreportshallbesubmitted(typed&boundcopynotlessthan7 5pages).

The internal and external examiner appointed by the University shall evaluate the project at thetimeofthePracticalexaminationsofothersemester(s).Theprojectsshallbeevaluatedasperthe criteriagivenbelow.

EvaluationofDissertationBook:

Objective(s)oftheworkdone	50Marks
Methodologyadopted	150marks
ResultsandDiscussions	250Marks
ConclusionsandOutcomes	50Marks
Total	**500Marks**

EvaluationofPresentation:

Presentationofwork	100Marks
Communicationskills	50Marks
Questionandanswerskills	100Marks
Total	**250Marks**

22. AwardofRanks:

RanksandMedalsshallbeawardedonthebasisof finalCGPA. However, candidateswho fail in one ormore courses during the M.Pharm program shall not be eligibleforaward of ranks.Moreover,the candidates should have completed the M. Pharmprogram in minimum prescribed number ofyears,(twoyears)fortheawardofRanks

23. DurationofthecompletionoftheProgramofthestudy

Theduration forthecompletionoftheprogramshallbe fixed asdoubletheactualdurationof theprogramandthestudentshavetopasswithinthesaidperiod,otherwisetheyhavetogetfreshRegistration.

24. RevaluationIRetotalingofanswerpapers

Thereisnoprovisionforrevaluationoftheanswerpapersinanyexamination.However,thecandidatescanapplyforretotalingbypayingprescribedfee.

25. Readmissionafterbreakofstudy

Candidatewho seeksre-admissiontotheprogramafterbreakofstudyhastogettheapproval from theuniversitybypayingacondonationfee.

PHARMACEUTICS
(MPH)MODERNPHARMACEUTICALANALYTICALTECHN
IQUES(MPH101T)I SEMESTER

THEORY **60HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification,characterizationandquantificationofdrugs.InstrumentsdealtareMassspectrometer,IR, HPLC,GC etc.

Objectives

Aftercompletionofcoursestudentisabletoknow,Chemical
- sandExcipients
- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoreticalandpractical
- skills oftheinstruments

UNIT-I **10HRS**

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated withUV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

b. IRspectroscopy:Theory,ModesofMolecularvibrations,Samplehandling,Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affectingvibrationalfrequencies andApplicationsofIR spectroscopy

c. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers,Instrumentationand Applicationsoffluorescence spectrophotometer.

UNIT-II **8HRS**

MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionization likeelectronimpact,chemical,field,FABandMALDI,APCI,ESI,APPIAnalyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules,Metastableions,IsotopicpeaksandApplicationsofMassspectroscopy.

UNIT-III **12HRS**

Chromatography: Principle,apparatus,instrumentation,chromatographic parameters,factorsaffectingresolutionandapplications ofthefollowing:
a)Paperchromatographyb)ThinLayerchromatographyc)Ionexchangechromatographyd)Column chromatographye)Gaschromatography f)High PerformanceLiquidchromatography
g) Affinitychromatography

UNIT-IV **10HRS**

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Electrophoresis:Principle,Instrumentation,Workingconditions,factorsaffectingsepa rationandapplications ofthefollowing:
a)Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresi se)Movingboundaryelectrophoresisf)Isoelectricfocusing

UNIT-V **10HRS**

a) Immunologicalassays:RIA(Radioimmunoassay),ELISA,Bioluminescenceassays.
b) Thermaltechniques:DSC,DTA,TGA,Principle,Instrumentation,factorsaffecting,advantages anddisadvantages andPharmaceuticalapplications.

UNIT-VI **8HRS**

NMR Spectroscopy: Quantum numbers and their role in NMR, Principle, instrumentation,solventrequirementsinNMR,Relaxationprocess,NMRsignalsinvariouscompou nds.Briefoutline ofFT-NMR andC^{13}NMR,applicationsofNMR Spectroscopy.

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds- RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis-Doglas ASkoog, F. JamesHoller,TimothyA. Nieman,5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBS Publishers,New Delhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugs inPharmaceuticalformulation- PDSethi, 3rd Edition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-Modernmethods–PartB-JWMunson,Volume11,MarcelDekkerSeries

DRUGDELIVERYSYSTEMS
(MPH102T)

THEORY **60Hrs**

SCOPE

Thiscourseisdesignedtoimpartknowledgeontheareaofadvancesinnoveldrugdeliverysystems.

OBJECTIVES

Uponcompletionofthecourse,studentshallbeabletounderstandThevario

- usapproachesfordevelopmentofnoveldrugdeliverysystems.
- Thecriteria forselectionofdrugsandpolymers forthedevelopmentofdeliveringsystem
- TheformulationandevaluationofNoveldrugdeliverysystems..

UNIT-I **9Hrs**

Sustained Release (SR) and Controlled Release (CR) formulations: Introduction & basicconcepts,advantages/disadvantages,factorsinfluencing,Physicochemical&biologicalappr oaches for SR/CR formulation, Mechanism of Drug Delivery from SR/CR formulationcomputation of desired release rate and dose for controlled release DDS, pharmacokineticdesignforDDS–intermittent,zeroorder&firstorderrelease.

UNIT-II **9Hrs**

CarriersforDrugDelivery:Polymers/co-polymersintroduction,classification,characterization, polymerization techniques, application in CDDS / NDDS, biodegradable &naturalpolymers.

UNIT-III **9Hrs**

RateControlledDrugDeliverySystems:Types,Activation;ModulatedDrugDeliverySystems; Mechanically activated, pH activated, Enzyme activated, and Osmotic activatedDrugDeliverySystemsFeedbackregulatedDrugDeliverySystems;Principles&Fundam entals.

UNIT-IV **9Hrs**

StudyofVariousDDS:Concepts,design,formulation&evaluationofcontrolledreleaseoralDDS,G RDDS,Mucoadhesiveandbuccal DDS,colon specific,liquidsustainedreleasesystems,Oculardeliverysystems.

UNIT-V **9Hrs**

Transdermal Drug Delivery Systems: Structure of skin and barriers, Penetration enhancers,TransdermalDrugDeliverySystems,Formulationandevaluation.

UNIT-VI **9Hrs**

Protein and Peptide Delivery: Barriers for protein delivery. Formulation and Evaluation ofdelivery systems ofproteins andothermacromolecules.

UNIT-VII **9Hrs**

Personalized Medicine: Introduction,Definition,Pharmacogenetics,Categories of Patientsfor Personalized Medicines, Customized drug deliverysystems, Bioelectronic Medicines, 3Dprintingofpharmaceuticals,Telepharmacy.6Hrs

REFERENCEBOOKS:

1. YW.Chien,NovelDrugDeliverySystems,2ndedition,revisedandexpanded,Marcel Dekker,Inc.,New York,1992.
2. Robinson, J. R.,LeeV.H. L,ControlledDrugDeliverySystems,MarcelDekker,Inc.,NewYork,1992.
3. Encyclopediaofcontrolleddelivery,Editor-EdithMathiowitz,PublishedbyWileyInterscience Publication,JohnWileyandSons,Inc,New York!Chichester/Weinheim
4. N.K.Jain,Controlled andNovelDrugDelivery,CBSPublishers&Distributors,NewDelhi,Firstedition1997(reprintin 2001).
5. S.P.VyasandR.K.Khar,ControlledDrugDelivery-conceptsandadvances,Vallabh Prakashan,New Delhi,Firstedition2002

JOURNALS

1. IndianJournalofPharmaceuticalSciences(IPA)
2. Indiandrugs(IDMA)
3. Journalofcontrolledrelease(ElsevierSciences)desirable
4. DrugDevelopmentandIndustrialPharmacy(Marcel&Decker)desirable

MODERNPHARMACEUTICS
(MPH103T)

THEORY **60HRS**

Scope

Coursedesignedtoimpartadvancedknowledgeandskillsrequiredtolearnvariousaspectsandconceptsatpharmaceuticalindustries.

Objectives

Uponcompletionofthecourse,studentshallbeabletounderstandThee

- lementsofpreformulationstudies.
- TheActivePharmaceuticalIngredientsandGenericdrugProductdevelopment
- IndustrialManagementandGMPConsiderations.
- Optimization Techniques & Pilot Plant Scale Up
- TechniquesStabilityTesting,sterilizationprocess&packagingofdosageforms.

UNIT-I **14Hrs**

a. Preformulation Concepts – Drug Excipient interactions - different methods, kinetics ofstability, Stability testing. Theories of dispersion and pharmaceutical Dispersion (Emulsionand Suspension, SMEDDS) preparation and stability. Large and small volume parental –physiologicalandformulationconsideration,Manufacturingand evaluation.

b. OptimizationtechniquesinPharmaceuticalFormulation:Conceptandparametersofoptimization,Optimizationtechniquesinpharmaceuticalformulationandprocessing.Statisticaldesign,Responsesurfacemethod,Contourdesigns,Factorialdesignsandapplicationinformulation

UNIT-II **10Hrs**

Validation:IntroductiontoPharmaceuticalValidation,Scope&meritsandtypesofValidation, Validation and calibration ofMaster plan, ICH & WHO guidelines for calibrationand validation of equipments(Tablet machine, Coating pan, auto clave, FBD, aseptic room),Validationofspecificdosageform(solidsandliquid).Governmentregulation,ManufacturingProcessModel,DQ,IQ,OQ &PQoffacilities.

UNIT-III **10Hrs**

cGMP & Industrial Management: Objectives and policies of currentgood manufacturingpractices,layoutofbuildings,services,equipmentsandtheirmaintenance.Productionmanagement: Production organization, materials management, handling and transportation,inventory management and control, production planning and control, Sales forecasting,budgetandcostcontrol,industrialandpersonalrelationship.ConceptofTotalQualityManagement.

UNIT-IV **10Hrs**

Compression, compaction and consolidation: Physics of tablet compression, Basic principlesof interaction, compression and consolidation, effect ofload, friction, distribution of forces incompaction, force volume relationship, Heckel plots, compaction profile, measurement ofcompressionwithstraingauge.

UNIT-V **10Hrs**

Dissolutiontesting:studyoffactorsinfluencingdissolution,Dissolutiondataanalysismathematical models ofdrugrelease (HiguchiandPeppas)

UNIT-VI **6Hrs**

Linearity(Regression) Concept ofsignificance, Standard deviation, standard error Chisquaretest,studentsT-test,ANOVA(onewayandtwo way)testandPvalue.

REFERENCEBOOKS:

1. TheoryandPracticeofIndustrialPharmacyByLachmannandLibermann
2. Pharmaceuticaldosageforms:TabletsVol.1-3byLeonLachmann.
3. PharmaceuticalDosageforms:Dispersesystems,Vol,1-2;ByLeonLachmann.
4. PharmaceuticalDosageforms:ParenteralmedicationsVol.1-2;ByLeonLachmann.
5. ModernPharmaceutics;ByGillbertandS.Banker.
6. Remington'sPharmaceuticalSciences.
7. AdvancesinPharmaceuticalSciencesVol.1-5;ByH.S.Bean&A.H.Beckett.
8. PhysicalPharmacy;ByAlfredmartin
9. Bentley'sTextbookofPharmaceutics–byRawlins.
10. GoodmanufacturingpracticesforPharmaceuticals:Aplanfortotalqualitycontrol,Secondeditio n;BySidneyH.Willig.
11. QualityAssuranceGuide;ByOrganizationofPharmaceuticalproducersofIndia.
12. Drugformulationmanual;ByD.P.S.KohliandD.H.Shah.Easternpublishers,NewDelhi.
13. HowtopracticeGMPs;ByP.P.Sharma.VandhanaPublications,Agra.
14. PharmaceuticalProcessValidation;ByFra.R.BerryandRobertA.Nash.
15. PharmaceuticalPreformulations;ByJ.J.Wells.
16. Appliedproductionandoperationsmanagement;ByEvans,Anderson,SweeneyandWilliams.
17. EncyclopaediaofPharmaceuticaltechnology,VolI–III.

IPR AND REGULATORYAFFAIRS
(MPH104T)

THEORY **60Hrs**

Scope

Course designed to impartadvanced knowledge and skills required to learn the conceptofgeneric drug and their development, various regulatory filings in different countries, differentphases of clinical trials and submitting regulatory documents: filing process of IND, NDA andANDA

- Toknowtheapprovalprocess
- Toknowthechemistry,manufacturingcontrolsandtheirregulatoryimportanceTole
- arnthedocumentationrequirements
- Tolearntheimportance

Objectives:

Uponcompletionofthecourse,itisexpectedthatthestudentswillbeabletounderstandTheConcep

- tsofinnovatorandgeneric
- drugs,drugdevelopmentProcessTheRegulatoryguidance'sandguidelinesforfilingandappr
- ovalprocessPreparationofDossiersandtheirsubmissiontoregulatoryagenciesindifferentcou
- ntriesPostapproval regulatory requirements for actives and drug
- productsSubmissionofglobaldocumentsinCTD/eCTDformatsClinicaltrialsrequirementsf
- orapprovalsforconductingclinicaltrials
- Pharmacovigilenceandprocessofmonitoring inclinicaltrials.

UNIT-I **10Hrs**

Drugproductdevelopment:Activepharmaceuticalingredients,drugmasterfile(DMF)andimpurities. Generic product development: Introduction, Hatch-Waxman act and amendments,GUDUFA, ANDA (505j), ANDA approval process. New drug application (505B1 and 505B2).NDAapprovalprocessincludingIND.Scaleupandpostapprovalchanges(SUPAC).Bioequiva lenceandBioavailability,differenttypesofstudiesfordrugproductapproval.

UNIT-II **10Hrs**

ICH- Guidelines of ICH – Q7 to Q11, M9. Clinical Trials. HIPPA – new, requirements toclinicalstudyprocess,Parmacovigilance safetymonitoringinclinicaltrials.

UNIT-III **10Hrs**

ANDA for generic drugs ways and means of US registration for foreign drugs. CMC, Postapprovalregulatoryaffairs.Regulationforcombinationproducts,medicaldevices&Biosimilars.

UNIT-IV **10Hrs**

BriefintroductiontoCDSCO,WHO,USFDA,EMEA,TGA,MHRA,MCC,ANVISA.

UNIT-V **10Hrs**

Definitions, Need for Patenting, Types of Patents, Conditions to be satisfied by an inventionto be Patentable, introduction to patent and patent search. Parts of Patent. Filing of patents.The essential elements of patent. Guidelines for preparation of laboratory notebook, Non-obviousnessinpatent.

UNIT-VI **10Hrs**

Copy right, Trademark, Geographical indication acts, Patentlitigation, 180 days marketexclusivityandDoctrineofequivalents.

REFERENCEBOOKS

1. GenericDrugProductDevelopment,SolidOralDosageforms,LeonShargeland IsaderKaufer,MarcelDekkerseries,Vol.143
2. ThePharmaceuticalRegulatoryProcess,Second EditionEditedbyIraR.BerryandRobertP.Martin, Drugs and the Pharmaceutical Sciences,Vol.185,InformaHealthcarePublishers.
3. NewDrugApprovalProcess:AcceleratingGlobalRegistrationsByRichardAGuarino, MD,5thedition,Drugs andthePharmaceuticalSciences,Vol.190.
4. Guidebookfordrugregulatorysubmissions/SandyWeinberg.ByJohnWiley&Sons.Inc.
5. FDAregulatoryaffairs:aguideforprescriptiondrugs,medicaldevices,andbiologics/editedByDouglas J.Pisano,DavidMantus.
6. ClinicalTrialsandHumanResearch:APracticalGuidetoRegulatoryComplianceByFayA. RozovskyandRodneyK.Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

MODERNPHARMACEUTICALANALYTICALTECHNIQUESPRACTICALS (MPH105P)

1. Analysisofpharmacopoeialcompoundsandtheirformulations byUVVisspectrophotometer(Minimum4Experiments)
2. Simultaneousestimationofmulticomponentcontainingformulations byUV/HPLCspectrophotometry(Minimum4Experiments)
3. ExperimentsbasedonHPLC
4. ExperimentsbasedonGasChromatography
5. Estimationofriboflavin/quininesulphatebyfluorimetry
6. Estimationofsodium/potassiumbyflamephotometry

PHARMACEUTICS-I PRACTICALS(MPH106P)

1. Tocarryoutpreformulationstudiesofdrugs,effectofsurfactantsandpHonthesolubilityofdrugs, compatibilityevaluationofdrugs andexcipients byDSC andFTIR.
2. Formulation andevaluation of SR/CRTabletsandcompareIn-Vitrodissolution profileofSR/CRMarketedformulation.
3. FormulationandevaluationosmoticallycontrolledDDS
4. PreparationandevaluationofFloatingDDS-hydrodynamicallybalancedDDS
5. FormulationandevaluationofMucoadhesivetablets.
6. Formulationandevaluationoftransdermalpatches.
7. StabilitystudiesofdrugsinsolutionsandsoliddosageformsaccordingtoICHguidelines.
8. Tostudytheeffectofcompressionalforce,particlesizeand bindersontabletsdisintegrationtime anddissolutionofatablet.
9. TostudyMicromeriticpropertiesofpowdersandgranulation.
10. AnalysisofdrugreleasefromCRtablets,Higuchi,Peppasplot,zeroorder.Similarityfactordetermination
11. Preparationandevaluationofdifferentpolymericmembranes.
12. ValidationofTabletmachine,coatingpan,dryers,autoclave

SEMESTER-II
ADVANCEDBIOPHARMACEUTICS&PHARMACOKINETICS(MPH201T)

THEORY **60Hrs**

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, doseadjustmentsandtoapplybiopharmaceuticstheoriesinpracticalproblemsolving.Basictheoretical discussions of the principles of biopharmaceutics and pharmacokinetics are providedtohelpthestudents'toclarifytheconcepts.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentswillbeableunderstand,Theb

- asicconceptsinbiopharmaceuticsandpharmacokinetics.
- Theuserawdataandderivethepharmacokineticmodelsandparametersthebestdescribetheprocesso fdrugabsorption,distribution,metabolismandelimination.
- Thecriticalevaluationofbiopharmaceuticstudiesinvolvingdrugproductequivalency.Thedesignandevaluati
- onofdosageregimensofthedrugsusingpharmacokineticand biopharmaceuticparameters.
- Thepotentialclinicalpharmacokineticproblemsandapplicationofbasicsofpharmacokinetic

UNIT-I **10Hrs**

DrugAbsorptionfrom theGastrointestinal Tract: Gastrointestinal tract, Mechanism of drugabsorption,Factorsaffectingdrugabsorption,pH–partitiontheoryofdrugabsorption.Formulationandphysicochemicalfactors:Dissolutionrate,Dissolution process,Noyes–Whitneyequation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption:role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as adosageform,Capsuleasadosageform,Tabletasadosageform,Dissolutionmethods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transportmodel:Permeability-Solubility-ChargeStateandthepHPartitionHypothesis,Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment,Tight-JunctionComplex.

UNIT-II **10Hrs**

Biopharmaceutic considerations in drug product design and In Vitro Performance: Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption,physicochemical nature of the drug, formulation factors affecting drug product performance, invitro:dissolutionanddrugreleasetesting,compendialmethodsofdissolution,alternativemethods ofdissolutiontesting,meeting dissolutionrequirements, problems ofvariable controlindissolution testing performance ofdrug products. In vitro–in vivo correlation, dissolution profilecomparisons.

UNIT-III **10Hrs**

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling:one compartment model- IV bolus, IV infusion, extra-vascular. Multi compartment model:twocompartment-modelinbrief.

UNIT-IV **10Hrs**

Non-linearpharmacokinetics:causeofnon-linearity,Michaelis–Mentenequation,estimation of Kmax and Vmax. Noncompartmental Pharmacokinetics- statistical momenttheoryandphysiologicalpharmacokineticmodel.Alteredpharmacokineticsinrenalandhepaticdiseases.Drug interactions: introduction,theeffect ofproteinbindingoninteractions, theeffect of tissue-binding on interactions, cytochrome p450-based drug interactions, and druginteractionslinkedtotransporters.

UNIT-V **10Hrs**

DrugProductPerformance,InVivo:BioavailabilityandBioequivalence:drugproductperformance, purpose of bioavailability studies, relative and absolute availability. Methodsforassessingbioavailability,bioequivalencestudies,designandevaluationofbioequivalencestudies,studydesigns,crossoverstudydesigns,evaluationofthedata,bioequivalenceexample, studysubmissionand drug review process. Biopharmaceuticsclassificationsystem,methods. Permeability: In-vitro, in-situ and In-vivo methods. generic biologics (biosimilardrugproducts),clinicalsignificanceofbioequivalencestudies,specialconcernsinbioavailabilityandbioequivalence studies,genericsubstitution.

UNIT-VI **10Hrs**

ApplicationofPharmacokinetics:ChronoPharmacokinetics,Modified-ReleaseDrugProducts, Targeted Drug Delivery Systems and Biotechnological Products. Introduction toPharmacokineticsandpharmacodynamicsofbiotechnology drugsProteinsandpeptides,Monoclonalantibodies,Oligonucleotides,Vaccines(immunotherapy),Genetherapies.**10Hrs**

REFERENCEBOOKS:

1. BiopharmaceuticsandClinicalPharmacokineticsbyMiloGibaldi,4th edition,Philadelphia,LeaandFebiger,1991
2. BiopharmaceuticsandPharmacokinetics,A.Treatise,D.M.BrahmankarandSunilB.Jaiswal., VallabPrakashan,Pitampura,Delhi
3. AppliedBiopharmaceuticsandPharmacokineticsbyShargel.LandYuABC,2ndedition, ConnecticutAppletonCenturyCrofts,1985
4. TextbookofBiopharmaceuticsandPharmacokinetics,Dr.ShobhaRaniR.Hiremath,PrismBook
5. PharmacokineticsbyMiloGibaldiandD.Perrier,2ndedition,MarcelDekkerInc.,NewYork,1982
6. CurrentConceptsinPharmaceuticalSciences:Biopharmaceutics,Swarbrick.J,LeaandFebiger, Philadelphia,1970

7. ClinicalPharmacokinetics,ConceptsandApplications3rdeditionbyMalcolmRowlandandTho m~ N.Tozer,Lea andFebiger,Philadelphia,1995
8. Dissolution,BioavailabilityandBioequivalence,Abdou.H.M,MackPublishingCompany, Pennsylvania 1989
9. BiopharmaceuticsandClinicalPharmacokinetics,AnIntroduction,4th edition,revisedand expandebyRobert.E.Notari,MarcelDekkerInc,New YorkandBasel,1987.
10. BiopharmaceuticsandRelevantPharmacokineticsbyJohn.GWagnerandM.Pemarowski,1stedit ion,DrugIntelligence Publications,Hamilton,Illinois,1971.
11. EncyclopediaofPharmaceuticalTechnology,Vol13,JamesSwarbrick,James.G.Boylan, MarcelDekkerInc,NewYork,1996.
12. BasicPharmacokinetics,1stedition,SunilSJambhekarandPhilipJBreen,pharmaceutical press,RPSPublishing,2009.
13. AbsorptionandDrugDevelopment-Solubility,Permeability,andChargeState,AlexAvdeef,JohnWiley&Sons,Inc,2003.

MOLECULAR PHARMACEUTICS
(NANOTECHNOLOGY&TARGETED DDS)(NTDS)
(MPH202T)

THEORY **60Hrs**

Scope

Thiscourseisdesignedtoimpartknowledgeontheareaofadvancesinnoveldrugdeliverysystems.

Objectives

UponcompletionofthecoursestudentshallbeabletounderstandThevariousapproach

- esfor
- developmentofnoveldrugdeliverysystems.Thecriteriaforselectionofdrugsandp
- olymersforthedevelopmentofNTDSTheformulationandevaluationofnoveldrug deliverysystems.

UNIT-I **9Hrs**

TargetedDrugDeliverySystems:Concepts,Eventsandbiologicalprocessinvolvedindrug targeting.TumortargetingandBrainspecificdelivery.

UNIT-II **9Hrs**

TargetingMethods:introduction,types,preparationandevaluationofNanoParticles&Liposomes
.

UNIT-III **9Hrs**

Micro Capsules / Micro Spheres: Types, preparation and evaluation, Monoclonal Antibodies;preparation and application, preparation and application of Niosomes, Aquasomes, Phytosomes,Electrosomes.

UNIT-IV **9Hrs**

PulmonaryDrugDeliverySystems:Aerosols,propellents,ContainersTypes,preparationandevaluation,Intra NasalRoute Deliverysystems;Types,preparationandevaluation.

UNIT-V **9Hrs**

Nucleic acid based therapeutic delivery system: Gene therapy, introduction (ex-vivo & in-vivo gene therapy). Potentialtarget diseases for gene therapy(inherited disorder and cancer).Geneexpression systems (viral and nonviral gene transfer). Liposomal gene delivery systems.Biodistribution and Pharmacokinetics. Knowledge of therapeutic antisense molecules andaptamersas drugs offuture.

UNIT-VI **8Hrs**

Vaccine delivery systems: Vaccines, uptake of antigens, single shot vaccines, mucosal andtransdermaldeliveryofvaccines.

UNIT-VII **7Hrs**

StudyofcommercialformulationsDOXIL,RISPERDALCONSTA,LUPRONDEPOT,INVEGASUSTENNA,andLANCOME.

REFERENCEBOOKS

1. YW.Chien,NovelDrugDeliverySystems,2ndedition,revisedandexpanded,Marcel Dekker,Inc.,New York,1992.
2. S.P.Vyas and R.K.Khar, Controlled Drug Delivery - concepts and advances,VallabhPrakashan,NewDelhi,Firstedition2002.
3. N.K.Jain,ControlledandNovelDrugDelivery,CBSPublishers&Distributors,NewDelhi,Firstedition1997(reprintin2001).

PHARMACEUTICALPRODUCTIONTECHNOLOGY

(MPH203T)

THEORY **60HRS**

Scope

Thiscourseisdesigned toimpartknowledge andskillsnecessaryto trainthestudentstobeonparwiththeroutineofIndustrialactivitiesinProduction

Objectives

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,H

- andlethe scheduledactivitiesina Pharmaceuticalfirm.
- Managetheproductionoflargebatchesofpharmaceuticalformulations.

UNIT-I **10Hrs**

a) Improved Tablet Production: Tablet production process, unit operation improvements,granulationandpelletizationequipments,continuousandbatchmixing,rapidmixinggranulators,rotagranulators,spheronizersandmarumerisers,andotherspecializedgranulationanddryingequipments.Problemsencountered.

b) CoatingTechnology:Process,equipments,particlecoating,fluidizedbedcoating,applicationtechniques.Problems encountered.

UNIT-II **9Hrs**

ParenteralProduction:Plant layout, design area planning & environmentalcontrol, wallandfloor treatment, fixtures and machineries, change rooms, personnel flow, utilities & utilitiesequipmentlocation,engineeringandmaintenance.

UNIT-III **9Hrs**

Lyophilization & Spray drying Technology: Principles,process,freeze-drying and spraydryingequipments.

UNIT-IV **9Hrs**

CapsuleProduction:Productionprocess,advancesincapsulemanufacturingandfillingmachinesforhard andsoftgelatincapsules.Layoutand problemsencountered.

UNIT-V **9Hrs**

Disperse Systems Production: Production processes, applications of mixers, mills, disperseequipmentsincludingfine solids dispersion,problemsencountered.

UNIT-VI **7Hrs**

PackagingTechnology:Typesofpackagingmaterials,machinery(stripandblister),labeling,package printingfordifferentdosageforms.

UNIT-VII **7Hrs**

AirHandlingSystems:StudyofAHUs,humidity&temperaturecontrol,airfiltrationsystems, dust collectors. Water Treatment Process: Techniques and maintenance – RO, DM,ultra–filtration,WFI.

REFERENCEBOOKS:

1. TheTheory&PracticeofIndustrialPharmacy,L.Lachman,VarghesePubl,Bombay.
2. ModernPharmaceuticsbyBanker,Vol72,MarcelDekker,NY.
3. PharmaceuticalDosageForms,Vol1,2,3byLachman,Lieberman,MarcelDekker,NY.
4. PharmaceuticalDosageForms,Parentralmedications,Vol1,2byK.E.Avis,MarcelDekker,NY.
5. PharmaceuticalProductionFacilities,designandapplications,byG.C.Cole,TaylorandFrancis.
6. DispersedSystemVol1,2,3byLachman,Lieberman,MarcelDekker,NY.
7. Productdesignandtestingofpolymericmaterialsby N.P.Chezerisionoff.
8. PharmaceuticalProjectManagement,T.Kennedy,Vol86,MarcelDekker,NY.
9. PackagingPharmaceuticalandHealthCare,H.Lockhard.
10. QualityControlofPackagingMaterialsinPharmaceuticalIndusty,.Kharburn,MarcelDekker, NY.
11. Freezedrying /LyophilizationofPharmaceuticals&BiologicalProducts,L.Ray,Vol96,MarcelDekker,NY.
12. TabletMachineInstrumentationInPharmaceuticals,PRWatt,EllisHorwoods,UK.

COSMETICSAND COSMECEUTICALS
(MPH 204T)

THEORY **60Hrs**

Scope

Thiscourseisdesignedtoimpartknowledgeandskillsnecessaryforthefundamentalneedforcosmetic andcosmeceuticalproducts.

Objectives

Uponcompletionofthecourse,thestudentsshallbeabletounderstandKeyi

- ngredientsusedincosmeticsandcosmeceuticals.
- Keybuildingblocksforvariousformulations.Currentte
- chnologiesinthemarket
- Variouskeyingredientsandbasicsciencetodevelopcosmeticsandcosmeceuticals
- Scientificknowledgetodevelopcosmeticsandcosmeceuticalswithdesired Safety,stability,andefficacy.

UNIT-I **10Hrs**

Cosmetics – Regulatory: Definition of cosmetic products as per Indian regulation. Indianregulatoryrequirements for labeling ofcosmetics Regulatoryprovisions relating to import ofcosmetics. Misbranded and spurious cosmetics. Regulatory provisions relating tomanufactureofcosmetics – Conditions for obtaining license, prohibition of manufacture and sale of certaincosmetics,loanlicense,offencesandpenalties.

UNIT-II **10Hrs**

Cosmetics - Biological aspects: Structure of skin relating to problems like dry skin, acne,pigmentation, prickly heat, wrinkles and body odor. Structure of hair and hair growth cycle.Common problems associated with oral cavity. Cleansing and care needs for face, eye lids,lips,hands,feet,nail,scalp,neck,bodyandunder-arm.

UNIT-III **10Hrs**

FormulationBuildingblocks:Buildingblocksfordifferentproductformulationsofcosmetics/cosmeceuticals.Surfactants–Classificationandapplication.Emollients,rheological additives:classification andapplication.Antimicrobial usedas preservatives,their merits and demerits. Factors affecting microbial preservative efficacy. Building blocksforformulationofamoisturizingcream,vanishingcream,coldcream,shampooandtoothpaste.Soaps andsyndetbars.

UNIT-IV **10Hrs**

Perfumes;Classificationofperfumes.Perfumeingredientslistedasallergens inEUregulation.Controversialingredients:Parabens,formaldehydeliberators,dioxane.

UNIT-V **10Hrs**

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatoryaspects. Addressing dry skin, acne, pigmentation, prickly heat, wrinkles, body odor,dandruff,dentalcavities,bleedinggums,mouthodorandsensitiveteeththroughcosmeceutical formulations.

UNIT-VI **10Hrs**

Herbal Cosmetics: Herbal ingredients used in Hair care, skin care and oral care. Review ofguidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives,emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulatingherbalcosmetics.

REFERENCEBOOKS

1. Harry'sCosmeticology.8thedition.
2. Poucher'sperfumecosmeticsandSoaps,10thedition.
3. Cosmetics-Formulation,Manufactureandqualitycontrol,PP.Sharma,4th edition
4. HandbookofcosmeticscienceandTechnologyA.O.Barel, M.PayeandH.I.Maibach. 3rdedition
5. CosmeticandToiletriesrecentsupplierscatalogue.
6. CTFAdirectory.

ADVANCED BIOPHARMACEUTICS AND PHARMACOKINETICSPRACTICALS(MPH205P)

1. Improvementofdissolutioncharacteristicsofslightlysolubledrugby Soliddispersiont echnique.
2. Comparisonofdissolutionoftwodifferentmarketedproducts/brands
3. Comparisonofdiffusionstudiesoftwodifferentmarketedproducts/brands
4. Proteinbindingstudiesofahighlyproteinbounddrug&poorlyproteinbounddrug
5. CalculationofallPharmacokineticparametersfromtheI.V.BolusData.
6. CalculationofallPharmacokineticparametersfromtheUrinaryDataofI.V. BolusInjection.
7. CalculationofallPharmacokineticparametersfromtheI.V.InfusionData.
8. CalculationofallPharmacokineticparametersfromtheExtravascularData – ResidualMethod.
9. CalculationofallPharmacokineticparametersfromtheExtravascularData– WagnerNelsonmethod
10. BioavailabilitystudiesofParacetamol(Animal).

PHARMACEUTICS-IIPRACTICALS(MPH206P)

1. Formulationandevaluationoftablets
2. Formulationandevaluationofcapsules
3. Formulationandevaluationofinjections
4. Formulationandevaluationofemulsion
5. Formulationandevaluationofsuspension.
6. Formulationandevaluationofentericcoatingtablets.
7. Preparationandevaluationofafreezedriedformulation.
8. Preparationandevaluationofaspraydriedformulation.
9. Tostudytheeffectoftemperaturechange,nonsolventaddition,incompatiblepolymera dditioninmicrocapsules preparation
10. PreparationandevaluationofAlginatebeads
11. Formulationandevaluationofgelatin/albuminmicrospheres
12. Formulationandevaluationofliposomes/niosomes
13. Formulationandevaluationofspherules
14. ToaddressDryskin,acne,blemish,Wrinkles,bleedinggumsanddandruff
15. FormulationandEvaluationofcosmeticproductspertainingtoskin,hairandteeth.

INDUSTRIALPHARMACY
(MIP)MODERNPHARMACEUTICALANALYTICALTECHNIQUE S(MIP101T)

THEORY **60HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification,characterizationand quantificationofdrugs. Instrumentsdealt are Massspectrometer, IR, HPLC,GC etc.

Objectives

Aftercompletionofcoursestudentisabletoknow,Chemical

- sandExcipients
- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoreticalandpractical
- skills oftheinstruments

UNIT-I **10Hrs**

a. UV-Visiblespectroscopy:Introduction,Theory,Laws,InstrumentationassociatedwithUV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visiblespectroscopy.

b. IRspectroscopy:Theory,ModesofMolecularvibrations,Samplehandling,Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affectingvibrationalfrequencies andApplicationsofIR spectroscopy

c. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers,Instrumentationand Applicationsoffluorescence spectrophotometer.

UNIT-II **8Hrs**

MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPIAnalyzersof Quadrupole and Time of Flight, Mass fragmentation and its rules,Metastableions,IsotopicpeaksandApplicationsofMassspectroscopy.

UNIT-III **12Hrs**

Chromatography:Principle,apparatus,instrumentation,chromatographicparameters,factorsaffecting resolutionandapplications ofthefollowing:
a)Paperchromatographyb)ThinLayerchromatographyc)Ionexchangechromatographyd)Column chromatography e)Gaschromatography f)HighPerformanceLiquidchromatography g)Affinitychromatography.

UNIT-IV **12Hrs**

Electrophoresis: Principle, Instrumentation, Working conditions, factorsaffecting separationandapplications of the following:a)Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresise) Movingboundaryelectrophoresisf)Isoelectricfocusing

UNIT-V **10Hrs**

a) Immunologicalassays:RIA(Radioimmunoassay),ELISA,Bioluminescenceassays.
b) Thermaltechniques:DSC,DTA,TGA,Principle,Instrumentation,factorsaffecting,advantages anddisadvantages andPharmaceuticalapplications.

UNIT-VI **8Hrs**

NMRSpectroscopy:Quantum numbersandtheirroleinNMR,Principle,instrumentation,solvent requirements in NMR, Relaxation process, NMR signals in various compounds.Briefoutline ofFT-NMR andC^{13}NMR,applicationsofNMRSpectroscopy.

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds- RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis -Doglas ASkoog, F. JamesHoller,TimothyA. Nieman,5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBS Publishers,New Delhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugs inPharmaceuticalformulation- PDSethi, 3rdEdition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-Modernmethods–PartB-JWMunson,Volume11,MarcelDekkerSeries

PHARMACEUTICALFORMULATIONDEVELOPMENT (MIP102T)

THEORY **60Hrs**

Scope

Thiscourseisdesignedtoimpartknowledgeandskillsnecessarytotrainthestudentsonparwiththeroutine ofIndustrialactivitiesinR&DandF&D.

Objectives

Oncompletionofthiscourse it isexpectedthat studentswillbeableto understand-

- Thescheduledactivitiesina Pharmaceuticalfirm.
- Thepreformulationstudiesofpilot batchesofpharmaceuticalindustry.
- Thesignificance ofdissolutionandproductstability

UNIT-I **10Hrs**

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphologyandvariations,powderflow,structuremodification,drug-excipientcompatibilitystudies,methodsfordeterminationofincompatability.

UNIT-II **12Hrs**

FormulationAdditives:Studyofdifferentformulationadditives,factorsinfluencingtheirincorporation, role of formulation development and processing, new developments in excipientscience.Designofexperiments–factorialdesignforproductandprocessdevelopment.

UNIT-III **12Hrs**

Solubility:Importance,experimentaldetermination,phasesolubilityanalysis,pH-solubilityprofile, solubilization techniques to improve solubility and utilization of analytical methods –cosolvency, salt formation, complexation, solid state manipulation, micellar solubilization andhydrotropy.

UNIT-IV **12Hrs**

Dissolution: Theories, mechanisms of dissolution, in-vitro dissolution testing models – sink andnon-sinkindissolution.Factorsinfluencingdissolutionandintrinsicdissolutionstudies.Dissolution test apparatus – designs, dissolution testing for conventional and controlled releaseproducts. Data handling and correction factor in dissolution calculation. Biorelevent media, in-vitroandin-vivocorrelations,levelsofcorrelations.

UNIT-V **12Hrs**

ProductStability:Degradationkinetics,mechanisms,stabilitytestingofdrugsandpharmaceuticals, factors influencing-media effects and pH effects, accelerated stability studies,interpretation of kinetic data (API & tablets). Solid state stability and shelf life assignment.Stabilityprotocols,reports andICHguidelines.

REFERENCEBOOKS:

1. LachmanL,LiebermanHA, KanigJL. TheTheoryandPracticeOfrdIndustrialPharmacy,3ed.,VargheseePublishers,Mumbai1991.th
2. SinkoPJ.Martin'sphysicalpharmacyandpharmaceuticalsciences, 5ed.,B.I.PublicationsPvt.Ltd,Noida,2006.
3. LiebermanHA,LachmanL,SchwartzJB. Pharmaceuticaldosage forms: nd tabletsVol.I-III, 2ed.,CBSPublishers&distributors,New Delhi,2005.
4. ConnersKA.ATextbookofpharmaceuticalanalysiWellsJI.Pharmaceuticalpreformulation:Theph ysicochemicalpropertiesofdrugsubstances.EllisHorwoodLtd.,England,1998.
5. YalkowskySH.Techniquesofsolubilizationofdrugs.Vol-12.MarcelDekkerInc.,New York,1981
6. DressmanJ,KramerJ.Pharmaceuticaldissolutiontesting.Saurahprinterpvt.Ltd.,New Delhi,2005.rd
7. SethiPD.Quantitativeanalysisofdrugsinpharmaceuticalformulations,3ed.,CBS publications,New Delhi,2008.Rd
8. CarstensenJT,RhodesCT.Drugstabilityprinciplesandpractices,3CBSPublishers& distributors,New Delhi,2005.ed.,
9. YoshiokaS, StellaVJ. Stabilityofdrugsanddosageforms, Springer(India) Pvt. Ltd.,NewDelhi,2006.th
10. BankerGS,RhodesCT.ModernPharmaceutics,4Inc,NewYork,2005.
11. W.Grimm-Stabilitytestingofdrugproducts.ed.,MarcelDekker
12. MazzoDJ.Internationalstability testing.EasternPressPvt.Ltd.,Bangalore,1999.13.BeckettAH,Stenlake JB.Practical pharmaceutical th chemistry,Part I& II.,4 2004.ed.,CBSPublishers&distributors,New Delhi,
14. IndianPharmacopoeia.ControllerofPublication.Delhi,1996.
15. BritishPharmacopoeia.BritishPharmacopoeiaCommissionOffice,London,2008.
16. UnitedStatesPharmacopoeia.UnitedStatesPharmacopeialConvention,Inc,USA,2003.
17. EncyclopaediaofPharm.Technology,VolI–III.
18. WellsJ.I.PharmaceuticalPreformulation:Thephysicochemicalpropertiesofdrug substances,EllisHorwoodLtd.England,1988.

NOVELDRUGDELIVERYSYSTEMS
(MIP103T)

THEORY **60Hrs**

Scope

This course is designed to impart knowledge and skills necessaryto trainthe students inthe area ofnoveldrugdeliverysystems.

Objective

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,

- Theneed,concept,designandevaluationofvariouscustomized,sustainedandcontrolled releasedosage forms.
- Toformulateandevaluatevariousnoveldrugdeliverysystems

UNIT-I **10Hrs**

SustainedRelease(SR)andControlledRelease(CR)formulations:Introduction&basic concepts,advantages/disadvantages, factors influencing, Physicochemical & biological approaches forSR/CR formulation, Mechanism of Drug Delivery from SR/CR formulationcomputationofdesiredreleaserateanddoseforcontrolledreleaseDDS,pharmacokinetic designforDDS–intermittent,zeroorder&firstorderrelease.

UNIT-II **8Hrs**

CarriersforDrugDelivery:Polymers/co-polymersintroduction,classification,characterization,polymerizationtechniques,applicationinCDDS/NDDS, biodegradable&naturalpolymers.

UNIT-III **8Hrs**

RateControlledDrugDeliverySystems:Principles&Fundamentals,Types,Activation;ModulatedDrugDeliverySystems;Mechanicallyactivated,pHactivated,Enzymeactivated,andOsmotic activated Drug Delivery Systems Feedback regulated Drug Delivery Systems;Principles&Fundamentals.

UNIT-IV **8Hrs**

Study of Various DDS: Concepts, design, formulation & evaluation of controlled release oralDDS, GRDDS, Mucoadhesive and buccalDDS, colon specific, liquid sustained release systems,Oculardeliverysystems.

UNIT-V **6Hrs**

Transdermal DrugDelivery Systems:Structure of skinandbarriers,Penetrationenhancers,TransdermalDrugDeliverySystems,Formulationandevaluation.

UNIT-VI **6Hrs**

Protein andPeptideDelivery:Barriersforprotein delivery.Formulation andEvaluation ofdeliverysystems ofproteins andothermacromolecules.

UNIT-VII **10Hrs**

TargetedDrugDeliverySystems: Importance,concept, biologicalprocessandeventsinvolved in drugtargeting,design,formulation&evaluation,methodsindrugtargeting– nanoparticles,liposomes,niosomes,pharmacosomes,resealederythrocytes,microspheres,magnetic microspheres.Specialized pharmaceutical emulsions–multiple emulsions,micro-emulsions.StudyofcommercialformulationsDOXIL,RISPERDALCONSTA,LUPRONDEPOT,INVEGASUSTENNA,andLANCOME.

UNIT-VIII **6Hrs**

BiotechnologyinDrugDeliverySystems:Briefreviewofmajorareas-recombinantDNAtechnology,monoclonalantibodies,genetherapy.

REFERENCEBOOKS:

1. NovelDrugDeliverySystem,Y.W.Chein,Vol50,MarcelDekker,NY.
2. ControlledDrugDeliverySystems,Robinson,Vol29,MarcelDekker,NY.
3. TransdermalControlledSystemicMedications,YWChein,Vol31,MarcelDekker,NY.
4. BioadhesiveDDS,E.Mathiowitz,Vol98,MarcelDekker,NY.
5. NasalSystemDrugDelivery,K.S.E.Su,Vol39,MarcelDekker,NY.
6. DrugDeliveryDevices,Vol32,PTyleMarcel Dekker,NY.
7. PolymersforControlledDrugDelivery,P.J.Tarcha,CRCPress.
8. PharmaceuticalBiotechnology,Vyas,CBS,Delhi.
9. BiotechnologyofIndustrialAntibiotics,E.J.Vandamme,MarcelDekker,NY.
10. ProteinFormulation&Delivery,E.J.McNally,Vol99,MarcelDekker,NY.
11. DrugTargeting,M.H.Rubinstein,JohnWiley,NY.

IPR AND REGULATORYAFFAIRS
(MPH104T)

THEORY **60Hrs**

Scope

Course designed toimpartadvanced knowledgeand skills required to learn the concept ofgeneric drug and their development, various regulatory filings in different countries, differentphases of clinical trials and submitting regulatory documents: filing process of IND, NDA andANDA

- Toknowtheapprovalprocessof
- Toknowthechemistry, manufacturingcontrolsandtheirregulatoryimportance
- Tolearnthedocumentationrequirementsfor
- Tolearntheimportanceand

Objectives:

Uponcompletionofthecourse,it isexpectedthat thestudentswillbeableto understand

- TheConceptsofinnovatorandgeneric
- drugs,drugdevelopmentProcessTheRegulatoryguidance'sandguidelinesforfilingandappr
- oval processPreparationofDossiersandtheirsubmissiontoregulatoryagencies indifferent
- countries Postapproval regulatory requirements for actives and drug
- productsSubmissionofglobaldocumentsinCTD/eCTDformatsClinicaltrialsrequirementsf
- orapprovalsforconductingclinicaltrials
- Pharmacovigilenceandprocessofmonitoring inclinicaltrials.

UNIT-I **10Hrs**

Drugproductdevelopment:Activepharmaceuticalingredients,drugmasterfile(DMF)andimpurities. Generic product development: Introduction, Hatch-Waxman act and amendments,GUDUFA, ANDA (505j), ANDA approval process. New drug application (505B1 and 505B2).NDAapprovalprocessincludingIND.Scaleupandpostapprovalchanges(SUPAC).Bioequivalenceand Bioavailability,differenttypesofstudiesfordrugproductapproval.

UNIT-II **10Hrs**

ICH- Guidelines of ICH – Q7 to Q11, M9. Clinical Trials. HIPPA – new, requirements toclinicalstudyprocess,Parmacovigilance safetymonitoringinclinicaltrials.

UNIT-III **10Hrs**

ANDA for generic drugs ways and means of US registration for foreign drugs. CMC, Postapprovalregulatoryaffairs.Regulationforcombinationproducts,medicaldevices&Biosimilars.

UNIT-IV **10Hrs**

BriefintroductiontoCDSCO,WHO,USFDA,EMEA,TGA,MHRA,MCC,ANVISA.

UNIT-V **10Hrs**

Definitions, Need for Patenting, Types of Patents, Conditions to be satisfied by an invention tobePatentable,introduction topatentand patentsearch.Parts of Patent. Filing of patents. Theessentialelementsofpatent. Guidelines for preparationoflaboratorynotebook, Non-obviousness inpatent.

UNIT-VI **10Hrs**

Copyright,Trademark,Geographicalindicationacts,Patentlitigation,180daysmarketexclusivityand Doctrineofequivalents.

REFERENCEBOOKS:

1. GenericDrugProductDevelopment,SolidOralDosageforms,LeonShargeland IsaderKaufer,MarcelDekkerseries,Vol.143
2. ThePharmaceuticalRegulatoryProcess,Second EditionEditedbyIraR.Berryand RobertP.Martin,Drugsandthe PharmaceuticalSciences,Vol.185, InformaHealthcarePublishers.
3. NewDrugApprovalProcess:AcceleratingGlobalRegistrationsByRichardAGuarino, MD,5thedition,Drugs andthePharmaceuticalSciences,Vol.190.
4. Guidebookfordrugregulatorysubmissions/SandyWeinberg.ByJohnWiley&Sons.Inc.
5. FDAregulatoryaffairs:aguideforprescriptiondrugs, medicaldevices,andbiologics/editedByDouglas J.Pisano,DavidMantus.
6. ClinicalTrialsandHumanResearch:APracticalGuidetoRegulatoryComplianceByFayA .RozovskyandRodneyK.Adams
7. www.ich.org/
8. www.fda.gov/
9. europa.eu/index_en.htm
10. https://www.tga.gov.au/tga-basics

MODERN PHARMACEUTICAL ANALYTICALTECHNIQUES PRACTICALS (MIP105P)

1. Analysisofpharmacopoeialcompoundsandtheirformulations byUVVisspectrophotometer(Minimum4Experiments)
2. SimultaneousestimationofmulticomponentcontainingformulationsbyUV/HPLCspectrophotometry(Minimum4Experiments)
3. ExperimentsbasedonHPLC
4. ExperimentsbasedonGasChromatography
5. Estimationofriboflavin/quininesulphatebyfluorimetry
6. Estimationofsodium/potassiumbyflamephotometry

INDUSTRIALPHARMACY– IPRACTICALS (MIP106P)

1. Tocarryoutpreformulationstudiesofdrugslikeeffectofsurfactantsandp Honthe solubilityofdrugs,compatibilityevaluationofdrugsandexcipients byDSCandFTIR .
2. FormulationandevaluationofSR/CRTabletsand compareIn-Vitro dissolutionprofileofSR/CRMarketedformulation.
3. Formulationandevaluationosmoticallycontrolled DDS
4. PreparationandevaluationofFloatingDDS-hydrodynamicallybalancedDDS
5. FormulationandevaluationofMucoadhesivetablets.
6. Formulationandevaluationoftransdermalpatches.
7. Stabilitystudiesofdrugsinsolutionsandsoliddosageformsaccordingtothe ICHguidelines.
8. Tostudytheeffectofcompressionalforce,particlesizeandbindersontabletsdisintegrationtime anddissolutionofatablet.
9. TostudyMicromeriticpropertiesofpowdersandgranulation.
10. Preparationandevaluationofdifferentpolymericmembranes.
11. Tostudytheeffectoftemperaturechange,nonsolventaddition,incompatiblepolymeradditionin microcapsulespreparation
12. PreparationandevaluationofAlginatebeads
13. Formulationandevaluationofgelatin/albuminmicrospheres
14. Formulationandevaluationofliposomes/niosomes

SEMESTER-II
ADVANCEDBIOPHARMACEUTICS&PHARMACOKINETICS
(MPH201T)

THEORY **60Hrs**

Scope

This course is designed to impart knowledge and skills necessary for dose calculations, doseadjustmentsandtoapplybiopharmaceuticstheoriesinpracticalproblemsolving.Basictheoretical discussions of the principles of biopharmaceutics and pharmacokinetics are providedtohelpthestudents'toclarifytheconcepts.

Objectives

Uponcompletionofthiscourse it isexpectedthatstudentswillbeable understand,

- Thebasicconceptsinbiopharmaceuticsandpharmacokinetics.
- Theuserawdataandderivethepharmacokineticmodelsandparametersthebestdescribetheproces sofdrug absorption,distribution,metabolismandelimination.
- Thecriticalevaluationofbiopharmaceuticstudiesinvolvingdrugproductequivalency.Thedesignandevaluati
- onofdosageregimensofthedrugsusingpharmacokineticand biopharmaceuticparameters.
- Thepotentialclinicalpharmacokineticproblemsandapplicationofbasicsofpharmacokinetic

UNIT-I **10Hrs**

DrugAbsorptionfrom theGastrointestinal Tract: Gastrointestinal tract, Mechanism of drugabsorption,Factorsaffectingdrugabsorption,pH–partitiontheoryofdrugabsorption.Formulationandphysicochemicalfactors:Dissolutionrate,Dissolution process,Noyes–Whitneyequation and drug dissolution, Factors affecting the dissolution rate. Gastrointestinal absorption:role of the dosage form: Solution (elixir, syrup and solution) as a dosage form ,Suspension as adosageform,Capsuleasadosageform,Tabletasadosageform,Dissolutionmethods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data.Transportmodel:Permeability-Solubility-ChargeStateandthepHPartitionHypothesis,Properties of the Gastrointestinal Tract (GIT), pH Microclimate Intracellular pH Environment,Tight-JunctionComplex.

UNIT-II **10Hrs**

Biopharmaceutic considerations in drug product design and In Vitro Performance: Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limiting steps in drug absorption,physicochemical nature of the drug, formulation factors affecting drug product performance, invitro:dissolutionanddrugreleasetesting,compendialmethodsofdissolution,alternativemethods ofdissolutiontesting, meeting dissolutionrequirements, problems of variable controlindissolution testing performance of drug products. In vitro–in vivo correlation, dissolution profilecomparisons.

UNIT-III **10Hrs**

Pharmacokinetics: Basic considerations, pharmacokinetic models, compartment modeling: onecompartmentmodel-IVbolus,IVinfusion,extra-vascular.Multi compartmentmodel:twocompartment-modelinbrief.

UNIT-IV **10Hrs**

Non-linear pharmacokinetics: cause of non-linearity, Michaelis – Menten equation, estimationofKmaxandVmax.NoncompartmentalPharmacokinetics-statisticalmomenttheoryandphysiological pharmacokinetic model.Altered pharmacokinetics in renal and hepatic diseases.Drug interactions: introduction, the effect ofprotein binding on interactions, the effect oftissue-binding on interactions, cytochrome p450-based drug interactions, and drug interactions linkedtotransporters.10Hrs

UNIT-V **10Hrs**

DrugProductPerformance,InVivo:BioavailabilityandBioequivalence:drugproductperformance, purpose of bioavailability studies, relative and absolute availability. Methods forassessingbioavailability,bioequivalencestudies,designandevaluationofbioequivalencestudies, study designs, crossover study designs, evaluation of the data, bioequivalence example,study submission and drug review process. Biopharmaceutics classification system, methods.Permeability:In-vitro,in-situandIn-vivomethods.genericbiologics(biosimilardrugproducts),clinical significance of bioequivalence studies, special concerns in bioavailability andbioequivalence studies,generic substitution.

UNIT-VI **10Hrs**

Application of Pharmacokinetics: Chrono pharmacokinetics, Modified-Release Drug Products,TargetedDrugDeliverySystemsandBiotechnologicalProducts.IntroductiontoPharmacokineticsandpharmacodynamicsofbiotechnologydrugsProteinsandpeptides,Monoclonalantibodies,Oligonucleotides,Vaccines(immunotherapy),Genetherapies.

REFERENCEBOOKS:

1. BiopharmaceuticsandClinicalPharmacokineticsbyMiloGibaldi,4th edition,Philadelphia,LeaandFebiger,1991
2. BiopharmaceuticsandPharmacokinetics,A.Treatise,D.M.BrahmankarandSunilB.Jaiswal., VallabPrakashan,Pitampura,Delhi
3. AppliedBiopharmaceuticsandPharmacokineticsbyShargel.LandYuABC,2ndedition, ConnecticutAppletonCenturyCrofts,1985
4. TextbookofBiopharmaceuticsandPharmacokinetics,Dr.ShobhaRaniR.Hiremath,PrismBook
5. PharmacokineticsbyMiloGibaldiandD.Perrier,2ndedition,MarcelDekkerInc.,NewYork,1982
6. CurrentConceptsinPharmaceuticalSciences:Biopharmaceutics,Swarbrick.J,LeaandFebiger, Philadelphia,1970

7. ClinicalPharmacokinetics,ConceptsandApplications3rdeditionbyMalcolmRowlandandTho m~ N.Tozer,Lea andFebiger,Philadelphia,1995
8. Dissolution,BioavailabilityandBioequivalence,Abdou.H.M,MackPublishingCompany, Pennsylvania 1989
9. BiopharmaceuticsandClinicalPharmacokinetics,AnIntroduction,4th edition,revisedand expandebyRobert.E.Notari,MarcelDekkerInc,New YorkandBasel,1987.
10. BiopharmaceuticsandRelevantPharmacokineticsbyJohn.GWagnerandM.Pemarowski,1stedi tion,DrugIntelligence Publications,Hamilton,Illinois,1971.
11. EncyclopediaofPharmaceuticalTechnology,Vol13,JamesSwarbrick,James.G.Boylan, MarcelDekkerInc,NewYork,1996.
12. BasicPharmacokinetics,1stedition,SunilSJambhekarandPhilipJBreen,pharmaceutical press,RPSPublishing,2009.
13. AbsorptionandDrugDevelopment-Solubility,Permeability,andChargeState,AlexAvdeef,JohnWiley&Sons,Inc,2003.

SCALEUPANDTECHNOLOGYTRANSFER
(MIP202T)

THEORY **60Hrs**

Scope

Thiscourseisdesigned toimpartknowledgeandskillsnecessaryto trainthestudentstobeonscaleup,technologytransferprocess andindustrialsafetyissues.

Objectives:

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,M

- anage the scale upprocessinpharmaceuticalindustry.
- Assistintechnologytransfer.
- Toestablishsafetyguidelines,whichpreventindustrialhazards.

UNIT-I **10Hrs**

Pilotplantdesign:Basic requirementsfordesign,facility,equipmentselection,for tablets,capsules, liquid orals, parenteral and semisolid preparations. Scale up: Importance, Technologytransfer from R & D to pilot plant to plant scale, process scale up for tablets, capsules, liquidorals,semisolids,parenteral,NDDSproducts– stressonformula,equipments,productuniformity,stability,rawmaterials,physicallayout,input,in-processandfinishedproductspecifications,problemsencounteredduringtransferoftechnology.12Hrs

UNIT-I **12Hrs**

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analyticalmethodvalidation,cleaningvalidation

UNIT-III **12Hrs**

Equipment Qualification: Importance, IQ, OQ, PQ for equipments – autoclave, DHS, membranefilter,rapid mixergranulator, cone blender, FBD, tablet compression machine, liquid filling andsealingmachine.Aseptic roomvalidation.

UNIT-IV **12Hrs**

Process validation: Importance, validation of mixing, granulation, drying, compression, tabletcoating,liquidfillingandsealing,sterilization,waterprocesssystems,environmentalcontrol.

UNIT-V **12Hrs**

Industrial safety: Hazards – fire, mechanical, electrical, chemical and pharmaceutical,Monitoring&preventionsystems,industrialeffluenttesting&treatment.Controlofen vironmentalpollution.

REFERENCEBOOKS:

1. Pharmaceuticalprocessvalidation,JRBerry,Nash,Vol57,MarcelDekker,NY.
2. PharmaceuticalProductionfacilities,designandapplications,byGCCole,TaylorandFrancis.
3. Pharmaceuticalprojectmanagement,T.Kennedy,Vol86,MarcelDekker,NY.
4. Thetheory&PracticeofIndustrialPharmacy,L.Lachman,H.A.Lieberman,nVarghesePubl.Bombay.
5. Tabletmachineinstrumentsinpharmaceuticals,PRWatt,JohnWiloy.
6. Pharmaceuticaldosageforms,Tablets,Vol1,2,3byLachman,Lieberman, MarcelDekker,NY.
7. Pharmaceuticaldosageforms,Parentralmedications, Vol1,2byK.E.Avis, MarcelDekker,NY.
8. DispersedsystemVol1,2,3byLachman,Lieberman,MarcelDekker,NY.
9. Subrahmanyam, CVS, Pharmaceuticalproductionand Management, 2007, VallabhPrakashan,Dehli.

PHARMACEUTICALPRODUCTIONTECHNOLOGY(MI P203T)

THEORY **60HRS**

Scope

Thiscourseisdesignedtoimpartknowledgeandskillsnecessaryto trainthestudentstobeonparwiththeroutineofIndustrialactivitiesinProduction

Objectives

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,H

- andlethe scheduledactivitiesinaPharmaceuticalfirm.
- Managetheproductionoflargebatchesofpharmaceuticalformulations.

UNIT-I **10Hrs**

a) ImprovedTabletProduction:Tabletproductionprocess,unitoperationimprovements,granulation and pelletization equipments, continuous and batch mixing, rapid mixinggranulators,rota granulators, spheronizers and marumerisers, and other specialized granulation and dryingequipments.Problems encountered.

b) CoatingTechnology:Process,equipments,particlecoating,fluidizedbedcoating,applicationte chniques.Problems encountered.

UNIT-II **9Hrs**

ParenteralProduction: Area planning &environmental control, walland floortreatment, fixturesandmachineries,changerooms,personnelflow,utilities&utilitiesequipmentlocation,enginee ringandmaintenance.

UNIT-III **9Hrs**

Lyophilization & Spray drying Technology: Principles, process, freeze-drying and spray dryingequipments.

UNIT-IV **9Hrs**

Capsule Production: Production process, improved capsule manufacturing and filling machinesforhardandsoftgelatincapsules.Layoutandproblemsencountered.

UNIT-V **9Hrs**

DisperseSystemsProduction:Productionprocesses,applicationsofmixers,mills,disperseequipments includingfine solidsdispersion,problemsencountered.

UNIT-VI **7Hrs**

Packaging Technology: Types ofpackaging materials, machinery, labeling, package printing fordifferentdosageforms.

UNIT-VII **7Hrs**

Air Handling Systems: Study of AHUs, humidity & temperature control, air filtration systems,dustcollectors. WaterTreatmentProcess: Techniques andmaintenance– RO,DM,ultra – filtration,WFI.

REFERENCES

1. TheTheory&PracticeofIndustrialPharmacy,L.Lachman,VarghesePubl,Bombay.
2. ModernPharmaceuticsbyBanker,Vol72,MarcelDekker,NY.
3. PharmaceuticalDosageForms,Vol1,2,3 byLachman,Lieberman,MarcelDekker,NY.
4. PharmaceuticalDosageForms,Parentralmedications,Vol1,2byK.E.Avis,MarcelDekker,NY.
5. PharmaceuticalProductionFacilities,designandapplications,byG.C.Cole,TaylorandFrancis.
6. DispersedSystemVol1,2,3byLachman,Lieberman,MarcelDekker,NY.
7. ProductdesignandtestingofpolymericmaterialsbyN.P.Chezerisionoff.
8. PharmaceuticalProjectManagement,T.Kennedy,Vol86,MarcelDekker,NY.
9. PackagingPharmaceuticalandHealthCare,H.Lockhard.
10. QualityControlofPackagingMaterialsinPharmaceuticalIndusty,.Kharburn,Marcel Dekker,NY.
11. Freezedrying /LyophilizationofPharmaceuticals&BiologicalProducts,L.Ray,Vol96,MarcelDekker,NY.
12. TabletMachineInstrumentationInPharmaceuticals,PRWatt,EllisHorwoods,UK.

ENTREPRENEURSHIPMANAGEMENT(MIP204T)

THEORY **60Hrs**

Scope: Thiscourseisdesignedtoimpartknowledgeandskillsnecessarytotrainthestudentsonentrepreneurship management.

Objectives:

Oncompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,TheRo
- le ofenterpriseinnationalandglobaleconomy
- Dynamics of motivation and concepts of
- entrepreneurshipDemandsandchallengesofGrowthStrategiesAndNetworking

UNIT-I **12Hrs**

Conceptual Frame Work: Concept need and process in entrepreneurship development. Role ofenterpriseinnationalandglobaleconomy.Typesofenterprise–MeritsandDemerits.Government policies and schemes for enterprise development. Institutional support in enterprisedevelopmentandmanagement.

UNIT-II **12Hrs**

Entrepreneur: Entrepreneurial motivation – dynamicsofmotivation. Entrepreneurialcompetency – Concepts.DevelopingEntrepreneurialcompetencies-requirementsandunderstandingtheprocessofentrepreneurshipdevelopment,self-awareness,interpersonalskills,creativity,assertiveness,achievement,factors affectingentrepreneurrole.

UNIT-III **12Hrs**

LaunchingAndOrganisingAnEnterprise:Environmentscanning–Information,sources,schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibilitystudy, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site andmanpower. Costing and marketing management and quality control. Feedback, monitoring andevaluation.

UNIT-IV **12Hrs**

Growth Strategies And Networking: Performance appraisal and assessment. Profitability andcontrol measures, demands and challenges. Need for diversification. Future Growth – Techniquesofexpansionanddiversification,visionstrategies.Conceptanddynamics.Methods,Jointventure,co-ordinationandfeasibilitystudy.

UNIT-V **12Hrs**

PreparingProjectProposalToStartOnNewEnterpriseProjectwork–Feasibility report;Planning,resource mobilizationandimplementation.

REFERENCES

1. Akhauri,M.M.P.(1990):EntrepreneurshipforWomeninIndia,NIESBUD,NewDelhi.
2. Hisrich,R.D&Brush,C.G.(1996)TheWomenEntrepreneurs,D.C.Health&Co.,Toranto.
3. Hisrich,R.D.andPeters,M.P.(1995):Entrepreneurship– Starting,DevelopingandManagingaNew Enterprise,RichardD.,Inwin,INC,USA.
4. Meredith,G.G.etal(1982):PracticeofEntrepreneurship,ILO,Geneva.
5. Patel,V.C.(1987):WomenEntrepreneurship – DevelopingNewEntrepreneurs,AhmedabadEDII.

PRACTICALS SEM– IIADVANCEDBIOPHARMACEUTICSANDPHARMACOKINETICSPRACTICALS(MIP205P)

1. Improvementofdissolutioncharacteristicsofslightly solubledrugbySoliddispersiontechnique.
2. Comparisonofdissolutionoftwodifferentmarketedproducts/brands
3. Comparisonofdiffusionstudiesoftwodifferentmarketedproducts/brands
4. Proteinbindingstudiesofahighlyproteinbounddrug&poorlyproteinbounddrug
5. CalculationofallPharmacokineticparametersfromtheI.V.BolusData.
6. CalculationofallPharmacokineticparametersfromtheUrinaryDataofI.V.BolusInjection.
7. CalculationofallPharmacokineticparametersfromtheI.V.InfusionData.
8. CalculationofallPharmacokineticparametersfromtheExtravascularData– ResidualMethod.
9. CalculationofallPharmacokineticparametersfromtheExtravascularData– WagnerNelsonmethod
10. BioavailabilitystudiesofParacetamol(Animal).

INDUSTRIALPHARAMCY-IIPRACTICALS(MIP206P)

1. Formulationandevaluationoftablets
2. .Formulationandevaluationofcapsules
3. Formulationandevaluationofinjections
4. Formulationandevaluationofemulsion
5. .Formulationandevaluationofsuspension.
6. Formulationandevaluationofentericcoatingtablets.
7. Preparationandevaluationofafreezedriedformulation.
8. Preparationandevaluationofaspraydriedformulation.
9. ValidationofRotarytabletmachine.
10. ValidationofCoatingpan.
11. Validationoftraydryer.
12. ValidationofAutoclaveandasepticroom.
13.

PHARMACEUTICAL QUALITY ASSURANCE(MQA)

MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES (MQA

101T)THEORY **60Hrs**

Scope

Thissubjectdealswithvariousadvancedanalyticalinstrumentaltechniquesforidentification,characterizationandquantificationofdrugs.Instrumentsdealt areNMR,Massspectrometer,IR,HPLC,GC etc.

Objectives

Aftercompletionofcoursestudentisabletoknowaboutchemicalsandexcipients

- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoretical and
- practicalskills oftheinstruments

UNIT-I **10Hrs**

a) UV-Visiblespectroscopy:Introduction,Theory,Laws,InstrumentationassociatedwithUV-Visiblespectroscopy,Choiceofsolventsandsolvent effectandApplicationsofUV-Visible spectroscopy,Difference/Derivative spectroscopy.

b) IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling,InstrumentationofDispersiveandFourier-TransformIRSpectrometer,Factorsaffectingvibrationalfrequenciesand Applications of IRspectroscopy, DataInterpretation.

c) Spectroflourimetry: Theory ofFluorescence, Factorsaffectingfluorescence(Characterestics of drugs that can be analysed by flourimetry), Quenchers,InstrumentationandApplicationsoffluorescence spectrophotometer.

d) FlameemissionspectroscopyandAtomicabsorptionspectroscopy:Principle, Instrumentation,InterferencesandApplications.

UNIT-II **10Hrs**

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation,SolventrequirementinNMR,Relaxationprocess,NMRsignalsinvariouscompounds,Chemicalshift,Factorsinfluencingchemicalshift,Spin-Spincoupling,Couplingconstant,Nuclearmagneticdouble resonance, Briefoutline ofprinciples ofFT-NMR and 13C NMR. Applications of NMRspectroscopy.

UNIT-III **10Hrs**

MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionization likeelectronimpact,chemical, field,FABandMALDI,APCI,ESI,APPIAnalyzersofQuadrupoleandTimeofFlight,Massfragmentation anditsrules,Metastableions,IsotopicpeaksandApplicationsofMass spectroscopy.

UNIT-IV **10Hrs**

Chromatography:Principle,apparatus,instrumentation,chromatographicparameters,factorsaffectingresolution, isolationofdrugfromexcipients,data interpretationandapplicationsofthefollowing:

- ThinLayerchromatography
- HighPerformance

ThinLayerChromatographyIonexchangechromatography

- Columnchromatography
- Gaschromatography
- High Performance Liquid
- chromatographyUltraHighPerformanceLiquidchromatography

Affinitychromatography

- GelChromatography

UNIT-V **10Hrs**

a) Electrophoresis:Principle,Instrumentation,Workingconditions, factors affecting separationandapplicationsofthefollowing:
b) Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresis e)Movingboundaryelectrophoresisf)Isoelectricfocusing
c) XrayCrystallography:ProductionofXrays,DifferentXray
d) methods,Bragg'slaw,Rotatingcrystaltechnique,Xraypowdertechnique,Typesofcrystalsandapplicationsof X-raydiffraction.

UNIT-VI **10Hrs**

a. Potentiometry:Principle,working,IonselectiveElectrodesandApplicationofpotentiometry.
b. Thermal Techniques: Principle, thermal transitions and Instrumentation(Heatfluxandpower-compensationanddesigns),ModulatedDSC,HyperDSC,experimentalparameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution,sourceoferrors)andtheir influence,advantageanddisadvantages,pharmaceuticalapplications.Differential ThermalAnalysis (DTA):Principle, instrumentation andadvantageand disadvantages,pharmaceutical applications, derivative differential thermal analysis (DDTA). TGA: Principle,instrumentation,factorsaffectingresults,advantageanddisadvantages,pharmaceuticalapplications.

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. Principlesof InstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman,5th edition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.

4. PracticalPharmaceuticalChemistry– BeckettandStenlake,VolII,4thedition,CBSPublishers,NewDelhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugsinPharmaceuticalformulation- PDSethi,3rdEdition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-ModernMethods–PartB-JWMunson,Vol11,Marcel.DekkerSeries
8. SpectroscopyofOrganicCompounds,2nd edn.,P.S/Kalsi,WileyesternLtd.,Delhi.
9. TextbookofPharmaceuticalAnalysis,KA.Connors,3rdEdition,JohnWiley&Sons,1982.
10. TextbookofPharmaceuticalAnalysis,KA.Connors,3rdEdition,JohnWiley&Sons,1982.

QUALITY MANAGEMENT SYSTEMS(MQA102T)

THEORY **60Hrs**

Scope

Thiscourseisdesignedto impart fundamentalknowledgeandconceptsabout variousqualitymanagementprinciplesandsystemsutilizedinthemanufacturingindustry.It alsoaidsinunderstandingthe qualityevaluationinthepharmaceuticalindustries.

Objectives

At completionofthiscourse it isexpectedthatstudentswillbeabletounderstand-

- Theimportance ofquality
- ISOmanagementsystemsToolsforqua
- lityimprovementAnalysisofissuesinq
- uality
- Quality evaluation of
- pharmaceuticalsStabilitytestingofdrugandd
- rugsubstancesStatisticalapproachesforquali ty

Unit-1:

Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of QualityQuality as a Strategic Decision: Meaning of strategy and strategic quality management, missionand vision statements, quality policy, Quality objectives, strategic planning and implementation,McKinsey7smodel,Competitiveanalysis,Managementcommitmentto quality CustomerFocus:Meaningofcustomerandcustomerfocus,Classificationofcustomers,Customerfocus ,Customerperceptionofquality,Factorsaffectingcustomerperception,Customer requirements, Meeting customer needs and expectations, Customer satisfaction andCustomer delight, Handling customer complaints, Understanding customer behavior, concept ofinternal and external customers. Case studiesCost of Quality: Cost of quality, Categories of costofQuality,Modelsofcostofquality,Optimisingcosts,Preventingcostofquality 10Hrs

Unit-2. PharmaceuticalqualityManagement:Basicsof QualityManagement,Total QualityManagement (TQM), Principles of Six sigma, ISO 9001:2008, 9001:2015, ISO 14001:2004,Pharmaceutical Quality Management– ICH Q10, Knowledge management, Quality Metrics,OperationalExcellenceandQualityManagementReview.OSHASguidelines,NABLcertific ationandaccreditation,CFR-21part11,WHO-GMPrequirements. 10Hrs

Unit-3: Six System Inspection model: Quality Management system, Production system, Facilityand Equipment system, Laboratory control system, Materials system, Packaging and labelingsystem.Conceptofselfinspection.
Qualitysystems:ChangeManagement/Changecontrol.
Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation andhandling,Investigationanddeterminationofrootcause,Corrective&PreventiveActions(CAPA),Returns and Recalls,Vendor Qualification,Annual Product Reviews,Batch ReviewandBatchRelease. ConceptofIPQC, areaclearance/Lineclearance. 10Hrs

Unit-4. Drug Stability: ICH guidelines for stability testing ofdrug substances and drug products.StudyofICHQ8,QualitybyDesignandProcessdevelopmentreport
Qualityriskmanagement:Introduction,riskassessment,riskcontrol,riskreview,riskmanagementtools, HACCP, riskrankingandfilteringaccordingtoICHQ9guidelines.10Hrs

Unit-5. StatisticalProcesscontrol(SPC):DefinitionandImportanceofSPC,Qualitymeasurementinmanufacturing,Statisticalcontrolcharts-conceptsandgeneralaspects,Advantages of statistical control, Process capability, Estimating Inherent or potential capabilityfrom a control chart analysis, Measuring process control and quality improvement, Pursuit ofdecreasedprocess variability.
10Hrs

Unit-6. RegulatoryCompliancethroughQualityManagementanddevelopmentofQualityCultureBenchmarking:Definitionofbenchmarking,Reasonsforbenchmarking,TypesofBenchmarking,Benchmarking process,Advantagesofbenchmarking,Limitationsofbenchmarking 10Hrs

REFERENCEBOOKS:

1. ImplementingJuran'sRoadMapforQualityLeadership:BenchmarksandResults,ByAl Endres,Wiley,2000
2. Understanding,ManagingandImplementingQuality:Frameworks,Techniquesand Cases,ByJijuAntony;DavidPreece,Routledge,2002
3. OrganizingforHighPerformance:EmployeeInvolvement,TQM,Reengineering,andKnowledgeManagementintheFortune1000:TheCEOReportByEdwardE.Lawler;SusanAlbersMohrman;George Benson,Jossey-Bass,2001
4. CorporateCultureandtheQualityOrganizationByJamesW. Fairfield- Sonn, QuorumBooks,2001
5. TheQualityManagementSourcebook:AnInternationalGuidetoMaterialsand ResourcesByChristineAvery;DianeZabel,Routledge,1997
6. TheQualityToolbox,SecondEdition,NancyR. Tague,ASQPublications
7. Juran'sQualityHandbook,SixthEdition,JosephM.JuranandJosephA.DeFeo,ASQ Publications
8. RootCauseAnalysis,TheCoreofProblemSolvingandCorrectiveAction,DukeOkes, 2009,ASQPublications.

QUALITY CONTROL AND QUALITY ASSURANCE

(MQA103T)THEORY **60Hrs**

Scope

This course deals with the various aspects of quality control and quality assurance aspects ofpharmaceuticalindustries.Itcoverstheimportantaspectslikec GMP,QCtests,documentation, qualitycertifications,GLPandregulatoryaffairs.

Objectives

Upon completion of this course the student should be able

- toUnderstandthecGMPaspectsinapharmaceuticalindustry
- Toappreciate theimportance ofdocumentation
- Tounderstandthescopeofqualitycertificationsapplicableto Pharmaceuticalindustries
- Tounderstandtheresponsibilities ofQA&QC departments.

Unit-1: **12Hrs**

Introduction:Concept and evolution and scopes of Quality Control and Quality Assurance,GoodLaboratoryPractice,GMP,OverviewofICHGuidelines-QSEM,withspecialemphasisonQ-seriesguidelines.

GoodLaboratoryPractices:ScopeofGLP,Definitions, Qualityassuranceunit, protocolforconductofnonclinicaltesting,controlonanimalhouse,reportpreparationanddocumentation.

CPCSEAguidelines.

Unit-2: **12Hrs**

cGMP guidelines according to schedule M, USFDA (inclusive of CDER and CBER)PharmaceuticalInspectionConvention(PIC),WHOandEMEAcovering:Organizationandpersonnelresponsibilities,training,hygieneandpersonalrecords,drugindustrylocation,design,construction and plant lay out, maintenance, sanitation, environmental control, utilities andmaintenanceofsterileareas,controlofcontaminationand Good Warehousing Practice.

Unit-3: **10Hrs**

Analysis of raw materials, finished products, packaging materials, in process quality control(IPQC),Developingspecification(ICHQ6andQ3),purchasespecificationsandmaintenanceof stores for raw materials.In process quality control and finished products quality control forfollowingdosage formsinPharma industryaccordingtoIndian,USandBritishpharmacopoeias:tablets,capsules,ointments, suppositories,creams, parenterals,ophthalmicandsurgicalproducts(Howtoreferpharmacopoeias).

Unit-4: **12Hrs**

Documentationinpharmaceuticalindustry:Threetierdocumentation,Policy,ProceduresandWork instructions, and records (Formats), Basic principles- How to maintain, retention andretrieval etc. Standard operating procedures (How to write), Master Batch Record, BatchManufacturing Record, Quality audit plan and reports. Specification and test procedures,Protocolsandreports.Distributionrecords.Electronicdatahandling.Conceptsofcontrolleddanduncontrolleddocuments Submissiondocumentsforregulators DMFs,asCommonTechnicalDocumentandElectronicCommon Technical Documentation (CTD, eCTD). Concept of regulated and non regulatedmarkets.

Unit-5: **12Hrs**

Manufacturingoperationsandcontrols:Sanitationofmanufacturingpremises,mix-upsandcrosscontamination, processing of intermediates and bulk products, packaging operations, IPQC,release of finished product, process deviations, charge-in of components, time limitations onproduction, drug product inspection, expiry date calculation, calculation of yields, productionrecordreview,changecontrol,sterileproducts,asepticprocesscontrol,packaging,reprocessing,salvaging,handlingofwasteandscrapdisposal.

Introduction,scopeand importanceofintellectualpropertyrights.Conceptoftrademark, copyrightandpatents.

REFERENCEBOOKS:

1. QualityAssuranceGuidebyorganizationofPharmaceuticalProceduresofIndia, 3rd revisededition,Volume I &II,Mumbai,1996.
2. GoodLaboratoryPracticeRegulations,2nd Edition,SandyWeinbergVol.69,MarcelDekker Series,1995.
3. QualityAssuranceofPharmaceuticals-AcompediumofGuidelinesandRelatedmaterialsVolI&II,2nd edition,WHOPublications,1999.
4. HowtoPracticeGMP's–PPSharma,VandanaPublications,Agra,1991
5. TheInternationalPharmacopoeia –volI,II,III,IV&V-GeneralMethodsofAnalysisandQualityspecification for Pharmaceutical Substances, Excepients and Dosage forms, 3rd edition, WHO,Geneva,2005.
6. GoodlaboratoryPracticeRegulations– AllenF.Hirsch,Volume38,MarcelDekkerSeries,1989.
7. ICHguidelines
8. ISO9000andtotalqualitymanagement
9. Thedrugsandcosmeticsact1940–Deshpande,NileshGandhi,4th edition,SusmitPublishers,2006.
10. QAManual–D.H.Shah,1st edition,BusinessHorizons,2000.
11. GoodManufacturingPracticesforPharmaceuticals a planfor total qualitycontrol –Sidney H. Willig,Vol.52,3rd edition,MarcelDekkerSeries.
12. SteinbornL.GMP/ISOQualityAuditManualforHealthcareManufacturersandTheirSuppliers,SixthEdition,(Volume1-WithChecklistsandSoftwarePackage).Taylor&Francis;2003.
13. Sarker DK. Quality Systems andControlsforPharmaceuticals.John Wiley &Sons;2008.
14. PackagingofPharmaceuticals.
15. ScheduleMandSchedu

PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER (MQA

104T)THEORY **60Hrs**

Scope

Thisdealwithtechnologytransfer coverstheactivitiesassociated withDrugSubstance,DrugProductandanalyticaltestsandmethods,requiredfollowingcandidatedrugselectiontocompletion of technology transfer from R&D to the first receiving site and technologytransferrelatedtopost-marketingchangesinmanufacturing places.

Objectives

UponcompletionofthiscoursethestudentshouldbeabletoTundersta

- nd thenewproduct developmentprocess
- TounderstandthenecessaryinformationtotransfertechnologyfromR&Dto actualmanufacturingbysorting outvariousinformationobtained during R&D
- Toelucidatenecessaryinformationtotransfertechnologyofexistingproductsbetween variousmanufacturingplaces

Unit-1: **12Hrs**

Principles ofDrugdiscovery and development: Introduction, Clinical research process.Development and informational content for Investigational New Drugs Application (IND),New Drug Application (NDA), Abbreviated New Drug Application (ANDA), SupplementalNewDrugApplication(SNDA),ScaleUpPostApprovalChanges(SUPAC)andBulkactivechemical Post approval changes (BACPAC), Post marketing surveillance, Productregistrationguidelines–CDSCO,USFDA.

Unit-2: **12Hrs**

Pre-formulation studies: Introduction/concept,organoleptic properties, purity, impurityprofiles,particlesize,shapeandsurfacearea.Solubility,Methods toimprovesolubilityof Drugs:Surfactants&itsimportance,co-solvency.TechniquesforthestudyofCrystalpropertiesandpolymorphism.Pre-formulationprotocol, Stabilitytestingduringproductdevelopment.

Unit-3: **12Hrs**

Pilotplantscaleup:Concept, Significance, design,layoutofpilotplantscaleupstudy,operations,largescalemanufacturingtechniques(formula,equipment,process,stabilityand qualitycontrol) of solids, liquids, semisolid and parenteral dosage forms. New era of drug products:opportunitiesandchallenges.

Unit-4: **12Hrs**

Pharmaceuticalpackaging:Pharmaceuticaldosageformandtheirpackagingrequirments,Pharmaceutical packaging materials, Medical device packaging, Enteral Packaging, Aseptic packagingsystems,Containerclosuresystems,Issuesfacing moderndrugpackaging,SelectionandevaluationofPharmaceuticalpackagingmaterials. Qualitycontroltest:Containers,closuresandsecondarypackingmaterials.

Unit-5: **12Hrs**

Technologytransfer:DevelopmentoftechnologybyR&D,

Technology transfer from R & D to production, Optimization and Production, Qualitative and quantitativetechnology models. Documentation in technology transfer: Development report, technology transfer planandExhibit.

REFERENCEBOOKS:

1. Theprocessofnewdrugdiscoveryand development.Iand IIEdition(2006)byCharlesG.Smith, JamesTandO.Donnell. CRCPress,GroupofTaylorandFrancis.
2. LeonLacLachman,Herbert A.Liberman,TheoryandPracticeofIndustrialPharmacy.MarcelDekkerInc. NewYork.
3. SidneyHWilling,MurrayM,Tuckerman.WilliamsHitchingsIV,Goodmanufacturingof pharmaceuticals (A Plan for total quality control) 3rd Edition. Bhalani publishinghouse Mumbai.
4. TabletsVol.I,II,IIIbyLeonLachman,HerbertA.Liberman,JosephB.Schwartz,2ndEdn.(1989)MarcelDekkerInc.NewYork.
5. Text bookofBio- PharmaceuticsandclinicalPharmacokineticsbyMilo Gibaldi, 3rdEdn, Lea&Febriger,Philadelphia.
6. Pharmaceuticalproductdevelopment.VandanaV.Patrevale.JohnI.Disouza.Maharukh T.Rustomji.CRC Press,GroupofTaylorandFrancis.
7. Dissolution,BioavailabilityandBio-EquivalencebyAbdouH.M,MackPublishing company,EasternPennsylvania.
8. RemingtonsPharmaceuticalSciences,byAlfonso&Gennaro,19thEdn.(1995)OO2C Lippincott;WilliamsandWilkinsAWoltersKluwer Company, Philadelphia.
9. ThePharmaceuticalSciences;thePharmaPathway'PureandappliedPharmacy' byD.ASawant,PragathiBooksPvt.Ltd.
10. PharmaceuticalPackagingtechnologybyD.A.Dean.E.R.Evans,I.H.Hall.1st Edition(Reprint2006).TaylorandFrancis.LondonandNewYork.

MODERNPHARMACEUTICALANALYTICALTECHNIQUES(MQA105P)PRACTICALS

ModernPharmaceuticalAnalyticalTechniques

1. AnalysisofPharmacopoeialcompoundsinbulkandintheirformulations(tablet/ capsules/semisolids)byUV Vis spectrophotometer
2. Simultaneousestimationofmulti-drugcomponentcontainingformulationsbyUV spectrophotometry
3. Ascending&radialpaperchromatography
4. Thinlayerchromatography
5. DeterminationoffunctionalgroupsbyFT-IR
6. EffectOfConcentrationOnViscosity
7. ExperimentsbasedonHPLC
8. ExperimentsbasedonGasChromatography
9. Estimationofriboflavin/quininesulphatebyfluorimetry
10. DeterminationofQuenchingeffectofQuininesulphatebypotassiumiodidesolutionbyF luorometry
11. Estimationofsodium/potassiumbyflame photometryorAAS
12. Potentiometrictitrationofstrongacidandstrongbase
13. DeterminationofPkaandLogpofdrugs.
14. Determinationofflowpropertiesandrheologicalbehaviorofsemi-solidorliquid formulations
15. Determinationofbioavailabilityofpoorlysolubledrugsusingsoliddispersiont echnique

QUALITYCONTROLANDQUALITYASSURANCE

(MQA106P)

1. PreparationandIn-processqualitycontroltestforimmediatereleasedtablets
2. Developmentofstabilitystudyprotocol
3. Estimationofprocesscapability
4. Assayofrawmaterialsasperofficialmonographs
5. Testingofrelatedandforeignsubstancesindrugsandrawmaterials
6. Tocarryoutpreformulationstudyfortablets,parenterals(2experiments).
7. TostudytheeffectofpHonthesolubilityofdrugs
8. QualitycontroltestsforPrimaryandsecondarypackagingmaterials
9. Acceleratedstabilitystudies(1experiment)
10. Improvedsolubilityofdrugsusingsurfactantsystems(1experiment)
11. Improvedsolubilityofdrugsusingco-solvencymethod(1experiment)
12. Investigatingthecompatibilityofdrugsubstanceswithdifferentexcipientstoidentify potentialinteractions ordegradation.
13. Determiningthesolubilityofadrugsubstance invarioussolventsorexcipientstoidentifysuitableformulationsand enhancebioavailability.
14. Developingandtestingdifferentformulationswithvaryingexcipientcompositions, concentrations,anddosageformstoidentifythemostsuitableformulation.
15. Optimizing the manufacturing process parameters (such as blending time,compressionforce,dryingtemperature,orcoatingconditions,toachievede sired productattributes, suchasuniformity, contentuniformity, andstability).
16. Casestudieson,
    - TotalQualityManagement
    - Sixsigma
    - ChangeManagement/Changecontrol.Deviations
    - OutofSpecifications(OOS)
    - OutofTrend(OOT)
    - Corrective&PreventiveActions(CAPA)
    - Deviations

SEMESTER-II

HAZARDS AND SAFETYMANAGEMENT(MQA201T)

THEORY **60Hours**

Scope

Thiscourseisdesignedtoconveytheknowledgenecessarytounderstandissuesrelatedtodifferent kinds of hazard and their management. Basic theoretical and practicaldiscussions integrate the proficiency to handle the emergency situation in thepharmaceuticalproductdevelopmentprocessandprovidestheprinciplebasedapproachtosolvethecomplextribulations.

Objectives

Atcompletionofthiscourseitisexpectedthatstudentswillbeableto

- Understandaboutenvironmentalproblems amonglearners.
- Impartbasicknowledgeabouttheenvironmentanditsalliedproblems.Devel
- opanattitudeofconcernfortheindustryenvironment.
- Ensuresafetystandardsinpharmaceuticalindustry Providecomprehensiveknowled
- geonthesafetymanagement Empoweranideastoclearmechanismandmanagementi
- ndifferentkindsofhazard

managementsystem Teachthemethodof Hazardassessment,procedure,methodologyforprovid

- esafeindustrial

atmosphere

Unit-1: **12Hrs**

Multidisciplinarynatureofenvironmentalstudies: NaturalResources, Renewableandnon-renewable resources,Naturalresourcesandassociatedproblems,

a)Forestresources;b)Waterresources;c)Mineralresources;d)Energyresources;e)Landresources

Ecosystems:ConceptofanecosystemandStructureandfunctionofanecosystem.Environmentalhazards: HazardsbasedonAir, Water,SoilandRadioisotopes.

Unit-2: **12Hrs**

Airbasedhazards:Sources,TypesofHazards,Aircirculationmaintenanceindustryforsterileareaandnon sterile area, Preliminary Hazard Analysis (PHA) Fire protection system: Fire prevention,typesoffire extinguishers andcriticalHazardmanagementsystem.

Unit-3: **12Hrs**

Chemical based hazards: Sources of chemical hazards, Hazards of Organic synthesis,sulphonating hazard, Organic solvent hazard, Control measures for chemical hazards,Managementofcombustiblegases, ToxicgasesandOxygendisplacinggases management,Regulationsforchemicalhazard,Managementofover-ExposuretochemicalsandTLVconcept

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Unit-4: **12Hrs**

Fire and Explosion: Introduction, Industrial processes and hazards potential, mechanicalelectrical,thermalandprocesshazards.Safetyandhazardsregulations,Fireprotectionsyste m:Fireprevention,typesoffireextinguishersandcriticalHazard management systemmechanicalandchemicalexplosion, multiphasereactions,transporteffectsandglobalrates.Preventiveandprotective management from fires and explosion- electricity passivation, ventilation, andsprinkling,proofing,reliefsystems-reliefvalves,flares,scrubbers.

Unit-5: **12Hrs**

Hazard andriskmanagement:Self-protective measures against workplace hazards. Critical trainingforriskmanagement,Processofhazardmanagement,ICHguidelinesonriskassessmentandRiskman agementmethodsandToolsFactoryactandrules,fundamentalsofaccidentprevention,elementsofsafet yprogrammeandsafetymanagement,Physicochemicalmeasurementsofeffluents,BOD,COD,Determ inationofsomecontaminants,Effluenttreatmentprocedure,Roleofemergencyservices.

REFERENCEBOOKS:

1. Y.K.Sing,EnvironmentalScience,NewAgeInternationalPvt,Publishers,Bangalore
2. "QuantitativeRiskAssessmentinChemicalProcessIndustries"AmericanInstituteofChemicalI ndustries,CentreforChemicalProcesssafety.
3. BharuchaErach,TheBiodiversityofIndia,MapinPublishingPvt.Ltd.,Ahmedabad– 380013,India,
4. HazardousChemicals:SafetyManagementandGlobalRegulations,T.S.S.Dikshith,CRCpress

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PHARMACEUTICAL VALIDATION(MQA202T)

THEORY **60Hours**

Scope

The mainpurposeofthesubjectistounderstandaboutvalidationandhowitcanbeappliedtoindustryandthus improvethequalityoftheproducts.Thesubject coversthecompleteinformationaboutvalidation,types,methodologyandapplication.

Objectives

At completionofthiscourse,it isexpectedthatstudentswillbeabletounderstand

- Theconcepts of calibration, qualification and
- validationThequalificationofvariousequipmentsandinstruments
- Process validation of different dosage
- formsValidationofanalyticalmethodforestimationof drugs
- Cleaningvalidationofequipmentsemployedinthemanufactureofpharmaceuticals

Unit-1: **10Hrs**

Introduction to validation: Definition of Calibration, Qualification and Validation, Scope,frequencyandimportance.Differencebetweencalibrationandvalidation.Calibrationofweights andmeasures. Advantages of Validation, scope of Validation, Organization for Validation,ValidationMaster plan, Types ofValidation, Streamlining ofqualification&ValidationprocessandValidationMasterPlan.

Qualification: User requirement specification, Designqualification,FactoryAcceptanceTest(FAT)/SiteAcceptanceTest(SAT),Installationqualification,Operational qualification, Performance qualification, Re-Qualification (Maintaining status-CalibrationPreventive Maintenance,Changemanagement).

Unit-2: **10Hrs**

Qualificationofmanufacturingequipment:DryPowder Mixers, Fluid Bed and Traydryers,TabletCompression(Machine),Dryheatsterilization/Tunnels,Autoclaves,Membranefiltration,Capsulefillingmachine.

Qualificationofanalyticalinstruments:UV-Visiblespectrophotometer,FTIR,DSC,GC, HPLC,HPTLC,LC-MS.

Unit-3: **10Hrs**

Qualificationoflaboratoryequipments:Hardnesstester, Friabilitytest apparatus,tapdensity tester,Disintegration tester, Dissolution test apparatus Validation of Utility systems: Pharmaceuticalwatersystem&pure steam,HVACsystem,Compressedairandnitrogen.

Unit-4: **10Hrs**

ProcessValidation:Concept,Processanddocumentationof ProcessValidation.Prospective,Concurrent& Retrospective Validation,Revalidation criteria,Process Validationofvarious formulations (Coated tablets,Capsules, Ointment/Creams, Liquid Orals and aerosols.), Aseptic filling: Media fill validation, USFDAguidelinesonProcessValidation-Alifecycleapproach.

Analyticalmethodvalidation:Generalprinciples,Validationofanalyticalmethodasper ICHguidelinesandUSP.

Unit-5: **10Hrs**

CleaningValidation:CleaningMethoddevelopment,Validationofanalyticalmethodusedin cleaning,CleaningofEquipment,CleaningofFacilities.Cleaninginplace(CIP). Validationof facilities in sterile and non-sterileplant.Computerizedsystemvalidation:Electronicrecordsanddigitalsignature-21CFRPart11andGAMP

Unit-6: **10Hrs**

General PrinciplesofIntellectual Property:ConceptsofIntellectual Property (IP),IntellectualPropertyProtection(IPP),IntellectualPropertyRights(IPR);Economicimportance,mechanismforprotectionofIntellectual Property - patents,Copyright,Trademark;FactorsaffectingchoiceofIPprotection;Penaltiesforviolation;RoleofIPinpharmaceuticalindustry;Globalramificationandfinancialimplications.Filingapatentapplications;patentapplicationformsandguidelines.Typespatentapplications-provisionalandnon provisional,PCTand convention patentapplications;Internationalpatentingrequirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regardingmaintainingofaPatentfile;Patentinfringementmeaningandscope.Significanceoftransfertechnology(TOT),IPandethics-positiveandnegativeaspectsofIPP;Societalresponsibility,avoidingunethicalpractices.

REFERENCEBOOKS:

1. B.T.Loftus&R.A.Nash,"PharmaceuticalProcessValidation",DrugsandPharmSci.Series, Vol.129,3rdEd.,MarcelDekkerInc.,N.Y.
2. TheTheory&PracticeofIndustrialPharmacy,3rdedition,LeonLachman,HerbertA.Lieberman,Joseph.L.Karig,VarghesePublishingHouse,Bombay.
3. ValidationMasterplanbyTerveeksorDeeks,DavisHarwoodInternationalpublishing.
4. ValidationofAsepticPharmaceuticalProcesses,2ndEdition,byCarleton&Agalloco,
5. (MarcelDekker).
6. MichaelLevin,PharmaceuticalProcessScale-Up",DrugsandPharm.Sci.Series,Vol. 157,2ndEd.,MarcelDekkerInc.,N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for AchievingComplianceinthePharmaceutical,MedicalDevice,andBiotechIndustries,SyedImtiaz Haider
8. PharmaceuticalEquipment Validation:TheUltimateQualificationHandbook,PhillipA.Cloud,InterpharmPress

9. ValidationofPharmaceuticalProcesses:SterileProducts,FrederickJ.Carlton(Ed.)and JamesAgalloco(Ed.),MarcelDekker
10. AnalyticalMethodvalidationandInstrument PerformanceVerificationbyChurgChan,HeimanLam,Y.C.Lee,Yue.Zhang,WileyInt erscience.
11. HuberL.ValidationandQualificationinAnalyticalLaboratories.InformaHealthcare
12. WingateG.ValidatingCorporateComputerSystems:GoodITPracticefor PharmaceuticalManufacturers.InterpharmPress
13. LeBlancDA.ValidatedCleaningTechnologiesforPharmaceuticalManufacturing. InterpharmPress

AUDITSANDREGULATORYCOMPLIANCE(MPA203T)

THEORY **60Hours**

Scope

Thiscoursedealswiththeunderstandingandprocessforauditing inpharmaceuticalindustries. Thissubject covers the methodology involved in the auditing process of different in pharmaceuticalindustries.

ObjectivesUponcompletionofthiscoursethestudentshouldbeab letoTo

- understand the importance of
- auditingTounderstandthemethodologyofauditing
- Tocarryoutthe
- auditprocessTopreparetheauditingreportToprepa
- rethechecklistforauditing

Unit-1: **12Hrs**

Introduction:Objectives,Managementofaudit,Responsibilities,Planningprocess,information gathering,administration,Classifications ofdeficiencies.

Unit-2: **12Hrs**

Roleofqualitysystemsandauditsinpharmaceuticalmanufacturing environment:cGMPRegulations, Quality assurance functions, Quality systems approach, Managementresponsibilities,Resource,Manufacturingoperations,Evaluationactivities,Transitio ningtoqualitysystemapproach,Auditchecklistfordrugindustries.

Unit-3: **12Hrs**

Auditingofvendorsandproductiondepartment:BulkPharmaceuticalChemicalsandpackaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting,coating,capsules,sterile productionandpackaging.

Unit-4: **12Hrs**

AuditingofMicrobiologicallaboratory:Auditingthemanufacturingprocess,Productandprocessinf ormation,Generalareasofinterest inthebuildingrawmaterials, Water,Packagingmaterials.

Unit-5: **12Hrs**

AuditingofQualityAssuranceandengineeringdepartment:QualityAssuranceMaintenance, Criticalsystems:HVAC,Water,WaterforInjectionsystems,ETP.

REFERENCEBOOKS:

1. ComplianceauditingforPharmaceuticalManufacturers.KarenGinsburyandGilBis muth,Interpharm/CRC,BocaRaton,LondonNewYork,WashingtonD.C.
2. PharmaceuticalManufacturingHandbook,RegulationsandQualitybyShayneCoxGad. Wiley-Interscience,AJohnWileyandsons,Inc.,Publications.
3. HandbookofmicrobiologicalQualitycontrol.RosamundM.Baird,Norman A.Hodges,StephenP.Denyar.CRCPress.2000.
4. Laboratoryauditingforqualityandregulatorycompliance.DonaldC.Singer,Raluca-loanaStefan,JacobusF.VanStaden.TaylorandFrancis(2005).

PHARMACEUTICALMANUFACTURINGTECHNOLOGY(MQA204T)

THEORY **60Hours**

Scope

Thiscourseisdesignedtoimpartknowledgeandskillsnecessarytotrainthestudentswiththeindustrialactivitiesduring PharmaceuticalManufacturing.

Objectives

Atcompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand,

• Thecommonpracticeinthepharmaceuticalindustrydevelopments,plantlayoutand productionplanning

• Willbefamiliarwiththeprinciplesandpracticesofasepticprocesstechnology,nonsterile manufacturingtechnologyandpackagingtechnology.

• HaveabetterunderstandingofprinciplesandimplementationofQualitybydesign(QbD)andprocessanalyticaltechnology(PAT)inpharmaceuticalmanufacturing

Unit-1: **12Hrs**

Pharmaceutical industry developments: Legal requirements and Licenses for API andformulationindustry,Plantlocation-Factorsinfluencing.Plantlayout:Factorsinfluencing,Specialprovisions,Storagespacerequirements,sterileand asepticarealayout.

Productionplanning:Generalprinciples,productionsystems,calculationofstandardcost,processplanning,routing,loading,scheduling,dispatchingofrecords,productioncontrol.

Unit-2: **12Hrs**

Asepticprocesstechnology:Manufacturing, manufacturingflowcharts,inprocess-qualitycontroltests for following sterile dosage forms: Ointment, Suspension and Emulsion, Dry powder,Solution (Small Volume & large Volume). Advancedsterileproductmanufacturing technology:Area planning & environmental control, wall and floor treatment, fixtures andmachineries,changerooms,personnelflow,utilities&utilitiesequipmentlocation,engineeringandmaintenance. Process Automation in Pharmaceutical Industry: With specific reference tomanufacturing of sterile semisolids, Small Volume Parenterals & Large Volume Parenterals(SVP & LVP), Monitoring of Parenteral manufacturing facility, Cleaning in Place (CIP),SterilizationinPlace(SIP),PrefilledSyringe,PowderedJet, Needle Free Injections, and Form FillSealTechnology(FFS).

Unit-3: **12Hrs**

Lyophilization technology: Principles, process, equipmentNonsterilemanufacturingprocesstechnology:Manufacturing,manufacturingflowcharts,inprocess-qualitycontroltestsfor followingNon-Sterilesoliddosageforms:Tablets(compressed&coated),Capsules(Hard&Soft).

Advancenon-sterilesolidproductmanufacturing

technology: Process Automation in Pharmaceutical Industry with specific reference tomanufacturingoftabletsandcoatedproducts,ImprovedTabletProduction:Tabletproductionprocess,granulationandpelletizationequipments,continuousandbatch mixing,rapidmixinggranulators, rota granulators, spheronizers and marumerisers, and other specialized granulation anddryingequipments.Problemsencountered.Coatingtechnology:Process,equipments,particlecoating,fluidizedbedcoating,applicationtechniques.Problemsencountered.

Unit-4: **12Hrs**

Containers andclosuresforpharmaceuticals:Types,performance,assuringqualityof glass;typesofplasticsused,Drugplasticinteractions,biologicaltests,modificationofplasticsbydrugs;differenttypesofclosuresandclosureliners;film wrapper;blisterpacks;bubblepacks;shrinkpackaging; foil/plasticpouches, bottleseals,tapeseals,breakablesealsand sealedtubes;qualitycontrolofpackagingmaterialandfillingequipment,flexiblepackaging,productpackagecompatibility,transitworthinessofpackage,Stabilityaspectsofpackaging.Evaluationofstabilityofpackagingmaterial.

Unit-5: **12Hrs**

Qualitybydesign(QbD)andprocessanalyticaltechnology(PAT):Currentapproachanditslimitations.WhyQbDisrequired,Advantages,Elements ofQbD,Terminology:QTPP.CMA,CQA,CPP,RLD,Designspace,DesignofExperiments,Risk Assessmentandmitigation/minimization.QualitybyDesign,FormulationsbyDesign,QbDfordrugproducts,QbDforDrugSubstances,QbDforExcipients,AnalyticalQbD.FDAinitiativeonprocessanalyticaltechnology.PATasadriverforimprovingqualityandreducingcosts:quality by design(QbD), QA, QCand GAMP.PATguidance, standardsandregulatoryrequirements.

REFERENCEBOOKS:

1. LachmanL,LiebermanHA,KanigJL.Thetheoryandpracticeofindustrial pharmacy,3rded.,Varghese Publishers,Mumbai1991.
2. SinkoPJ.Martin'sphysicalpharmacyandpharmaceuticalsciences,5th ed.,B.I.Publications Pvt.Ltd,Noida,2006.

QUALITYASSURANCE PRACTICAL–III PRACTICALS(MQA205P)

Pharmaceuticalvalidation

1 OrganiccontaminantsresidueanalysisbyHPLC
2 SystemsuitabilityparametersforGradientHPLC
3 EstimationofMetalliccontaminantsbyFlamephotometer
4 IdentificationofantibioticresiduebyTLC
5 EstimationofHydrogenSulphideinAir.
6 EstimationofChlorineinWorkEnvironment.
7 SamplingandanalysisofSO2usingColorimetricmethod
8 QualificationoffollowingPharmaequipment

a. Autoclave
b. HotairovenC.PowderMixer
(Dry)d.TabletCompressionM
achine

9 Validationofananalyticalmethodforadrugby UV&HPLC
10 Validationofaprocessingarea
11 Qualificationofatleasttwoanalyticalinstruments
12 Cleaningvalidationofoneequipment
13 QualificationofPharmaceuticalTestingEquipment(Dissolutiontestingapparatus, FriabilityApparatus,DisintegrationTester)

QUALITYASSURANCE PRACTICAL–IV PRACTICALS(MQA206P)

PharmaceuticalManufacturingTechnology

1. ChecklistforBulkPharmaceuticalChemicalsvendors
2. Checklistfortabletingproduction.
3. Checklistforsterileproductionarea
4. ChecklistforWaterforinjection.
5. Demonstratingtheprocessoftabletcompressionusingatabletpunching machine.
6. Hands-ontrainingoncapsule filling machinestounderstandtheprocessoffillingpowders,pellets,orgranulesin tohardgelatincapsules
7. Formulationandmanufacturingofcreamsandointments.
8. Performingqualitycontroltestsonpharmaceuticalproducts, includingidentificationtests,assaydetermination,dissolutiontesting,and contentuniformitytests.
9. PracticalexercisesonGoodManufacturingPractices(GMP)
10. Preparationofsuppositoriesusingdifferentbasesandactiveingredients.
11. Practicalsessionsonregulatoryrequirementsandcomplianceinpharmaceutical manufacturing
12. Designofplantlayout:Sterileandnon-sterile
13. CasestudyonapplicationofQbDCasestudyonapplicationofPAT.

PHARMACEUTICALREGULATORYAFFAIRS
GOODREGULATORYPRACTICES(MRA101T)

THEORY **60Hours**

Scope:

This course is designed to impart fundamental knowledge on various GoodRegulatory Practices viz., cGMP, GLP, GALP and GDP for Pharmaceuticals,Cosmetics,Food&Nutraceuticals,Medicaldevices,In-vitroDiagnosticMedicalDevices(IVDs)andbiologicalproductsandunderstandtherationalebehindtheserequirementsand willpropose waysandmeansofcomplying withthem.

Objectives

At completion of this course it is expected that students will be able to understand,Thekeyregulatoryandcomplianceelementswithrespecttogood ManufacturingPractices,GoodLaboratoryPractices,GoodAutomatedLaboratoryPracticesandGood DocumentationPractices.

- Prepareandimplementthechecklistsand SOPsforvariousGoodRegulatory
- PracticesImplementGoodRegulatoryPracticesintheHealthcareandrelatedIndustries Prepare
- forthereadinessandconductofauditsandinspections

.

Unit-1: **12Hrs**

CurrentGoodManufacturingPractices:Introduction,UScGMPPart210andPart211.EC PrinciplesofGMP(Directive91/356/EEC)Article6toArticle14andWHO cGMPguidelinesGAMP-5; Medical device and IVDs Global Harmonization TaskForce(GHTF)Guidancedocs.

Unit-2: **12Hrs**

Good LaboratoryPractices: Introduction, USFDAGLP Regulations(Subpart Ato Subpart K),ControllingtheGLPinspectionprocess, Documentation,Audit, goalsofLaboratoryQualityAudit,Audit tools,FutureofGLPregulations,relevant ISOandQualityCouncilofIndia(QCI)Standards

Unit-3: **12Hrs**

GoodAutomatedLaboratoryPractices:IntroductiontoGALP,PrinciplesofGALP,GALPRequirements,SOPsofGALP,TrainingDocumentation,21CFRPart 11,Generalcheck list of21CFRPart11,SoftwareEvaluationchecklist,relevantISOandQCIStandards.

Unit-4: **12Hrs**

Good Distribution Practices: Introduction to GDP, Legal GDP requirements put worldwide,Principles, Personnel, Documentation, Premises and Equipment, Deliveries to Customers,Returns,Self-Inspection,Provisionofinformation,Stabilitytestingprinciples,WHOGDP,USPGDP(Supplychainintegrity),relevantCDSCO guidance andISO standards.

Unit-5: **12Hrs**

Quality management systems: Concept of Quality, Total Quality Management, Quality bydesign, SixSigma concept,Out ofSpecifications(OOS), Change control. Validation: TypesofValidation, Types of Qualification, Validation master plan (VMP), Analytical MethodValidation.Validationofutilities,[Compressedair,steam,watersystems,Heat Ventilationand Airconditioning (HVAC)]and Cleaning Validation. The International Conference onHarmonization(ICH)process,ICHguidelinesto establishquality,safetyand efficacyofdrugsubstances and products, ISO13485,SchMIII andother relevant CDSCO regulatoryguidancedocuments

REFERENCEBOOKS

1. GoodLaboratoryPracticeRegulations,bySandyWeinberg,FourthEditionDrugsandthe PharmaceuticalSciences,Vol.168

DOCUMENTATION AND REGULATORYWRITING(MRA102T)

THEORY **60Hours**

Scope

Thiscourseisdesignedto impart fundamentalknowledgeondocumentationandgeneral principlesinvolvedinregulatorywritingandsubmissiontoagencies.

Objectives

Uponcompletionofthecoursethestudentshallbeableto,Knowthevariousdocumentsp

ertainingtodrugsinpharmaceuticalindustry Understandthebasics

ofregulatorycompilation

CreateandassembletheregulationsubmissionasperthерequirementsofagenciesFollowupthe

submissionsandpostapprovaldocumentrequirements

Unit-1: **12Hrs**

Documentation in pharmaceutical industry: ExploratoryProductDevelopmentBrief(EPDB) for Drug substance and Drug product, Product Development Plan (PDP), ProductDevelopment Report(PDR),MasterFormulaRecord,BatchManufacturingRecordanditscalculations, Batch Reconciliation, Batch Packaging Records, Print pack specifications,Distributionrecords,Certificate ofAnalysis(CoA), Site Master File and Drug Master Files(DMF)

Unit-2: **12Hrs**

Dossierpreparationandsubmission:Introduction andoverviewofdossiers,contentsando rganization of dossier, binders and sections, compilation and review of dossier. Papersubmissions, overview and modules of CTD, electronic CTD submissions; Electronicsubmission:Planningelectronicsubmission,requirementsforsubmission,regulatorybin dingsand requirements, Tooland Technologies, electronicdossier submissionprocessand validatingthe submission, Electronic Submission Gateway (ESG). Non eCTD electronic submissions(NeeS), Asian CTD formats (ACTD) submission. Organizing, process and validation ofsubmission.SubmissioninSugamsystemofCDSCO

Unit-3: **12Hrs**

Audits:Introduction,Definition,Summary,Typesofaudits,GMPcomplianceaudit,Auditpolicy,InternalandExte

rnalAudits,SecondPartyAudits,Externalthirdpartyaudits,Auditing strategies,Preparationandconductingaudit,Auditingstrategies,auditanalysis,auditreport, auditfollowup.Auditing/inspectionofmanufacturingfacilitiesbyregulatoryagencies.

Timelinesforaudits/inspection.GHTFstudygroup4guidancedocument.ISO13485.

Unit-4: **12Hrs**

Inspections: Pre-approval inspections, Inspection ofpharmaceuticalmanufacturers, Inspection of drug distribution channels, Quality systems requirements for national goodmanufacturingpracticeinspectorates,inspectionreport,modelcertificateofgoodmanufacturing practices,Rootcauseanalysis,Corrective andPreventiveaction(CAPA).

Unit-5: **12Hrs**

Product life cycle management: Prior Approval Supplement (PAS), Post Approval Changes[SUPAC],ChangesBeingEffectedin30Days(CBE-30),AnnualReport,PostmarketingReportingRequirements,PostapprovalLabeling Changes,Lifecycle Management,FDAInspectionandEnforcement,EstablishmentInspectionReport(EIR),WarningLetters,Recalls,Seizure andInjunctions.ISO RiskManagementStandard.

REFERENCEBOOKS

1. ComplianceauditingforPharmaceuticalManufacturers.KarenGinsburyandGilBismuth,Interpharm/CRC,BocaRaton,LondonNewYork,WashingtonD.C.
2. PharmaceuticalManufacturingHandbook,RegulationsandQualitybyShayneCox Gad.Wiley-Interscience,AJohnWileyand sons,Inc.,Publications.
3. HandbookofmicrobiologicalQualitycontrol.RosamundM.Baird,NormanA. Hodges,StephenP.Denyar.CRCPress.2000.
4. Laboratoryauditing forqualityandregulatorycompliance.DonaldC.Singer,Raluca-loanaStefan,JacobusF.VanStaden.TaylorandFrancis(2005).
5. ImplementingJuran'sRoadMapforQualityLeadership:BenchmarksandResults,By AlEndres,Wiley,2000
6. Understanding,ManagingandImplementingQuality:Frameworks,Techniquesand Cases,ByJijuAntony;DavidPreece,Routledge,2002

CLINICAL RESEARCHREGULATIONS(MRA103T)

THEORY **60Hours**

Scope

This course is designed to impart the fundamental knowledge on the clinicaldevelopment process of drugs, pharmaceuticals and Medical Devices, phases andconduct of clinical trials and research, regulations and guidance governing theconductofclinicalresearch inIndia,USAand EU.

Itpreparesthestudentstolearnindetailonvariouslaws,legislationsandguidancerelatedtosafety,efficacy,ethicalconductandregulatoryapprovalofclinicalresearch.

Objectives

Uponcompletionofthecourse,thestudent shallbeableto(know,doand

- appreciate)History, origin and ethics of clinical and biomedical research and
- evaluationClinicaldrug,medicaldevicedevelopmentprocessanddifferenttypesa ndphases

ofclinicaltrials

- Regulatoryrequirementsandguidanceforconductofclinicaltrialsandresearch

Unit-

- **1:**ClinicalDrugDevelopmentProcessDifferent
- types of Clinical
- StudiesPhasesofclinicaltrials,ClinicalTrialproto colPhase 0studies
- Phase I and subtype studies (single ascending, multiple ascending, doseescalation,methods,foodeffectstudies,drug–druginteraction,PKendpoints
- PhaseIIstudies(proofofconceptorprinciplestudiestoestablishefficacy)PhaseIIIstudie
- s(Multiethnicity,globalclinicaltrial,registrationstudies)
- PhaseIVstudies(PostMarketingStudies;PSUR)ClinicalInvestigati onandEvaluationofMedicalDevices&IVDs

Different Types ofStudies: Key Concepts ofMedicalDevice Clinical EvaluationKeyconcepts ofClinicalInvestigation **12hrs**

Unit-2:EthicsinClinicalResearch:

- HistoricalPerspectives:NurembergCode,Thalidomidestudy ,NazisTrials,TuskegeeSyphilisStudy,TheBelmontReport,ThedeclarationofHelsinki
- OriginofInternationalConferenceonHarmonization-GoodClinicalPractice(ICH-GCP)guidelines.
- Theethicsofrandomizedclinicaltrials•Theroleofplaceboinclinicaltrials
- Ethicsofclinicalresearchinspecialpopulation

- Institutional Review Board/Independent EthicsCommittee/EthicsCommittee – composition, roles,responsibilities,reviewand approvalprocessandongoingmonitoringofsafetydata
- Datasafetymonitoringboards.
- Responsibilitiesofsponsor, CRO,and investigatorinethicalconductofclinicalresearch
- Ethicalprinciplesgoverninginformedconsentprocess
- PatientInformationSheetandInformedConsentForm
- The informedconsentprocessanddocumentation

12hrsUnit-3. RegulationsgoverningClinicalTrials India:ClinicalResearchregulationsinIndia– ScheduleY&MedicalDeviceGuidanceUSA:Regulationstoconductdrugstudiesin USA(FDA)
- NDA505(b)(1)oftheFD&CAct(Applicationforapprovalofanewdrug)NDA505(b)(2)oftheFD&C
- Act(Applicationforapprovalofanewdrugthatrelies,atleastinpart, ondatanotdevelopedbytheapplicant)
- ANDA505(j)oftheFD&CAct (Applicationforapprovalofagenericdrugproduct)
- FDAGuidanceforIndustry-Acceptance ofForeignClinical Studies
- FDAClinicalTrialsGuidanceDocument:GoodClinicalPracticeEU:ClinicalResearchregulatio nsinEuropeanUnion(EMA) **12hrs**

Unit-4 .Clinical ResearchRelated
- GuidelinesGoodClinicalPracticeGuidelines(ICH
- GCPE6)Indian
- GCPGuidelinesICMREthicalGuidelinesforBiome
- dicalResearchCDSCO guidelines

GHTFstudygroup5guidancedocuments
Regulatory Guidance onEfficacy and Safety ICH
- Guidance'sE4– DoseResponseInformationtosupportDrugRegistrationE7
- – Studies in support of General Population: GeriatricsE8–
- GeneralConsiderationsofClinicalTrialsE10–
- ChoiceofControlGroupsandRelated IssuesinClinicalTrials,
- E11–
- ClinicalInvestigationofMedicinalProductsinthePediatricPopulationGeneralbiostaticsprincip leappliedinclinicalresearch 12hrs

Unit-
- **5.**USA&EUGuidanceUSA:FDAGuidanceCFR21Part50:Protec

tionofHumanSubjects

- CFR21Part54:FinancialDisclosurebyClinicalInvestigatorsCFR
- 21Part312:INDApplication
- CFR21Part 314:ApplicationforFDAApprovaltoMarketaNewDrugCFR21Part320: Bioavailabilityandbioequivalence requirementsCFR21Part812:InvestigationalDeviceExemptions
- CFR21Part822:Post-
- marketsurveillanceFDASafetyReportingRequirementsforINDsandBA/BEStudies
- FDAMedWatchGuidanceforIndustry:GoodPharmacovigilancePracticesandPharmacoepidemiologicAssessmentEuropeanUnion:EMAGuidance
- EUDirectives2001
- EudraLex(EMEA)Volume3 –Scientificguidelinesformedicinalproductsforhumanuse
- EUAnnualSafetyReport(ASR)
- Volume9A–
- PharmacovigilanceforMedicinalProductsforHumanUseEUMDD withrespecttoclinicalresearch
- ISO14155 **12hrs**

REFERENCEBOOKS

1. ClinicalTrialsandHumanResearch:APracticalGuidetoRegulatoryComplianceByFay A.RozovskyandRodneyK.Adams
2. HIPAAandHumanSubjectsResearch:AQuestionandAnswerReferenceGuideByMark Barnes,JD,LLMandJenniferKulynych,JD,PhD
3. PrinciplesandPracticesofClinicalResearch, SecondEditionEditedbyJohnI. Gallin andFrederickP.Ognibene
4. ReviewingClinicalTrials:AGuidefortheEthicsCommittee;JohanPEKarlbergand MarjorieASpeers;Karlberg,JohanPetterEinar,HongKong.
5. InternationalPharmaceuticalProduct Registration: AspectsofQuality,SafetyandEfficacy;AnthonyC.Cartwright;Taylor&FrancisIn c.,USA.
6. NewDrugApprovalProcess:TheGlobalChallenge;Guarino,RichardA;Marcel DekkerInc.,NY.
7. FDAregulatoryaffairs:aguide forprescriptiondrugs,medicaldevices,and biologics;DouglasJ.Pisano,DavidMantus;CRC Press,USA
8. CountrySpecificGuidelinesfromofficialwebsites.Drugs&CosmeticsAct&RulesandAmendments

REGULATIONSANDLEGISLATIONFORDRUGS&COSMETICS,MEDICALDEVICES,BIOLOGICALS&HERBALS,ANDFOOD&NUTRACEUTICALSININDIA ANDINTELLECTUALPROPERTYRIGHTS
(MRA104T)

THEORY **60Hours**

Scope

Thiscourseisdesignedtoimpartfundamentalknowledgeonregulationsandlegislationin India w.r.t.Drugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticals.Itprepares the students for basic regulatory requirements in India of Drugs & Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticals.formanufacture,import&registration, export, sale, marketing authorization, clinical trials and intellectualpropertyrights.**Objectives**

Uponthecompletionofthecoursethestudentshallbeableto:

- Knowdifferent Actsandguidelinesthat regulateDrugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticalsindustry inIndia.
- Understand the approvalprocessandregulatoryrequirementsforDrugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticals

Unit-1:Biologicals&Herbals,andFood&NutraceuticalsActsandRules(withlatestamendments):

1. DrugsandCosmeticsAct1940andRules1945:DPCOandNPPA
2. Otherrelevantprovisions(rulesschedulesandguidelinesforapprovalofDrugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&NutraceuticalsinIndia

Other relevant Acts: Narcotics Drugs and Psychotropic Substances Act; Medicinaland ToiletPreparations (Excise Duties) Act, 1955; Pharmacy Act, 1948; Drugs and Magic Remedies(ObjectionableAdvertisements) Act, 1955;PreventionofCrueltytoAnimals Act.

10Hrs

Unit-2: Regulatory requirements and approval proceduresforDrugs & Cosmetics MedicalDevices, Biologicals & Herbals, and Food & Nutraceuticals CDSCO (CentralDrug StandardControlOrganization)andStateLicensingAuthority:Organization,Responsibilities

10hrs

- Rules,regulations,guidelinesandstandardsforregulatoryfilingofDrugs&Cosmetics,MedicalDevices,Biologicals&Herbals,andFood&Nutraceuticals
- FormatandcontentsofRegulatorydossierfilingClinicaltrial/investigations

Unit-3: IndianPharmacopoeialStandards,BISstandardsandISOandotherrelevantstandards 10Hrs

Unit-4: Bioavailability and Bioequivalence data (BA &BE), BCS Classification of Drugs,Regulatory Requirements for Bioequivalence study Stability requirements:ICH and WHOGuidelines for Drug testing in animals/Preclinical StudiesAnimal testing: Rationale forconductingstudies,CPCSEAGuidelinesEthicalguidelinesforhumanparticipantsICMR-DBTGuidelinesforStemCellResearch 10Hrs

Unit-5: Intellectual Property Rights: Patent, Trademark, Copyright, Industrial Designs andGeographicalIndications, IndianPatentScenario. IPRvsRegulatoryAffairs. 10Hrs

REFERENCEBOOKS

1. ManualofPatentPractice&Procedure,3rdEdition,byThePatentOfficeofIndia
2. PatentFailureHowJudges,Bureaucrats,andLawyersputinnovatorsatriskbyJames BessenandMichaelJ.Meurer
3. PrinciplesandPracticeofClinicalTrialMedicinebyRichardChinandBruceY.Lee
4. EthicalGuidelinesforBiomedicalResearchonHumanParticipantsbyIndianCouncilof MedicalResearchNewdelhi2006.

CPCSEAGuidelines for LaboratoryAnimalFacilitybyCommitteeforthepurposeofcontrol andsupervisiononexperiments onanimals(CPCSEA)

REGULATORYAFFAIRS PRACTICAL-I(MRA105P)

ListofExperiments:

1. Casestudies(4Nos.)ofeachofGoodPharmaceuticalPractices.
2. Documentationforinprocessand finishedproductsQualitycontroltestsforSolid,liquid,SemisolidandSterile preparations.
3. PreparationofSOPs,Analyticalreports(Stabilityandvalidation)
4. Protocolpreparationfordocumentationofvarioustypesofrecords(BMR,MFR, DR)Labelingcomparisonbetweenbrand&generics.
5. PreparationofregulatorydossierasperIndianCTDformatandsubmissioninSUGAM
6. CasestudiesonresponsewithscientificrationaletoUSFDAWarningLetter
7. PreparationofsubmissionchecklistofIMPDforEUsubmission.
8. ComparisonstudyofmarketingauthorizationproceduresinEU.

REGULATORYAFFAIRSPRACTICAL– II(MRA106P)

ListofExperiments:

1. CasestudiesonChangeManagement/Changecontrol.DeviationsandCorrective& Preventive Actions (CAPA)
2. Importofdrugsforresearchanddevelopmentalactivities
3. GMPAuditRequirementsasperCDSCO
4. PreparationofchecklistforregistrationofINDasperICHCTDformat.
5. PreparationofchecklistforregistrationofNDAasperICHCTDformat.
6. PreparationofchecklistforregistrationofANDAasperICHCTDformat.
7. ComparativestudyofDMFsysteminUS,EUandJapan
8. PreparationofregulatorysubmissionusingeCTDsoftware
9. Documentationofrawmaterialsanalysisasperofficialmonographs
10. Preparationofauditchecklistforvariousagencies
11. PreparationofsubmissiontoFDAusing eCTDsoftware
12. PreparationofsubmissiontoEMAusingeCTDsoftware
13. PreparationofsubmissiontoMHRAusingeCTDsoftware

SEMESTERII

REGULATORYASPECTSOFDRUGS&COSMETICS(MRA201T)

THEORY **60Hours**

Scope

Thiscourseisdesignedtoimpartthefundamentalknowledgeonthedrugdevelopmentprocess,regulatoryrequirementsforapprovalofnewdrugs,drugproductsandcosmeticsinregulatedand semi-regulatedcountriesItpreparesthestudentstolearnindetailontheregulatoryrequirements,documentation requirements, and registration procedures for marketing the drug products andcosmeticsinregulatedandsemi-regulatedcountries.

Objectives

Uponcompletionofthe course,thestudentshallbe

- abletoknowprocessofdrugdiscoveryanddevelopmentandgenericproductdevelopmentregulatorya
- pprovalprocessandregistrationproceduresforAPIanddrugproductsinUS,EUCosmeticsregulations
- inregulatedandsemi-
- regulatedcountriesAcomparativestudyofIndiawithotherglobalregulatedmarkets

Unit-1. USA & CANADA: Organization structure and functions of FDA. Federal register andCode of Federal Regulations (CFR), History and evolution of United States Federal, Food, Drugand Cosmetic Act (FFDCA), Hatch Waxman act and Orange book, Purple book, Drug MasterFiles(DMF)systeminUS,RegulatoryApproval

Process for Investigational New Drug (IND), New Drug Application (NDA), Abbreviated NewDrugApplication(ANDA),SupplementalNewDrugApplication(SNDA);Regulatoryrequirements for Orphan drugs and Combination Products, Changes to an approved NDA /ANDA.Regulatoryconsiderationsfor manufacturing,packagingand labelingofpharmaceuticals inUSA. Legislation and regulations for import, manufacture, distribution and sale of cosmeticsinUSAand Canada. **12Hrs**

Unit-2: European Union & Australia: Organization and structure of EMA & EDQM, Generalguidelines, Active Substance Master Files (ASMF) system in EU, Content and approvalprocessofIMPD,MarketingAuthorizationproceduresinEU(Centralizedprocedure Decentralized procedure, Mutual recognition procedure and National Procedure). Regulatoryconsiderations for manufacturing, packaging and labeling of pharmaceuticals in EU, Eudralexdirectivesforhumanmedicines,Variations&extensions,ComplianceofEuropeanPharmacopoeia(CEP)/Certificateof Suitability (CoS), Marketing Authorization (MA) transfers,Qualified Person (QP) in EU. Legislation and regulations for import, manufacture, distributionandsaleofcosmeticsinEuropeanUnion&Australia. **12HRS**

Unit-3:Japan:OrganizationofthePMDA,PharmaceuticalLawsandregulations,typesofregistrationapplications,DMF systeminJapan,drugregulatory approval process,Regulatoryconsiderationsformanufacturing,packagingandlabelingofpharmaceuticalsinJapan,PostmarketingsurveillanceinJapan.Legislationandregulationsforimport,manufacture,distributionandsaleofcosmeticsinJapan. **12 Hrs**

Unit-4.EmergingMarket:Introduction,Countriescovered,Studyoftheworldmap,studyof variouscommitteesacrossthe globe(ASEAN,APEC,EAC,GCC,PANDRH,SADC) WHO:WHO,GMP,RegulatoryRequirementsforregistrationofdrugsandpostapprovalrequirementsinWHOthroughprequalificationprogramme,CertificateofPharmaceuticalProduct (CoPP) - General and Country Specific (South Africa, Egypt, Algeria and Morocco,Nigeria,KenyaandBotswana) **12hrs**

Unit-5.Brazil,ASEAN,CISandGCCCountries:ASIANCountries:IntroductiontoACTD,Regulatory Requirements for registration of drugs and postapproval requirements inChinaandSouthKorea&AssociationofSoutheastAsianNations(ASEAN)Regioni.e.Vietnam,Malaysia,Philippines,SingaporeandThailand.
CIS(CommonwealthIndependentStates):Regulatorypre-requisitesrelatedtoMarketingauthorizationrequirementsfordrugsandpostapprovalrequirementsinCIScountriesi.e.Russia,Kazakhstan and Ukraine GCC (Gulf Cooperation Council)forArab states:Regulatory pre-requisitesrelatedtoMarketingauthorizationrequirementsfordrugsandpostapprovalrequirements in Saudi Arabia and UAE Legislation and regulations for import, manufacture,distributionandsaleofcosmeticsinBrazil,ASEAN,CISandGCCCountries. **12hrs**

REFERENCEBOOKS

1. GenericDrugProductDevelopment,SolidOralDosage forms,LeonShargelandIsaderKaufer,MarcelDekkerseries,Vol.143
2. ThePharmaceuticalRegulatoryProcess,EditedbyIraR.BerryMarcelDekkerSeries,Vol.144
3. ThePharmaceuticalRegulatoryProcess,SecondEditionEditedbyIraR.BerryandRobertP.Martin,Drugsand thePharmaceuticalSciences,Vol.185InformaHealthcarePublishers
4. Guidebookfordrugregulatorysubmissions/SandyWeinberg.ByJohnWiley&Sons.Inc

REGULATORYASPECTSOFHERBALANDBIOLOGICALS(MRA202T)

THEORY **60Hours**

Scope

ThiscourseisdesignedtoimpartfundamentalknowledgeonRegulatoryRequirements,LicensingandRegistration, Regulation on Labelling of Biologics in India, USA and EuropeItpreparesthestudentstolearnindetailonRegulatoryRequirementsforbiologics, Vaccinesand BloodProducts

Objectives

Uponthecompletionofthecoursethestudentshallbeableto:

•KnowtheregulatoryRequirementsforBiologicsandVaccines

•Understandtheregulationfornewlydeveloped biologicsandbiosimilars

•Knowthepre-clinicalandclinicaldevelopmentconsiderationsofbiologics

•UnderstandtheRegulatoryRequirementsofBloodand/orItsCo mponentsIncludingBloodProductsandlabelrequirements

Unit1: India : Introduction, Applicable Regulations and Guidelines , Principles for Developmentof Similar Biologics, Data Requirements for Preclinical Studies, Data Requirements for ClinicalTrial Application, Data Requirements for Market AuthorizationApplication,Post-Market DataforSimilarBiologics, Pharmacovigilance. GMPandGDP. **12HRS**

Unit-2:USA:IntroductiontoBiologics;biologics,biologicalandbiosimilars,differentbiologicalproducts, difference between generic drug and biosimilars, laws, regulations and guidance onbiologics/biosimilars,developmentandapprovalofbiologicsandbiosimilars(IND,PMA,BLA,NDA, 510(k), pre-clinical and clinical development considerations, advertising, labelling andpackingofbiologics. **12hrs**

Unit-3.EuropeanUnion:IntroductiontoBiologics;directives,scientificguidelinesandguidancerelatedtobiologicsinEU,comparability/biosimilarityassessment,Plasmamasterfile,TSE/BSE evaluation, development and regulatory approval of biologics(Investigationalmedicinalproductsandbiosimilars),pre-clinicalandclinicaldevelopmentconsiderations;stability, safety,advertising,labellingandpackingofbiologicsinEU**12Hrs**

Unit-4. Vaccine regulations in India, US and European Union: Clinical evaluation, Marketingauthorisation,Registrationorlicensing,Qualityassessment,Pharmacovigilance,AdditionalrequirementsBloodandBloodProductsRegulationsinIndia,USandEuropeanUnion:RegulatoryRequirementsofBloodand/orItsComponentsIncludingBloodProducts,

LabelRequirements,ISBT (International Society of Blood Transfusion) and IHN (InternationalHaemovigilenceNetwork) **12hrs**

5. HerabalProducats:Quality,safetyandlegislationforherbalproductsinIndia,USAand EuropeanUnion **12hrs**

REFERENCEBOOKS

1. FDARegulatoryAffairs:AGuideforPrescriptionDrugs,MedicalDevices,andBiologics,DouglasJ.Pisano,DavidS.Mantus;Informa ,2008
2. DevelopmentofVaccines:FromDiscoverytoClinicalTesting;ManmohanSingh,IndreshK.Srivastava;Wiley,2011
3. BiologicalDrugProducts:DevelopmentandStrategies;WeiWang,ManmohanSingh;wiley ,2013

REGULATORYASPECTSOFMEDICALDEVICES(MRA203T)

THEORY **60Hours**

Scope

Thiscourseisdesignedtoimpartthefundamentalknowledgeonthemedicaldevicesandinvitrodiagnostics,basisofclassificationandproductlifecycleofmedicaldevices,regulatoryrequirements for approval of medical devices in regulated countries like US, EU and AsiancountriesalongwithWHOregulations.Itpreparesthestudentstolearnindetailontheharmonizationinitiatives,qualityandethicalconsiderations,regulatoryanddocumentationrequirementsformarketingmedicaldevicesandIVDsinregulatedcountries.

Objectives

Uponcompletionofthecourse,thestudentshallbeabletoknow

•basicsofmedicaldevicesandIVDs,processofdevelopment,ethicalandqualityconsiderations

•harmonizationinitiativesforapprovalandmarketingofmedicaldevicesandIVDs

•regulatoryapprovalprocessformedicaldevicesandIVDsinIndia,US,Canada,EU,JapanandASEAN

•clinicalevaluationandinvestigationofmedicaldevicesandIVDs

Unit-1 Medical Devices: Introduction, Definition, Risk based classification and EssentialPrinciplesofMedicalDevicesandIVDs.Differentiating medicaldevicesIVDsandCombinationProductsfromthatofpharmaceuticals,HistoryofMedicalDeviceRegulation,ProductLifecycleofMedicalDevices andClassificationofMedicalDevices. IMDRF/GHTF:Introduction,OrganizationalStructure,PurposeandFunctions,RegulatoryGuidelines, Working Groups, Summary Technical Document (STED), Global Medical DeviceNomenclature(GMDN). **12Hrs**

Unit-2:Ethics:ClinicalInvestigationofMedicalDevices,ClinicalInvestigationPlanforMedical Devices, Good Clinical Practice for Clinical Investigation of medical devices (ISO14155:2011) Quality: QualitySystemRegulations of MedicalDevices: ISO 13485, QualityRiskManagement of Medical Devices: ISO 14971, Validation and Verification of Medical device,AdverseEventReporting ofMedicaldevice **12hrs**

Unit-3:USA:Introduction,Classification,Regulatory approval processforMedicalDevices(510k)PremarketNotification,Pre-MarketApproval (PMA),Investigational DeviceExemption(IDE)andInvitroDiagnostics,QualitySystemRequirements21CFRPart820,Labelingrequirements21CFRPart801,PostmarketingsurveillanceofMDandUniqueDeviceIdentification(UDI).BasicsofInvitrodiagnostics,classificationandapprovalprocess.**12Hrs**

Unit-4:EuropeanUnion:Introduction,Classification,RegulatoryapprovalprocessforMedicalDevices(MedicalDeviceDirective, ActiveImplantableMedicalDeviceDirective)andInvitroDiagnostics (In Vitro Diagnostics Directive), CE certification process. Basics of In vitrodiagnostics,classificationandapprovalprocess **12hrs**

Unit-5:ASEAN,China &Japan:MedicalDevicesandIVDs,Regulatoryregistration procedures,QualitySystemrequirementsandclinicalevaluationandinvestigation.

IMDRFstudygroupsand guidancedocuments.

12hrs

REFERENCEBOOKS:

1. FDAregulatoryaffairs:aguideforprescriptiondrugs,medicaldevices,andbiologics byDouglasJ.Pisano,DavidMantus.
2. MedicalDeviceDevelopment:ARegulatoryOverviewbyJonathanS.Kahan
3. MedicalProductRegulatoryAffairs:Pharmaceuticals,Diagnostics,MedicalDevicesby JohnJ.TobinandGaryWalsh
4. ComplianceHandbookforPharmaceuticals,MedicalDevicesandBiologicsbyCarmen MedinaCountrySpecificGuidelinesfromofficialwebsites

REGULATORYASPECTSOFFOOD&NUTRACEUTICALS(MRA204T)

THEORY **60Hours**

Scope

This course is designed to impart the fundamental knowledge on RegulatoryRequirements,RegistrationandLabelingRegulationsofNutraceuticalsinIndia,USAandEurope.Itpreparesthestudentstolearnindetailon RegulatoryAspectsfornutraceuticalsandfoodsupplements.

Objectives

Uponcompletionofthecourse,thestudent

- shallbeabletoKnowtheregulatoryRequirementsfornutraceuticals
- Understandtheregulationforregistrationand labelingofnutraceuticalsand foodsupplementsinIndia,USAandEurope.

Unit-1: Nutraceuticals: Introduction, History of Food and Nutraceutical Regulations,Meaning of Nutraceuticals, Dietary Supplements, Functional Foods, Medical Foods,Scopeand OpportunitiesinNutraceuticalMarket. **12hrs**

Unit-2:GlobalAspects:WHOguidelinesonnutrition. NSFInternational:ItsRoleintheDietarySupplementsand NutraceuticalsIndustries, NSFCertification, NSFStandardsforFoodAndDietarySupplements.GoodManufacturingPracticesforNutraceuticals.**12hrs**

Unit-3:India:FoodSafetyandStandardsAct,FoodSafetyandStandardsAuthorityofIndia:Organization and Functions, Regulations for import, manufacture and sale ofnutraceuticalproductsinIndia,RecommendedDietaryAllowances(RDA)inIndia.

12hrs

Unit-4:USA:USFDAFoodSafetyModernizationAct,DietarySupplementHealthandEducation Act. U.S. regulations for manufacture and sale of nutraceuticals and dietarysupplements, Labelling Requirements and Label Claims for Dietary Supplements,RecommendedDietaryAllowances(RDA)intheU.S **12hrs**

Unit-5: European Union: European Food Safety Authority (EFSA): Organization andFunctions.EUDirectivesandregulationsformanufactureandsaleofnutraceuticalsanddietarysupplements. Nutritionlabelling.

EuropeanRegulationonNovelFoodsandNovelFoodIngredients.

RecommendedDietaryAllowances(RDA)inEurope. **12Hrs**

REFEERENCEBOOKS:

1. RegulationofFunctionalFoodsandNutraceuticals:AGlobalPerspectivebyClare M.Hasler(WileyOnlineLibrary)

2. HandbookofNutraceuticalsbyYashwantPathak

REGULATORYAFFAIRS PRACTICAL-III(MRA205P)

ListofExperiments:

1. PreparationofBiologicsLicenseApplications(BLA)
2. PreparationofdocumentsrequiredforVaccineProductApproval
3. ComparisonofclinicaltrialapplicationrequirementsofUS,EU andIndiaofBiologics
4. PreparationofChecklistforRegistrationofBloodandBloodProducts
5. Registrationrequirement comparisonstudyin5emergingmarkets(WHO) andpreparingchecklistformarketauthorization
6. Registrationrequirementcomparisonstudyinemergingmarkets(BRICS)andpreparing checklistformarketauthorization
7. Registrationrequirementcomparisonstudyinemergingmarkets(ChinaandSouth Korea)andpreparingchecklistformarketauthorization
8. Registrationrequirementcomparisonstudyinemergingmarkets(ASEAN)and preparingchecklistformarketauthorization
9. Registrationrequirementcomparisonstudyinemergingmarkets(GCC)andpreparing checklistformarketauthorization
10. Preparationofdocumentrequiredfortheapprovalofherbalproductsofdiversedosagef orms(3products)as perregulations requirements

REGULATORYAFFAIRSPRACTICAL-IV(MRA206P)

1. Checklistsfor510kandPMAforUSmarket
2. ChecklistforCEmarkingforvariousclassesofdevicesforEU
3. STEDApplicationforClassIIIDevices
4. AuditChecklistforMedicalDeviceFacility
5. ClinicalInvestigationPlanforMedicalDevices
6. Preparationandsubmissionofmedicaldevicesforapproval(3products)
7. GMPofmanufacturingofmedicaldevicesofdiversenature(3products)
8. preparationandsubmissionofnutraceuticalsdevicesforapproval(3products)

PHARMACYPRACTICECLINICALPHARMACYPRACTICE

(MPP101T)

THEORY **60Hours**

Scope: This course is designed to impart the basic knowledge and skills that arerequiredtopracticepharmacyincludingtheprovisionofpharmaceuticalcareservices tobothhealthcare professionals andpatientsinclinicalsettings.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:

- Understandtheelementsofpharmaceuticalcareandprovidecomprehensivepatient careservices
- Interpretthe
- laboratoryresultstoaidtheclinicaldiagnosisofvariousdisordersProvideintegrated,criticallyanalyzedmedicineandpoisoninformationtoenable healthcareprofessionalsintheefficientpatientmanagement

Unit-1: Introduction to Clinical Pharmacy:Definition, evolution and scope ofclinicalpharmacy,Internationalandnationalscenarioofclinicalpharmacypractice,Pharmaceutical care Clinical Pharmacy Services: Ward round participation, Drugtherapyreview (Drug therapy monitoring including medication order review, chartendorsement,clinicalreviewandpharmacistinterventions) **12hrs**

Unit-2: Clinical Pharmacy Services: Patient medication history interview, Basic conceptofmedicineandpoisoninformationservices,Basicconceptofpharmacovigilance,Hemovigilance,MateriovigilanceandAEFI,Patientmedicationcounselling,Drugutilisation evaluation, Documentation of clinical pharmacy services, Quality assurance ofclinicalpharmacyservices. **12hrs**

Unit-3:PatientDataAnalysis:PatientData&PracticeSkills:Patient'scasehistory-its structureandsignificancesindrugtherapymanagement,Commonmedicalabbreviationsanddterminologiesusedinclinicalpractice,Communicationskills:verbal and non-verbal communications, its applications in patient care services LabDataInterpretation: Hematologicaltests,Renalfunctiontests,Liverfunctiontests

12hrs

Unit-4:LabDataInterpretation:Testsassociatedwithcardiacdisorders,Pulmonaryfunction tests,Thyroidfunction

tests,Fluidandelectrolytebalance,Microbiologicalculturesensitivitytests. **12Hrs**

Unit-5:Medicines&PoisonInformationServicesMedicineInformationService:Definition and need for medicine information service, Medicine information resources,Systematic approach in answeringmedicineinformation queries, Preparation of verbaland writtenresponse, Establishing a drug informationcentre. PoisonInformationService:Definition,need,organizationandfunctionsofpoisoninformationcentre

12hrs

REFERENCEBOOKS:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – ParthasarathiG,KarinNyfort-HansenandMilapNahata
2. PracticeStandardsandDefinitions-TheSocietyofHospitalPharmacistsofAustralia
3. Basicskillsininterpretinglaboratorydata-ScottLT,AmericanSocietyofHealthSystemPharmacistsInc
4. Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

PHARMACOTHERAPEUTICS-I(MPP102T)

THEORY **60Hours**

Scope: This course aims to enable the students to understand the different treatmentapproaches in managing various disease conditions. Also, it imparts knowledge andskills in optimizing drug therapy of a patient by individualizing the treatment planthroughevidence-basedmedicines.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Describeandexplai

- ntherationalefordrugtherapy
- Summarizethetherapeuticapproachformanagementofvariousdiseaseconditionsinclu dingreference tothelatestavailable evidence
- Discusstheclinicalcontroversiesindrugtherapyandevidencebasedmedicine
- Prepareindividualizedtherapeutic plans basedondiagnosis
- Identify the patient specific parameters relevant in initiating drug therapy, andmonitoring therapy (including alternatives, time- course of clinical andlaboratoryindicesoftherapeuticresponse andadverseeffect/s)

Etiopathogenesisandpharmacotherapyofdiseasesassociatedwithfollowingsystems

Unit-1:Cardiovascularsystem:Hypertension,Congestivecardiacfailure,Acutecoronary syndrome,Arrhythmias,Hyperlipidemias.

Unit-2-Respiratorysystem:Asthma,Chronicobstructiveairwaysdisease,Druginduced pulmonarydiseasesEndocrine system:Diabetes,Thyroiddiseases

Unit-3:Gastrointestinalsystem:Pepticulcerdiseases,Refluxesophagitis,Inflammatory boweldiseases,Jaundice&hepatitis

Unit-4:Gastrointestinalsystem:Cirrhosis,DiarrheaandConstipation,Drug-inducedliver disease, Hematological diseases: Anemia, Deep vein thrombosis, Drug inducedhematologicaldisorders

Unit-5:Boneandjointdisorders:Rheumatoidarthritis,Osteoarthritis,Gout,Osteoporosis

DermatologicalDiseases:Psoriasis,Eczemaandscabies,impetigo,druginducedskin disordersOphthalmology:Conjunctivitis,Glaucoma

REFERENCEBOOKS:

1. RogerandWalker.ClinicalPharmacyandTherapeutics-ChurchillLivingstonepublication

2. JosephT.Dipiroet al.Pharmacotherapy:APathophysiologicApproach-Appleton&LangeRobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication

HOSPITAL&COMMUNITY PHARMACY(MPP103T)

THEORY **60Hours**

Scope:Thiscourseisdesignedtoimpart basicknowledgeandskillsthat arerequired to practice pharmacy in both hospital and community settings**Objectives**

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Underst
- andtheorganizationalstructureofhospitalpharmacyUnderstanddrugpolicy
- anddrugcommitteesKnowaboutprocurement&drugdistributionpractices
- Know the admixtures of
- radiopharmaceuticalsUnderstand the community
- pharmacy
  managementKnowaboutvalueaddedservicesincommunit
  ypharmacies

Unit-1:IntroductiontoHospitals–
Definition,classification,organizationalstructureHospitalPharmacy:Definition, Relationshipofhospitalpharmacydepartment withotherdepartments, Organizational structure, legal requirements, work load statistics,Infrastructural requirements, Hospital Pharmacy Budget and Hospital Pharmacymanagement
HospitalDrugPolicy:Pharmacy&TherapeuticsCommittee,InfectionControlcommittee,R esearch&EthicsCommittee,ManagementofMedicines asper NABH. **12hrs**

Unit-2 : Hospital FormularyGuidelines and its development, Developing Therapeuticguidelines, Drug procurement process, and methods of Inventory control, Methods ofDrugdistribution, Intravenousadmixtures,HospitalWasteManagement. **12hrs**

Unit-3: Education and training: Training of technical staff, training and continuingeducationforpharmacists,Pharmacystudents,Medicalstaffandstudents,Nursingsta ff andstudents, Formal and informal meetings and lectures, Drug and therapeuticsnewsletter.Community Pharmacy Practice: Definition, roles & responsibilities ofcommunitypharmacists,andtheirrelationship withotherhealthcareproviders.
Community Pharmacymanagement:Legal requirementsto start communitypharmacy,siteselection, layout &design,drugdisplay,superdrugstoremodel,accounts andaudits, Good dispensing practices, Different softwares & databases used in communitypharmacies.
Entrepreneurshipincommunitypharmacy **12Hrs**

Unit-4:Prescription–Legalrequirements&interpretation,prescriptionrelatedproblems Responding to symptomsofminorailments:Headache, pyrexia, menstrual pains, foodand drug allergy, OTC medication: Rational use ofoverthe counter medicationsMedicationcounselinganduseofpatient informationleafletsMedicationadherence–Definition, factors influencing adherence behavior, strategies to improve medicationadherencePatientreferralstothedoctors,ADRmonitoringincommunityphar macies.

12 hrs

Unit-5:HealthPromotion– Definitionandhealthpromotionactivities,familyplanning,Healthscreeningservices,first aid,preventionofcommunicableandnon-communicablediseases, smoking cessation, Child & mother care NationalHealthPrograms-RoleofCommunityPharmacistin Malaria and TB control programs Home Medicines reviewprogram – Definition, objectives, Guidelines, method and outcomes Research incommunitypharmacyPractice . **12hrs**

REFERENCEBOOKS:

1. HospitalPharmacy-HassanWE.LeaandFebigerpublication.
2. Textbookofhospitalpharmacy-AllwoodMCandBlackwell.
3. Avery'sDrugTreatment,AdisInternationalLimited.
4. CommunityPharmacyPractice–RameshAdepu,BSPPublishers,Hyderabad
5. RemingtonPharmaceuticalSciences

CLINICALRESEARCH (MPP104T)

THEORY **60Hours**

Scope: This course aims to provide the students an opportunity to learn drug developmentprocessespeciallythephasesofclinicaltrialsandalsotheethicalissues involved intheconduct
ofclinicalresearch.Also,itaimstoimpartsknowledgeanddevelopskillsonconceptualizing,designing,conductingandmanagingclinicaltrials

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Knowt
Γhe newdrugdevelopmentprocess.
ΓUnderstandtheregulatoryandethicalrequirements.Ap
Γpreciate and conduct the clinical trials
ΓactivitiesKnowsafetymonitoringandreportinginclini
ΓcaltrialsManage thetrialcoordinationprocess

Unit-1: Drug development process: Introduction, variousapproachesto drug discovery,InvestigationalnewdrugapplicationsubmissionEthicsinBiomedicalResearch: EthicalIssues in Biomedical Research – Principles of ethics in biomedical research, Ethicalcommittee [institutional review board] - its constitution and functions, Challenges inimplementation of ethical guidelines, ICH GCP guidelines and ICMR guidelines inconductofClinicaltrials,DrugSafetyReporting. **12Hrs**

Unit-2:TypesandDesignsused inClinicalResearch:Planningandexecutionofclinical trials,Various Phases of clinical trials, Bioavailability and Bioequivalence studies,Randomization techniques (Simple randomization, restricted randomization, blockingmethod and stratification), Types of research designs based on Controlling Method(Experimental, Quasi experimental, and Observational methods) Time Sequences(Prospective and Retrospective), Sampling methods (Cohort study, case Control studyand cross sectional study), Health outcome measures (Clinical & Physiological,Humanisticand economic) ClinicalTrialStudyteam:Rolesand responsibilitiesof:Investigator,
StudyCoordinator,Sponsor,Monitor,ContractResearchOrganization

12hrs

Unit-3: Clinical trial Documents: Guidelines to the preparation of following documents:Protocols,Investigator'sBrochure,InformedConsentForm,Casereportforms,Contracts andagreements,DairyCards
ClinicalTrialStartupactivities:SiteFeasibilityStudies,Site/Investigatorselection,
Pre-studyvisit,Investigatormeeting, Clinical trial agreement execution,

Ethicscommitteedocumentpreparationandsubmission. **12Hrs**

Unit-4:InvestigationalProduct:ProcurementandStorageofinvestigationproductFilingprocedures: Essentialdocumentsforclinicaltrial,TrialMasterFilepreparationandmaintenance,InvestigatorSiteFile,PharmacyFile,Siteinitiationvisit,Conduct,ReportandFollowup ClinicalTrialMonitoringandCloseout:Preparationandconductofmonitoringvisit:Reviewofsourcedocuments,CRF,ICF,IPstorage,accountabilityandreconciliation,StudyProcedure,ECcommunications,Safetyreporting,Monitoringvisitreportingandfollow-upClose-Outvisit:Studyrelateddocumentscollection,Archivalrequirement,InvestigationalProductreconciliationanddestruction, Close-Outvisit report. **12hrs**

Unit-5:QualityAssuranceandQualityControlin Clinical Trials: Types ofaudits,Audit criteria,Auditprocess,Responsibilitiesofstakeholdersinaudit process,Audit follow-upanddocumentation,AuditresolutionandPreparingforFDAinspections,Fraudandmisconductmanagement

DataManagementInfrastructure and System Requirement for DataManagement: Electronic data capture systems, Selection and implementation of newsystems, System validation and test procedures, Coding dictionaries, Data migration andarchival Clinical Trial Data Management: Standard Operating Procedures, Datamanagementplan,CRF&Databasedesignconsiderations,Studyset-up,Dataentry,CRFtrackingandcorrections,Datacleaning,ManaginglaboratoryandADRdata, Datatransferand database lock, QualityControland Quality Assurance in CDM, Data mining andwarehousing **12 hrs**

REFERENCEBOOKS:

1. Principlesandpracticeofpharmaceuticalmedicine,Secondedition.Authors:Lionel.D.Edward,Aadrew.J.FletherAnthonyWFos,PeterDSloaierPublisher:Wiley;
2. Handbookofclinicalresearch.JuliaLloydand AnnRavenEd.ChurchillLivingstone
3. PrinciplesofClinicalResearcheditedbyGiovannadiIgnazio,DiGiovannaandHaynes.
4. Central Drugs Standard Control Organization. Good Clinical Practices- Guidelines forClinicalTrialsonPharmaceuticalProductsinIndia.New Delhi:MinistryofHealth.
5. International Conference on Harmonisation of Technical requirements for registration ofPharmaceuticalsforhuman use.ICH HarmonisedTripartite Guideline.Guideline forGoodClinicalPractice.E6;May1996.
6. EthicalGuidelinesforBiomedicalResearchonHumanSubjects.IndianCouncilofMedicalResearch,NewDelhi.
7. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, JohnWileyandSons.
8. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. SecondEdition,Jan2000,WileyPublications.
9. Goodman&Gilman:JGHardman,LELimbard,McGrawHillPublications.

Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

PHARMACYPRACTICE PRACTICAL–I(MPP105P)

Thestudentsarerequiredtobepostedtovariousclinicalwardsfortheirexposurewiththerapeutic management and other clinicalaspects. Theyare expected to have experience and do atutorial as well as case presentation in the following clinical conditions. The students have tomake at least 10 case presentations covering most common diseases found in the hospital towhich the college is attached. The student should also submit a record of the cases presented.Thelist of clinical cases presented should include follow-up of the clinical cases mentioned belowfrom the day of admission till discharge and presented in the SOAP (Subjective, Objective,AssessmentandPlan)format.

1. TreatmentChartReview(one)
2. MedicationHistoryInterview(one)
3. PatientMedicationCounseling(two)
4. DrugInformationQuery(two)
5. PoisonInformationQuery(one)
6. LabDataInterpretation(two)
7. ABCAnalysisofagivenlistofmedications(one)
8. Preparation ofcontentofamedicine,withproperjustification,fortheinclusioninthe hospitalformulary(one)
9. FormulationanddispensingofagivenIVadmixtures(one)

REFERENCEBOOKS

1. RogerandWalker.ClinicalPharmacyandTherapeutics–ChurchillLivingstonepublication
2. JosephT.Dipiroetal.Pharmacotherapy:APathophysiologicApproach-Appleton&Lange
3. RobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication
4. EricT.Herfindal.ClinicalPharmacyandTherapeutics-WilliamsandWilkinsPublication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinicalUse ofDrugs-LippincottWilliams andWilkins
6. Chisholm- Burns Wells Schwinghammer Malone and Joseph P Dipiro.PharmacotherapyPrinciplesandpractice-–McGrawHillPublication

PHARMACYPRACTICEPRACTICAL–II (MPP106P)

Thestudentsarerequiredtobepostedtovariousclinicalwardsfortheirexposurewiththerapeutic management and other clinicalaspects. Theyare expected to have experience and do atutorial as well as case presentation in the following clinical conditions. The students have tomake at least 10 case presentations covering most common diseases found in the hospital towhich the college isattached.Thestudentshouldalsosubmitarecordofthecasespresented.Thelistofclinicalcasespresentedshouldincludefollow-upof theclinical casesmentionedbelowfrom theday ofadmission till discharge and presented in the SOAP (Subjective, Objective, Assessment andPlan)format.

1. Presentation of clinical cases of various disease conditions adopting Pharmaceutical CarePlanModel(eight).The casesmaybe selectedfromthefollowingWards:
   - Gastroenterology
   - Cardiology
   - Pulmonology
   - Orthopedics
   - Endocrinology
   - Dermatology
2. Preparationofapatientinformationleaflet(two)
3. PreparationofStudyProtocol(one)
4. PreparationofInformedConsentForm(one)

REFERENCEBOOKS

1. PracticeStandardsandDefinitions-TheSocietyofHospitalPharmacistsofAustralia
2. ThomasJJohnson,CriticalCarePharmacotherapeutics
3. CollenDL,SnehaBS,FundamentalSkillsforPatientCareinMPP
4. PatientAssessmentinPharmacy,byYolandaMH
5. Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

SEMESTER-II

PRINCIPLESOFQUALITYUSEOFMEDICINES(MPP201T)

THEORY **60Hours**

Scope: This course is designed to impart basic knowledge and skills that are required to practicequalityuseofmedicines(QUM)indifferenthealthcaresettingsandalsotopromotequalityuseof medicines,inclinicalpractice,throughevidence-basedmedicine approach.

Objectives:

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Understandthe

Γprinciples of quality use of

ΓmedicinesKnowthebenefitsandrisksassociatedwithuseofmedicines

ΓUnderstandregulatoryaspects ofqualityuse

ΓofmedicinesIdentifyandresolvemedicationrelatedproblem

ΓsPromote qualityuseofmedicines

ΓPracticeevidence-basedmedicines

Unit-1:Introductionto Qualityuseofmedicines(QUM):DefinitionandPrinciplesofQUM, Keypartnersandresponsibilitiesofthepartners,BuildingblocksinQMC,Evaluationprocessin QMC,CommunicationinQUM,Costeffectiveprescribing. **12 hrs**Unit-2:ConceptsinQUMEvidencebasedmedicine:Definition,conceptofevidencebased medicine,Approachandpracticeofevidencebasedmedicineinclinicalsettings Essentialdrugs:Defin ition,need,conceptofessentialdrug,Nationalessentialdrugpolicyandlist.

Rationaldruguse:Definition,conceptandneedforrationaldruguse,Rationaldrugprescribing,Roleof pharmacistinrationaldruguse. **12 hrs**

Unit-3:QUMinvarioussettings:Hospitalsettings,Ambulatorycare/Residentialcare,Roleofhealthcareprofe ssionalsin promoting the QUM, Strategiesto promotetheQUM, Impact of QUMonE-health,integrativemedicineandmultidisciplinarycare.QUMinspecialpopulation:Pediatricprescribin g,Geriatricprescribing,Prescribinginpregnancyandlactation,Prescribinginimmunecompromisedan dorganfailurepatients. **12hrs**

Unit-4: Regulatory aspects of QUM in India: Regulation including scheduling, Regulation ofcomplementarymedicines,RegulationofOTCmedicines,Professionalresponsibilityofpharmacist, RoleofindustryinQUMinmedicinedevelopment. **12hrs**

Unit-5: Medication errors: Definition, categorization and causes of medication errors, Detectionand prevention of medication errors, Role of pharmacistin monitoring and managementofmedicationerrorsPharmacovigilance: Definition, aims andneedforpharmacovigilance,Types,predisposingf actorsandmechanismofadversedrugreactions(ADRs),Detection,reportingandmonitoringofADRs, CausalityassessmentofADRs,ManagementofADRs, Roleofpharmacistinpharmacovigilance. **12hrs**

REFERENCEBOOKS:

1. A Textbook of Clinical Pharmacy Practice – Essential concepts and skills – ParthasarathiG,KarinNyfort-HansenandMilapNahata
2. AndrewsEB,MooreN.Mann'sPharmacovigilance
3. DipiroJT,TalbertRL,YeeGC.Pharmacotherapy:APathophysiologicApproach
4. StrausSE,RichardsonWS,GlasziouP,HaynesRB.Evidence-BasedMedicine:Howtopracticeandteachit
5. CohenMR.MedicationErrors

PHARMACOTHERAPEUTICSII (MPP202T)

THEORY **60Hours**

Scope: This course aims to enable the students to understand the different treatmentapproaches in managing variousdisease conditions. Also, it impartsknowledge and skillsin optimizing drug therapy of a patient by individualizing the treatment plan throughevidence-basedmedicines.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:

- Describeandexplaintherationalefordrugtherapy
- Summarize the therapeutic approach for management of various disease conditionsincludingreference tothelatestavailable evidence
- Discusstheclinicalcontroversiesindrugtherapyandevidencebasedmedicine
- Prepareindividualizedtherapeuticplansbasedondiagnosis
- Identifythepatientspecificparametersrelevantininitiatingdrugtherapy,andmonitoring therapy(including alternatives, time- courseofclinicaland laboratoryindices oftherapeutic responseandadverseeffect/s

Unit-1: Nervous system: Epilepsy, Parkinson's disease, Stroke, Headache, Alzheimer'sdisease, NeuralgiasandPainpathwaysandPainmanagement. **12hrs**

Unit-2:Psychiatricdisorders:Schizophrenia,Depression,Anxietydisorders,Sleepdisorders, Drug induced psychiatric disorders Renal system: Acute renal failure, Chronicrenalfailure, Renaldialysis,Druginducedrenaldisease **12hrs**

Unit-3: Infectious diseases: General guidelines for the rational use of antibiotics andsurgicalprophylaxis,Urinarytractinfections,Respiratorytractinfections,Gastroenteritis, Tuberculosis,Malaria,Bacterialendocarditis,Septicemia. **12hrs**

Unit-4:Infectiousdiseases:Meningitis,HIVandopportunisticinfections,Rheumaticfever,Denguefever,H1N1,Helmenthiasis,FungalinfectionsGynecologicaldisorders:Dysmenorrhea,Hormone replacementtherapy. **12hrs**

Unit-5:Oncology:Generalprinciplesofcancerchemotherapy,pharmacotherapyofbreastcancer, lung cancer, head & neck cancer, hematological malignancies, Management ofnauseaandvomiting,Palliativecare **12hrs**

REFERENCEBOOKS

1. RogerandWalker.ClinicalPharmacyandTherapeutics-ChurchillLivingstonepublication.
2. JosephT.Dipiroetal.Pharmacotherapy:APathophysiologicApproach-Appleton&Lange
3. RobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication
4. EricT.Herfindal.ClinicalPharmacyandTherapeutics-WilliamsandWilkinsPublicationLloyd Young and Koda-Kimble MA Applied Therapeutics: The clinical Use of Drugs-LippincottWilliams andWilkins

CLINICALPHARMACOKINETICSANDTHERAPEUTICDRUGMONITORING (MPP203T)

THEORY **60Hours**

Scope:

This course is designed to enable students to understand the basics principles and applications ofpharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drugconcentration profilein alteredpharmacokinetics,drug interactionsandin therapeuticdrugmonitoringprocessestooptimizethedrugdosageregimen.Also,itenablesstudentstoun derstandthebasicconceptsofpharmacogenetics,pharmacometricsformodelingandsimulationofphar macokineticdata.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Designthe

- drugdosage regimenforindividualpatients
- Interpretandcorrelatetheplasmadrugconcentrationswithpatients'therapeutic
- outcomesRecommenddosageadjustmentforpatientswithrenal/hepaticimpairment
- Recommenddosage adjustmentforpaediatrics
- andgeriatricsManagepharmacokineticdruginteractions
- Applypharmacokineticparametersinclinicalsettings
- Interprettheimpactofgeneticpolymorphismsofindividualsonpharmacokineticsandorpha rmacodynamics ofdrugs
- Do pharmacokinetic modeling for the given data using the principles ofpharmacometrics

Unit-1: Introduction toClinical pharmacokinetics:Compartmental and Non compartmentalmodels, Renalandnon-renalclearance, Organextractionandmodelsofhepaticclearance,Estimation and determinants of bioavailability, Multiple dosing, Calculation of loadingand maintenance doses Designing ofdosageregimens: Determination of dose and dosingintervals, Conversion from intravenous to oral dosing, Nomograms and Tabulations indesigningdosageregimen.

12hrs

Unit-2:PharmacokineticsofDrugInteraction:Pharmacokineticdruginteractions, Inhibitionand Induction of Drug metabolism, Inhibition of Biliary Excretion Pharmacogenetics:Genetic polymorphisminDrugmetabolism: CytochromeP-450Isoenzymes,GeneticPolymorphism inDrug Transport and DrugTargets, Pharmacogenetics and Pharmacokinetic / Pharmacodynamic considerationsIntroductiontoPharmacometrics:IntroductiontoBayesianTheory, AdaptivemethodorDosingwith feedback,AnalysisofPopulationpharmacokineticData.

12hrs

Unit-3:Non Linier Mixed Effects Modelling: The Structural or Base Model, ModelingRandom Effects, Modeling Covariate Relationships, Mixture Model, EstimationMethods,ModelBuildingTechniques,CovariateScreeningMethods,Testingthemodelassumptions,Precisionoftheparameterestimatesandconfidenceintervals,Modelmisspecification and violation of the model assumptions, Model Validation, Simulationofdosing regimensand dosingrecommendations,Pharmacometricssoftware.**12hrs**

Unit-4:AlteredPharmacokinetics:Drugdosingintheelderly,Drugdosinginthepaediatrics, Drug dosing in the obese patients, Drug dosing in the pregnancy andlactation,Drug dosing in the renal failure and extracorporeal removal of drugs, Drug dosing in theinhepaticfailure. **12hrs**

Unit-5:TherapeuticDrugmonitoring:Introduction,Individualizationofdrugdosage regimen(Variability – Genetic,age,weight,disease and Interacting drugs),Indications for TDM,Protocol for TDM, Pharmacokinetic/PharmacodynamicCorrelationindrugtherapy,TDMofdrugsusedinthefollowingconditions:Cardiovasculardisease: Digoxin,Lidocaine, Amiodarone; Seizure disorders: Phenytoin,Carbamazepine,SodiumValproate;Psychiatricconditions:Lithium,Fluoxetine,Amitriptyline; Organtransplantations:Cyclosporine;CytotoxicAgents:Methotrexate,5-FU, Cisplatin; Antibiotics:Vancomycin,Gentamicin,Meropenem **12 hrs**

REFERENECEBOOKS:

1. Leon Shargel, Susanna Wu-Pong, Andrew Yu. Applied Biopharmaceutics &Pharmacokinetics.NewYork:McGrawHill.
2. PeterL.Bonate.Pharmacokinetic-PharmacodynamicModelingandSimulation.Springer Publications.
3. Michael E.Burton,Leslie M.Shaw,Jerome J.Schentag,William E.Evans.AppliedPharmacokinetics&Pharmacodynamics:Principlesof TherapeuticDrugMonitoring.IippincottWilliams&Wilkins.
4. Steven How-YanWong,IrvingSunshine.Handbook of Analytical Therapeutic DrugMonitoringandToxicology.CRCPress,USA.
5. Soraya Dhillon, Andrzej Kostrzewski. Clinical pharmacokinetics. 1st edition. London:PharmaceuticalPress.
6. JosephT.Dipiro,WilliamJ.Spruill,WilliamE.Wade,RobertA.BlouinandJaneM.Pruemer .Concepts in Clinical Pharmacokinetics. American Society of Health-SystemPharmacists,USA.
7. MalcolmRowland, Thomas N. Tozer.ClinicalPharmacokinetics and pharmacodynamics:conceptsandapplications.IippincottWilliams&Wilkins,USA.
8. Evans, Schentag, Jusko. Applied pharmacokinetics. American Society of Health systemPharmacists,USA.

9. MichaelE.Winter.BasicClinicalPharmacokinetics.IippincottWilliams&Wilkins,USA.
10. MiloGibaldi.BiopharmaceuticsandClinicalPharmacokinetics.PharmaBookSyndicate,USA.
11. DhillonandKostrzewski.Clinicalpharmacokinetics.PharmaceuticalPress,London.
12. JohnE .Murphy. ClinicalPharmacokinetics. 5thedition. US:AmericanSocietyofHealth-System Pharmacist,
USA.Relevantreviewarticlesfromrecentmedicalandpharmaceuticalliterature

PHARMACOEPIDEMIOLOGY&PHARMACOECONOMICS(MPP204T)

THEORY **60Hours**

Scope: Thiscourseenablesstudents tounderstandvariouspharmacoepidemiologicalmethods andtheirclinical applications.Also,itaims toimpartknowledge on basicconcepts, assumptions, terminology, and methods associated with Pharmacoeconomicsand health related outcomes, and when should be appropriate Pharmacoeconomic modelshouldbeappliedfora healthcare regimen.

Objectives

Uponcompletionofthiscourseitisexpectedthatstudentsshallbeableto:Unders
⌜tandthe variousepidemiologicalmethodsandtheirapplicationsUnderstand
⌜thefundamentalprinciplesofPharmacoeconomics.
⌜Identifyanddeterminerelevantcostandconsequencesassociatedwithpharmacyproducts andservices.
⌜PerformthekeyPharmacoeconomicsanalysismethodsUnderstandthePharmacoeconomicd
⌜ecisionanalysismethodsanditsapplications.DescribecurrentPharmacoeconomicmethods
⌜andissues.
⌜UnderstandtheapplicationsofPharmacoeconomicstovariouspharmacysettings.

Unit-1: Introduction to Pharmacoepidemiology:Definition,Scope, Need, Aims & Applications;Outcome measurement: Outcome measures, Drug use measures: Monetary units, Number ofprescriptions, units of drug dispensed, defined daily doses, prescribed daily doses, Diagnosis
andTherapysurveys,Prevalence,Incidencerate,Monetaryunits,numberofprescriptions,unitofdrugsd ispensed,defineddailydosesandprescribeddailydoses,medicationsadherencemeasurements.
Concept of risk: Measurement of risk, Attributable risk and relative risk, Time-riskrelationshipandoddsratio. **12hrs**

Unit-2: Pharmacoepidemiological Methods: Qualitative models: Drug Utilization Review;Quantitativemodels:casereports,caseseries,Crosssectionalstudies,Cohortandcasecontr olstudies, Calculation of Odds' ratio, Meta analysis models, Drug effects study in populations:Spontaneous reporting, Prescription event monitoring, Post marketing surveillance, Recordlinkagesystems, ApplicationsofPharmacoepidemiology **12hrs**

Unit-3: Introductionto Pharmacoeconomics: Definition, historyofPharmacoeconomics, Need ofPharmacoeconomic studiesinIndianhealthcaresystem.
Cost categorization and resources forcostestimation:Directcosts. Indirectcosts. Intangiblecosts.OutcomesandMeasurementsofPharmacoeconomics:Typesofoutcomes:Clinicalout come, Economic outcomes, Humanistic outcomes; Quality Adjusted Life Years, DisabilityAdjusted Life Years Incremental Cost Effective Ratio, Average Cost Effective Ratio. PersonTime,WillingnessTo Pay,TimeTradeOffandDiscounting. **12hrs**

Unit-4: Pharmacoeconomic evaluations: Definition, Steps involved, Applications, Advantagesand disadvantages of the following Pharmacoeconomic models: Cost Minimization Analysis(CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis(CUA), CostofIllness(COI), CostConsequencesAnalysis(COA). **12hrs**

Unit-5: Definition, Steps involved, Applications, Advantages and disadvantages of thefollowing:Health related quality of life (HRQOL): Definition, Need for measurement of HRQOL, CommonHRQOL measures. Definition, Stepsinvolved, Applicationsofthe following: Decision Analysisand Decision tree, Sensitivity analysis, Markov Modeling,Software used in pharmacoeconomicanalysis,Applications ofPharmacoeconomics.**12hrs**

REFERENCEBOOKS:

1. Rascati K L. Essentials of Pharmacoeconomics, Woulters Kluwer Lippincott Williams &Wilkins,Philadelphia.
2. Thomas E Getzen. Health economics. Fundamentals and Flow of Funds. John Wiley &Sons,USA.
3. Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health EconomicEvaluation,OxfordUniversityPress,London.

MichaelDrummond,MarkSculpher,GeorgeTorrence,BernieO'BrienandGregStoddart. Methods for the Economic Evaluation of Health Care Programmes OxfordUniversityPress,London

PHARMACYPRACTICEPRACTICAL-III(MPP205P)

The students are required to be posted to various clinical wards for their exposure withtherapeutic management and other clinical aspects. Theyare expected to have experienceand do a tutorial as well as case presentation in the following clinical conditions. Thestudents have to make at least 10 case presentations covering most common diseasesfound in the hospital to which the college is attached. The student should also submit arecord of the cases presented. The list of clinical cases presented should include follow-up of the clinical cases mentioned below from the day of admission till discharge andpresentedintheSOAP (Subjective,Objective,Assessmentand Plan)format.

ListofExperiments(12)

1. Causalityassessmentofadversedrugreactions(three)
2. Detectionandmanagementofmedicationerrors(three)
3. CalculationofBioavailabilityandBioequivalencefromthegivendata(two)
4. InterpretationofTherapeuticDrugMonitoringreportsofagivenpatient(two)
5. Assessmentofdruginteractionsinthegivenprescriptions
6. Answeringdruginformationquestions

REFERENCEBOOKS:

1. RogerandWalker.ClinicalPharmacyandTherapeutics–ChurchillLivingstonepublication.
2. JosephT.Dipiroetal.Pharmacotherapy:APathophysiologicApproach-Appleton&Lange
3. RobinsSL.Pathologicbasisofdisease-W.B.Saunderspublication
4. EricT.Herfindal.ClinicalPharmacyandTherapeutics-WilliamsandWilkinsPublication
5. Lloyd Young and Koda-Kimble MA Applied Therapeutics: The clinicalUse ofDrugs-LippincottWilliams andWilkins
6. Clinical Pharmacy and Pharmacotherapeutics by Ravi Shankar, Pharma med

PressChisholm- Burns WellsSchwinghammer Malone and JosephP Dipiro.PharmacotherapyPrinciplesandpractice-–McGrawHillPublication

PHARMACYPRACTICEPRACTICAL-IV(MPP206P)

ListofExperiments(12)

1. PresentationofclinicalcasesofnervoussystemdiseasesadoptingSOAP(Subjective, Objective,AssessmentandPlan)
2. PresentationofclinicalcasesofpsychiatricdisordersadoptingSOAP(Subjective, Objective,AssessmentandPlan)
3. PresentationofclinicalcasesofinfectiousdiseasesadoptingSOAP(Subjective, Objective,AssessmentandPlan)
4. PresentationofclinicalcasesofgynecologicaldisordersadoptingSOAP(Subjective, Objective,AssessmentandPlan)
5. PresentationofclinicalcasesofcancerdiseaseadoptingSOAP(Subjective,Objective,Asse ssmentandPlan)
6. PresentationofclinicalcasesofrenalsystemdisordersadoptingSOAP(Subjective, Objective,AssessmentandPlan)
7. DeveloppharmacokineticskillsbyusingNONMEMWinNonlinsoftware.
8. PresentationofclinicalcasesofvariousdiseaseconditionsadoptingPharmaceuticalCarePlan Model
9. CalculationofvariousPharmacoeconomicoutcomeanalysisforthegivendata
10. RationaluseofmedicinesinspecialpopulationadmittedinthewardsREFERENCEBOOKS:

1. LeonShargel,SusannaWu-Pong,AndrewYu.AppliedBiopharmaceutics&Pharmacokinetics.NewYork:McGrawHill .
2. PeterL.Bonate.Pharmacokinetic-PharmacodynamicModelingandSimulation.SpringerPublications.
3. Michael E. Burton, Leslie M. Shaw, Jerome J. Schentag, William E. Evans. AppliedPharmacokinetics & Pharmacodynamics: Principles of Therapeutic Drug Monitoring.IippincottWilliams&Wilkins.
4. Steven How-Yan Wong, Irving Sunshine. Handbook of AnalyticalTherapeutic DrugMonitoringandToxicology.CRCPress,USA.
5. Joseph T. Dipiro, William J. Spruill, William E. Wade, Robert A.Blouin and Jane M.Pruemer Concepts in Clinical Pharmacokinetics. AmericanSociety of Health-SystemPharmacists,USA.

MalcolmRowland,ThomasN.Tozer.ClinicalPharmacokineticsandpharmacodynamics: conceptsandapplications.IippincottWilliams& Wilkins,USA.

PHARMACOLOGY

(MPL)MODERNPHARMACEUTICALANALYTICALTECHNIQUES(MPL101T)

THEORY **60HOURS**

Scope

This subject deals with various advanced analytical instrumental techniques for identification,characterizationandquantificationofdrugs.InstrumentsdealtareMassspectrometer,IR, HPLC,GC etc.

Objectives

Aftercompletionofcoursestudentisabletoknow,Chemical

- sandExcipients
- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoreticalandpractical
- skills oftheinstruments

Unit-1: a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associatedwithUV-Visible spectroscopy, Choice ofsolventsand solvent effect and ApplicationsofUV-Visible spectroscopy.

b.IRspectroscopy:Theory,ModesofMolecularvibrations,Samplehandling,Instrumentation of Dispersive and Fourier - Transform IR Spectrometer, Factors affectingvibrationalfrequencies andApplicationsofIR spectroscopy

c. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers,Instrumentationand Applicationsoffluorescencespectrophotometer. **10HRS**

Unit-2:.MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionizationlikeelectronimpact,chemical,field,FABandMALDI,APCI,ESI,APPIAnalyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules,Metastableions,IsotopicpeaksandApplicationsofMassspectroscopy. **8HRS**

Unit-3.Chromatography:Principle,apparatus,instrumentation,chromatographicparameters,factorsaffectingresolutionandapplications ofthefollowing:
a)Paperchromatographyb)ThinLayerchromatographyc)Ionexchangechromatographyd)Column chromatographye)Gaschromatography f)High PerformanceLiquidchromatography g)Affinitychromatography **12HRS**

Unit-4.Electrophoresis: Principle, Instrumentation, Working conditions, factorsaffectingseparationandapplications ofthefollowing:
a) Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresis e)Movingboundaryelectrophoresisf)Isoelectricfocusing**12HRS**

Unit-5a)Immunologicalassays:RIA(Radioimmunoassay),ELISA,Bioluminescenceassays.
b) Thermaltechniques:DSC,DTA,TGA,Principle,Instrumentation,factorsaffecting,advantages anddisadvantagesandPharmaceuticalapplications. **10HRS**

Unit-6:NMRSpectroscopy:QuantumnumbersandtheirroleinNMR,Principle,instrumentation, solvent requirements in NMR, Relaxation process, NMR signals in variouscompounds.BriefoutlineofFT-NMRandC^{13}NMR,applicationsofNMRSpectroscopy. **8HRS**

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis-Doglas ASkoog, F. JamesHoller,TimothyA. Nieman,5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBS Publishers,New Delhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugs inPharmaceuticalformulation- PDSethi, 3rd Edition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-Modernmethods–PartB-JWMunson,Volume11,MarcelDekkerSeries

ADVANCEDPHARMACOLOGY-I(MPL102T)

THEORY **60HOURS**

Scope

The subject is designed to strengthen the basic knowledge in the field of pharmacologyand to impart recent advances in the drugs used for the treatment of various diseases. Inaddition, this subject helps the students to understand the concepts of drug action andmechanismsinvolved

Objectives

Uponcompletionofthe coursethe

- studentshallbeableto:Discussthepathophysiologyandpharmacotherapyofc
- ertaindiseasesExplainthemechanismofdrugactionsatcellularandmolecula rlevel
- Understandtheadverseeffects,contraindicationsandclinicalusesofdrugsusedin treatmentofdiseases

Unit-1:GeneralPharmacology

a. Pharmacokinetics: The dynamics of drug absorption, distribution, biotransformation andelimination.Concepts oflinearandnon-linearcompartmentmodels.SignificanceofProteinbinding.

b. Pharmacodynamics:Mechanismofdrugactionandtherelationshipbetweendrugconcentration andeffect.Receptors,structuralandfunctionalfamiliesofreceptors,quantitationofdrug receptorsinteractionand elicited effects. **10Hrs**

Unit-2:Neurotransmission

a. Generalaspectsandstepsinvolvedinneurotransmission.
b. Neurohumoraltransmissioninautonomicnervoussystem(Detailedstudyabout neurotransmitters-AdrenalineandAcetylcholine).
c. Neurohumoraltransmissionincentralnervoussystem(Detailedstudyaboutneurotrans mitters-histamine,serotonin,dopamine, GABA,glutamateandglycine].
d. Nonadrenergicnoncholinergictransmission(NANC).Co-transmission. **10Hrs**

Unit-3:Systemicpharmacology:Adetailedstudyonpathophysiologyofdiseases,mechanismofaction,pharmacologyandtoxicology of existing as well as novel drugs used in the following systemsAutonomicPharmacologyParasympathomimeticsandlytics,sympathomimeticsandlytics,agentsaffectingneuromuscularjunction

10hrs

Unit-4: Centrel Nervous System pharmacology General andlocal anestheticsSedatives andhypnotics,drugsusedtotreatanxiety.Depression,psychosis,mania,epilepsy,neurodegenerativediseases.Narcoticandnon-narcoticanalgesics **10hrs**

Unit-5:CardiovascularPharmacology:
Diuretics,antihypertensives,antiischemics,anti-
arrhythmics,drugsforheartfailureandhyperlipidemia. Hematinics, coagulants,anticoagulants, fibrinolyticsandanti- plateletdrugs

Unit-
6:Autocoidpharmacology:ThephysiologicalandpathologicalroleofHistamine,Serotonin,KininsProstaglandinsOpioidautocoids.Pharmacologyofantihistamines,5HTantagonists. **10Hrs**

REFERENCEBOOKS

1. ThePharmacologicalBasisofTherapeutics,GoodmanandGillman‘s
2. Principles of Pharmacology. The Pathophysiologic basis of drug Therapy by DavidEGolan,ArmenH,TashjianJr,EhrinJ,Armstrong,AprilW,Armstrong,Wolters,Kluwer-LippincottWilliams &Wilkins Publishers.
3. BasicandClinicalPharmacologybyB.GKatzung
4. HandbookofClinicalPharmacokineticsbyGibaldiandPrescott.
5. AppliedbiopharmaceuticsandPharmacokineticsbyLeonShargelandAndrewB.C.Yu.
6. GrahamSmith.OxfordtextbookofClinicalPharmacology.
7. AveryDrugTreatment
8. DipiroPharmacology,Pathophysiologicalapproach.

GreenPathophysiologyforPharmacists

PHARMACOLOGICALANDTOXICOLOGICALSCREENINGMETHODS-I(MPL 103T)

THEORY **60HOURS**

Scope: This subject is designed to impart the knowledge on preclinical evaluation of drugs andrecentexperimentaltechniquesinthedrugdiscoveryanddevelopment.Thesubjectcontenthelpsthe student to understand the maintenance of laboratoryanimals as per the guidelines, basicknowledgeofvariousin-vitroandin-vivopreclinicalevaluationprocesses

Objectives

Uponcompletionofthecoursethestudentshallbeableto,

- Appraisetheregulationsandethicalrequirementfortheusageofexperimentalanimals.
- Describethevariousanimalsusedinthedrugdiscoveryprocessandgoodlaboratory practicesinmaintenance andhandlingofexperimentalanimals
- Describethevariousnewerscreeningmethodsinvolvedinthedrugdiscoveryprocess
- Appreciateandcorrelatethepreclinicaldatatohumans

Unit-1: Laboratory Animals: Common laboratory animals: Description, handling andapplicationsofdifferentspeciesandstrainsofanimals.Transgenicanimals:Production, maintenanceand applications Anaesthesia and euthanasia of experimental animals.Maintenance and breedingof laboratory animals. CPCSEA guidelines to conduct experiments on animals Good laboratorypractice.Bioassay-Principle,scopeandlimitationsandmethods.

12hrs

Unit-2: Preclinical screening of new substances forthe pharmacological activity using in vivo, invitro,andotherpossibleanimalalternativemodels.

Generalprinciplesofpreclinicalscreening.CNSPharmacology:behavioralandmusclecoordination,CNSstimulantsanddepressants,anxiolytics,anti-psychotics,anti epilepticsandnootropics. Drugs for neurodegenerative diseases like Parkinsonism, Alzheimers and multiplesclerosis. DrugsactingonAutonomicNervousSystem. **12hrs**

Unit-3: Preclinical screening of new substancesforthe pharmacological activity using in vivo, invitro,andotherpossibleanimalalternativemodels.

Respiratory Pharmacology: anti-asthmatics, drugs for COPD and anti allergics. ReproductivePharmacology: Aphrodisiacs and antifertility agents Analgesics, antiinflammatory andantipyreticagents.Gastrointestinaldrugs:antiulcer,anti-emetic,anti-diarrhealandlaxatives.

12hrs

Unit-4: Preclinical screening of new substances forthe pharmacological activity using in vivo, invitro,andotherpossibleanimalalternativemodels.
Cardiovascular Pharmacology: antihypertensives, antiarrythmics, antianginal, antiatherosclerotic agents and diuretics. Drugs for metabolic disorders like anti-diabetic, antidyslipidemic agents.Anticanceragents.Hepatoprotectivescreeningmethods. **12hrs**

Unit-5: Preclinical screening of new substances forthe pharmacological activity usingin vivo,invitro,andotherpossibleanimalalternativemodels.Iimmunomodulators,Immunosuppressants and immunostimulants Generalprinciples of immunoassay: theoretical basis and optimization ofimmunoassay, heterogeneous and homogenous immunoassay systems. Immunoassay methodsevaluation; protocol outline, objectives and preparation. Immunoassay for digoxin and insulinLimitations of animal experimentation and alternate animal experiments. Extrapolation of invitrodatato preclinicaland preclinicaltohumans. **12hrs**

REFERENCEBOOKS:

1. BiologicalstandardizationbyJ.H.BurnD.J.FinneyandI.G.Goodwin
2. ScreeningmethodsinPharmacologybyRobertTurner.A
3. EvaluationofdrugsactivitiesbyLaurenceandBachrach
4. MethodsinPharmacologybyArnoldSchwartz.
5. FundamentalsofexperimentalPharmacologybyM.N.Ghosh
6. PharmacologicalexperimentonintactpreparationsbyChurchillLivingstone
7. DrugdiscoveryandEvaluationbyVogelH.G.
8. ExperimentalPharmacologybyR.K.Goyal.
9. PreclinicalevaluationofnewdrugsbyS.K.Guta
10. HandbookofExperimentalPharmacology,SK.Kulkarni
11. PracticalPharmacologyandClinicalPharmacy,SK.Kulkarni,3rdEdition.
12. DavidR.Gross.AnimalModelsinCardiovascularResearch,2ndEdition,KluwerAcademic Publishers,London,UK.
13. ScreeningMethodsinPharmacology,RobertA.Turner.
14. RodentsforPharmacologicalExperiments,Dr.TapanKumarchatterjee.
15. PracticalManualofExperimentalandClinicalPharmacologybyBikashMedhi(Author), AjayPrakash

CELLULAR AND MOLECULAR PHARMACOLOGY (MPL

104T)THEORY **60HOURS**

Scope:

Thesubjectimpartsafundamentalknowledgeonthestructureandfunctionsofcellularcomponentsandh elptounderstandtheinteractionofthesecomponentswithdrugs.Thisinformationwill furtherhelpthestudenttoapplytheknowledgeindrugdiscoveryprocess.

Objectives:

Uponcompletionofthecourse,thestudentshallbeable to,

•Explainthereceptorsignaltransductionprocesses.

•Explainthemolecularpathwaysaffectedbydrugs.

•Appreciatetheapplicabilityofmolecularpharmacologyandbiomarkersindrugdiscoveryprocess.

•Demonstratemolecularbiologytechniquesasapplicableforpharmacology

Unit-

1:CellbiologyStructureandfunctionsofcellanditsorganelles.Genomeorganization.Geneexpressiona nditsregulation,importanceofsiRNAandmicroRNA,genemappingandgenesequencingCellcyclesan ditsregulation.Celldeath–events,regulators,intrinsicandextrinsicpathwaysofapoptosis. Necrosisandautophagy. **12hrs**

Unit-2:CellsignalingIntercellularandintracellularsignalingpathways.

Classification of receptor family and molecular structure ligand gated ion channels; G-proteincoupledreceptors,tyrosinekinase receptors andnuclearreceptors.

Secondary messengers: cyclic AMP, cyclic GMP, calcium ion, inositol 1,4,5-trisphosphate,(IP3),NO,anddiacylglycerol.

Detailed study of following intracellular signaling pathways: cyclic AMP signaling pathway,mitogen-activated protein kinase (MAPK) signaling, Janus kinase (JAK)/signal transducer andactivatoroftranscription(STAT) signaling pathway. **12hrs**

Unit-3:Principlesandapplicationsofgenomicandproteomictools DNAelectrophoresis,PCR(reverse transcription and real time), Gene sequencing, micro array technique, SDS page, ELISAandwesternblotting,RecombinantDNAtechnologyandgenetherapyBasicprinciplesofrecomb inant DNA technology-Restriction enzymes, various types of vectors. Applications ofrecombinant DNA technology. Gene therapy- Various types of gene transfer techniques, clinicalapplicationsandrecentadvances ingenetherapy. **12hrs**

Unit-

4:PharmacogenomicsGenemappingandcloningofdiseasegene.Geneticvariationanditsroleinhealth/pharmacol ogyPolymorphismsaffectingdrugmetabolism

Genetic variation in drug transporters,Genetic variation in G protein coupled receptors,Applicationsofproteomicsscience:Genomics,proteomics,metabolomics,functionomics ,nutrigenomicsImmunotherapeutics,Typesofimmunotherapeutics,humanisationantibodytherapy, Immunotherapeuticsinclinicalpractice **12 hrs**

Unit-5:a.Cellculturetechniques
Basicequipmentsusedin cellculturelab.Cellculturemedia,varioustypesof cell culture,general procedure for cell cultures; isolation of cells, subculture, cryopreservation,characterizationofcellsandtheirapplication.Principlesandapplicationsof cellviabilityassays,glucose uptake assay, Calcium influx assays ,Principles and applications of flow cytometryb.Biosimilars

12hrs

REFERENCEBOOKS:

1. TheCell,AMolecularApproach.GeoffreyMCooper.
2. Pharmacogenomics:TheSearchforIndividualizedTherapies.EditedbyJ.LicinioandM -L.Wong
3. HandbookofCellSignaling(SecondEdition)EditedbyRalphA.et.al
4. MolecularPharmacology:FromDNAtoDrugDiscovery.JohnDickensonet.al
5. BasicCellCultureprotocolsbyCherilD.HelgasonandCindyL.Miller
6. BasicCellCulture(PracticalApproach)byJ.M.Davis(Editor)
7. AnimalCellCulture:

APracticalApproachbyJohnR.Masters(Editor)Currentporotocolsinmolecularbiol ogyvolItoVIeditedbyFrederickM.Ausuveletla

PHARMACOLOGY PRACTICAL-I(MPL105P)

Listofexperiments

1. AnalysisofpharmacopoeialcompoundsandtheirformulationsbyUVVisspectrophotometer
2. Simultaneousestimationofmulticomponent containingformulationsbyUVspectrophotometry
3. ExperimentsbasedonHPLC
4. ExperimentsbasedonGasChromatography
5. Estimationofriboflavin/quininesulphatebyfluorimetry
6. Estimationofsodium/potassiumbyflamephotometry
7. Handlingoflaboratoryanimals.
8. Variousroutesofdrugadministration.
9. Techniquesofbloodsampling,anesthesiaandeuthanasiaofexperimentalanimals.
10. Functionalobservationbatterytests(modifiedIrwintest)
11. EvaluationofCNSstimulant,depressant,anxiogenicsandanxiolytic,anticonvulsantactivity.
12. Evaluationofanalgesic,anti-inflammatory,localanesthetic,mydriaticandmioticactivity.
13. Evaluationofdiureticactivity.
14. Evaluationofantiulceractivitybypylorusligationmethod.
15. Oralglucosetolerancetest.

REFERENCEBooks:

1. CPCSEA,OECD,ICH,USFDA,ScheduleY,EPAguidelines,
2. FundamentalsofexperimentalPharmacologybyM.N.Ghosh
3. ExperimentalPharmacologybyM.C.Prabhakar
4. HandbookofExperimentalPharmacologybyS.K.Kulkarni.
5. PracticalsinPharmacologybyR.K.Goel
6. DrugdiscoveryandEvaluationbyVogelH.G.
7. SpectrometricIdentificationofOrganiccompounds- RobertMSilverstein,
8. PrinciplesofInstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman,
9. Vogel‘sTextbookofquantitativechemicalanalysis-Jeffery,Basset,Mendham,Denney,
10. BasicCellCultureprotocolsbyCherilD. HelgasonandCindyL.Mille
11. BasicCellCulture(PracticalApproach)byJ.M.Davis(Editor)
12. AnimalCellCulture:APracticalApproachbyJohnR.Masters(Editor)
13. PracticalManualofExperimentalandClinicalPharmacologybyBikashMedhi(Author), AjayPrakash(Author)Jaypeebrothers’medicalpublishersPvt.Ltd

PHARMACOLOGYPRACTICAL-II(MPL106P)

1. IsolationandidentificationofDNAfromvarioussources(Bacteria, Cauliflower,onion, Goatliver).
2. IsolationofRNAfromyeast
3. EstimationofproteinsbyBraford/Lowry'sinbiologicalsamples.
4. EstimationofRNA/DNAbyUVSpectroscopy
5. GeneamplificationbyPCR.
6. ProteinquantificationWesternBlotting.
7. Enzymebasedin-vitroassays(MPO,AChEs,αamylase,αglucosidase).
8. Cellviabilityassays(MTT/Trypanblue/SRB).
9. DNAfragmentationassaybyagarosegelelectrophoresis.
10. DNAdamagestudybyCometassay.
11. Apoptosisdeterminationbyfluorescentimagingstudies.
12. Pharmacokineticstudiesanddataanalysisofdrugsgivenbydifferent routesofadministrationusingsoftwares
13. Enzymeinhibitionandinductionactivity
14. Extractionofdrugfromvariousbiologicalsamplesandestimationofdrugsinbiologicalfluidsusingdifferentanalyticaltechniques (UV)
15. Extractionofdrugfromvariousbiologicalsamplesandestimationofdrugsinbiologicalfluidsusingdifferentanalyticaltechniques(HPLC)

REFERENCEBOOKS:

1. CPCSEA,OECD,ICH,USFDA,ScheduleY,EPAguidelines,
2. FundamentalsofexperimentalPharmacologybyM.N.Ghosh
3. ExperimentalPharmacologybyM.C.Prabhakar
4. HandbookofExperimentalPharmacologybyS.K.Kulkarni.
5. PracticalsinPharmacologybyR.K.Goel
6. DrugdiscoveryandEvaluationbyVogelH.G.
7. SpectrometricIdentificationofOrganiccompounds- RobertMSilverstein,
8. PrinciplesofInstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman,
9. Vogel'sTextbookofquantitativechemicalanalysis-Jeffery,Basset,Mendham,Denney,
10. BasicCellCultureprotocolsbyCherilD. HelgasonandCindyL.Mille
11. BasicCellCulture(PracticalApproach)byJ.M.Davis(Editor)
12. AnimalCellCulture:APracticalApproachbyJohnR.Masters(Editor)
13. PracticalManualofExperimentalandClinicalPharmacologybyBikashMedhi(Author), AjayPrakash(Author)Jaypeebrothers'medicalpublishersPvt.Ltd

SEMESTER-II
ADVANCEDPHARMACOLOGY-II(MPL201T)

THEORY **60Hours**

Scope

The subjectis designedtostrengthen the basic knowledgein thefieldof pharmacology andtoimpartrecentadvancesin the drugs usedfor the treatmentof various diseases.In addition, thesubjecthelpsthestudenttounderstandtheconceptsofdrugactionandmechanisminvolved**Objecti ves**

Uponcompletionofthe coursethe

Γstudentshallbeableto:Explainthemechanismofdrugactionsatcellularandmolecular

ΓlevelDiscussthePathophysiologyandpharmacotherapyofcertaindiseases

ΓUnderstandtheadverseeffects,

contraindicationsandclinicalusesofdrugsusedintreatmentofdiseases

Unit-1:EndocrinePharmacology

Molecularandcellular

mechanismofactionofhormonessuchasgrowthhormone,prolactin,thyroid,insu

linandsexhormones

Anti-

thyroiddrugs,Oralhypoglycemicagents,Oralcontraceptives,Corticosteroids.Drugsaffectingcalc iumregulation **12hrs**

Unit-2Chemotherapy:Cellularandmolecularmechanismofactionsandresistanceofantimicrobial agentssuchasß-

lactams,aminoglycosides,quinolones,Macrolideantibiotics.Antifungal,antiviral,andanti-TBdrugs **12hrs**

Unit-3Chemotherapy

Drugs usedin Protozoal Infections Drugs usedinthe treatment of Helminthiasis ChemotherapyofcancerImmunopharmacologyCellularandbiochemicalmediatorsofinflammationa ndimmune response. Allergic or hypersensitivity reactions. Pharmacotherapy of asthma andCOPD.ImmunosuppressantsandImmunostimulants **12hrs**

Unit-4GITPharmacology

Antiulcerdrugs,Prokinetics,antiemetics,anti-diarrhealsanddrugsforconstipation andirritablebowelsyndrome.

Chronopharmacology

Biological and circadian rhythms, applications of chronotherapy in various diseases likecardiovasculardisease,diabetes,asthmaandpepticulcer **12hrs**

Unit-5:FreeradicalsPharmacology:Generationoffreeradicals,roleoffreeradicalsinetiopathologyofvariousdiseasessuchasdiabetes,neurodegenerativediseasesandcancer.Protective activity of certain important antioxidant : Recent Advances in Treatment:Alzheimer'sdisease,Parkinson'sdisease,Cancer,Diabetesmellitus **12hrs**

REFEERENCEBOOKS:

1. ThePharmacologicalbasisoftherapeutics-GoodmanandGillman's
2. PrinciplesofPharmacology.ThePathophysiologicbasisofdrugtherapybyDavidEGolanetal.
3. BasicandClinicalPharmacologybyB.G-Katzung
4. PharmacologybyH.P.RangandM.M.Dale.
5. HandbookofClinicalPharmacokineticsbyGibaldiandPrescott.
6. TextbookofTherapeutics,druganddiseasemanagementbyET.HerfindalandGourley.
7. AppliedbiopharmaceuticsandPharmacokineticsbyLeonShargelandAndrewB.C.Yu.
8. HandbookofEssentialPharmacokinetics,PharmacodynamicsandDrugMetabolismforIndustrialScientists
9. Robbins&CortanPathologicBasisofDisease,9thEd.(RobbinsPathology)
10. ACompleteTextbookofMedicalPharmacologybyDr.S.KSrivastavapublishedbyAPC AvichalPublishingCompany.
11. KD.Tripathi.EssentialsofMedicalPharmacology

Principles of Pharmacology.The Pathophysiologicbasis of drug Therapy by DavidEGolan,Armen H, Tashjian Jr, Ehrin J,Armstrong, April W, Armstrong, Wolters, Kluwer-LippincottWilliams&Wilkins Publishers

PHARMACOLOGICALANDTOXICOLOGICALSCREENING METHODS-II (MPL202T)

THEORY **60Hours**

Scope:

This subject imparts knowledge on the preclinical safety and toxicological evaluation of drug &new chemical entity. This knowledge will make the student competent in regulatorytoxicologicalevaluation.

Objectives:

Uponcompletionofthecourse,thestudentshallbeableto,Explaint

⌜he various types oftoxicitystudies.

⌜Appreciatetheimportanceofethicalandregulatoryrequirementsfortoxicitystudies.

⌜Demonstratethe practicalskills requiredtoconductthepreclinicaltoxicitystudies.

Unit-1Basicdefinitionandtypesoftoxicology(general, mechanistic,regulatoryanddescriptive)

Regulatoryguidelinesforconducting toxicitystudiesOECD,ICH,EPAandScheduleY

OECD principles ofGood laboratorypractice (GLP) History, concept and its importance indrugdevelopment **12 hrs**

Unit-2Acute,sub-acuteandchronic-oral,dermalandinhalationalstudiesasperOECDguidelines.Acuteeyeirritation,skinsensitization,dermalirritation&dermaltoxicitystudies.

Testitemcharacterization-importanceandmethodsinregulatorytoxicologystudies **12hrs**

Unit-3Reproductivetoxicologystudies,Malereproductivetoxicitystudies,femalereproductivestudies(segmentIandsegmentIII),teratogenecitystudies(segmentII)Genotoxicitystudies(AmesTest,invitroandinvivoMicronucleusandChromosomal aberrationsstudies)Invivocarcinogenicitystudies **12hrs**

Unit-4:INDenablingstudies(INDstudies)-DefinitionofIND,importanceofIND,industryperspective,listofstudiesneededforINDsubmissionSafetypharmacologystudies-origin,conceptsandimportanceofsafetypharmacology.Tier1-CVS,CNSandrespiratorysafetypharmacology, HERGassay. Tier2- GI, renalandotherstudies **12hrs**

Unit-5:Toxicokinetics-Toxicokineticevaluationinpreclinicalstudies,saturationkineticsImportanceandapplicationsoftoxicokineticstudies.Alternativemethodstoanimaltoxicitytesting **12hrs**

REFERENCEBOOKS:

1. Hand book on GLP, Quality practices for regulated non-clinical research

anddevelopment(http://www.who.int/tdr/publications/documents/glp-handbook.pdf).

2. ScheduleYGuideline:drugsandcosmetics(secondamendment)rules, 2005,ministryofhealthandfamilywelfare(departmentofhealth)NewDelhi
3. DrugsfromdiscoverytoapprovalbyRickNG.
4. AnimalModelsinToxicology,3rdEdition,LowerandBryan
5. OECDtestguidelines.PrinciplesoftoxicologybyKarenE.Stine,ThomasM.Brown

PRINCIPLES OF DRUG DISCOVERY

(MPL203T)

THEORY **60Hours**

Scope:Thesubjectimpartsbasicknowledgeofdrugdiscoveryprocess.Thisinformationwillmakethestudentcompetentindrugdiscoveryprocess

Objectives:

Uponcompletionofthecourse,thestudentshallbeableto,Explaint

⌜he various stagesofdrugdiscovery.

⌜Appreciatetheimportanceoftheroleofgenomics,proteomicsandbioinformaticsindrug

⌜discoveryExplainvarioustargetsfordrugdiscovery.

⌜ExplainvariousleadseekingmethodandleadoptimizationAppreciatetheimportanceoftheroleofcomputeraide

⌜ddrugdesignindrugdiscovery

Unit-1:An overview of modern drug discovery process: Target identification, target validation,leadidentificationandleadOptimization.Economicsofdrugdiscovery.

Target Discovery and validation-Role of Genomics, Proteomics and Bioinformatics. Role ofNucleicacidmicroarrays,Proteinmicroarrays,Antisensetechnologies,siRNAs,antisenseoligonucleotides, Zincfinger proteins. Roleoftransgenicanimals intargetvalidation.12hrs

Unit-2: Lead Identification- combinatorial chemistry& high throughput screening, in silico leaddiscoverytechniques,Assaydevelopmentforhitidentification.

Protein structure Levels of protein structure, Domains, motifs, and folds in protein structure.Computational predictionof proteinstructure:Threadingandhomologymodelingmethods.ApplicationofNMRandX-raycrystallographyinproteinstructureprediction **12hrs**

Unit-3:RationalDrugDesign

Traditional vs rational drug design, Methods followed in traditional drug design, Highthroughputscreening, Concepts of Rational Drug Design, Rational Drug Design Methods: Structure

andPharmacophorebasedapproachesVirtualScreeningtechniques:Druglikenessscreening,Conceptofpharmacophoremappingandpharmacophorebasedscreening.**12hrs**

Unit-4 Molecular docking: Rigid docking, flexible docking, manual docking; Docking basedscreening.Denovodrugdesign.QuantitativeanalysisofStructureActivityRelationship

History and development of QSAR, SAR versus QSAR, Physicochemical parameters, Hanschanalysis, FeeWilsonanalysisandrelationshipbetweenthem **12hrs**

Unit-5: QSAR Statistical methods – regression analysis, partial least square analysis (PLS) andother multivariate statistical methods. 3D-QSAR approacheslike COMFA and COMSIA Prodrugdesign-Basicconcept,Prodrugstoimprovepatient acceptability,Drug solubility,Drugabsorption anddistribution,sitespecificdrugdelivery andsustaineddrugaction.Rationaleof prodrugdesignandpracticalconsiderationofprodrugdesign.

12hrs

REFERENCEBOOKS:

1. MouldySioud.TargetDiscoveryandValidationReviewsandProtocols:Volume2Emerging MolecularTargetsandTreatmentOptions.2007HumanaPressInc.
2. DarrylLeón.ScottMarkelIn. Silico TechnologiesinDrugTargetIdentificationandValidation.2006byTaylorandFrancisGroup,LLC.
3. Johanna K. DiStefano. Disease Gene Identification. Methods and Protocols. SpringerNewYorkDordrechtHeidelbergLondon.
4. Hugo Kubiny. QSAR: Hansch Analysis and Related Approaches. Methodsand PrinciplesinMedicinalChemistry.PublisherWiley-VCH
5. Klaus Gubernator, Hans-Joachim Böhm. Structure-Based Ligand Design. Methods andPrinciplesinMedicinalChemistry.PublisherWiley-VCH
6. Abby L .Parrill.M .Rami Reddy.RationalDrugDesign.Novel Methodology andPracticalApplications.ACSSymposiumSeries;AmericanChemicalSociety:Washington, DC,1999.

J. Rick Turner. New drug development design, methodology and, analysis. John Wiley & Sons,Inc.,NewJersey

CLINICALRESEARCHANDPHARMACOVIGILANCE(MPL204T)

THEORY **60Hours**

Scope:

This subject will provide a value addition and current requirement for the students in clinicalresearchandpharmacovigilance.Itwillteachthestudentsonconceptualizing,designing,conducting, managing and reporting of clinical trials. This subject also focuses on globalscenarioof Pharmacovigilance in different methods that can be used to generate safety data. It will teachthe students in developingdrug safety data in Pre-clinical, Clinical phasesof Drug developmentandpostmarketsurveillance.

Objectives:

Upon completion of the course, the student shall be able

- to,Explaintheregulatoryrequirementsforconductingclinicaltrial
- Demonstrate the types of clinical trial
- designsExplaintheresponsibilitiesofkeyplayersinvolvedinclinica
- ltrialsExecute safety monitoring, reporting and close-out
- activitiesExplain the principles of
- PharmacovigilanceDetectnewadversedrugreactionsandtheirasse ssment
- PerformtheadversedrugreactionreportingsystemsandcommunicationinPharmacovigilance

Unit-1:RegulatoryPerspectivesofClinicalTrials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice(ICH-GCP)guidelinesEthicalCommittee:InstitutionalReviewBoard,EthicalGuidelinesforBiomedicalResearchandHumanParticipant-Schedule Y,ICMR InformedConsentProcess:StructureandcontentofanInformedConsentProcessEthicalprinciplesgoverning informedconsentprocess **10hrs**

Unit-2:ClinicalTrials: Typesand DesignExperimentalStudy-RCTand NonRCT,ObservationStudy:Cohort,CaseControl, CrosssectionalClinicalTrialStudyTeam RolesandresponsibilitiesofClinicalTrialPersonnel:Investigator,StudyCoordinator,Sponsor,ContractResearchOrganizationanditsmanagement. **10hrs**

Unit-3:ClinicalTrial Documentation- Guidelines to the preparation ofdocuments, Preparation ofprotocol,InvestigatorBrochure,CaseReportForms,ClinicalStudyReportClinicalTrialMonitoring-SafetyMonitoringinCT

Adverse Drug Reactions: Definition and types. Detection and reporting methods. Severity andseriousnessassessment.Predictability andpreventability assessment,Managementof adversedrugreactions;TerminologiesofADR. **10hrs**

Unit-4:

Basicaspects,terminologiesandestablishmentofpharmacovigilanceHistoryandprogressofpharmacovigilance,Significanceofsafetymonitoring,PharmacovigilanceinIndiaandinternational aspects, WHO international drug monitoring programme, WHO and Regulatoryterminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centresinHospitals,IndustryandNationalprogrammesrelatedtopharmacovigilance.Rolesandresponsibilitiesin Pharmacovigilance

10hr

Unit-5:Methods,ADRreportingandtoolsusedinPharmacovigilance

International classification of diseases, International Non- proprietary names for drugs, Passiveand Active surveillance, Comparative observational studies, Targeted clinical investigations

andVaccinesafetysurveillance.SpontaneousreportingsystemandReportingtoregulatoryauthorities, GuidelinesforADRsreporting.Argus,ArisGPharmacovigilance,VigiFlow,Statisticalmethods forevaluatingmedicationsafetydata.

Unit-6:Pharmacoepidemiology,pharmacoeconomics,safetypharmacology

10hrs

REFERENCEBOOKS:

1. CentralDrugsStandardControlOrganization-GoodClinicalPractices,GuidelinesforClinicalTrialsonPharmaceuticalProductsinIndia.NewDelhi:MinistryofHealth;2001.
2. InternationalConferenceonHarmonizationofTechnicalrequirementsforregistrationofPharmaceuticalsforhuman use.ICHHarmonizedTripartite Guideline.Guidelinefor GoodClinicalPractice.E6;May1996
3. Ethical GuidelinesforBiomedical Research onHuman Subjects2000.Indian Council ofMedicalResearch,NewDelhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March2005,JohnWileyandSons
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition,Jan2000,WileyPublications

PHARMACOLOGY PRACTICAL-III(MPL205P)

ListofExperiments

1. TorecordtheDRCofagonistusingsuitableisolatedtissuespreparation.
2. Tostudytheeffectsofantagonist/potentiatingagentsonDRCofagonistusingsuitableisolate dtissuepreparation.
3. Todeterminetothestrengthofunknownsamplebymatchingbioassaybyusingsuitabletissuepr eparation.
4. Todeterminetothestrengthofunknownsamplebyinterpolationbioassaybyusing suitabletissue preparation
5. Todeterminetothestrengthofunknownsamplebybracketingbioassaybyusingsuitabletissuep reparation
6. Todeterminetothestrengthofunknownsamplebymultiple pointbioassay byusingsuitable tissuepreparation.
7. EstimationofPA2valuesofvariousantagonistsusingsuitableisolatedtissuepreparations.
8. Tostudytheeffectsofvariousdrugsonisolatedheartpreparations
9. RecordingofratBP,heartrateandECG.
10. RecordingofratECG

REFERENCEBOOKS:

1. ThePharmacologicalbasisoftherapeutics-GoodmanandGillman‘s
2. PrinciplesofPharmacology.ThePathophysiologicbasisofdrugtherapybyDavidEGolanetal .
3. BasicandClinicalPharmacologybyB.G-Katzung
4. PharmacologybyH.P.RangandM.M.Dale.
5. HandbookofClinicalPharmacokineticsbyGibaldiandPrescott.
6. TextbookofTherapeutics,druganddiseasemanagementbyET.HerfindalandGourley.
7. AppliedbiopharmaceuticsandPharmacokineticsbyLeonShargelandAndrewB.C.Yu.
8. HandbookofEssentialPharmacokinetics, PharmacodynamicsandDrugMetabolismforIndustrialScientists
9. ApracticalbookofPharmacologybyRameshAlluri
10. Robbins&CortanPathologicBasisofDisease,9thEd.(RobbinsPathology)AComplete

TextbookofMedicalPharmacologybyDr.S.KSrivastavapublishedbyAPC AvichalPublishingCompany

PHARMACOLOGY PRACTICAL-IV(MPL206P)

ListofExperiments

1. Drugabsorptionstudiesbyavertedratileumpreparation.
2. AcuteoraltoxicitystudiesasperOECDguidelines.
3. AcutedermaltoxicitystudiesasperOECDguidelines.
4. Repeateddosetoxicitystudies-Serumbiochemical,haematological,urineanalysis, functionalobservationtests andhistologicalstudies.
5. Drugmutagenicitystudyusingmicebone-marrowchromosomalaberrationtest.
6. Protocoldesignforclinicaltrial.(3Nos.)
7. DesignofADRmonitoringprotocol.
8. In-silicodockingstudies.(2Nos.)
9. In-silicopharmacophorebasedscreening.
10. In-silicoQSARstudies.
11. ADRreporting

REFERENCEBOOKS

1. FundamentalsofexperimentalPharmacology-byM.N.Ghosh
2. HandbookofExperimentalPharmacology-S.K.Kulakarni
3. TextbookofIn-vitropracticalPharmacologybyIanKitchen
4. ExperimentalPharmacologybyM.C.Prabhakar.
5. PracticalsinPharmacologybyR.K.Goel
6. BioassayTechniquesforDrugDevelopmentbyAtta-ur-Rahman,Iqbalchoudharyand WilliamThomsen
7. AppliedBiopharmaceuticsandPharmacokineticsbyLeonShargelandAndrewB.C.Yu.
8. HandbookofEssentialPharmacokinetics,PharmacodynamicsandDrugMetabolismforIndustrial Scientists.

PHARMACOGNOSY(MPG)

SEMESTER-I

MODERNPHARMACEUTICALANALYTICALTECHNIQUES(MIP 101T)

THEORY **60HOURS**

Scope

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

Objectives

Aftercompletionofcoursestudentisabletoknow,Chemical

- sandExcipients
- Theanalysisofvariousdrugsinsingleandcombinationdosageforms Theoreticalandpracticals
- kills oftheinstruments

Unit-1: **10Hrs**

a. UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visiblespectroscopy.

b. IRspectroscopy:Theory,ModesofMolecularvibrations,Samplehandling,Instrumentationof Dispersive and Fourier - Transform IR Spectrometer, Factors affecting vibrationalfrequenciesandApplications ofIR spectroscopy

c. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers,Instrumentationand Applications offluorescence spectrophotometer.

Unit-2: **8Hrs**

MassSpectroscopy:Principle,Theory,InstrumentationofMassSpectroscopy,Differenttypesofionizationlikeelectronimpact,chemical,field,FABandMALDI,APCI,ESI,APPIAnalyzersofQuadrupoleandTimeofFlight,Massfragmentationanditsrules,Metastableions,IsotopicpeaksandApplications ofMass spectroscopy.

Unit-3: **12Hrs**

Chromatography:Principle,apparatus,instrumentation,chromatographic parameters,factorsaffectingresolutionandapplications ofthefollowing:

a)Paperchromatography b)ThinLayerchromatography c)Ion exchangechromatography d)Columnchromatographye)Gaschromatographyf)HighPerformanceLiquidchromatograp hyg)Affinitychromatography.

Unit-4: **10Hrs**

Electrophoresis:Principle,Instrumentation,Workingconditions,factorsaffectingseparationandappli cationsofthefollowing:

a)Paperelectrophoresisb)Gelelectrophoresisc)Capillaryelectrophoresisd)Zoneelectrophoresis e)Movingboundaryelectrophoresisf)Iso electric focusing

Unit-5: **10Hrs**

a) Potentiometry:Principle,Workinf,IonSelectiveelectrodesandapplicationsofpotentiometry.

b) Thermaltechniques:DSC,DTA,TGA,Principle,Instrumentation,factorsaffecting, advantagesanddisadvantages andPharmaceuticalapplications.

Unit-6: **8Hrs**

NMRSpectroscopy:Quantum numbersandtheirroleinNMR,Principle,instrumentation,solvent requirements in NMR, Relaxation process, NMR signals in various compounds.Briefoutline ofFT-NMR andC^{13}NMR,applicationsofNMRSpectroscopy.

REFERENCEBOOKS:

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition, JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman,5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBS Publishers,New Delhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugsinPharmaceuticalformulation-PDSethi,3rd Edition, CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-Modernmethods–PartB-JWMunson,Volume11,Marcel DekkerSeries

ADVANCEDPHARMACOGNOSY-I(MPG102T)

THEORY **60HOURS**

SCOPE

Tolearnandunderstand theadvancesinthefieldofcultivationandisolationofdrugsofnaturalorigin, various phytopharmaceuticals, nutraceuticals and their medicinaluse and health benefits.**OBJECTIVES**

Uponcompletionofthecourse,thestudent shallbeableto

- knowthe,advancesinthe cultivationandproductionofdrugs
- variousphyto-pharmaceuticalsandtheirsource,itsutilizationandmedicinalvalue.
- variousnutraceuticals/herbsandtheirhealthbenefits
- Drugsofmarineorigin
- Pharmacovigilanceofdrugsofnaturalorigin

Usethebiotechnologicaltechniquesfor obtainingandinimpropvingthe qualityofthe naturalproducts/Medicinalplants

1.UNITI **10Hrs**

Abriefaccount onChemicaland Pharmacologicalaspectsand usesofthefollowingmedicinalplants-

1. **Immunomodulators**a.Asparagusracemosusb.Withaniasomnifera
2. **Hepatoprotectives**a.Phyllanthusamarusb.Silybummarianum
3. **Cardioprotectives**a.Coleusforskolin b.Alliumsativum
4. **Antivirals** a.Oreganovulgareb.Sambucusnigra
5. **Antidiabetics** a.Gymnemasylvestreb.Momordicacharantia

UNIT-II **10Hrs**

Marine natural products: General methods of isolation and purification, Study of Marine toxins,Recent advances in research in marine drugs, Problems faced in research on marine drugs suchastaxonomicalidentification,chemicalscreeningandtheirsolution.

UNIT-III **10Hrs**

Nutraceuticals:

Currenttrendsandfuturescope,Inorganicmineralsupplements,Vitaminsupplements,Digestiveenzymes,Dietaryfibres,Cerealsandgrains,Healthdrinksofnaturalorigin,Antioxidants,Polyunsaturatedfattyacids,Herbsasfunctionalfoods,Formulationandstandardization neutraceuticals, Regulatoryaspects, FSSAI guidelines, Sources, name of markercompounds and their chemical nature, medicinaluses and health benefits of followingi)Spirulinaii)Soyabeaniii)Ginsengiv)Garlicv)Broccolivi)GreenandHerbal Teavii)Flax seeds viii)Blackcohoshix)Turmeric.

UNITIV:Phytopharmaceuticals:Occurrence,isolationandcharacteristicfeatures(Chemical nature,usesinpharmacy,medicinalandhealthbenefits)offollowing.

a) Carotenoids–i)αandβ-Caroteneii)Xanthophyll(Lutein)
b) Limonoids–i)d-Limoneneii)α–Terpineol
c) Saponins–i)Shatavarins
d) Flavonoids–i)Resveratrolii)Rutiniii)Hesperidiniv) Naringinv)Quercetin
e) Phenolicacids-Ellagicacid
f) Vitamins
g) TocotrienolsandTocopherols
h) Andrographolide,Glycolipids,Gugulipids,Withanolides, Vascine,Taxol
i) Miscellaneous **10hrs**

UNIT-V Secondary metabolism in tissue cultures with emphasis on production of medicinalagents- Production of Secondary metabolites from callus culture and suspension culture withemphasisonproductionofbiomedicinalslike-Ajmalicine,Shikonin,CarotenoidsandRosemarinicacid. **10hrs**

UNIT-VI

Biotransformation and Trangenesis: Biotransformation of PlantCell Culture anditsimportancein secondary metabolite production. Bioreactors for pilot and large scale cultures of plant cells.Hairyrootculturesandtheir applications. **10hrs**

REFERENCES(LatestEditionsof)

1. Pharmacognosy-G.E.TreaseandW.C.Evans.SaundersEdinburgh,NewYork.
2. Pharmacognosy-Tyler,Brady,Robbers
3. ModemMethodsofPlantAnalysis-Peach&M.V.Tracey,Vol.I&II
4. TextBookofPharmacognosybyT.E.Wallis
5. MarineNaturalProducts-Vol.ItoIV.
6. Naturalproducts:AlabguidebyRaphaelIkan,AcademicPress1991.
7. GlimpsesofIndianEthanoPharmacology,P.Pushpangadam.UlfNyman.V.George TropicalBotanic Garden&ResearchInstitute,1995.
8. Medicinalnaturalproducts(abiosyntheticapproach),PaulM.Dewick,JohnWiley&SonsLtd., England,1998.
9. ChemistryofMarineNaturalProducts-PaulJ.Schewer1973.
10. HerbalDrugIndustrybyRD.Choudhary,EasternPublisher,NewDelhi,1996.
11. CultivationofMedicinalPlantsbyC.K.Atal&B.M.Kapoor.
12. CultivationandUtilizationofAromaticPlants,C.K.Atal&B.M.Kapoor

13. Cultivationofmedicinalandaromaticcrops,AAFarooquiandB.S.Sreeramu.UniversityPress,2001.
14. MedicinalplantbiotechnologybyCiddiVeeresham
15. PharmaceuticalsbiotechnologybyS.P.Vyas&V.K.Dixit
16. BiotechnologicalapplicationstotissueculturebyShargool,PeterD,Shargoal,CKCPress
17. NaturalProductsfromPlants,1stedition,byPeterB.Kaufman,CRCPress,NewYork,1998
18. Recent AdvancesinPhytochemistry-Vol.1&4:ScikelRuneckles-AppletonCenturycrofts.
19. TextbookofPharmacognosy,C.K.Kokate,Purohit,Ghokhale,NiraliPrakasshan,1996.
20. PharmacognosyandPharmacobiotechnology,Ashutoshkar,NewAgePublications,NewDelhi.

PHYTOCHEMISTRY (MPG103T)

THEORY **60HOURS**

Scope: Studentsshallbeequippedwiththeknowledgeofnaturalproductdrugdiscoveryandwillbeableto isolate,identifyandextractandthephyto-constituents

OBJECTIVES

Uponcompletionofthecourse,thestudentshallbeabletoknowthe,

- differentclassesofphytoconstituents,theirbiosyntheticpathways,theirproperties,extractionandg eneralprocess ofnaturalproductdrugdiscovery
- phytochemicalfingerprintingandstructureelucidationofphytoconstituents

UNIT-I **10Hrs**

Isolation,characterizationandpurificationwithaspecialreferencetotheirimportanceinherbalindustrie soffollowingphytopharmaceuticalscontainingdrugs.

a. Alkaloids:Ephedrine,Quinine,Strychnine,Piperine,Berberine,Taxol,Vincaalkaloids
b. Glycosides:Digitoxin,Glycyrrhizin,Sennosides,Quercetin,Bacosides
c. Steroids:Hecogenin,Guggulsterone,Withanolides
d. Coumarins:Umbelliferone

UNIT-II **10Hrs**

Drug discovery and development: History of herbs as source of drugs and drug discovery, theleadstructure selection process,structure development,productdiscovery process anddrugregistration, Selection and optimization of lead compounds with suitable examples from thefollowingsource:artemesin,andrographolides.Clinicalstudiesemphasisingonphasesofclinicaltri als,protocoldesignforleadmolecules.

UNIT-III **10Hrs**

Extraction and Phytochemical studies: Recent advances in extractions with emphasis onselectionofmethodandchoiceofsolventforextraction, successiveandexhaustiveextractionandothermethodsofextractioncommonlyused like microwaveassistedextraction, Methodsoffractionation. Separation of phytoconstituents by latest CCCET, SCFE techniques includingpreparative HPLC andFlashcolumnchromatography.

UNIT_IV:Phytochemicalfingerprinting:

HPTLC and LCMS/GCMS applications in the characterization of herbal extracts. **10Hrs**

UNIT-V: Spectral (UV,IR ,NMR (1H,13C) characteristics of the following compounds

a. Carvone b).Citral c).Menthol d). Nicotine e). Kaempferol 10hrs

REFERENCEBOOKS:

1. OrganicchemistrybyI.L.FinarVol.II
2. PharmacognosybyTreaseandEvans,ELBS.
3. PharmacognosybyTylorandBrady.
4. TextbookofPharmacognosybyWallis.
5. Clark'sisolationandIdentificationofdrugsbyA.C.Mottal.
6. PlantDrugAnalysisbyWagner&Bladt.
7. Wilsonand GisvoldstextbookofOrganicMedicinnaland PharmaceuticalChemistrybyDeorge.R.F.
8. TheChemistryofNaturalProducts,EditedbyR.H.Thomson,SpringerInternationalEdn.1994.
9. NaturalProductsChemistryPracticalManualbyAneesASiddiquiandSeemiSiddiqui
10. OrganicChemistryofNaturalProducts,Vol.1&2.GurdeepRChatwal.
11. ChemistryofNaturalProducts-Vol.1onwardsIWPAC.
12. ModemMethodsofPlantAnalysis-Peach&M.V.Tracey,Vol.I&II
13. MedicinalNaturalproducts –abiosyntheticapproach, DewickPM,JohnWiley&Sons,Toronto,1998.
14. ChemistryofNaturalProducts,BhatSV,NagasampagiBA,MeenakshiS,NarosaPublishingHouse,NewDelhi.
15. Pharmacognosy&PhytochemistryofMedicinalPlants,2nd edition,BrunetonJ,InterceptLtd.,NewYork,1999

INDUSTRIAL PHARMACOGNOSTICAL TECHNOLOGY (MPG

104T)THEORY **60HOURS**

Scope:TounderstandtheIndustrialandcommercialpotentialofdrugsofnaturalorigin,integratetraditional Indian systems of medicine with modern medicine and also to know regulatory andqualitypolicyforthetradeofherbals anddrugs ofnaturalorigin.

OBJECTIVES

Bytheendofthecoursethestudentshallbeabletoknow,

•therequirementsforsettinguptheherbal/naturaldrugindustry.

•theguidelinesforqualityofherbal/naturalmedicinesandregulatoryissues.

•thepatenting/IPRofherbals/naturaldrugsandtradeofrawandfinishedmaterials.

UNIT-1 **12hrs**

Herbaldrugindustry:

a) Studyofinfrastructure,staffrequirements,projectprofile,plantandequipmentapplicabletoherbal drug industry.Plantdesign,layoutandconstruction.Pilotplantscale –uptechniques.

b) GMPandGLP

UNIT-II:Regulatoryrequirementsforsettingherbaldrugindustry:

Globalmarketingmanagement.RegulatoryrequirementsExport-Import(EXIM)policy.TRIPS : Qualityassuranceinherbal/naturaldrugproducts.ConceptsofTQM,ISO-9000.RecentguidelinesofDCGIonherbalformulations **12hrs**

UNIT-IIIMonographsofherbaldrugs:GeneralparametersofmonographofherbaldrugsinAyurvedicPharmacopoeia,HerbalPharmacopoeiaandAmericanPharmacopoeia**12 hrs**

UNIT-IV: **12hrs**

Testingofnaturalproductsanddrugs:Herbalmedicines-clinicallaboratorytesting.Stabilitytestingofnaturalproducts,protocols.

UNIT:V **12hrs**

Patents: Patenting of herbaldrugs: Benefits ofpatent protection, Patent application, drafting andfilinganapplication.Indianandinternationalpatentlaws,proposedamendmentsasapplicabletoherbal/naturalproductsandprocess.Geographicalindication,Copyright,Patentablesubjectmaters,novelty,non-obviousness,utility,patentprocessingand grantofpatents

Referencebooks

1. HerbaldrugindustrybyR.D.Choudhary(1996),EasternPublisher,NewDelhi.
2. GMPforBotanicals-RegulatoryandQualityissuesonPhytomedicinebyPulokKMukharjee(2003),IstEdition,BusinesshorizonsRobertVerpoorte,NewDelhi.
3. QualitycontrolofherbaldrugsbyPulokKMukarjee(2002),BusinessHorizonsPharmaceutical Publisher,NewDelhi.
4. PDRforHerbalMedicines(2000),MedicinalEconomicCompany,NewJersey.
5. IndianHerbalPharmacopoeia(2002),IDMA,Mumbai.
6. TextbookofPharmacognosybyC.K.Kokate,Purohit,Gokhlae(1996),NiraliPrakashan,NewDelhi.
7. TextbookofPharmacognosyand PhytochemistrybyVinod D.RangarI (2002),PartI&II,CareerPublication,Nasik,India.
8. PlantdruganalysisbyH.WagnerandS.Bladt,Springer,Berlin.
9. StandardizationofBotanicals.TestingandextractionmethodsofmedicinalherbsbyV.Rajpal (2004),Vol.I,EasternPublisher,New Delhi.
10. PhytochemicalDictionary.HandbookofBioactive CompoundsfromPlantsbyJ.B.Harborne,(1999),IIndEdition,TaylorandFrancisLtd,UK.
11. HerbalMedicine. ExpandedCommissionEMonographsbyM.Blumenthal, (2004),ISTEdition,
12. DrugFormulationManualbyD.P.S.KohliandD.H.Shah(1998),EasternPublisher,NewDelhi.

ADVANCEDPHARMACOGNOSY PRACTICAL–I (MPGI05P)

1. Extraction of Carotene from Carrot
2. Extraction of Hesperidin from orange peels
3. Extraction of Rutin from Nicotiana tobaccum
4. Isolation of Pectin from Orange peels
5. Isolation of starch from potatoes and rice
6. Isolation of Bixin from Bixa Orellana
7. Isolation of Lawsone from Henna
8. Isolation of Curcuminoids from Curcuma Longa
9. Identification of bioactive constituents from plant extracts
10. TLC studies of Phytoconstituents

Phytochemistry (MPGI06P)

1. Extraction of Glyrrhizic acid from Glycyrrhiza glabra
2. Extraction of oleo-resin from ginger
3. Isolation of the following Phytoconstituents
    a. Caffeine from Tea Leaves
    b. Caffeine from marketed product
    c. Strychnine and Brucine from Nux-Vomica by Columnchromatography.
    d. Piperine from black pepper
    e. Citric acid from Lemon
    f. Nicotine from Tobacco
4. TLC studies of Phytoconstituents
5. Estimation of phytoconstituents by various analytical methods (UV, FTIR)
6. Extraction of Quercetin from Onion using column chromatography
7. Detectionof Phytoconstituents by test tube reactions and TLC studies, such as
    a. Alkaloids,
    b. Steroids, Triterpenoids and their glycosides and saponins,
    c. Anthracene glycosides
    d. Flavanoids and their glycosides
    e. Coumarinsm
    f. Tannins
8. Identification of alkaloids in a mixture by TLC
    e.g. Atropine, Caffeine, Ergot, Piperine, Quinine, Reserpine, Strychnine andBrucine
9. Detection, extraction, and estimation of volatile oils by Clevenger's method
(Hydro distillation method), TLC of volatile oils and their pure constituents.

SEMESTER-II
ADVANCEDPHARMACOGNOSY-II(MPG201T)

THEORY **60HOURS**

SCOPE

To know and understand the Adulteration and Deterioration that occurs in herbal/natural drugsand methods of detection of the same. Study of herbal remedies and their validations, includingmethodsofscreening

OBJECTIVES

Uponcompletionofthecourse,thestudentshallbeabletoknowthe,v

Γalidationofherbalremedies

Γmethodsofdetectionofadulterationandevaluationtechniques forthe herbaldrugs methods

Γofscreeningofherbalsforvariousbiologicalproperties

Unit-1: Herbal remedies – Toxicityand Regulations: Herbals vs Conventional drugs, EfficacyofHerbalmedicineproducts,Validationofherbaltherapies,PharmacodynamicandPharmaco kineticissues. **12hrs**

Unit-2:AdulterationandDeterioration:Introduction,TypesofAdulteration/SubstitutionofHerbal drugs, Causes and Measures of Adulteration, Sampling Procedures, Determination ofForeign Matter, DNA Finger printing techniques in identification of drugs of natural origin,detection of heavy metals, pesticide residues, phytotoxin, microbial contamination in herbs andtheir formulations. **12hrs**

Unit-3: Ethnobotanyand Ethnopharmacology: Ethnobotany in herbal drug evaluation, Impact ofEthnobotany in traditional medicine, New development in herbals, Bio-prospecting tools fordrugdiscovery,RoleofEthnopharmacologyindrug evaluation,ReversePharmacology.**12 Hrs**

Unit-4: Analytical Profiles of herbal drugs: Andrographis paniculata, Boswellia serata, Coleusforskholii,Curcumalonga,Embelicaofficinalis,Psoraleacorylifolia. **12hrs**

Unit-5: Biological screening of herbal drugs: Introduction and Need for Phyto-PharmacologicalScreening, New Strategies for evaluatingNatural Products, In vitro evaluation techniques forAntioxidants,AntimicrobialandAnticancerdrugs.InvivoevaluationtechniquesforAnti-inflammatory,Antiulcer, Anticancer,Wound healing, Antidiabetic, Hepatoprotective, Cardioprotective,DiureticsandAntifertility,ToxicitystudiesasperOECDguidelines. **12Hrs**

REFERENCEBOOKS:

1. GlimpsesofIndianEthanoPharmacologybyP.Pushpangadam.UlfNyman.V.GeorgeTropicalBotanicGarden&ResearchInstitute.
2. Naturalproducts:AlabguidebyRaphaelIkan,AcademicPress.
3. Pharmacognosy-G.E.TreaseandW.C.Evans.WB.SaundersEdinburgh,NewYork.
4. Pharmacognosy-Tyler,Brady,Robbers,Lee&Fetiger.
5. ModemMethodsofPlantAnalysis-Peach&M.V.Tracey,Vol.I&II,SpringerPublishers.
6. HerbalDrugIndustrybyRD.Choudhary,EasternPublishers,NewDelhi.
7. TextbookofPharmacognosybyC.K.Kokate,Purohit,Ghokhale,NiraliPrakashan.
8. TextBookofPharmacognosybyT.E.Wallis,J&AChurchillLtd.,London.
9. QualitycontrolofherbaldrugsbyPulokKMukherjee,BusinessHorizonsPharmaceuticalPublishers,NewDelhi.
10. IndianHerbalPharmacopoeia,IDMA,Mumbai.
11. TextbookofPharmacognosyandPhytochemistrybyVinodD.RangarI,PartI&II,CareerPublication,Nasik,India.
12. PlantdruganalysisbyH.WagnerandS.Bladt,2ndedition,Springer,Berlin.
13. StandardizationofBotanicals.Testingandextractionmethodsofmedicinalherbsby V.Rajpal(2004),Vol.I,EasternPublisherS,NewDelhi.
14. HerbalMedicine.ExpandedCommissionEMonographs,M.Blumenthal

INDIANSYSTEMSOFMEDICINE (MPG203T)

THEORY **60HOURS**

SCOPE

To make the students understand thoroughlythe principles, preparations of medicines of variousIndian systems of medicine like Ayurveda, Siddha, Homeopathy and Unani. Also focusing onclinical research of traditional medicines, quality assurance and challenges in monitoring thesafetyofherbalmedicines.

OBJECTIVES

AftercompletionofthecourseStudentisabletoTounderstandthebasicprinciplesofvariousIndiansystemsofmedic ine

To know theclinicalresearchoftraditionalmedicines,

CurrentGoodManufacturingPracticeofIndiansystemsofmedicine andtheirformulations.

Unit-1:FundamentalconceptsofAyurveda,Siddha,UnaniandHomoeopathysystemsofmedicine Differentdosageforms oftheISM.

Ayurveda:AyurvedicPharmacopoeia,Analysisofformulationsandbiocrudedrugswithreferences to: Identity, purity and quality. Siddha: Gunapadam (Siddha Pharmacology), rawdrugs/Dhatu/JeevaminSiddhasystemofmedicine,Purificationprocess(Suddhi).**12 Hrs**

Unit-2:Naturopathy,YogaandAromatherapypractices

a) Naturopathy-Introduction,basicprinciplesandtreatmentmodalities.
b) Yoga-IntroductionandStreamsofYoga.Asanas,Pranayama,MeditationsandRelaxationtechniques.
c) Aromatherapy–Introduction,aromaoilsforcommonproblems,carrieroils. **12Hrs**

Unit-3: Formulation developmentof various systemsof medicine Salient featuresofthe techniquesofpreparationofsomeoftheimportantclassofFormulationsasperAyurveda,Siddha,Homeopathy andUnaniPharmacopoeia andtexts.Standardization,

ShelflifeandStabilitystudiesofISMformulation. **12hrs**

Unit-4:ScheduleT-GMPofIndianSystems

Components of GMP (Schedule – T) and its objectives, Infrastructural requirements, workingspace,storagearea,machineryandequipments,standardoperatingprocedures,healthandhygiene,documentationandrecords.

Qualityassurance inISMformulation industry- GAP, GMP and GLP. Preparationofdocuments fornew drugapplicationandexportregistration.

Challengesinmonitoringthesafetyofherbalmedicines:Regulation,qualityassuranceandcontrol,National/RegionalPharmacopoeias **12Hrs**

Unit-5:

TKDL,GeographicalindicationBill,GovernmentbillsinAYUSH,ISM,CCRAS,CCRS,CCRH,CCRU. **12Hrs**

REFERENCEBOOKS:

1. AyurvedicPharmacopoeia,TheControllerofPublications,CivilLines,Govt.ofIndia,NewDelhi.
2. HandBookonAyurvedicMedicines,H. Panda,NationalInstituteofIndustrialResearch,New Delhi.
3. Ayurvedic Systemof Medicine, Kaviraj Nagendranath Sengupata, SriSatguruPublications,NewDelhi.
4. AyurvedicPharmacopoeia.FormularyofAyurvedicMedicines,IMCOPS,Chennai.
5. HomeopathicPharmacopoeia.FormularyofHomeopathicMedicines,IMCOPS,Chennai.
6. HomeopathicPharmacy:Anintroduction&Handbook,StevenB.Kayne,Churchill Livingstone,NewYork.
7. IndianHerbalPharmacopoeia,IDMA,Mumbai.
8. BritishHerbalPharmacopoeia,bRITISHHerbalMedicineAssociation,UK.
9. GMPforBotanicals-RegulatoryandQualityissuesonPhytomedicine,PulokKMukharjee,BusinessHorizons,NewDelhi.
10. IndianSystemofMedicineandHomeopathyinIndia,PlanningandEvaluationCell,Govt.ofIndia,NewDelhi.
11. EssentialofFoodandNutrition,Swaminathan,Bappco,Bangalore.
12. ClinicalDietiticsandNutrition,F.P.Antia,OxfordUniversityPress,Delhi.
13. Yoga-TheScienceofHolisticLivingbyV.K.Yoga,VivekanandaYogaPrakashnaPublishing,Bangalore

HERBAL COSMETICS (MPG203T)

THEORY **60HOURS**

SCOPE

This subject deals with the study of preparation and standardization of herbal/natural cosmetics.This subject gives emphasis to various national and international standards prescribed regardingherbalcosmeceuticals.

OBJECTIVES

Aftercompletionofthecourse,studentshallbeableto,understandthebasicprinciplesof

- variousherbal/naturalcosmeticpreparations
- currentGoodManufacturingPracticesofherbal/naturalcosmeticsaspertheregulatoryauthorities

Unit-1:Introduction:Herbal/naturalcosmetics,Classification&Economicaspects. RegulatoryProvisionsrelationtomanufactureofcosmetics:-License,GMP,offences&Penalties, Import & Export of Herbal/natural cosmetics, Industries involved in the production ofHerbal/naturalcosmetics. **12Hrs**

Unit-2: Commonly used herbal cosmetics, raw materials, preservatives, surfactants, humectants,oils, colors, and some functional herbs, preformulation studies, compatibility studies, possibleinteractionsbetweenchemicalsandherbs,designofherbalcosmeticformulation.**12 hrs**

Unit-3: HerbalCosmetics : Physiologyand chemistryofskin and pigmentation, hairs, scalp, lipsand nail, Cleansing cream, Lotions,Facepowders,Facepacks,Lipsticks, Bath products, soaps andbabyproduct,Preparationandstandardisationofthe following: Tonic,Bleaches,DentifricesandMouthwashes&ToothPastes,CosmeticsforNails.**12hrs**

Unit-4:Cosmeceuticalsofherbal andnatural origin:Hairgrowthformulations,Shampoos,Conditioners, Colorants& hair oils, Fairness formulations, vanishing & foundationcreams, anti-sunburnpreparations,moisturizingcreams,deodorants. **12Hrs**

Unit-5: Analysis ofCosmetics, Toxicityscreening and test methods: Qualitycontroland toxicitystudiesasper Drugand CosmeticsAct. **12hrs**

REFERENCEBOOKS:

1. PandaH.HerbalCosmetics(Handbook),AsiaPacificBusinessPressInc,NewDelhi.
2. ThomsonEG.ModernCosmetics,UniversalPublishingCorporation,Mumbai.
3. P.P.Sharma.Cosmetics-Formulation,Manufacturing&QualityControl,Vandana Publications,NewDelhi.
4. SupriyaKB.HandbookofAromaticPlants,PointerPublishers,Jaipur.
5. SkariaP.AromaticPlants(HorticultureScienceSeries),NewIndiaPublishingAgency,Ne w Delhi.
6. KathiKevilleandMindyGreen.Aromatheraphy(ACompleteGuidetotheHealingArt),SriSatg uruPublications,New Delhi.
7. Chattopadhyay PK. Herbal Cosmetics & Ayurvedic Medicines (EOU), National InstituteofIndustrialResearch,Delhi.
8. BalsamMS&EdwardSagarin.CosmeticsScienceandTechnology,WileyInterscience,New York

CLINICALRESEARCH AND PHARMACOVIGILANCE (MPG204T)

THEORY **60HOURS**

Scope:

This subject will provide a value addition and current requirement for the students in clinicalresearchandpharmacovigilance.Itwillteachthestudentsonconceptualizing,designing,conducting, managing and reporting of clinical trials. This subject also focuses on globalscenarioof Pharmacovigilance in different methods that can be used to generate safety data. It will teachthe students in developingdrug safety data in Pre-clinical, Clinical phasesof Drug developmentandpostmarketsurveillance.

Objectives:

Upon completion of the course, the student shall be able

- to,Explaintheregulatoryrequirementsforconductingclinicaltrial
- Demonstrate the types of clinical trial
- designsExplaintheresponsibilitiesofkeyplayersinvolvedinclinica
- ltrialsExecute safety monitoring, reporting and close-out
- activitiesExplain the principles of
- PharmacovigilanceDetectnewadversedrugreactionsandtheirasse ssment
- Performtheadversedrugreactionreportingsystemsandcommunicationin Pharmacovigilance

Unit-1:RegulatoryPerspectivesofClinicalTrials:

Origin and Principles of International Conference on Harmonization - Good Clinical Practice(ICH-GCP)guidelinesEthicalCommittee:InstitutionalReviewBoard,EthicalGuidelinesforBiomedicalResearchandHumanParticipant-ScheduleY,ICMR InformedConsentProcess:StructureandcontentofanInformedConsentProcessEthicalprinciplesgoverning informedconsentprocess **10hrs**

Unit-2:ClinicalTrials: Typesand DesignExperimentalStudy-RCTand NonRCT,ObservationStudy:Cohort,CaseControl,CrosssectionalClinicalTrialStudyTeam RolesandresponsibilitiesofClinicalTrialPersonnel:Investigator,StudyCoordinator,Sponsor,ContractResearchOrganizationanditsmanagement. **10hrs**

Unit-3:ClinicalTrial Documentation- Guidelines to the preparation ofdocuments, Preparation ofprotocol,InvestigatorBrochure,CaseReportForms,ClinicalStudyReportClinicalTrialMonitoring-SafetyMonitoring in CT, Adverse Drug Reactions: Definition and types. Detectionand reportingmethods. Severity and seriousness assessment.Predictability and preventabilityassessment, Managementofadversedrugreactions;TerminologiesofADR. **10hrs**

Unit-4:

Basicaspects,terminologiesandestablishmentofpharmacovigilanceHistoryandprogressofpharmacovigilance,Significanceofsafetymonitoring,PharmacovigilanceinIndiaandinternational aspects, WHO international drug monitoring programme, WHO and Regulatoryterminologies of ADR, evaluation of medication safety, Establishing pharmacovigilance centresinHospitals,IndustryandNationalprogrammesrelatedtopharmacovigilance.Rolesandresponsibilitiesin Pharmacovigilance

10hr

Unit-5:Methods,ADRreportingandtoolsusedinPharmacovigilance

International classification of diseases, International Non- proprietary names for drugs, Passiveand Active surveillance, Comparative observational studies, Targeted clinical investigations

andVaccinesafetysurveillance.SpontaneousreportingsystemandReportingtoregulatoryauthorities, GuidelinesforADRsreporting.Argus,ArisGPharmacovigilance,VigiFlow,Statisticalmethods forevaluatingmedicationsafetydata.

Unit-6:Pharmacoepidemiology,pharmacoeconomics,safetypharmacology **10Hrs**

REFERENCEBOOKS:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines forClinicalTrialsonPharmaceuticalProductsinIndia. NewDelhi:MinistryofHealth;2001.
2. InternationalConferenceonHarmonizationofTechnicalrequirementsforregistrationofPharmaceuticalsforhuman use.ICH Harmonized Tripartite Guideline.GuidelineforGoodClinicalPractice.E6;May1996
3. Ethical GuidelinesforBiomedical Research onHuman Subjects2000.Indian Council ofMedicalResearch,NewDelhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March2005,JohnWileyandSons
5. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition,Jan2000,WileyPublications

ADVANCED PHARMACOGNOSY-II

(MPG 205 P)

List of Experiments:

1. Preparation and standardization of any two herbal tablets
2. Estimation of total alkaloid content in herbal raw materials
3. Estimation of total flavonoid content in herbal raw materials
4. Formulation of different dosage forms and their standardization.
5. Estimation of aldehyde and ketone in volatile oils by titrimetric methods
6. Estimation of phenolic substances
7. Determination of Sennoside content in Senna leaves by colorimetric analysis
8. Determination of Withania alkaloids/steroids by colorimetric analysis
9. Determination of moisture content, heavy metals and ash values of crude drugs
10. Microscopical evaluation of organized powder crude drugs
11. Screening of herbal extracts/ products for anti microbial and antifungal
12. Screening of herbal extracts/ products for antioxidant activity by free radical scavenging methods
13. Study of analytical profile of any two plants mentioned in theory with special emphasis on marker compounds

HERBAL COSMETICS

(MPG 206 P)

1. Preparation and standardization of various simple dosage forms from Ayurvedic system.
2. Preparation of certain formulations used for Aroma therapy formulations
3. Preparation of herbal cosmetic formulation such as lipstick, herbal hair and nail care products
4. Evaluation of herbal tablets and capsules
5. Preparation of sunscreen, skin care formulations.
6. Preparation and evaluation of any two of each hair care and skin care products
7. Preparation and evaluation of poly herbal formulation face cream.
8. Preparation and evaluation of single herbal formulation face cream.
9. Preparation and evaluation of herbal ointments
10. Preparation and evaluation of herbal shampoos

PHARMACEUTICAL CHEMISTRY

MODERNPHARMACEUTICALANALYTICALTECHNIQUES (MPC101T)

THEORY **60Hours**

Scope: The appreciable knowledge will be gained by the students in the Modern AnalyticalTechniquesandcanapplythetheoriesintheAnalysisofvariousbulkdrugsandtheirformulations. The students will also be in a position to apply their knowledge in developing thenewmethods forthedeterminationandvalidatetheprocedures.

Objectives: The course is designed toimpart the knowledgein differentanalytical techniqueslike UV-Visible, IR, GC, HPLC etc so that it can be used in the analysis of bulk drugs andformulations.

UNITI **12Hours**

Introduction to chromatography and classification of chromatographic methods based on themechanismofseparation

A. Column Chromatography: Adsortion and partition, materials used for separation, solventsystem, procedureand method ofdetection. Theory, principles involved inseparation, apparatus,column materials, number of theoretical plates, elution, method of detection. Modifications likeVLC,Flash,MPLC,theiradvantage overopencolumnCC.

B. PaperChromatography: Theory,differenttechniquesemployed,filterpapersused,qualitative andquantitativedetection

UNITII **12Hours**

A. ThinLayerChromatography: Theory,principlesofseparation,apparatus,coatingmaterials, spotting, solvent systems, detection, Uses ofTLC: Finding the number ofcompounds;the class of compounds; Testing for purity/ detection of impurities; identifying compounds-Co-TLC,MixedTLC;isolatingcompounds inapureform-preparativeTLC;TwodimensionalTLC.

B. HPTLC: Theoryandprinciple,instrumentation,elutiontechniquesandpharmaceuticalapplications

C. Acomparativestudy;howisHPTLCisdifferentfromTLC,apparatus;Coatingmaterials-particle size;detection;uses.

UNITII **12Hours**

a. GasChromatography: Introduction,fundamentals,instrumentation,columns:preparation andoperation,detection;derivatization.

b. HPLCandUPLC: Principlesandinstrumentation,solventsandcolumnsusedOperationalmodes,detectionandapplications.

UNITIII **12Hours**

A. Electrophoresis:Principle,Instrumentation,Workingconditions,factors affectingseparation andapplications ofthefollowing:a) Paperelectrophoresisb)Gelelectrophoresisc)Capillary electrophoresis d)Zoneelectrophorese)Moving boundaryelectrophoresisf)Isoelectricfocusing

B. XrayCrystallography: ProductionofXrays,DifferentXraymethods,Bragg'slaw,Rotatingcrystaltech nique,Xraypowdertechnique,TypesofcrystalsandapplicationsofX-raydiffraction.

UNITIV **12Hours**

A. UV-Visiblespectroscopy: Theoryandinstrumentationinbrief.Chromophore;Auxochrome;Types of electronic transitions; Solvent effects; Quantitative estimation of Riboflavin,Paracetamol,Diclofenac,Metronidazole,Aspirin..

B.IRspectroscopy: Theory,ModesofMolecularvibrations,Samplehandling,InstrumentationofDisp ersiveandFourier – TransformIRSpectrometer,Factorsaffectingvibrationalfrequencies,Quantitative estimationofAPIsusingIRspectroscopy.

UNITV **12Hours**

A. Spectroflourimetry:TheoryofFluorescence,Factorsaffectingfluorescence,Quenchers, InstrumentationandApplicationsoffluorescence spectrophotometer.

B. FlameemissionspectroscopyandAtomicabsorptionspectroscopy: Principle, Instrumentation,InterferencesandApplications.

REFERENCES

1. SpectrometricIdentificationofOrganiccompounds-RobertMSilverstein,Sixthedition,JohnWiley&Sons,2004.
2. PrinciplesofInstrumentalAnalysis-DoglasASkoog,F.JamesHoller,TimothyA.Nieman, 5thedition,Easternpress,Bangalore,1998.
3. Instrumentalmethodsofanalysis–Willards,7thedition,CBSpublishers.
4. PracticalPharmaceuticalChemistry–BeckettandStenlake,VolII,4th edition,CBSPublishers,NewDelhi,1997.
5. OrganicSpectroscopy-WilliamKemp,3rdedition,ELBS,1991.
6. QuantitativeAnalysisofDrugsinPharmaceuticalformulation-PDSethi,3rdEdition,CBSPublishers,NewDelhi,1997.
7. PharmaceuticalAnalysis-ModernMethods–PartB-JWMunson,Vol11,Marcel.DekkerSeries
8. SpectroscopyofOrganicCompounds,2ndedn.,P.S/Kalsi,WileyesternLtd.,Delhi.
9. TextbookofPharmaceuticalAnalysis,KA.Connors,3rdEdition,JohnWiley&Sons,1982.

ADVANCED ORGANIC CHEMISTRY–I (MPC102T)

THEORY **60Hours**

Scope: Subjectisdesignedtoprovidein-depthknowledgeaboutadvancesinorganicchemistry,differenttechniquesoforganicsynthesisand their applicationsto processchemistryaswellasdrugdiscovery.

Objectives:

Theaimofthecourseistoimpartknowledgetothestudentsof:

- Nucleophilicaliphaticsubstitution,
- lectrophilicaromaticsubstitution
- Eliminationreaction,theirmechanismandapplications.
- Knowledgeofsomenamedorganicreactions,syntheticreagentsandtheirapplication willbeimparted.
- Anotherimportantobjectiveofthecourseistointroducethestudenttothechemistryof heterocycliccompoundsasdrugs,byandlarge,haveheterocyclicrings.
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Unit-I

Nucleophilicaliphaticsubstitution: **12Hours**

$S_N1$and$S_N2$reactions;mechanismandkinetics;structureandreactivity;stereochemistry;SN1VsSN2;r oleofsolvent;substitutionVselimination;necleophilicsubstitution–alkylhalidesVsalcohols; SN1 and rearrangement; stability of carbocations, carbanions, free radicals, carbenesandnitrenes:Theirmethodofformationandsynthetic applications.

Unit-II **10Hours**

Electrophilicaromaticsubstitution:reactions;mechanism;proofforthemechanism;sulfonation – a reversible reaction; theory of reactivity; theory of orientation; orientation andsynthesis.

Unit-III **10Hours**

Elimination reactions: E1 and E2 mechanisms of alkyl halides and alcohols; evidence; E1 VsE2;elimination Vssubstitution;1,1and1,2-elimination;E1CB;Saytzeff'srule;Hofmannrule/elimination;stereochemistryofE2reactions;elimin ationfromalicyclic compounds.

Unit-IV **14Hours**

a) **Study of mechanism and synthetic applications of following named Reactions**:Ugireaction, Diekmann reaction, Sandmeyer reaction, Mannich reaction, Vilsmeyer-Haackreaction,Beckmannrearrangement,Friesrearrangement,Phillip'scondensationandMic haeladditionreaction.

b) SyntheticReagents&Applications:

Aluminiumisopropoxide,N-bromosuccinamide,diazomethane,dicyclohexylcarbodimide,Wittingreagent,Osmiumtetroxide,die thylazodicarboxylate,Triphenylphosphine,Lithiumaluminiumhydride, Sodiumborohydride, DCC(N,N-diacylohexylcarbodiamide)reagent.

Unit-V **14Hours**

A.Heterocylicchemistry: Structuresofheterocylic compounds;aromaticandnonaromaticheterocylces;nomenclature;

B.Five-membered ring compounds with one heteroatom: Pyrroles, Furans and Thiophenes;Aromaticity;acidity;basicity; twosyntheticmethodsforeach class; reactions; electrophillicsubstitution; reactions with acids, carbenes, nitrenes; oxidizing and reducing agents; Diels-Alderreaction;photochemicalreactions;alkylationofpyroles;metalationoffurans;reactionsofthiophe neswithnucleophiles.Comparethe reactivityofPyrroles,Furansand Thiophenes.

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C. Six-memberedheterocyclicringcompoundswithoneheteroatom: Pyridines:nomenclature; physical and spectroscopic properties; tautomerism; synthetic methods; chemicalreactions–withacids,electrophilicandnucleophilicsubstitution,Diels-Alderreactions,quaternization, reaction with oxidizing and reducing agents; hetaryne formation; ring openingreactions;reactionswithfreeradicals;photochemicalreactions;theClaisenrearrangement;der ivatives of pyridine – alkyl and aryl pryidinesl halopyridines, aminopyridines, pyridine N-oxide,hydroxypyridines,pyridine aldhydesandketones

D.Synthesisofheterocycliccompounds:

Twomethodsofsynthesisandreactionsofthefollowingheterocyliccompoundsortheirderivatives; a) quinolines b) isoquinolines c) indoles d) pridazines e) pyrimidines f) pyrazines g)thiazolesh)imidazolesi)oxazoles

REFERENCES

1. "AdvancedOrganicchemistry,Reaction,MechanismsandStructure",J.March,John WileyandSons,NewYork.
2. "MechanismandStructureinOrganicChemistry",ESGould,HoldRinchartand Winston,NewYork.
3. "OrganicChemistry"Clayden,Greeves,WarrenandWoihers.,OxfordUniversityPress 2001.
4. "OrganicChemistry"VolIandII.I.L.Finar.ELBS,PearsonEducationLts,Dorling KindersleyIndiaPvt.Ltd.
5. AguidetomechanismsinOrganicChemistry,PeterSkyes(OrientLongman,New Delhi).
6. ReactiveIntermediatesinOrganicChemistry,TandomandGowel,Oxford&IBH Publishers.
7. PrinciplesofOrganicSynthesis,ROCNormanandJMCoxan,NelsonThorns.
8. OrganicSynthesis-SpecialTechniques.VKAhluwaliaandRAgarwal,Narosa Publishers.
9. OrganicReactionMechanismsIVthEdtn,VKAhluwaliaandRKParashar,Narosa Publishers.
10. HeterocyclicChemistry–J.A.Joule,K.MillsandG.F.Smith3rdEdition,CRCpress.
11. HeterocyclicChemistry–ThomasL.Gilchrist,3rdEdition,Pearsonpublications
12. HeterocyclicChemistry–RajK.Bansal,7thEdition,NewageInternationalPublishers.

ADVANCED MEDICINAL CHEMISTRY(MPC103T)

THEORY **60Hrs**

Scope:
Thesubjectisdesignedtoimpart knowledgeaboutrecent advancesinthefieldofmedicinalchemistryatthemolecularlevelincludingdifferenttechniquesforthe rationaldrugdesign.**Objective:**
Theobjectiveofthecourseistoimpartknowledgein

- Drugdiscovery
- Roleofmedicinalchemistryindrugresearch
- Differenttechniquesfordrugdiscovery
- Variousstrategiestodesignanddevelopnewdruglikemoleculesforbiologicaltargets
- Thecourseisalsoimpartsknowledgeabout different classesofdrugs,theirorigin,mechanismofaction,use,toxicityetc.

Unit-I **12Hours**

Abriefreviewofthefollowingtopics:

a. SourcesOfNewDrugs;
b. LeadsFromNaturalProducts;
c. MolecularModifications;
d. RandomScreening;
e. HighThroughtPutScreening;
f. InsilicoScreening;
g. StructuralFeaturesAndPharmacologicalAcivity;
h. Prodrugs;
i. SoftDrugs;
j. Isosterism

Unit-II **12Hours**

Anaccountoftheiroriginanddevelopment,classification,structures,mechanismofaction,SAR, usesandtoxicityof:

a. Analgesics(non-opioid)andantipyretics
b. Non-steroidalanti-inflammatoryagents
c. SynnthesisofParacetamol,Ibuprofen,Aceclofenac
d. Antidiabeticagents
e. SynnthesisofTolbutamide,Chlopropamide,Glipizide,Glimepride,Metformin
d.Screeningmethodsoftheseclasses

Unit-III **12Hours**

Anaccountoftheiroriginanddevelopment,classification,structures,mechanismofaction, SAR,usesandtoxicityof:

a. β-Adrenergicblockers
b. ACEinhibitors
c. Diuretics
d. Synthesis of Propranolol, Hydralazine, Minoxidil, Captopril, Lisinopril, Furosemide,Hydrochlorthiazide
e. H_1-receptorantagonists
f. H_2-receptorantagonists
g. Gastric-ProtonPumpInhibitors
h. SynthesisofLevocitrizine,Ranitidine,Omeprazole
i. Screeningmethodsoftheseclasses

Unit-IV **12Hours**

Anaccountoftheiroriginanddevelopment,classification,structures,mechanismofaction, SAR,usesandtoxicityof:

a. Anthihyperlipidemicagents
b. Phosphodiesteraseinhibitors
c. Quinoloneantibacterialagents.
d. Screeningmethodsoftheseclasses

Unit-V **12Hours**

Anaccountoftheiroriginanddevelopment,classification,structures,mechanismofaction, SAR,usesandtoxicity:

a. Anticanceragents
b. Antiviralagents
c. Immunosupressantsandimmunostimulatns
d. SynthesisofChlorambucil,Methotrexate,Stavudine
e. Screeningmethodsoftheseclasses

BooksRecommended:

1. Textbook of Wilson andGisvolds organicmedicinal andpharmaceutical by CharlesOwens Wilon, 12th edition , 2010, publisher: Lippincott Williams & Wilkins .Foye'sprinciplesofmedicinalchemistry
2. Burger'smedicinalchemistryanddrugdiscovery
3. Organicchemistryofsyntheticdrugs–Lednier
4. Screeningmethodsinpharmacology–RobertA.Turner.
5. DrugEvaluation–Vogel.
6. EvaluationofDrugActivities–LawrenceandBachrach.
7. MethodsinPharmacology–Swarbrick.
8. MedicinalChemistry-SurendranathPandeya,VolumeIandVolumeII
9. MedicinalChemistry-Ashutoshkar,NewAgeInternationalPublications
10. Pharmacopoeias

CHEMISTRYOFNATURALPRODUCTS(MPC104T)

THEORY **60Hrs**

Scope:
The subject is designed to provide a detailed knowledge about chemistry, biological activity,mechanism of action, SAR, toxicity, and use of medicinal compounds of natural origin, theirsemisynthetic derivatives and development of clinically used drugs taking natural products asleads.

Objectives:
Theobjectivesofthiscoursearetoimpartknowledgetostudentsof:

- Differenttypesofnaturalcompounds,theirchemistryandmedicinalimportance.
- Hownaturalcompoundsactasdrugsperseandasleadmoleculesindrugdiscovery.
- Howstructuresareimportantforbiologicalactivityandhowachangeinstructureaffects biologicalactivity.
- Howbiotechnologyiscontributingtothedevelopmentofpharmaceuticalsofnatural origin.

UNIT-I **10Hrs**

(a) **Naturalproductsasleadsindrugdiscoveryanddevelopment:**Hownaturalproductsactedaslead moleculesindrugdiscoveryanddevelopmentwithemphasisonthesourceofthe naturalcompound, history/origin, how synthetic drugs were devoloped from them .From:

a. Salicintoaspirin
b. Quininetoantimalarials
c. Cocainetolocalanaesthetics
d. Curarealkaloidstoneuromuscularblockingdrugs.
e. Fungalmetabolitestomodernstatins
f. Snakevenomtoantihypertensives

(b) RecombinantDNAtechnologyanddrugdiscovery.

UNIT-II **10Hrs**

a. **Alkaloidsofopium:**Structureofmorphine;peripheralgroups;
modification in pheripheralgroups and effect on analgesic / biologic activity; relative potencies;opioidreceptors;endorphins andenkephalins.

b. **Ring analogues of morphine;**morphinans-levorphanol and butorphanol; benzomorphans-pentazocineandphenazociane;aminotetralins-dezocine;4-phenylpiperidines-meperidine(pethidine);4-Anilidopiperidinesorthefentanylgroup-fentanyl,alfentanyl,sufentanyl,remifentanil, lofentanil; diphenylheptanone derivatives-methadone; structures; receptoraffinities;relative potencies;advantages ofthesecompounds;structuraldifference
between4-phenyland4-anilidopiperidines.

c. **Opioidantidiarrheals**-Howstructuralmodificationof4-phenylpiperidinesandmethadoneledtothediscoveryofdiphenoxylateandloperamidestructures.Mode ofaction;usage;metabolism

ofdiphenoxylate;diphenoxin;combinationwithatropine;bindingofthesecompounds toopioidreceptor;abusepotential;use.

d. Antitissueagents(opioid)

Studyofcodeine,hydrocodonehydromorphone,noscapine, dextromethorphan, levopropoxyphene, pholcodine. Their structures, relative advantages, uses.Relationshipbetweenlevorphanolanddextromethorphan;betweenlevopropoxypheneandmethadone.

e. **Morphineantagonists-**Nalorphine,levallorphan,naloxone,naltrexone,nalmefene,cyclazocine. Structures; a comparative study of the structures of levorphanol and levallorphan,oxymorphone,naloxoneandnaltrexone,cyclazocineandpentazocine;receptoraffinities; relativeadvantages,uses.

UNIT-III **10Hours**

Anticanceragentsofnaturalorigin:

a. Anticanceragentsofplantorigin:Source;structures;descriptionofthestructuralfeatures; SAR;semisynthetic derivatives;mechanismofaction;toxicity;anduses of:

(1) Vincristineandvinblastine
(2) Podophyllotoxin
(3) Taxol
(4) Camptothecin

(b) Anticancerantibiotics:source;structures;descriptionsofthestructuralfeatures;mechanismofaction;SAR;andusesofthefollowingantibiotics :

(1) Dactinomycin
(2) Daunorubicin,doxorubicin(adriamycin),idarubicin;metabolismofdaunorubicinand doxorubicin; analogous of doxorubicin - esorubicin,epirubicin,pirarubicin,valrubicin.
(3) Abriefaccountofnogalamycin,menogaril,mithramycin,mitomycins,streptozocin

(c) Anticanceragentsfrommarineorganisms:bryostatin,dolostatin.

UnitIV **20Hours**

Steroids:

(a) **Definition**;numberingthecarbonsandlabellingtherings;somebasicsteroidskeleta;nomenclature; sterochemistry; chemical and physical properties of steroids; changes to modifypharmacokineticsproperties ofsteroids.

(b) **Sources of steroid drugs:** source and structures of cholesterol, ergosterol, stigmasterol anddiosgenin,historyofdevelopmentofsteroidindustry.Marker'ssynthesis.

(c) **Steroidalantiinflammatoryagents:**structures;SAR;routesof administration;mainpharmacologiceffects-immuno-suppression,anti-allergicandantiinflammatory; therapeutic users; toxicity; contraindications; esters and salts of corticoids andtheir formulation suitability. A detailed study of the following classes with additionalinformationindicated.

(i) **Systemicglucocorticoids**: list of compounds and their derivatives; classification;interconversion of cortisone and hydrocortisone; prednisone and prednisolone; rationale behinddevelopment of so many glucocorticoids; effect of substituent groups on glucocorticoid /mineralocorticoidactivity;relative potencies;derivatives;formulation.

(ii) **Topical glucocorticoids**; systemic absorption; determining relative potency; classification;compoundsused;formulations;the21-chlorocorticoids;non-fluorinatedcompounds;theirrelationtoknowncorticoids;metabolismofprednicarbate anditslowsystemic side effects.

(iii) **Inhaled and intranasalglucocorticoids**:pharmacokineticsproperties/qualitiesdesirableforthese compounds; modification of pharmacokinetics through modification of structures and itsconsequences;specialqualitiesofthenewinhaledandintranasalglucocorticoids;characteristicsof inhaledglucocorticoidsusedinasthma and allergic rhinitis; namesofinhalers.

(iv) **Ophthalmicglucocorticoids**:Differenceinstructurebetweenophthalmicandother glucocorticoids.

(d) **Steroidalantifertilityagents:**History;estrogens;pregnaneprogestins;androstanes;importance s of ethisterone; development of 19-norandrostanes; structures; mechanism of action;role of estrogens; regimens; toxicity; metabolism of desogestrel and norgestimate; androgenicactivity; uses of medroxyprogesterone, norethindrone, magestrol acetate. Progestinantagonists.Steroidreceptors-newinsights.

(e) **Anabolicsteroids:**Rationalefordevelopment;19-norandrogens (19-nortestosteronederivatives);androstanes;oxasteroids;heterocyclicringfusedcompounds;experimentalcompounds;structures;therapeutic uses;sideeffects.

(f) **Steroidsinthetreatmentofcancers:**Estrogens;antiestrogens;aromataseinhibitors;progestins; progestin antagonists; androgens and anabolic steroids; antiandrogens; 5α-reductaseinhibitors;gonadotropininhibitors;glucocorticoids.

UNITV **10Hours**

Cephalosporins:

Historicalbackground;classification;structures;numberingtheringsystem;nomenclature;degradation; spectrum of activity; SAR; β-lactamase resistance; antipseudomonalcephalosporins;mechanismofaction;uses;toxicity;developmentofnew cephalosporins-recentadvances;prodrugsincephalosporins;penicillinsVscephalosporins-acomparative account of the structural features and biological activity; β-lactamase inhibitors;mechanismofβ-lactamaseinhibition;monobactams.

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1. TextbookofWilsonand GisvoldsorganicmedicinalandpharmaceuticalbyCharlesOwensWilon,12thedition,2010,publisher:LippincottWilliams&Wilkins.
2. Foyesprinciplesofmedicinalchemistry,7theditionbyLemke, ThomasL,8thedition,2019,LippincottWilliams&Wilkins.
3. Burgersmedicinalchemistry,drugdiscoveryanddevelopmentbyDonaldJ.Abraham, 8volumes,8th edition,2021.
4. OrganicChemistryOfNaturalProducts,volumes1&2,GurdeepChatwal,Himalayapublishinghouse.
5. Organicchemistryofnaturalproducts,volumes1&2,O.P.Agarwal.
6. Organicchemistry,volume2,I.L.Finar,5thedition,1975.
7. Elementsofbiotechnology,P.K.Gupta, Rastogipublishers.
8. Pharmaceuticalbiotechnology,S.P.Vyas&V.K.Dikshit,CBSPublishers.

CHEMISTRYOFNATURALPRODUCTS(MPC105P)

1. Isolationandpurificationofsomeofthefollowingnaturalproducts.
    a. Piperinefromblackpepper
    b. StrychnineandBrucinefromStrychnosnuxvomicaseeds
    c. CaffeinefromTeaPowder
    d. CurcuminfromTurmeric
    e. BixinfromBixaorellanaseeds
    f. DiosgeninfromDiascoriatubers
    g. SennosidesfromSennaleaves
    h. EmbelinfromEmblicaribesfruits

2. The use ofcolumn, flash and cuumliquidchrmatographiesforisolatingsomeoftheabovementionedphytoconstituents

3.

1. IdentificationofalkaloidsinmixturebyTLC.
2. PreparativeTLCforseparationandisolation of alkaloids
3. Identificationofphytoconstituentslikealkaloids,steroids, flavanoidsetcinplantextractsbyTLC.
4. Separationofsugars/aminoacidsbypaperchromatography.
5. SeparationofcompoundsbyHPLC
6. Analysisofrecordedspectraofsomesimpleorganiccompounds.
7. Teststodetectalkaloids,steroids,flavanoidsandtheirglycosides.

BooksRecommended:

1. Naturalproducts,alaboratoryguide–RephaelIkan.
2. Laboratoryhandbookforthefractionofnaturalextracts– PeterJ.Houghton&AmalaRaman.
3. AnAtlasofTLC–H.Wagner.

ADVANCEDMEDICINALCHEMISTRY–I(MPC106P)

1. Synthesis,purificationandidentificationsomeofthe

followingdrugs.a)Sulfanilmideb)Uracilc)Phenytoind)Ibuprofene)para-

Aminosalicylicacid(PAS)f)Paracetamol
g)Atenolol(h)proranolol.i)Benzocaine

2. Screeningforthefollowingactivities

. CNS–RotarodexperimentCatatoniatesting
. Experimentsonisolatedtissues–Testingforanti-histaminicandanti-cholinergicactivities.
. Localanestheticactivity.

3. Spectralanalysis:

. Spectratoberecordedforsomecompoundsandanalyzed.
. Analysisofpre-recordedspectra.

BooksRecommended:
PracticalOrganicChemistry–Vogel.

Organicchemistryofsyntheticdrugs–Lednicer.

SEMESTER-II

Spectroscopic Identification of Organic Compounds

(MPC201T)THEORY **60Hours**

Objective:

StudentsofM.Pharm,Pharmaceutical/MedicinalChemistrybranchcarry outresearchinIIIandIVsemesters.Theysynthesizeorganiccompoundsorisolatenaturalcompoundsand screenthemforbiological activity.Theyhavetocharacterizethecompounds.Thishelpsinidentifyingorganiccompoundsbyspectroscopicmeans.Theaimofthiscourseistotrainthestudentinthespectroscopic techniques so that he will be able to interpret different spectra andelucidate/confirmthestructureofcompoundshehasisolated/synthesized.Therefore,theemphasiswhileteachingthesubjectshouldbeontheapplicationsofthetechniques.Adetailedstudy ofapplicationsofthefollowingspectroscopictechniquesinthedeterminationofstructureofthefollowing classesofcompoundswiththehelpofsimpleexamplesistobetaught.(i)Alkanesandcycloalkanes(ii)Alkenesandalkynes(iii)Aldehydesandketones(iv)Alcoholsandphenols(v)Carboxylicacidsandderivatives(vi)Aromaticcompoundsandarenes(vii)Amines(viii)Alkylandarylhalides(ix)Simpleheterocyclic compounds.The followingtechniquestobetaught:

UnitI: **10Hours**

- **a. UV Spectroscopy**: Woodward-Fieser rules; Applications of UV-Visible spectroscopy instructuralelucidation;Studyofketo-enoltautomerism;Solvingproblems.**(3-4Hours)**
- **b. IR spectroscopy:** Theory and instrumentation in brief. Molecular vibrations; Factorsinfluencing vibrational frequencies; Sampling techniques; Finger print region; Study ofKeto-enol tautomerism; intra & inter-molecular hydrogen bonding; Studying progress inChemical reactions; geometric and rational isomerism; Conformational analysis; spectralfeaturesofClassesofcompoundsindicatedabove.Solving problems.**(6-7 Hours)**

UnitII:Massspectrometry: **12Hours**

Theoryandinstrumentation.Ionizationtechniques-EI,CI,ESI,FAB,MALDIetc.Highresolution MS; Molecularions; importantfeatures of molecular ion peak; Determination ofmolecular formula; Mc Lafferty rearrangement; Metastable ions or peaks; Isotope peaks, Thenitrogen rule; general fragmentation modes; Fragmentation in the classes of compoundsindicatedabove.Problems andtheirsolution.

UnitIII:^{1}HNMR **10Hours**

Theoryandinstrumentationinbrief.Solvents;Numberofsignalschemicalequivalence,stereochemical equivalence in predicting the number of signals. intensity of signals; Chemicalshift; factors influencing chemical shift; Spin-Spin Coupling; Coupling Constants;long- rangecoupling; Shielding and deshielding; Magnetic anisotropy; Protons on oxygen and nitrogen;Protonexchange;NMRspectraoftheclassesofcompoundsindicatedabove.Problemsandtheirsolution.

UnitIV:^{13}CNMR,DEPTand2DNMR **18Hours**

a. Differences between^{1}H and ^{13}C NMR; Chemical shifts and scale; proton-coupled andproton-decoupled^{13}Cspectra;Off-resonancedecoupling;Solvents;Couplingofcarbontodeuterium,fluorineandphosphorus;Spectra of theclassesof compoundsindicatedabove.Problemsandtheirsolution.

b. AnaccountofDEPT. InterpretationofDEPTspectra.

c. Abriefaccountofthefollowing2DNMRtechniques withemphasisontheinterpretation of thespectraandtheiruse.

(a) COSY(b)HETCOR(c)HSQC,HMBC(d)HMBC

Problems and their solution: Students are to be provided with the spectra of simple compoundsand taught their interpretation. How they help in confirming the structural features, the^{1}H and ^{13}CNMRassignments ofcompoundsis tobetaught.

UNITV:Problemsandtheirsolution. **10Hours**

Determination of structures using a combination ofspectra/spectral data. Here the emphasis isonsolvingproblemsthroughinterpretationofdifferentspectraordatalikeUV,IR,Mass,^{1}Hand ^{13} C NMR including 2D-NMR spectra. Simple problems to be worked from books like Pavia,Silverstein, Field etc., mentioned under the "Books recommended" sections, apart from otherbooks.

BooksRecommended:

1. OrganicChemistry-MorrisonandBoyd-alongwiththestudyguide.
2. Spectroscopy-Pavia,Lampman,Kriz,Vyvyan-Publisher:Book/cole,Cengagelearning.
3. Spectroscopicmethodsofidentificationoforganiccompounds-Silverstein,Webster,Kiemle, Bryce.8th edition-Wiley.
4. StructureelucidationbymodernNMR,aworkbook-Duddeck,DetrichandToth.
5. Elementaryorganicspectroscopy-Y.R.Sharma.Publisher:S.Chand.
6. Spectroscopyoforganiccompounds-P.S.Kalsi.Publisher:NewAgeInternational Publisher.
7. Organicstructuresfromspectra-L.D.Field,H.L.Li,A.M.Magill-6thedition-Wiley.
8. Organicstructuresfrom2DNMRspectra-L.D.Field,H.L.Li,A.M.Magill-Published2015-Wiley.
9. Websites

ADVANCEDORGANICCHEMISTRY–II(MPC202T)

THEORY **60Hours**

Objective:

Theaimofthecourseistoimpartknowledgetothestudentof:

- retrosynthesis
- chiralsynthesis
- greenchemistry
- peptidechemistry
- catalysis

.

UnitI: **12Hours**

Synthonapproachandretrosynthesisapplications

i. Basicprinciples,terminologiesandadvantagesofretrosynthesis;guidelinesfordissectionof molecules.
Functionalgroupinterconvertionandaddition(FGIandFGA),chemioselectivity,regioselectivity.

ii. C-Xdisconnections;C-Cdisconnections–alcoholsandcarbonylcompounds;1,2-, 1,3-,1,4-, 1,5-,1,6-difunctionalizedcompounds

iii. Strategiesforsynthesisofthree,four,fiveandsix-memberedring.

UnitII: **12Hours**

Stereochemistryandchiralsynthesis

a.Basicconceptsinstereochemistry–opticalactivity,specificrotation,racematesandresolution ofracemates, the Cahn, Ingold, Prelog (CIP) sequence rule, meso compounds, pseudoasymmetric centres, axes of symmetry, Fischers D and L notation, cis-trans isomerism, E and Znotation.

b. Chiral drug synthesis: Introduction to chiral drugs; importance of stereochemistry in drugaction; concepts of eutomer; distomer and eudesmic ratio, stereospecific and stereoselectivesynthesis;synthesisofchiraldrugslike Ibuprofen,Propranolol,Ramipril,Levofloxacin.

UnitIII **12Hours**

a. Green chemistry: Introduction, Green reagents; ionic solvents; phase transfer catalysis ingreensynthesis;applicationofphasetransfercatalystsingreensynthesisofheterocycliccompounds; Williamson'ssynthesis,Wittingreactions.

b. Microwaveassistedreactions:Meritanddemeritsofitsuse,increasedreactionrates,mechanism,superheatingeffectsofmicrowave,effectsofsolventsinmicrowaveassistedsynthesis, microwave technology in process optimization, its applications in various organicreactionsandheterocycles synthesis

c. Microwaveassistedsynthesis: Introduction;microwavereactionsinwater(Hofmannelimination, hydrolysisandoxidation);microwavereactionsin organicsolvents; solidstatereactions;advantagesofmicrowavetechnique.

UnitIV **12Hours**

a. Chemistryofpeptides:
Definition,C-terminalandN-terminalconcept,endgroupanalysis,Abriefaccountonpharmaceuticalimportanceofpeptides andproteins.
b. Couplingreactionsinpeptidesynthesis
c. Principlesof**s**olidphasepeptidesynthesis,t-BOCandFMOCprotocols,varioussolidsupports and linkers: Activation procedures, peptide bond formation, deprotection and cleavagefrom resin, low and high HF cleavage protocols, formation of free peptides and peptide amides,purificationandcase studies,site-specific chemicalmodificationsofpeptides
d. Segment and sequentialstrategies for solution phase peptide synthesis with any two casestudies

UnitV **12Hours**
Catalysis:
Typesofcatalysis,heterogeneousandhomogenouscatalysis,advantagesanddisadvantages
a. Heterogeneouscatalysis–
Preparation,characterization,kinetics,supportedcatalysts,catalystdeactivation andregeneration,someexamples of heterogeneous catalysisusedinsynthesis ofdrugs.
b. Homogenouscatalysis,hydrogenation,hydroformylation,hydrocyanation,Wilkinsoncatalysts, chiralligandsandchiralinduction,Ziegler-Nattacatalysts,someexamplesofhomogenouscatalysis usedinsynthesis ofdrugs
c. Phasetransfercatalysis-theoryandapplications

REFERENCES

1. "AdvancedOrganicchemistry,Reaction,mechanismsandstructure",JMarch,JohnWileyands ons,NewYork.
2. "Mechanismandstructureinorganicchemistry",ESGould,HoldRinchartand Winston,NewYork.
3. "OrganicChemistry"Clayden,Greeves,WarrenandWoihers.,OxfordUniversityPress 2001.
4. "OrganicChemistry"VolIandII.I.L.Finar.ELBS,Sixthed.,1995.
5. Carey,Organicchemistry,5thedition(VivaBooksPvt.Ltd.)
6. Organicsynthesis-thedisconnectionapproach,S.Warren,WilyIndia
7. Principlesoforganicsynthesis,ROCNormanandJMCoxan,Nelsonthorns
8. Organicsynthesis-SpecialtechniquesVKAhluwaliaandRAggarwal,NarosaPublishers.
9. OrganicreactionmechanismsIVedtn,VKAhluwaliaandRKParashar,NarosaPublishers.
10. TheoryandpracticeofGreenChemistry-PaulTAnastasandJohnC.Warner
11. NewtrendsinGreenChemistry-V.K.AhulwaliaandM.Kidwai
12. ChiroTechnology-RogerA.Sheldon

COMPUTERAIDEDDRUGDESIGN(MPC203T)

THEORY **60Hrs**

Scope:

Thesubjectisdesignedtoimpartknowledgeonthecurrentstateofthearttechniquesinvolvedincomputer assisteddrugdesign.

Objectives:

Atcompletionofthiscourseitisexpectedthatstudentswillbeabletounderstand

- RoleofCADDindrugdiscovery
- DifferentCADDtechniquesandtheirapplications
- Variousstrategiestodesignanddevelopnewdruglikemolecules.
- Workingwithmolecularmodelingsoftwarestodesignnewdrug molecules
- Theinsilicovirtualscreeningprotocols
- Analyzeeffectivityofnew moleculesfrommedicinalchemistryperspective
- Correlatebiologicalresponsesofmoleculeswithdifferentattributes

Unit1.IntroductiontoComputerAidedDrugDesign(CADD) **12Hrs**

History,differenttechniquesandapplications.

Quantitative Structure Activity Relationships: Basics, History and development of QSAR:Physicochemicalparameters:Hydrophobicity(Thepartitioncoefficient(*P*),Thesubstituenthyd rophobicityconstant(π),*P*versusπ);Electroniceffects(TheHammettsubstituentconstant(sigmaσx),an dstericeffects(TaftstericandMRparameters).Methodstocalculatephysicochemicalparameters,withe xamplessuchascalculationoflogPofchlorobenzene,benzamideand*m*-chlorobenzamide:HammettequationExperimentalandtheoreticalapproachesforthe determination ofthese physicochemical parameters explanation for steric and electronic factors and Craig plot andTopliss scheme. Quantitative Structure Activity Relationships(QSAR): ApplicationsHanschanalysis,FreeWilsonanalysisandrelationshipbetweenthem,Advantagesanddisa dvantages;Deriving2D-QSARequations. 3D-QSARapproaches and contourmapanalysis. StatisticalmethodsusedinQSARanalysisandimportanceofstatisticalparameters.

Unit2:PharmacophoreMappingandVirtualScreening **12Hrs**

ConceptofpharmacophoreпharmacophoremappingпidentificationofPharmacophore featuresandPharmacophoremodeling;Conformationalsearchusedinpharmacophoremapping. InSilicoDrugDesignandVirtualScreeningTechniques:SimilaritybasedmethodsandPharmacophoreba sedscreening,structurebasedIn-silicovirtual screeningprotocols.Differentchemicalanddrug databases used invirtualscreening.

Unit3:MolecularModelingandDocking **12Hrs**

a) MolecularandQuantumMechanicsindrugdesign.BriefintroductiontoDFT(DenistyFunctional Theory)

b) EnergyMinimizationMethods:comparisonbetweenglobalminimumconformationandbioactive conformation

c) Molecular docking and drug receptor interactions: Rigid docking, flexible docking and extra-precision docking. Different types of Scoring functions. Agents acting on enzymes such as DHFR,HMG-CoAreductaseand HIV protease, cholineesterase(AchE&BChE)

Unit4:MolecularPropertiesandDrugDesign 12Hrs

a) PredictionandanalysisofADMET(Absorption,Distribution,Metabolism,Excretionand Toxicity)properties of new moleculesanditsimportanceindrugdesign.

b) Denovodrug design:Receptor/enzyme-interactionanditsanalysis,Receptor/enzymecavitysizeprediction,predictingthefunctionalcomponents ofcavities,Fragmentbaseddrugdesign.

c) Homologymodelingandgenerationof3D-structureofprotein. methodsandmathematicalexpressions,Proteinstructurevalidation, activesiteprediction

Unit5:Moleculardynamicsimulation(MDS)studies 12 Hrs Introduction to MDS and software tools employed. Different file formats in GROMACS.Detailedprocess ofprotein inwater and protein-ligand complex inwater MDS. Analysis of MDStrajectories: RMSD(Root Mean Square Deviation),RMSF(Root Mean Square SquareFluctuation),Radiusof GyrationandhydrogenbondanalysisBriefmathematicalconceptofMM-PBSA(MolecularMechanics-Poisson-BoltzmannSurfaceArea)

REFERENCES

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2. IntroductiontoQuantitativeDrugDesignbyY.C.Martin,CRCPress,Taylor&Francisgroup..
3. DrugDesignbyAriensVolume1to10,AcademicPress,1975,ElsevierPublishers.
4. PrinciplesofDrugDesignbySmithandWilliams,CRCPress,Taylor&Francis.
5. TheOrganicChemistryoftheDrugDesignandDrugactionbyRichardB.Silverman,Elsevier Publishers.
6. MedicinalChemistrybyBurger,WileyPublishingCo.
7. Justin A. Lemkul. FromProteins to Perturbed Hamiltonians: A Suite of Tutorials for the GROMACS-2018 Molecular. Simulation Package [Article v1.0]. Living J. Comp. Mol. Sci. 2019, 1(1), 5068.https://doi.org/10.33011/livecoms.1.1.5068(MDS)8.https://doi.org/10.3390/pr9010071OutiM.H.Salo-Ahen, Ida Alanko, et al., Molecular Dynamics Simulations in Drug Discovery and PharmaceuticalDevelopment.Development.Processes2021,9,71.https://doi.org/10.3390/pr9010071
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10. ComputationalMedicinalChemistryfor DrugDiscovery. EditedByPatrickBultinck, HansDeWinterWilfriedLangenaeker,JanP.Tollenaere
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13. SamuelGenheden& UlfRyde(2015)TheMM/PBSAandMM/GBSAmethods to estimateligand-binding affinities, Expert Opinion on Drug Discovery, 10:5, 449-461, DOI:10.1517/17460441.2015.1032936

ADVANCEDMEDICINALCHEMISTRY-II(MPC204T)

THEORY **60Hours**

Scope

Thesubjectisdesignedtoimpart knowledgeaboutrecentadvancesinthefieldofmedicinalchemistryat themolecularlevelincludingdifferenttechniquesfortherationaldrugdesign**.Objective:**

Theobjectiveofthecourseistoimpartanin-depthknowledgeofsyntheticdrugsbelongingtodifferentclasses,theirorigin,mechanismofaction,SAR,use andtoxicity.

UnitI: **12Hours**

Psychopharmacologicalagents: Biochemical basis of mentaldisorders;abnormalprotein factors;endogenous amines and related substances; faulty energy metabolism; genetic disorders andnutritional disorders; phenothiazines – chemistry; synthesis. Screening methods;pharmacologicalactions;SAR;mechanismofaction;uses;toxicity;ringanaloguesofphenothiazines;fluorobutyrophenones;Developmentofatypicalantipsychotics.ofChlorpromazine,Prochlorperazine,Fluphenazine,Haloperidol.

UnitII: **12Hours**

AnxiolyticsSedativesAndHypnotics:Screeningmethods;Benzodiazepinesandrelatedcompounds; barbiturates; other classes; mechanism of acition, SAR; uses and toxicity SynthesisofChlordiazepoxide,Diazepam,Alprazolam,Phenobarbital,Meprobamate**.**

UnitIII: **12Hours**

Antidepressants: MAOinhibitors; tricylic antidepressants; SAR; mechanism of action; uses;toxicityotherclasseslike:selectiveserotoninreuptakeinhibitors,selective5-HTandNEreuptake inhibitors;selectiveserotoninergicreuptake inhibitorsand5-HT2Aantagonists;5-HT1Aagonistsandpartialagonistsandα2-antagonists.SyntheisofTranycypromine,Amitriptyline,Fluoxetine,Buspirone**.**

UnitIV: **12Hours**

Antiepileptics&CNSstimulants:

a. Antiepileptics:Screeningmethods;classification ofepilepsies;symptoms;drugsused;classification; structural feactuers common to drugs; SAR; mechanism of action; toxicity anduses;synthesis ofDiphenylhydantion,Carbamazepine,SodiumValproate.

b.CNSstimulants:anaccountofthedrugswithCNSstimulantactivity;structuresanduses.

UnitV: **12Hours**

RationalDesignofEnzymeInhibitors

Enzyme kinetics & Principles of Enzyme inhibitors, Enzyme inhibitors in medicine, Enzymeinhibitors in basic research, rational design of non-covalently and covalently binding enzymeinhibitors**.**

BooksRecommended:

1. WilsonandGisvold'stextbookofpharmaceuticalorganicmedicinalchemistry.
2. Foye'sprinciplesofmedicinalchemistry.
3. Burger'stextbookofmedicinalchemistry
4. Organicchemistryofsyntheticdrugs–Lednicer.
5. Screeningmethodsinpharmacology–RobertA.Turner.
6. DrugEvaluation–Vogel.
7. EvaluationofDrugActivities–LawrenceandBachrach.
8. MethodsinPharmacology–Swarbrick.
9. MedicinalChemistry-SurendranathPandeya,VolumeIandVolumeII
10. MedicinalChemistry-Ashutoshkar,NewAgeInternationalPublications
11. Pharmacopoeias

ADVANCEDORGANICCHEMISTRY–I(MPC205P)

Someofthefollowingexperimentstobetaught.

1. BasicTechniques:

a) Calibrationofthermometerandfindingmeltingpoint,mixedmeltingpointandboilingpoint.
b) Purificationanddryingoforganicsolvents
c) Crystallization
d) Distillation,FractionalDistillation,Distillationunderreducedpressure

2. Separationandidentificationoforganiccompoundsfrombinarymixtures:

Solid-solid,solid-liquidandliquid-liquid–atleastonemixtureofeachcategorytobedone.

3. Synthesisofsomeofthefollowingheterocycliccompounds:

a)Quinolineb)benzimidazole/derivativec)flavone/chromoned)indole/derivativee)phenothiazinef) oxazole/oxazolone g)benzoxazole h)3,5 dimethylisoxazole

4. Someofthefollowingreactions:

1. Beckmann rearrangement 2) Fries rearrangement 3) Acetylation, methylation 4) Metal/acidreductions 5) Oppenauer oxidation 6) Friedel-Craafts alkylation & Acylation 7) Nitration usingdifferentreagents

BooksRecommended:

PracticalOrganicChemistry–Vogel.

ADVNCEDMEDICINALCHEMISTRY(MPC206P)

1. Synthesis,purificationandidentificationofsomeofthefollowingdrugs;
    a) Dapsone
    b) Benzocaine
    c) Hydralazine
    d) Imipramine
    e) Sufadiazine

2. Synthesisusingmicrowaveoven:oneexperimenttobeconducted
3. Screeningforthefollowingactivities:
    a) Analgesicactivity
    b) Antiinflammatoryactivity
    c) Acutetoxicitystudies
    d) Antibacterialandantifungalactivity
    e) Freeradicalscavengingandanti-oxidantactivities

4. SpectralanalysisSpectratoberecordedforsomecomp
oundsandanalyzed.Analysis ofpre-recordedspectra
2.Impurityprofilingforoneortwosa

BooksRecommended:

1. PracticalOrganicChemistry–Vogel.
2. Organicchemistryofsyntheticdrugs–Lednicer.

PHARMACEUTICALANALYSIS

.MODERNPHARMACEUTICALANALYTICALTECHNIQUES(MPA101T)

THEORY **10 Hours**

Scope: The appreciable knowledge will be gained by the students in the Modern Analytical Techniques and can apply the theories in the Analysis of various bulk drugs and their formulations. The students will also be in a position to apply their knowledge in developing the new methods for the determination and validate the procedures.

Objectives: The course is designed to impart the knowledge in different analytical techniques like UV-Visible, IR, GC, HPLC etc so that it can be used in the analysis of bulk drugs and formulations.

UNIT I **12Hours**

Introduction to chromatography and classification of chromatographic methods based on the mechanism of separation

A. Column Chromatography: Adsorption and partition, materials used for separation, solvent system, procedure and method of detection. Theory, principles involved in separation, apparatus, column materials, number of theoretical plates, elution, method of detection. Modifications like VLC, Flash, MPLC, their advantage over open column CC.

B. Paper Chromatography: Theory, different techniques employed, filter papers used, qualitative and quantitative detection

UNIT II **12Hours**

A. Thin Layer Chromatography: Theory, principles of separation, apparatus, coating materials, spotting, solvent systems, detection, Uses of TLC: Finding the number of compounds; the class of compounds; Testing for purity/ detection of impurities; identifying compounds-Co-TLC, Mixed TLC; isolating compounds in a pure form-preparative TLC; Two dimensional TLC.

B. HPTLC: Theory and principle, instrumentation, elution techniques and pharmaceutical applications

C. A comparative study; how is HPTLC is different from TLC, apparatus; Coating materials-particle size; detection; uses.

UNIT II **12Hours**

a. Gas Chromatography: Introduction, fundamentals, instrumentation, columns: preparation and operation, detection; derivatization.

b. HPLC and UPLC: Principles and instrumentation, solvents and columns used, Operational modes, detection and applications.

UNIT III **12Hours**

A. Electrophoresis:Principle,Instrumentation,Workingconditions,factors affectingseparation and applications ofthefollowing:a) Paperelectrophoresisb)Gelelectrophoresisc)Capillary electrophoresis d) Zone electrophores e) Moving boundaryelectrophoresis f)Isoelectricfocus

B.X-rayCrystallography: Production of X rays, Different X raymethods, Bragg's law, Rotating crystal technique, X ray powdertechnique,Typesof crystalsandapplicationsofX-raydiffraction.

UNIT IV **12Hours**

A.UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect; Quantitative estimation of Riboflavin, Paracetamol, Diclofenac, Metronidazole,Aspirin..

B.IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies, Quantitative estimation of APIs using IR spectroscopy.

UNIT V **12Hours**

A. Spectro flourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

B. Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein,Sixth edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1996. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi, 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis - Modern Methods – Part B - J W Munson, Vol 11, Marcel. Dekker Series
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley estern Ltd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley & Sons, 1982.

ADVANCED PHARMACEUTICAL ANALYSIS-I (MPA 102T)

THEORY **60 Hrs**

Scope: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to differentcategories are discussed in detail. The applications of the important reagents like MBTH, FC, PDAB, 2, 3, 5 - triPhenyltetrazolium salt , . 2,6 di -ChloroquinoneChlorimide ,N - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent), Carr price reagent etc. in the determination of the pharmaceuticals are also discussed.

Objective: The quantitative determination of various organic compounds is clearly understood. The spectral analysis, dissolution parameters and microbial assays are also learned.

UNIT I **12Hours**

a. Impurityandstabilitystudies:

Definition, classification of impurities in drug Substance or ActivePharmaceutical Ingredients and quantification of impurities as perICHguidelines

b.Impuritiesinnewdrugproducts:

Rationale for the reporting and control of degradation products,reportingdegradationproductscontentofbatches,listingofdegradation productsin specifications, qualificationof degradationproducts

c. Impuritiesinresidualsolvents:

General principles,classification of residualsolvents, Analyticalprocedures,limits of residualsolvents, reporting levels of residualsolvents

UNIT II **12Hours**

A. Principles and procedures involved in the determination of the official compounds in IP with the following analytical techniques

- A. Non-aqueous
- B. Oxidation-reduction
- C. Complexometric
- D. Diazotization methods
- E. Neutralization
- F. Acid – Base

B.A detailed study of the principles and procedures involved in the quantitative determination of the following organic functional groups

- A. Amines
- B. Esters
- C. Carbonyl compounds
- D. Hydroxy and carboxyl
- E. Amino Acids

UNIT III **12Hours**

Principles and procedures involved in using the following reagents in the determination of pharmaceutical dosage forms official in IP

a. MBTH (3-methyl-2-benzothiazolone hydrazone)

b. F.C. Reagent (Folin-Ciocalteu)
c. PDAB (para-Dimethyl Amino Benzaldehyde)
d. 2, 3, 5 - triPhenyltetrazolium salt
e. 2,6 di -ChloroquinoneChlorimide
f. N - (1-naphthyl) ethylenediaminedihydrochloride (B.M. Reagent)
g. Carr – Price Reagent
h. 2,4 – DNP

UNIT – IV **12Hours**

Elemental impurities: Element classification, control of elemental impurities, Potential Sources of elemental Impurities, Identification of Potential Elemental Impurities, analytical procedures, instrumentation & C, H, N and S analysis.

UNIT-V **12Hours**

a.Biological tests and assays of the following:

a. Adsorbed Tetanus vaccine
b. Adsorbed Diphtheria vaccine
c. Human anti haemophilic vaccine
d. Rabies vaccine
e. Tetanus Anti toxin
f. Tetanus Anti serum
g. Oxytocin
h.Heparin sodium IP
i. Antivenom.

b. PCR, PCR studies for gene regulation, instrumentation (Principle and Procedures)
c. Microbiological assays and Biological tests: Antimicrobial effectiveness testing, microbial limit tests, sterility test. Antibiotics-microbial assays, bacterial endotoxins test.

REFERENCES:

1. Pharmaceutical Chemistry by Becket and Stanlake
2. Pharmaceutical Analysis by Higuchi, Bechmman and Hassan
3. Instrumental Methods of Chemical Analysis By B.K. Sharma
4. A Text Book of Pharmaceutical Analysis by Kennenth A. Conners
5. Organic spectroscopy by Y.R Sharma Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
6. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.
7. Remington's Pharmaceutical Sciences by Alfonso and Gennaro
8.Quantitative Analysis of Drugs in Pharmaceutical Formulations by P.D. Sethi
9.Indian Pharmacopoeia 2010.
10.Journals (Indian Drugs, IJPS etc

PHARMACEUTICAL VALIDATION (MPA 103T)

THEORY **60Hours**

Scope: The main purpose of the subject is to understand about validation and how it can be applied to industry and thus to improve the quality of the products. The subject covers the complete information about validation, types, methodology and application.

Objective: Upon completion of the subject student shall be able to

Explain the aspect of validation

Carryout validation of manufacturing processes

Apply the knowledge of validation to instruments and equipments

UNIT I **12Hours**

Introduction: Definition of Qualification and Validation, Advantage of Validation, Streamlining of Qualification & Validation process and Validation Master Plan.

Validation of Manufacturing Equipment, Qualification of Analytical Instruments and Laboratory equipments.

UNIT II **12Hours**

Validation of analytical instruments: Electronic balance, pH meter, UV-Visible spectrophotometer, FTIR, GC, HPLC, HPTLC.

Validation of Glassware: Volumetric flask, pipette, Measuring cylinder, beakers and burette.

UNIT III **12Hours**

Validation of Utility systems: Pharmaceutical water system & pure steam, HVAC system, Compressed air and nitrogen.

Cleaning Validation: Cleaning Validation - Cleaning Method development, Validation and validation of analytical method used in cleaning. Cleaning of Equipment. Cleaning of Facilities. Cleaning in place (CIP).

UNIT IV **12Hours**

Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP. Validate the manufacturing facilities

UNIT V **12Hours**

a. General Principles of Intellectual Property: Concepts of Intellectual Property (IP), Intellectual Property Protection (IPP), Intellectual Property Rights (IPR); Economic importance, mechanism for protection of Intellectual Property –patents, Copyright, Trademark; Factors affecting choice of IP protection; Penalties for violation; Role of IP in Pharmaceutical industry; Global ramification and financial implications.

b. Patent: Filing a patent applications; patent application forms and guidelines. Types patent applications-provisional and non-provisional, PCT and convention patent applications; International patenting requirement procedures and costs; Rights and responsibilities of a patentee; Practical aspects regarding maintaining of a Patent file; Patent infringement meaning and scope.

c. Significance of transfer technology (TOT), IP and ethics-positive and negative aspects of IPP; Societal responsibility, avoiding unethical practices.

REFERENCES:

1. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129, 3rd Ed., Marcel Dekker Inc., N.Y.
2. The Theory & Practice of Industrial Pharmacy, 3rd edition, Leon Lachman, Herbert A. Lieberman, Joseph. L. Karig, Varghese Publishing House, Bombay.
3. Validation Master plan by Terveeks or Deeks, Davis Harwood International publishing.
4. Validation of Aseptic Pharmaceutical Processes, 2nd Edition, by Carleton & Agalloco, (Marcel Dekker).
5. Pharmaceutical Facilities: Design, Layouts and Validation, Potdar,Pharmamed Press
6. Michael Levin, Pharmaceutical Process Scale-Up‖, Drugs and Pharm. Sci. Series, Vol. 157, 2nd Ed., Marcel Dekker Inc., N.Y.
7. Validation Standard Operating Procedures: A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries, Syed Imtiaz Haider
8. Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip A. Cloud, Interpharm Press
9. Validation of Pharmaceutical Processes: Sterile Products, Frederick J.Carlton (Ed.) and James Agalloco (Ed.), Marcel Dekker, 2nd Ed.
10. Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam

FOODANALYSIS (MPA104T)

60Hrs

Scope

This courseis designedto impart knowledgeon analysis of food constituentsand finishedfood products.The courseincludesapplicationof instrumentalanalysisinthedeterminationofpesticidesinvarietyoffoodproducts.

Objectives

Atcompletionofthiscoursestudentshallbe able tounderstand variousanalyticaltechniquesinthedeterminationof

- Foodconstituents
- Foodadditives
- Finishedfoodproducts
- Pesticidesinfood
- And alsostudentshallhave theknowledgeon foodregulationsandlegislations

UNIT-I **12Hours**

Carbohydrates:classificationandpropertiesoffood carbohydrates,Generalmethodsofanalysisoffoodcarbohydrates, Changesin food carbohydrates during processing,Digestion, absorptionand metabolism of carbohydrates, Dietaryfibre,Crudefibreandapplicationoffoodcarbohydrates

Proteins:Chemistryandclassificationofaminoacidsandproteins,Physico-Chemicalpropertiesofprotein and their structure, general methods of analysis of proteins and aminoacids,Digestion,absorptionandmetabolism of proteins

UNIT-II **12Hours**

Lipids : Classification , general methods of analysis , refining of fats and oils; hydrogens of vegetables oils, determinations of adulteration in fats and oils, various methods used for measurements of spoilage of fats and fatty foods .

Vitamins: Classification of vitamins methods of analysis of vitamins, principle of microbial assay of vitamins of B –series

UNIT-III **12Hours**

Food additives: Introduction, analysis of preservatives, antioxidants, artificial sweeteners, flavors, flavor, enhancers, stabilizers, thickening and jelling agents.

Pigments and synthetic dyes: Natural pigments , their occurrences and characteristics properties , permitted synthetics dyes , Non permitted synthetics dyes used by industries , Method of detection of natural , permitted and Non permitted dyes.

UNIT-IV **12Hours**

General Analytical methodsfor milk, milk constituentsand milkproducts like ice cream,milk powder, butter, margarine, cheeseincluding adulterantsandcontaminantsofmilk Analysis of fermentation products like wine, spirits, beer and vinegar

UNIT-V **12Hours**

Pesticide analysis: Effects of pest and insects on various food,useof pesticidesinagriculture, pesticidecycle,organophosphorusand organochlorine pesticides analysis,determinationof pesticide residues in grain,fruits, vegetables,milkandmilkproducts.

Legislationregulationsoffoodproductswithspecialemphasis onBIS,Agmark,FDAandUS-FDA.

REFERENCES

1. Thechemicalanalysisoffoods–DavidPearson,Seventhedition,ChurchillLivingstone,EdinburghLondon,1976
2. IntroductiontotheChemicalanalysisoffoods–S.Nielsen,Jones&Bartlettpublishers,BostonLondon,1994.

3. OfficialmethodsofanalysisofAOACInternational,sixthedition,VolumeI &II,1997.
4. AnalysisofFoodconstituents–Multon,WileyVCH.
5. Dr.WilliamHorwitz,OfficialmethodsofanalysisofAOACInternational,18thedition,2005.

MODERN PARMACEUTICAL ANALYTICAL TECHNIQUES LAB (MPA 105P)

LIST OF EXPERMINTS

1. Calibration of glassware
2. Calibration of pH meter
3. Identification of Amino acids by Paper Chromatography
4. Identification of Amino acids by Thin Layer Chromatography
5. Identification of Alkaloids by Thin Layer Chromatography
6. Calibration of UV- Visible spectrophotometer
7. Calibration of HPLC instrument
8. Determine the λ max of $KMNO_4$
9. Assay of Ibuprofen by using U.V spectrophotometer
10. Assay of Paracetamol by using U.V spectrophotometer
11. Assay of Metronidazole by using U.V spectrophotometer
12. Assay of Aspirin by using U.V spectrophotometer
13. Assay of Aceclofenac by using U.V spectrophotometer
14. Assay of Nimesulide by using U.V spectrophotometer
15. Calibration of Ondansetron by using U.V spectrophotometer
16. Assay of caffeine by using HPLC
17. Assay of Nimesulide by using HPLC
18. Determination of Viscosity of Different Polymeric Solution By Brook Field Viscometer
19. Effect of Concentration on Viscosity of Glycerin Solution By Brook Field Viscometer

ADVANCED PHARMACEUTICAL ANALYSIS-I LAB (MPA 106P)

LIST OF EXPERIMENTS:

1. Determination of Acid value
2. Determination of Fatty acid
3. Determination of Saponification value
4. Determination of Ester value
5. Determination of Peroxide value
6. Determination of Acetyl value
7. Determination of Iodine value
8. Determination of Hydroxyl value
9. Assay of ascorbic acid
10. Assay of Atropine sulphate
11. Assay of Ammonium chloride
12. Assay of Magnesium carbonate
13. Assay of Mohr's salt
14. Spectrophotometric determination of Nimesulide by colorimetry
15. Colorimetric estimation of Metronidazole by vanillin
16. Colorimetric estimation of Metronidazole by PDAB
17. Estimation of Creatinine in urine by alkaline pictrate (jaffe's method)
18. Assay of Aceclofenac by FC reagent
19. Determination of Quinine sulphate by fluorimetry
20. Determination of amount of amine salts by titration in aqueous solutions
21. Assay of Ascorbic acid by UV spectrophotometer
22. Assay of Riboflavin by UV spectrophotometer
23. Determination of sulphates by nephlometry
24. Potentiometric titration of strong acid and strong base
25. Potentiometric titration of weak acid and strong base
26. Conductometric titration of strong acid and strong base

SEMESTER-II **ADVANCED INSTRUMENTAL ANALYSIS (MPA 201T)**

THEORY **60 Hours**

Scope: This subject deals with various hyphenated analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are , X-ray crystallography, super critical chromatography and hyphenated techniques.

Objective: By the completion of topics the students will come out with the thorough knowledge of various spectral aspects of X-Ray, IR, SEM, ORD etc which help them in further projects works and also industrial opportunities.

Unit I: **10 Hours**

a. UV Spectroscopy: Woodward-Fieser rules; Applications of UV-Visible spectroscopy in structural elucidation; Study of keto-enol tautomerism; Solving problems. **(3-4 Hours)**

b. IR spectroscopy: Theory and instrumentation in brief. Molecular vibrations; Factors influencing vibrational frequencies; Sampling techniques; Finger print region; Study of Keto-enol tautomerism; intra & inter-molecular hydrogen bonding; Studying progress in Chemical reactions; geometric and rational isomerism; Conformational analysis; spectral features of Classes of compounds indicated above. Solving problems. **(6-7 Hours)**

Unit II: Mass spectrometry: **12 Hours**

Theory and instrumentation. Ionization techniques-EI, CI, ESI, FAB, MALDI etc. High resolution MS; Molecular ions; important features of molecular ion peak; Determination of molecular formula; Mc Lafferty rearrangement; Metastable ions or peaks; Isotope peaks, The nitrogen rule; general fragmentation modes; Fragmentation in the classes of compounds indicated above. Problems and their solution.

Unit III: ^{1}H NMR **10 Hours**

Theory and instrumentation in brief. Solvents; Number of signals chemical equivalence, stereochemical equivalence in predicting the number of signals. intensity of signals; Chemical shift; factors influencing chemical shift; Spin-Spin Coupling; Coupling Constants;long- range coupling; Shielding and deshielding; Magnetic anisotropy; Protons on oxygen and nitrogen; Proton exchange; NMR spectra of the classes of compounds indicated above. Problems and their solution.

UNIT IV **12 Hours**

a. Biochromatography: Size exclusion chromatography, ion exchange chromatography, ion pair chromatography, affinity chromatography general principles, stationary phases and mobile phases.

b. Super critical fluid chromatography: Principles, instrumentation, pharmaceutical applications.

c. **Scanning electron microscope (SEM):** Principles, Instrumentation and applications. Optical Rotatory Dispersion (ORD), Circular Dichroism, Cotton effect, Octane rule and applications.

UNIT V **10Hours**

a. DSC: Principle, thermal transitions, instrumentation (Heat flux and power- compensation designs), Modulated DSC, Hyper DSC, experimental parameters (sample preparation, experimental conditions, calibration, heating and cooling rates, resolution, Sources of errors) and their influence, advantages and disadvantages, pharmaceutical applications.

b. DTA: Principle, instrumentation, advantage and disadvantage, pharmaceutical application, derivative differential thermal analysis (DDTA).

c. TGA: Principle, instrumentation, factors affecting results, advantages and disadvantages, pharmaceutical application.

REFERENCES:

1. Instrumental Methods of Chemical Analysis by B.K Sharma
2. A Text book of Pharmaceutical Analysis by Kerrenth A. Connors
3. Vogel's Text book of Quantitative Chemical Analysis by A.I. Vogel
4. Practical Pharmaceutical Chemistry by A.H. Beckett and J.B. Stenlake
5. Organic Chemistry by I. L. Finar
6. Quantitative Analysis of Drugs by D. C. Garrett
7. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi

MODERN BIO-ANALYTICAL TECHNIQUES (MPA 202T)

THEORY **60 Hrs**

Scope: This subject is designed to provide detailed knowledge about the importance of analysis of drugs in biological matrices.

Objective: Upon completion of the course, the student shall be able to understand
Extraction of drugs from biological samples
Separation of drugs from biological samples using different techniques
Guidelines for BA/BE studies

UNIT I **12 Hours**

Extraction of drugs and metabolites from biological matrices: General need, principle and procedure involved in the Bioanalytical methods such as Protein precipitation, Liquid -Liquid extraction and Solid phase extraction and other novel sample preparation approach.

UNIT II **12 Hours**

Biopharmaceutical Consideration: Introduction, Biopharmaceutical Factors Affecting Drug Bioavailability, In Vitro: Dissolution and Drug Release Testing, Alternative Methods of Dissolution Testing Transport models, Biopharmaceutics Classification System. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

UNIT III **12 Hours**

Bioanalysis and bioanalytical method validation:
a. Types of body fluids, requirement of analysis, matrix effects, non-biological analytical samples.
b. Bioanalytical method validation: USFDA and EMEA guidelines. Acceptance criteria in comparison to non-biological samples.

UNIT IV **12 Hours**
Cell culture techniques

a. Basic equipments used in cell culture lab. Cell culture media, various types of cell culture, general procedure for cell cultures;isolation of cells, subculture, cryopreservation, characterization of cells and their applications.
b.Principles and applications of cell viability assays (MTT assays)
c. Principles and applications of flow cytometry.

UNIT V **12 Hours**
Drug Product Performance, In Vivo: Bioavailability and Bioequivalence:
Drug Product Performance, Purpose of Bioavailability Studies,Relative and Absolute Availability. Methods for Assessing Bioavailability, Bioequivalence Studies, Design and Evaluation of Bioequivalence Studies, Study Designs, Crossover Study Designs, Generic Biologics (Biosimilar Drug Products), Clinical Significance of Bioequivalence Studies.

REFERENCES:

1. Analysis of drugs in Biological fluids - Joseph Chamberlain, 2nd Edition.CRC Press, New York. 1995.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
3. Pharmaceutical Analysis - Higuchi, Brochmman and Hassen, 2nd Edition, Wiley – Interscience Publications, 1961.
4. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series
5. Practical HPLC method Development – Snyder, Kirkland, Glaich, 2nd Edition, John Wiley & Sons, New Jercy. USA.
6. Chromatographic Analysis of Pharmaceuticals – John A Adamovics, 2nd Edition, Marcel Dekker, New York, USA. 1997.
7. Chromatographic methods in clinical chemistry & Toxicology – Roger L Bertholf, Ruth E Winecker, John Wiley & Sons, New Jersey, USA. 2007.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg Vol.69, Marcel Dekker Series, 1995.
9. Good laboratory Practice Regulations – Allen F. Hirsch, Volume 38, Marcel Dekker Series, 1989.
10. ICH, USFDA & CDSCO Guidelines

QUALITY CONTROL AND QUALITY ASSURANCE (MPA 203T)

THEORY **60 Hrs**

Scope: This course deals with the various aspects of quality control and quality assurance aspects of pharmaceutical industries. It covers the important aspects like cGMP, QC tests, documentation, quality certifications, GLP and regulatory affairs.

Objective: The study of this subject builds the confidence in the minds on the students to develop and formulate high quality pharmaceutical products.

Unit I **12 Hours**

Concept of quality assurance, total quality management, philosophy of GMP, cGMP and GLP, organization and functioning of accreditation bodies: ISO 9000, ISO 14000, NABL and OSHA 18000

Unit II **12 Hours**

a. Organization and personal, responsibilities, training hygiene

b. Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile area, control of contamination

c. Equipments: selection, purchase, specifications, maintenance, clean in place, sterilized in place - Raw – materials; purchase specifications, maintenance of stores, selection of vendors, controls and raw materials

Unit III **12 Hours**

Manufacture and controls on dosage forms

a. Manufacturing documents, master formula records, batch formula records, standard operating procedures, Quality audits of manufacturing processes and facilities

b. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.

c. Guideline for Quality Assurance of Human Blood Products and large volume parenterals.

Unit-IV **12 Hours**

a. Packaging and labeling controls, line clearance and other packaging materials.

b. Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities – finished products release: quality review, quality audits and batch release document.

Unit V **12 Hours**

a. Distribution and Distribution records: Handling of returned goods recovered materials and reprocessing.

b. Complaints and recalls, evaluation of complaints recall procedures, related records and documents.

REFERENCES:

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd edition: General methods of analysis quality specifications for Pharmaceutical substances, Excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals. A compendium of guidelines and related material Vol.1 and Vol.2, WHO (1999)
3. GMP- Mehra
4. Pharmaceutical Process Validation – Berry and Nash
5. Basic test for Pharmaceutical substances-WHO(1988)
6. Basic test for Pharmaceutical substances-WHO(1991)
7. How to practice GMP's-P P SharmaVandanaPublications,Agra,1991.
8. The drugs and cosmetics Act-1940-Deshpande, NileshGandhi,4th edition,SusmitPublishers,2006.
9. QA Manual byD.H. Shah, 1st edition, Business Horizons, 2000.
10. SOP guidelines by DH Shah
11. Quality Assurance guide-OPP
12. Quality AssuranceGuide by organizationof PharmaceuticalProcedures ofIndia,3rd revisededition,VolumeI&II,Mumbai,1996.
13. GoodLaboratoryPracticeRegulations,2nd Edition,SandyWeinbergVol.69,MarcelDekkerSeries,1995.
14. QualityAssuranceofPharmaceuticals-AcompendiumofGuidelinesand Relatedmaterials VolI&II,2nd edition,WHOPublications,1999.
15. TheInternationalPharmacopoeia–volI,II,III,IV&V-GeneralMethodsofAnalysisandQualityspecificationforPharmaceuticalSubstances,ExcepientsandDosageforms,3rd edition,WHO,Geneva,2005.
16. GoodlaboratoryPracticeRegulations–AllenF.Hirsch,Volume38,MarcelDekkerSeries,1989.
17. ICHguidelines
18. ISO9000andtotalqualitymanagement
19. Good Manufacturing Practices for Pharmaceuticals a plan for total quality control – Sidney H. Willig, Vol. 52, 3rd edition, Marcel Dekker Series.
20. SteinbornL.GMP/ISOQualityAuditManualforHealthcareManufacturers and TheirSuppliers, Sixth Edition, (Volume1 -With ChecklistsandSoftwarePackage).Taylor&Francis;2003.
21. SarkerDK.QualitySystemsandControlsforPharmaceuticals.JohnWiley &Sons;2008

ADVANCED PHARMACEUTICAL ANALYSIS - II (MPA 204T)

Scope: The principles and procedures for the determination of various pharmaceutical bulk drugs and their formulations belonging to different categories are discussed in detail. The applications of the important reagents like GLC, GC-MS, HPLC, HPTLC, UV/Vis, LC-MS, MS-MS etc. in the determination of the pharmaceuticals are also discussed.

Objective: The qualitative and quantitative determination of various organic compounds is clearly understood. The chromatographic techniques, elemental analysis, evaluation of cosmetic products are also learned.

Unit I **12 Hours**

An advanced study of the principles and procedures and applications of instrumental methods in the development of medicines (GLC, GC-MS, HPLC, HPTLC, UV/Vis, LC-MS, MS-MS)

Unit II **12 Hours**

a. Elemental analysis such as determination of sodium, potassium, calcium, phosphorous, sulphur, chlorine, bromine and Iodine,

B. Optical rotator dispersion technique for the analysis of chiral compounds

Unit III **12 Hours**

An advanced study of the principles and procedures involved in the instrumental methods and applications of Flame Photometry, Fluorimetry, Nephelo - Turbidimetry and Refractrometry, Study of general principles and methods for the determination of Proteins, Carbohydrates, Fats, Crude fibre, Moisture and Nitrogen

Unit IV **12 Hours**

a. Evaluation of cosmetic products: Determination of Ash, volatile matter, heavy metals, fineness ofPowder, density, viscosity of cosmetic raw materials and finished products. Study of quality of raw materials and general methods of analysis of raw material used in cosmetic manufacture as per BIS.

b. Standard specification laid down for sampling and testing of various cosmetics in finished forms such as baby care products, skin care products, dental products, personal hygiene preparations, lips sticks. Hair products and skin creams by the Bureau of Indian Standards.

Unit V **12 Hours**

a.Identification and quantitative determination of preservatives, Antioxidants, Colouring materials, Emulsifiers and Stabilizers in Pharmaceutical formulation

b.Methodology involved

Moisture content determination in dosage forms
Alcohol determination
Essential oil determination
Surfactant analysis

REFERENCES:

1. Remington's Pharmaceutical Sciences – Alfonso and Gennaro
2. Pharmaceutical Chemistry – Becket and Stanlake
3. Quantitative Analysis of Drugs in Pharmaceutical Formulations – P.D. Sethi

4. Pharmaceutical Analysis – Higuchi, Bechmman and Hassan
5. Theory and Practice of Industrial Pharmacy – Liebermann and Lachmann
6. Indian Pharmacopoeia – 1996
7. Instrumental Methods of Chemical Analysis – B.K. Sharma
8. A Text Book of Pharmaceutical – Kenneth A. Conner
9. Thechemicalanalysisoffoods–DavidPearson,Seventhedition,ChurchillLivingstone,EdinburghLondon,1976
10. IntroductiontotheChemicalanalysisoffoods–S.Nielsen,Jones&Bartlettpublishers,BostonLondon,1994.
11. OfficialmethodsofanalysisofAOACInternational,sixthedition,VolumeI &II,1997.
12. AnalysisofFoodconstituents–Multon,WileyVCH.
13. .Dr.WilliamHorwitz,OfficialmethodsofanalysisofAOACInternational,18thedition,2005.

ADVANCED INSTRUMENTAL ANALYSIS (MPA 205P)

1. Preparation and In-process quality control test for Immediate released tablets
2. System suitability parameters for HPLC
3. Analytical method development for given drug by using HPLC
4. Determination of linearity and range by using HPLC
5. Determination of accuracy and precision by using HPLC
6. Determination of specificity by using HPLC
7. Determination of robustness by using HPLC
8. Determination of ruggedness by using HPLC
9. Determination of Limit of Detection and Limit of Quantitation by using HPLC
10. Analytical method development for Ibuprofen by using U.V spectroscopy
11. Determination of linearity and range by using U.V spectroscopy
12. Determination of accuracy and precision by using U.V spectroscopy
13. Determination of specificity by using U.V spectroscopy
14. Determination of robustness by using U.V spectroscopy
15. Determination of ruggedness by using U.V spectroscopy
16. Determination of Limit of Detection and Limit of Quantitation by using U.V spectroscopy
17. Assay of ibuprofen by using U.V spectroscopy
18. Standard addition method in support of determination of accuracy of the method by using U.V spectroscopy
19. Stability testing of drug substances as per ICH
20. Short term stability studies at different pH
21. pH dependent saturation solubility testing of given API
22. Determination of drug release kinetics of given CR/ER/SR tablets by dissolution testing method
23. Optimization of solvent system for immiscible liquids by ternary phase diagram

ADVANCED PHARMACEUTICAL ANALYSIS-II PRACTICALS (MPA 206P)

1. Determination of the percentage of sodium chloride by Mohr's method
2. Determination of the percentage of sodium chloride by Volhard's method
3. Estimation of Sulphate ions by Nephelometry
4. Determination of Linearity and Range of an analytical method to determine the content of sulphate ions by Nephelometry
5. Determination of Accuracy and Precision of an analytical method to determine the content of sulphate ions by Nephelometry
6. Determination of LOD(Limit of Detection) and LOQ(Limit of Quantitation) of an analytical method to determine the content of sulphate ions by Nephelometry
7. Determination of amount of amines present in Hydroxylamine Hcl
8. Estimation of Sodium ions by Flame photometry
9. Determination of unknown concentration of Quinine sulphate Fluorometry
10. Determination of Quenching effect of Quinine sulphate by Potassium iodide solution in Fluorometry
11. Estimation of unknown concentration of Glycerin by Abbe's Refractometry
12. Estimation of unknown concentration of Tartaric acid by Polarimetry
13. Assay of Diclofenac sodium and Paracetamol by SEM(Simultaneous Equation Method) by using U.V spectrophotometer
14. Assay of Ibuprofen and Paracetamol by SEM (Simultaneous Equation Method) by using U.V spectrophotometer
15. Assay of Diclofenac sodium by using U.V spectrophotometer

SemesterIII

MRM301T-ResearchMethodology&Biostatistics

(Commontoallspecializations)

UNIT–I

General Research Methodology: Research, objective, requirements, practical difficulties, reviewofliterature,studydesign,typesofstudies,strategiestoeliminateerrors/bias,controls,randomization,crossoverdesign,placebo,blindingtechniques. **10Hrs**

UNIT–II

Biostatistics: Definition, application, sample size, importance ofsample size, factors influencingsamplesize,dropouts,statistical tests of significance,typeof significancetests,parametrictests(students"t"test,ANOVA,Correlationcoefficient,regression),non-parametrictests(wilcoxan rank tests, analysis of variance, correlation, chisquare test), null hypothesis, P values,degreeoffreedom,interpretationofP values. **10Hrs**

UNIT–III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence,doubleeffect,conflictsbetweenautonomyandbeneficence/non-maleficence,euthanasia,informedconsent,confidentiality,criticismsoforthodoxmedicalethics,importanceofcommunication,controlresolution,guidelines,ethicscommittees,culturalconcerns,truthtelling,online business practices, conflicts of interest, referral, vendor relationships, treatment of familymembers,sexualrelationships,fatality. **10hrs**

UNIT–IV

CPCSEAguidelinesforlaboratoryanimalfacility:Goals,veterinarycare,quarantine,surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animalfacilitiestolaboratories,anesthesia,euthanasia,physicalfacilities,environment,animalhusbandry,recordkeeping,SOPs,personneland training,transportoflabanimals.10 hrs

UNIT–V

DeclarationofHelsinki:History,introduction,basicprinciplesforallmedicalresearch,and additionalprinciples formedicalresearchcombinedwithmedicalcare.

10hrs

Reference Books

1. PhilipKotlerandKevinLaneKeller:MarketingManagement,PrenticeHallofIndia,NewDelhi.
2. ArunKumar,Meenakshi:MarketingManagement,VikasPublishing,india