

Gawande College Of Pharmacy Sakherkherda

M.PHARM. SYLLABUS

SPECIALIZATION:PHARMACEUTICALQUALITYASSURANCE

SCHEME:M.Pharm(PharmaceuticalQualityAssurance)

Semester I

SubjectCode		Subject	Hr/ Week	Hr/ Week	Credits	Credits	Marks	Marks
Theory	Practical		TH	PR	TH	PR	TH	PR
1101	1201	ModernAnalytical TechniquesI	4	8	4	4	100	100
1102	-	QualityManagementI	4	-	4	-	100	-
1103	-	ProductDevelopment I	4	-	4	-	100	-
1104	1204	BiologicalEvaluation	4	8	4	4	100	100
		Total	16	16	16	8	400	200

SemesterII

SubjectCode		Subject	Hr/ Week	Hr/ Week	Credits	Credits	Marks	Marks
Theory	Practical		TH	PR	TH	PR	TH	PR
2101	2201	ModernAnalytical TechniquesII	4	8	4	4	100	100
2102	-	ProductDevelopment-II	4	-	4	-	100	-
2103	-	QualityManagementII	4	-	4	-	100	-
2104	-	PackagingDevelopment	4		4		100	-
-	2204	ProductandPackaging Development	-	8	-	4	-	100
		Total	16	16	16	8	400	200

SemesterIII

SubjectCode		Subject	Hr/ Week	Hr/ Week	Credits	Credits	Marks	Marks
Theory	Practical		TH	PR	TH	PR	TH	PR
3101		Computing& Statistics	4	-	4	-	100	-
3102		Validation	4	-	4	-	100	-
3103		ResearchMethodology	4	-	4	-	100	-
3104		ResearchSeminar	2	-	2	-	50	-
3105		ResearchProject	-	16	-	8	-	200
3106		IndustrialTraining	One Month		2		50	
		Total	14	16	16	8	400	200

SemesterIV

SubjectCode		Subject	Hr/ Week	Hr/ Week	Credits	Credits	Marks	Marks
Theory	Practical		TH	PR	TH	PR	TH	PR
4101		ResearchProjectandviva	32	-	20	-	500	-
4102		ResearchColloquium	-	-	4	-	100	-
		Total		-	24	-	600	-

GrandTotal(Semester):I+II+III +IV

Marks :600 +600+600 +600= 2400

Credits :24 +24 +24 +24 =96

ExaminationPatternforM.Pharm.inPharmaceuticalQualityAssurance

Semester-I

SubjectCode		SUBJECT	Exam Dur. (hr)	Theory				Exam Dur. (hr)	Practical			
Theor y	Practical			Int.	Ext.	Total	Credits		Int.	Ext.	Total	Credits
1101	1201	Modern Analytical TechniquesI	2	50	50	100	4	6	50	50	100	4
1102	-	Quality ManagementI	2	50	50	100	4					
1103	-	Product DevelopmentI	2	50	50	100	4	-	-	-	-	-
1104	1204	Biological Evaluation	2	50	50	100	4	6	50	50	100	4

SemesterI: Total credits= 24, Marks= 600

Semester- II

SubjectCode		SUBJECT	Exam	Theory				Exam	Practicals			
Theor y	Practic al		Dur. (hr)	Int.	Ext.	Tota l	Credit s	Dur. (hr)	Int.	Ext.	Total	Cre dits
2101	2201	ModernAnalytical TechniquesII	2	50	50	100	4	6	50	50	100	4
2102	-	Product Development-II	2	50	50	100	4					
2103	-	QualityManagement II	2	50	50	100	4	-	-	-	-	-
2104	-	Packaging Development	2	50	50	100	4	-	-	-	-	-
-	2204	Productand Packaging Development						6	50	50	100	4

Totalcredits= 24,Marks= 600

SemesterIII

SubjectCode		SUBJECT	Exam Dur. (hr)	Theory				Exam Dur. (hr)	Practicals			
Theory	Practical			Int.	Ext.	Total	Credits		Int.	Ext.	Total	Credits
3101		Computing & Statistics	2	50	50	100	4					
3102		Validation	2	50	50	100	4					
3103		Research Methodology	2	50	50	100	4	-	-	-	-	-
3104		Research Seminar	2	25	25	50	2	-	-	-	-	-
3105		Research Project	-	-	-	-	-	-	-	-	200	8
3106		Industrial Training				50	2					

SemesterIII: Totalcredits =24,Marks =600

SemesterIV

SubjectCode		SUBJECT	Exam Dur. (hr)	Theory				Exam Dur. (hr)	Practicals			
Theory	Practical			Int.	Ext.	Total	Credits		Int.	Ext.	Total	Credits
4101		ResearchProject (Thesis+Viva)	-	200	300	500	20	-	-	-	-	
4102		ResearchColloquium	-	100		100	4		-	-	-	
		Total	-	300	300	600	24					

SemesterIV:Totalcredits=24,Marks=600

SemesterI+II +III +IV= 96Credits Course

Project and Thesis work

Every student for the degree of Master of Pharmacy shall be required to undertake a project involving methodical research under the supervision of an approved guide and submit three copies of the thesis, duly certified by the supervisor to the Head of the Department/Principal.

SEMESTER-III

Research Project and Industrial training

The students should complete industrial training for one month during the course work. The research project will be evaluated as follows:

Research Project	Marks
Reference work	100
Experimental work	100
Total marks	200

Research seminar	Marks
Total marks	50

Industrial Training	Marks
Total marks	50

SEMESTER-IV

Research Project and Thesis work

The research project will be evaluated as follows:

Thesis work	Marks
Experimental work	200
Presentation/communication	50
Result/ conclusion	50
Research Colloquium	100
Vivavoce and external assessment	200
Total marks	600

Semester I

M.Pharm.1101:AnalyticalTechniquesI

SEMESTER		SUBJECT			
I		AnalyticalTechniquesI			
WEEKLYASSIGNMENT		CREDITS		MARKS	
TH	PR	TH	PR	TH	PR
4	8	4	4	100	100

Thecourseisdivided into4 modules of **onecrediteach**with15 instructional hrs/module

Objectives:Analyticaltechniqueshavebecomeanintegralpartofpharmaceuticalandother industries.

Thorough knowledge of these techniques is essential for the following reasons.

1. Tounderstandimportanceofvarious analyticaltechniques indeterminingpurityofcompounds
2. Tocarryout quantitativeestimation ofdrugs fromformulations andplant extracts
3. Tocarryoutqualitative estimationof compoundsforcorrect identification
4. Toelucidatethestructureofcompoundsfromtheanalytical data
5. Toisolateand identifythe impurities in the sample
6. Tomonitorchemicalreactionsusinganalyticaldata

TheknowledgeofthesetechniqueswouldmakestudentsconfidentwhileworkingwithR&Dand Quality Control departments of industry.

LearningOutcomes:To enablelearnerto:

1. Understand the principles and applications of various analytical techniques such as UV spectrophotometry, spectrofluometry, IR and Absorption spectroscopy, thermal analysis, diffractometry etc. in determining purity of compounds, quantitative as well as qualitative evaluation of drugs.
2. Useethoroughknowledgeoftheseinstrumental techniquesconfidentlywhileworkingwithR &DandQualityControldepartmentsof industry.

Pre-assessment:

1. To determine the entry level knowledge of students about electromagnetic radiation, wave lengths, colors, principles of spectrometry, absorption and emission spectrometry, electronic transitions and type of spectra
2. Toassessthe knowledge of studentsaboutroleof waterasan impurity
3. Toknowthe fundamentalconcepts of solubilityandrole ofsolubilityinPharmacy

Module 1	Spectroscopy & Phase Analysis	1 credit
Objectives	<ol style="list-style-type: none"> 1. To make students familiar with the principles of quantitative estimation using UV-visible spectrometry 2. To enable students to use spectrometers with proper understanding 3. To make students competent for the basic quality control requirements or needs of industries 4. To make students familiar with the principles of quantitative estimation of moisture in various pharmaceutical products and commonly used solvents using simple instrumental techniques 5. To enable students to use Karl Fischer method of analysis with proper understanding 6. To make students familiar with the principles of quantitative estimation of solubility of a compound 7. To enable students to understand effect of impurities on solubility of a compound 	
Contents	Topics covered	hrs
	<ul style="list-style-type: none"> • Ultraviolet-Visible Spectrometry <p>General Principles of Spectrometry: Line spectrum, band spectrum, absorption spectroscopy, emission spectroscopy, electromagnetic spectrum, meaning of various terms like absorbance, transmittance, absorptivity, molar absorptivity, $E_{1\text{cm}}^{1\%}$ and λ_{max}. Various electronic transitions, auxochromes, auxochromic effect, bathochromic and hypsochromic shifts. Instrumentation with respect to sources, Monochromators -prisms and gratings, absorption and interference filters, detectors - Barrier cell, photocell, photomultiplier tube, refractive index detector, single and double beam UV spectrometers, Applications of UV spectroscopy, Fieser Woodward rules, calculation of λ_{max} values for important functional groups.</p>	(7)

Assigned Reading/References	<ol style="list-style-type: none"> 1. Principles of Instrumental Analysis: Douglas A. Skoog (Author), F. James Holler, Stanley R. Crouch, 6th edition, Publisher: Brooks Cole. 2006. 2. Practical Pharmaceutical Chemistry: A. H. Beckett and J. B. Stenlake, 4th edition, Part II, CBS Publishers, 2011 3. Instrumental Methods of Analysis: S. S. Mahajan, , Popular Prakashan Pvt. Ltd., Mumbai, 2010. 4. Quantitative Analysis of Drugs in Pharmaceutical Formulations: P.D. Sethi, 3rd edition, CBS Delhi. 2008. 5. Published articles pertaining to the learnt techniques in reputed journals like Analytical Chemistry, Analytical Communications, The Analyst, Indian Drugs, etc. 	
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Module 2	Spectrofluorimetry, Atomic Absorption and Emission Spectrometry & X-Ray Diffraction Analysis	1 credit
Objectives	<ol style="list-style-type: none"> 1. To make students familiar with the principles of selective quantitative estimation using instrumental methods 2. To enable students to use spectrofluorometer with proper understanding 3. To make students competent for the basic quality control requirements of industries 5. To make students familiar with the principles of absorption and emission spectrometry 6. To enable students to use atomic absorption spectrometer with proper understanding and make them competent for quality control activities of industry 7. To make students familiar with the concept of analysis of crystal structures 	
Contents	Topics covered	Hrs
	<ul style="list-style-type: none"> • Spectrofluorimetry Principle, definition and types of fluorescence, Resonance	(7)

	<p>fluorescence and Stokes' effect, Mechanism of fluorescence and phosphorescence, singlet and triplet states, quenching of fluorescence, factors affecting fluorescence, intrinsic structure of a molecule and fluorescence, instrumentation and applications.</p> <p>Analysis of directly fluorescing substances – inorganic species, vitamins, alkaloids, steroids and medicinal agents</p> <p>Analysis of indirectly fluorescing substances -by derivatization</p> <p>Derivatizing agents for metals, non-metals and organic compounds. Use of derivatising agents such as – salicylaldehyde, 8-hydroxyquinoline, dansyl chloride, disyl chloride, NBD chloride, fluorescamine, o-phthalaldehyde and Br-MMC.</p> <p>Fluorescent indicators.</p> <p>Quenching Methods and fluoroimmunoassays</p> <p>• Atomic Absorption And Emission Spectrometry</p> <p>Principle, Sample atomization techniques, Introduction of singlet, doublet and triplet molecular states, atomic absorption and emission spectra for metals, Fuels and oxidants, Temperature profile, flame absorption and flame emission profiles, flame and non-flame atomizers</p> <p>Turbulent flow burners, laminar flow burners, Applications</p> <p>• X-Ray Diffraction Analysis</p> <p>Principle, Bragg's Law, instrumentation, sources of X-rays, Applications</p>	<p>(4)</p> <p>(2)</p>
<p>Assigned writing & Exercise activities</p>	<ul style="list-style-type: none"> • To make students write answers to the commonly asked questions on the above topics • To write down reactions involved in derivatization. • To draw neat diagrams for absorption and emission profiles and atomizers 	

Tutorial	<ul style="list-style-type: none"> To carry out literature survey to compile names of drugs analyzed by spectrofluorimetry, atomic absorption spectrometry and X-ray crystallography To find updates in the learnt techniques 	(2)
Assigned Reading/References	<ol style="list-style-type: none"> Principles of Instrumental Analysis: Douglas A. Skoog (Author), F. James Holler, Stanley R. Crouch, 6th edition, Publisher: Brooks/Cole, 2006. Practical Pharmaceutical Chemistry: A. H. Beckett and J. B. Stenlake, 4th edition, Part II, CBS Publishers., 2011. Instrumental Methods of Analysis: S. S. Mahajan, January, Popular Prakashan Pvt. Ltd., Mumbai, 2010. Published articles pertaining to the learnt techniques in reputed Journals like Analytical Chemistry, Analytical Communications, The Analyst, Indian Drugs, etc. 	

Module 3	X-Ray Diffraction Studies, Thermal Analysis & Electrophoresis	1 credit
Objectives	<ul style="list-style-type: none"> To make students familiar with the principles of qualitative estimation using analytical techniques To enable students to use IR spectrometers with proper understanding To make students competent for the R & D requirements or needs of industries To make students familiar with the quantitative and qualitative applications of various thermal methods To enable students to use DSC with proper understanding To learn a unique technique for analysis of charged molecules and proteins To understand use of electrophoresis in formulations 	
Contents	Topics covered	Hrs
	<ul style="list-style-type: none"> IR Spectrometry Principle, types of vibrations, Instrumentation with respect to sources, monochromators-prisms and gratings,	(7)

Assigned Reading/References	<ol style="list-style-type: none"> 1. Principles of Instrumental Analysis: Douglas A. Skoog (Author), F. James Holler, Stanley R. Crouch, 6th edition, Publisher: Brooks Cole, 2006. 2. Practical Pharmaceutical Chemistry: A. H Beckett and J. B. Stenlake, 4th edition, Part II, CBS Publishers, 2011. 3. Instrumental Methods of Analysis: S. S. Mahajan, Popular Prakashan Pvt. Ltd., Mumbai. , 2010, 4. Applications of Absorption Spectroscopy of Organic Compounds: Dyer J.R., Prentice-Hall, London 5. Spectrometric Identification of Organic Compounds: R. M. Silverstein, Francis X. Webster and David Kiemle, 7th edition, Wiley Publication, NY., 2005 6. Published articles pertaining to the learnt techniques in reputed journals like Analytical Chemistry, Analytical Communications, The Analyst, Indian Drugs, etc. 	
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Module 4	Project and Seminar	1 credit
	Presentation on some recent research/seminars based on the above topics	(15)

M.Pharm.1201--:ModernAnalyticalTechniques-I(Practical)

The course is divided into **4** modules of **one credit each** with **30** instructional hrs/module.

<p>Objective:</p> <ul style="list-style-type: none"> • To give hands on training to students using different instruments used for qualitative and quantitative analysis • To monitor chemical reactions using different analytical techniques • To perform quantitative estimation of drugs from formulations • To enable learners to identify impurities in the sample • To enable learner to understand pharmacopoeial requirements <p>Learning Outcomes: The learners will be able to:</p> <ol style="list-style-type: none"> 1. Use different analytical instruments used for qualitative and quantitative analysis of drugs and formulations as per pharmacopoeial requirements 2. Identify structure of any given compounds by determination of functional groups, nature of given compound (amorphous, crystalline) as well as polymorphic forms by use of analytical instruments such as FTIR, DSC, etc. 		
<p>Pre-assessment:</p> <ol style="list-style-type: none"> 1. To assess the entry level knowledge of students about quantitative and qualitative estimation 2. To assess the entry level knowledge of students about selective estimation 3. To assess the entry level knowledge of students about quantitative and qualitative estimation 4. To assess the entry level of students about selective estimation. 		
Module 1	UV-Visible spectrometry (Fundamental Aspects)	1 credit
Objectives	<ol style="list-style-type: none"> 1. To learn fundamental aspects of quantitative and qualitative estimation using UV-visible spectrometry 2. To study Beer Lambert Law 	
Contents	Experiments	(30)
	1. Calibration of UV-Visible spectrometer for absorbance	(4)
	2. Determination of wavelength of maximum absorption (λ_{max}) of a compound	(4)
	3. Determination of cut-off wavelength of commonly used solvents for	(6)
	4. UV spectroscopy	(6)
	5. Determination of $E_{1\%}^{1cm}$ and molar absorptivity of a substance	(4)

	6. Determination of range of linearity in accordance with Beer Lambert Law Determination of Limit of Quantitation (LOQ) and Limit of Detection (LOD) of compounds in UV range	(4)
Assigned Writing/ Practical Activities	<ul style="list-style-type: none"> Experiments pertaining to the designing of a method based on UV-visible spectrometry would be assigned to the students and they would perform the same and document in the journals. 	(2)
Assigned Reading/ References	<ol style="list-style-type: none"> 1. Practical Pharmaceutical Chemistry: <u>A. H. Beckett</u> and <u>J. B. Stenlake</u>, 4th edition, Part II, CBS Publishers., 2011. 2. Pharmacopoeia of India, 6th Edition, Govt. of India, Ministry of Health & welfare, 2010 3. British Pharmacopoeia, General Medicine Commission, UK, 2011 4. Vogel's Textbook of Quantitative Chemical Analysis, 6th Edition, Prentice Hall, 2000 	

Module 2	UV –Visible spectrometry, Moisture determination and Differential Scanning Calorimetry (DSC)	1 credit
Objectives	<ol style="list-style-type: none"> 1. To perform quantitative estimation using UV-visible spectrometry 2. To perform Karl-Fischer titration for determination of moisture content 3. To learn differential scanning calorimetry 	
Contents	Experiments	(30)
	1 Analysis of a single component system from bulk drugs by using Beer Lambert law and by Absorption ratio method	(6)
	2 Analysis of an active ingredient from its formulations such as tablets, capsules, suspensions, ointments and injections	(8)
	3 Analysis of binary mixtures by simultaneous equation method	(6)
	4 Standardization of Karl Fischer reagent	(2)
	5 Quantitative estimation of moisture by using Karl Fischer reagent	(2)
	6 Recording of a thermograph using differential scanning calorimeter	(2)

	<ol style="list-style-type: none"> 1. Calibration of IR spectrometer with polystyrene film (6) 2. IR spectrum of neat liquid (6) 3. Preparation of KBr pellet for any solid sample (6) 4. Preparation of a 'mull' for samples with different functional groups such as amine, nitro, aldehyde, keto, carboxylic, hydroxyl, etc. (4) 5. To monitor chemical reaction using IR spectrometry (4) 6. To identify impurities in the sample (2)
Assigned Writing & Exercise	<ol style="list-style-type: none"> 1. Experiments pertaining to the qualitative estimation of drugs would be assigned to the students for identification of functional groups and they would record IR spectrum of various drugs and enter the results in their Journals (2)
Assigned Reading/References	<ol style="list-style-type: none"> 1. A.H. Beckett and J.B. Stenlake, Practical Pharmaceutical Chemistry, Part 1 & 2, The Athlone Press, London, 2011. 2. Vogel's Textbook of Quantitative Chemical Analysis, 6th Edition, Prentice Hall, 2000 3. Spectroscopic identification of organic compounds. John Dyer, Willy, NY. 4. Spectrometric Identification of Organic Compounds: R. M. Silverstein, Francis X. Webster and David Kiemle, 7th edition, 2005, Wiley Publication, NY. 5. Instrumental Methods of Analysis: S.S. Mahajan, 2010, Popular Prakashan Pvt.Ltd., Mumbai.

M.Pharm.1103:ProductDevelopment-I

SEMESTER		SUBJECT			
I		ProductDevelopmentI			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	0	4	0	100	0

Thecourseisdivided into4 modules of **onecrediteach**with15 instructional hrs/module.

Objective: The subject is concerned with the understanding of need for preformulation and drug stability studies. It also deals with principles and techniques of solid dosage forms, coating technology, study of pharmaceutical polymers and details about dissolution studies. It also introduces pharmacokinetic modeling. Using these techniques, learner will be able to develop and evaluate pharmaceutical dosage forms

LearningOutcomes:Thelearnerwillbeableto:

1. Understand the applications of preformulation, chemical kinetics and stability testing in pharmaceutical product development.
2. Apply principles and techniques of coating technologyto solid dosage forms and select various biodegradable & non-biodegradable polymers, stimuli sensitive polymers, mucoadhesive polymers etc. in product development.
3. Understandtheprinciplesofdissolutionanddiffusionandpharmacokineticsinproduct development

Pre-assessment:Determinationofentrylevelknowledgeofstudentaboutconceptsand applications for preformulation studies, various formulation aspects & stability studies based onquizzes, question & answers.

Module1	I. Preformulation,ChemicalKineticsandDrug Stability	Instr.hrs
Objectives	<ol style="list-style-type: none"> 1. To enable the learner to understand the need of preformulation studies inpharmacy. 2. Tostudyconcepts,applications andprotocols forpreformulation studies. 3. Tounderstandphysical&chemicalstabilityprotocolsasperICHGuidelines. 	

	4. To provide an insight into accelerated stability testing and study of calculations for shelf life in details.	
Contents	Topics Covered	Hrs
	<ul style="list-style-type: none"> Preformulation Studies: pka and solubility kinetics, pH profile, partition coefficient, crystal morphology, polymorphism, powder flow, surface characteristics, dissolution, solubilization techniques, drug – excipients compatibility studies, protocol for preformulation studies.. Chemical Kinetics & Drug Stability: Pathways of drug degradation, Rate & order of reactions, Factors affecting reaction kinetics, stability testing, Accelerated studies and shelf life assignment, ICH guidelines. 	(6) (6)
Assigned writing & Exercise activities	<ul style="list-style-type: none"> The assignments will be given to the students based on the stability protocols as per ICH guidelines. The students will ask to collect data on need for preformulation studies in the pharmaceutical industries. 	(2)
Tutorial	<ul style="list-style-type: none"> Topics pertaining to the study of preformulation studies & stability studies will be assigned to the students & they will present the same 	(1)
Assigned Reading/ References	<ol style="list-style-type: none"> Carstensen, Thuro J., “Pharmaceutical principles of solid dosage forms” , Volume 110, Marcel Dekker New York, 2001, CRC Ray and Weller, “Handbook of Pharmaceutical Excipients”, Pharmaceutical Press, 2009. Lachman, Lieberman, “Pharmaceutical dosage forms: Dispersed systems”, Vol. I, II, Marcel-Dekker New York, 2008. Lisbeth, Illum & Stanley S. Davis, “Polymers in Controlled Drug Delivery”, Wright, Bristol, 1987. ICH Guidelines available at: http://www.ich.org 	

Module 2	II.Principlesand Techniquesof Solid DosageFormsand CoatingTechnology&StudyofPharmaceutical polymers	1credit
Objectives	<ol style="list-style-type: none"> 1. To enable learner to understand about recent advances in tablet and capsule technology. 2. To provide an insight to oral controlled released drug delivery systems and machinery used for the same. 3. To provide an insight view in various types of coating techniques and equipments. 4. To provide overview in selection of excipients in development of various solid dosage forms. 5. To enable the learner to understand the basic principles of conventional polymers and polymers used for controlled released drug delivery system. 6. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics Covered	Hrs
	<ul style="list-style-type: none"> • Solid dosage forms: Recent advances in tablet and capsule technology like double compression, direct compression, capsule filling machine, Novel tableting excipients binding agents, superdisintegrants, lubricants and diluents 	(4)
	<ul style="list-style-type: none"> • Coating of solid dosage forms: Various types of functional coatings, polymers, Advances in process controls, coating equipments, coating pans, Accelacota, Hi-coater, Driacoater, fluid bed coating equipment se.g. Glatt & Kugelcoaters. Coating application and metering equipment, particle coating methods, pelletization. Technology. 	(4)
	<ul style="list-style-type: none"> • Pharmaceutical polymers: Biodegradable & nonbiodegradable polymers block copolymers, stimulisensitive polymers, mucoadhesive polymers 	(4)

Assigned writing	<ul style="list-style-type: none"> The assignments will be given to the students based on the various solid dosage forms available and coating of solid dosage forms using various polymers. 	(2)
Tutorial	<ul style="list-style-type: none"> Topics pertaining to the recent advancements in various solid dosage forms and coating technologies will be assigned to the students & they will present the same. 	(1)
Assigned Reading/References	<ol style="list-style-type: none"> Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms", Volume 110, New York Marcel Dekker, 2001, CRC. Lachman, L., Lieberman, H. A., & Kanig, J. L. "The Theory and Practice of Industrial Pharmacy" 3rd edition. Mumbai, Varghese Publishing House. 1991. Rawlins, E. A., "Bentley's text book of Pharmaceutics" 8th edition, London: Bailliere Tindal. 1995. Rubinstein, M. H. M. E. Aulton, "Pharmaceutics: the science of dosage form design", 3rd edition, pp. 304-321, London: ELBS Longman Group Ltd., 1988 Rudnic, E. M., & Schwartz, J. D. "Remington: The Science and Practice of Pharmacy" Philadelphia: Lippincott Williams & Wilkins. 2006. Saha, S., & Shahiwala, A. F., "Multifunctional coprocessed excipients for improved tableting performance". Expert Opinion on Drug Delivery, pp 197-208, 2009. David K Platt, Biodegradable Polymers, iSmithers Rapra Publishing, 2006. Catia Bastioli, Handbook of biodegradable polymers, iSmithers Rapra 	<ul style="list-style-type: none">

Assigned writing	The assignments will be given to the students based on the above topics.	(2)
Tutorial	Topics pertaining to the study of drug dissolution and diffusion principles in biological systems will be assigned to the students & they will present the same.	(1)
Assigned Reading/References	<ol style="list-style-type: none"> 1. J.T. Carstensen, "Drug Stability: Principles and Practices", Drugs and Pharm. Sci. Series, Vol. 43, Marcel Dekker Inc., N.Y. 2. Shaikh R., Sial A., "Stability of pharmaceutical formulations", Pak. J. Pharm. Sci., 2nd edition, pp 83-86 1996,. 3. ICH Q1A (R2), "Stability testing of new drug substances and products", International Conference on Harmonisation, IFPMA, Geneva, 1996 Milo Gibaldi and Donald Perrier, "Pharmacokinetics", Drugs and Pharm. Sci. Series, Vol. 15, Marcel Dekker Inc., N.Y. 4. Shargel L, Susanna Wu-Pong, Andrew B.C. Yu. "Applied Biopharmaceutics and pharmacokinetics", 3rd edition, McGraw-Hill, Medical Pub. Division, 2005 5. Malcolm Rowland, Thomas N. Tozer, "Clinical Pharmacokinetics: Concept and Application"; 3rd Edn. B. I. Lea & Febiger, 1989. 6. Shargel, "Generic Drug Product Development Specialty Dosage Form", 1st Edition, 2010. 	

Module 4	Project & Seminar	1 credit
Objectives	<ul style="list-style-type: none"> • The learners will be assigned reading from books and related published articles from journals followed by interactive discussion, presentation of the same & submission of report 	(15)

M.Pharm–1104:Biological Evaluation

SEMESTER		SUBJECT			
I		BiologicalEvaluation			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	8	4	4	100	100

Thecourseisdivided into4 modules of **onecrediteach**with15 instructional hrs/module

Objective: Thispaperisdesignedtogiveinsightofdifferentproceduresofbiologicalevaluationof drugs,pharmacologicalaspectsof newtherapies,toxicological studiesondrugsandBio-safetystudies.

LearningOutcomes: Thelearnerwillbeableto:

1. Understandtheimportanceandapplicationsofpre-clinicaldrugevaluation,varioustesting methods such as microbiological and animal models.
2. Applyprinciples and techniquesofradioimmunoassays forsomedrugs likeinsulin, digitalis etc. Fluoroimmunoassay, Fluorescent Labelling
3. ~~Select,analyzeandinterpretresultsofvarious microbiologicaltestsas pyrogenest.~~

Pre-assessment: Theentrylevelknowledgeofstudentaboutthepharmacology,microbiologyand bioassayswillbedeterminedbased onquizzes,question& answers.

Module 1	Pre-clinicaldrug evaluation	1 credit
Objectives	Thismoduleisdesigned toexpandstudent'sknowledge regarding <ul style="list-style-type: none"> ➤ NCE Development ➤ Testingof NCE (animal/microbiological) ➤ Clinical Trials 	
Contents	Topics Covered	Inst.hrs
	1. NewDrugDiscoveryanddevelopment process	(2)
	2. Pre-clinicaldrugevaluationofNCE,NBEandBiologicalasper ScheduleYandICHguidelines:singledose,repeatdosetoxicity studies, safety pharmacology, genetic toxicology, reproduction toxicity studies (including segment I, II, and III), and carcinogenicity studies.	(3)
	3. ClinicalTrials,Phase I,II&II	(3)

	4. After completion of this module student will have better understanding different phases of clinical trials as well as Schedule Y and ICH guidelines.	(3)
Assigned writing & Exercise activities	<ul style="list-style-type: none"> • Assignments will be given to the students based on different topics such as drug discovery process, NCE development. • Students will be asked to interpret clinical data. 	(2)
Tutorials	<ul style="list-style-type: none"> • Topics pertaining to the study of toxicity studies will be assigned to the students & they will present the same 	(2)
Assigned Readings/References	<ol style="list-style-type: none"> 1. Charles G. Smith and James T. O'Donnel , "The Process of New Drug Discovery and Development" 2nd Edition, CRC press, USA, 2006. 2. Mukund Chorghade, "Drug Discovery and Development", Vol 1 & 2, 2nd Edition, Wiley Interscience, USA, 2007. 3. Schedule Y guidelines as given in Drugs and Cosmetics Act, in part 122-DAA, by Govt. of India, 1945. 4. Duolao Wang and Ameet Bakhai , "Clinical Trials A practical guide to Design, Analysis and Design" , Remedica Medical Education and Publishing, 1st edition, Spain, 2007. 	
Module 2	II. Biological standardization and Molecular biology	1 Credit
Objectives	<p>This module is designed to gain understanding of</p> <ul style="list-style-type: none"> ➤ Various bioassay methodologies ➤ Principles of bioassay techniques. ➤ Molecular targeting of drugs 	
Contents	Topics Covered	Hrs
	1. General principles, scope and limitations of bioassay, bioassay of official drugs	(3)

	<ol style="list-style-type: none"> 1. Microbiological limit tests (2) 2. Sterility tests: Methodology & Interpretation (3) 3. Tests for effectiveness of antimicrobial preservatives. (2) 4. Chemistry and properties of bacterial Pyrogens and endotoxins, (2) 5. Mechanism of action of Pyrogens and Pharmaceutical aspects of the same. (2) 6. Pyrogen test of IP compared to that of BP & USP, Interpretation of data, and comparison of LAL and official pyrogen tests. (2) 7. After completion of this module student will be able to analyze and interpret results of various microbiological tests such as sterility test. (2) 	
Assigned writing & Exercise activities	<ul style="list-style-type: none"> • Assignments will be given to the students based on different topics such as Sterility tests given in different official publications. • Students will be asked to present comparison of LAL tests in IP, BP, USP. 	(1)
Tutorials	Topics pertaining to the study of pyrogen science will be assigned to the students & they will present the same	(1)
Assigned Reading	<ol style="list-style-type: none"> 1. Bengt Land Berit, "Microbiological Risk Assessment in Pharm. Clean rooms", 1st Edition, Davis Harwood International Publishing, 2001. 2. Richard Prince, "Microbiology in Pharmaceutical Manufacturing" 1st Edition, Davis Harwood International Publishing, 2001. 3. Anne Marie Dixon, "Environmental Monitoring & Clean Rooms & Controlled Environments", Vol 164, 2006. 4. Chilukuri D., "Pharmaceutical Product Development: In Vitro-In Vivo Correlation", Vol 165, 2007. 	

	5. Michael J. Akers and Daniel S. Larrimore, "Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing", 3rd Edition, Marcel Dekker Inc, USA, 2002.	
Module 4	Project and Seminar	1 credit
Objectives	The learners will give one seminar in each semester, based on principles, theory and the application of topics suggested based on the above modules.	

M.Pharm–1204:BiologicalEvaluation(Practicals)

Thecourseisdivided into4 modules of **onecrediteach**with30 instructional hrs/module

<p>Objective: Practical course in Biological Evaluation is designed to give hands-on training in animal handling, dosing and animal experimentation as well as to train a student with various microbiological testing of various formulations.</p> <p>LearningOutcomes:Thelearnerwillbeableto:</p> <ol style="list-style-type: none"> 1. Understandandapplypre-clinical drugevaluation,various testingmethods in animal models 2. Performmicrobiologicalevaluation,analyseandinterpretthe results 3. Get hands on training on animal handling and study various dosing methods in animal models as well as to train students on various sophisticated instruments 		
<p>Pre-assessment:Theentrylevelknowledgeofstudentaboutthepharmacology,microbiologyand bioassayswillbedeterminedbasedonquizzes,question& answers.</p>		
Module1	IntroductiontoAnimal Models	Credit1
Objective	The classical way of pharmacological screening involves sequential testing of new chemical entities or extracts from biological material in isolated organs followed by tests in whole animals, mostly rats and mice. This module will help students to understand pharmacological activity of various formulations by performing various animal model experiments.	
Contents	Experiments	Practical hrs
	1. To Study Effect of diazepam on locomotor activity by actophotometer.	(4)
	2. To Study Effect of diazepam on muscle grip by rota-rod apparatus	(4)
	3. To Study Effect of diazepam on behavioral activity by hole-board technique and elevated plus maze.	(6)
	4. To Study of chlorpromazine induced catatonia.	(4)
	5. Effect of analgesic by hot plate technique	(6)

	<p>2. Hugo and Russell's "Pharmaceutical Microbiology", Edited by Stephen P. Denyer, Norman A. Hodges, Sean P. Gorman, 7th edition, Blackwell Publishing, United Kingdom, 2004.</p> <p>3. Anne Marie Dixon, "Environmental Monitoring & Clean Rooms & Controlled Environments", Vol 164, 2006.</p> <p>4. Chilukuri D., "Pharmaceutical Product Development: In Vitro-In Vivo Correlation", Vol 165, 2007.</p>	
Module 3	Demonstrations	Credit 1
Objective	This module is designed to enable learners to have hands on training on animal handling and various dosing methods as well as to train students on various sophisticated instruments used for measurement of hematological parameters.	
Contents	Experiments	15
	1. Demonstration of animal handling techniques.	(4)
	2. Demonstration of various routes of administration	(4)
	3. Demonstration of Bioanalyser	(6)
	4. Demonstration of Blood Cell Counter	(4)
	5. Demonstration of Water Maize Apparatus	(6)
Assigned writing & Exercise activities	<ul style="list-style-type: none"> Experiments pertaining to the animal handling and different instruments will be demonstrated to the students Experimental work demonstrated to the student will be documented and submitted in the form of Journal. 	(3) (3)
Assigned Reading	<p>1. Updated Manual book of instruments</p> <p>2. S.K. Kulkarni, "Handbook of Experimental Pharmacology", 1st edition, Vallabh Prakashan, Delhi, 2000.</p>	
Module 4	Development of Protocols & Data Handling	Credit 1

Objectives	<ul style="list-style-type: none"> This module is designed to enable the learners to understand stages in the development of Protocols for various activities as per guidelines. To understand various Hematological & biochemical parameters & interpretation of them. 	
Contents	Experiments	15
	1 Study of various standard Protocols	(4)
	2. Development of Protocols for various Pharmacological activities like Anti-inflammatory, Wound healing, Anti-diabetic etc.	(6)
	3. Development of Protocols for Toxicity Studies.	(6)
	4. Development of Protocols for gamma scintigraphic imaging	(4)
	5. Interpretation of Hematological & Biochemical data	(6)
Assigned Writing	Experimental work demonstrated to the student will be documented and submitted in the form of Journal	(4)
Assigned Reading / References	OECD guidelines. ICH Guidelines available at: http://www.ich.org	

M.Pharm-1102 : Quality Management I

SEMESTER		SUBJECT			
I		Quality Management I			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	0	4	0	100	0

The course is divided into 4 modules of **one credit each** with 15 instructional hrs/module.

Objective: Learning of concepts of Quality Management in pharmaceutical products.

Course Outcome

Pre-assessment: Determination of entry level knowledge of student based on importance of quality management in pharmaceutical products.		
Module 1	I. Study of basic principles of total quality management and its importance in pharmacy.	1 credit
Objectives	<ol style="list-style-type: none"> 1. To enable learner to understand basic principles of TQM to built quality in products. 2. To study current guidelines of GLP and GMP. 3. To familiarize learner to the concepts of four M's for quality variation in various pharmaceutical products. 4. To develop an understanding of Revised Schedule M. 5. To provide an insight of good laboratory practices, routine controls, instruments and standard test procedures, non-clinical testing, controls on animal house, site. 6. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion/submission of report <p>Learning Outcomes: The learner will be able to:</p> <ol style="list-style-type: none"> 1. Understand basic principles of TQM and building quality in products using current guidelines of GLP and GMP, factors controlling four M's for quality variation in various pharmaceutical products and documentation according to revised Schedule M. 2. Deal with regulatory aspects of pharmaceuticals and bulk drug manufacturing and include applications for INDA, ANDA and Clinical Trials approval, risks associated with different occupational hazards in pharmaceutical industries and safety procedures and waste disposal techniques to be followed in pharmaceutical industries 	
Contents	Topics Covered	Hrs

	<ul style="list-style-type: none"> • Concept of Total Quality Management, Quality control and quality assurance, Four M's responsible for quality variation. • Philosophy of GMP's, Organization of pharmaceutical manufacturing unit, production management, Revised schedule M. • Concept of GLP and GCP, Quality control laboratory responsibilities, good laboratory practices, routine controls, instruments and standard test procedures, non-clinical testing, control on animal house, site, Data generation and storage. 	(5) (5) (3)
Assigned writing & Tutorials	<ul style="list-style-type: none"> • The assignments will be given to the students based on the above topics. • Topics pertaining to the quality management and its importance in pharmacy will be assigned to the students & they will present the same. 	(2)
Assigned Reading/References	<ol style="list-style-type: none"> 1. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals, Marcel Dekker, Inc., New York 7. 2. S. Weinberg, Ed. Marcel Dekker, Good Laboratory Practice Regulations. 4th Edition, New York, 2007 3. Andrew A . Signore and Terry Jacobs Good Design Practices for GMP Pharmaceutical Facilities Informa Healthcare 2005 4. ICH Guidelines available at: http://www.ich.org 	

Module 2	II. Study of four M's which include Personnel, Premises, Equipment, Materials and Manufacturing methods for quality variation in various pharmaceutical products	1 credit
Objectives	<ol style="list-style-type: none"> 1. To develop an understanding of personnel management, human resource development in pharmaceutical industries. 2. To introduce selection of equipment, purchase specifications, Preventive maintenance and calibration of equipment. 3. To study in detail plant layout and environmental controls in pharmaceutical industries. 	

	4. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report	
Contents	Topics covered	Hrs
	1. Personnel management: Human resource development, Hierarchical structure, Personnel performance appraisal.	(3)
	2. Premises: Plant layout: Controls of contamination and Environmental controls.	(3)
	3. Equipment: Selection, purchase specifications, Preventive maintenance and Calibration.	(2)
	4. Materials: API's and raw materials, purchase specifications, Selection of vendors, Material management, Warehousing, Good Warehousing Practices.	(2)
	5. Manufacturing methods, Production controls and In process controls, Line clearance.	(2)
Assigned Writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the understanding of plant layout and material handling will be assigned to the students & they will present the same. 	(3)
Assigned Reading/References	<ol style="list-style-type: none"> Carlton F, Agallaco J, "Validation of aseptic Pharmaceutical Processes", 1st edition, New York, Marcel Dekker. Loftus, B.T., Nash, R.A., ed. Pharmaceutical Process Validation. vol. 57. New York: Marcel Dekker (1993). S. H. Willig, M.M. Tuckerman and W.S. Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y. 	

Module 3	III. Study of Documentation and its importance in pharmaceutical industries & Study of Distribution and supply chain management	1 credit
Objectives	<ul style="list-style-type: none"> • To develop an understanding of documentation required as per revised Schedule M. • To enable learner to understand the Standard Operating Procedures and its importance in pharmaceutical industry. • The learners will be assigned reading from books and related published articles from journals followed by interactive discussion/submission of report • To introduce learner to distribution and supply chain management. • To enable learner to understand handling of returned goods, recovered materials and Reprocessing. • To understand risks associated with different occupational hazards in pharmaceutical industries. • To teach safety procedures and waste disposal techniques to be followed. 	
Contents	Topics covered	Hrs
	<ul style="list-style-type: none"> • Documentation and its importance: Manufacturing documents, Standard Operating Procedures, Finished product released document. 	(6)
	<ul style="list-style-type: none"> • Distribution and supply chain management: Handling of returned goods, Recovered materials and Reprocessing. Waste disposal and Treatment of Effluent. 	(3)
	<ul style="list-style-type: none"> • Complaints and recalls, evaluation of complaints, Recall procedures, related records and documents. 	(3)
Assigned Writing & Tutorials	<ul style="list-style-type: none"> • The assignments will be given to the students based on the above topics, • Topics pertaining to the application of importance of documentation will be assigned to the students & they will present the same. 	(3)
Assigned Reading/	<ol style="list-style-type: none"> 1. Malik, V, Drugs and Cosmetics Act, 1940, Eastern Book Co. 2. S.H. Willig, M.M. Tuckerman and W.S. Hitchings, "Good Manufacturing 	

References	<p>Practices forPharmaceuticals”,Drugsand Pharm. Sci.Series, Vol.16,Marcel Dekker Inc., N.Y.</p> <p>3. SIGAR. Pharmacovigilance Education and Certification—Report on a Feasibility Survey. Pharmacoepia & Drug Safety. 1995.</p> <p>4. TalbotJCC.<i>Drugsafety—asharedresponsibility</i>.Edinburgh:Churchill Livingstone;. Spontaneous reporting,1991</p> <p>5. ReportofCIOMS(CouncilforInternationalOrganisationsofMedical Sciences) Working Group III, Guidelines for Preparing Core Clinical-Safety Information on Drugs, Geneva. 1995</p>	
Module 4	IV Project&Seminar	1 credit
Objectives	<p>1. Thelearnerswillbeassignedreadingfrombooksandrelatedpublished articlesfromjournalsfollowedbyinteractivediscussion/,presentationof seminar&submissionofreport</p>	

Semester II

M.Pharm-2101:AnalyticalTechniquesII

SEMESTER		SUBJECT			
I		ModernAnalyticalTechniquesII			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	8	4	4	100	100

The course is divided into 4 modules of one credit each with 15 instructional hrs/module.

Objective: The subject of Analytical techniques II consists of the basic principles and advances of various techniques of chromatographic separation of mixtures of organic compounds. Using these techniques the learner can elucidate the structure of separated constituents.

Learning Outcomes: To enable learners to:

- 1 Understand the principles and use various analytical techniques such as the basic principles, techniques and instrumentation of thin layer chromatography (TLC), HPLC, PC
HPLC in determining purity of compounds, quantitative as well as qualitative evaluation drug
- 2 Use the thorough knowledge of these instrumental techniques confidently while working with R & D and Quality Control departments of industry

Pre-assessment: The entry level knowledge of student about the various chromatographic techniques will be determined based on quizzes, question & answers.

Module 1	Principles and Techniques of planar chromatography	1 credit
Objectives	<ul style="list-style-type: none"> • To enable the learners to understand the basic principles of various techniques of planar or flat bed chromatography • To enable the learners to understand the basic principles, techniques and instrumentation of thin layer chromatography (TLC) • To enable the learners to understand the basic principles, techniques and instrumentation of Paper chromatography (PC) • To enable the learners to understand the basic principles, techniques and instrumentation of High performance thin layer chromatography (HPTLC) • The learners will be assigned reading from books and related published articles from journals followed by interactive discussion/submission of report. 	
Contents	Topics covered	Hrs

	<p>General principles, theory and the applications of planar chromatographic techniques</p> <ul style="list-style-type: none"> • Techniques and instrumentation of thin layer chromatography (TLC) (4) • Techniques and instrumentation of Paper chromatography (PC) (2) • Techniques and instrumentation of High performance thin layer chromatography (HPTLC) (2) • Applications of TLC, PC, HPTLC (2) • Comparison of planar chromatography and column chromatography (2) 	
Assigned writing & Exercise activities	<ul style="list-style-type: none"> • The assignments will be given to the students to collect and compile information about different mechanisms of separation of components in a mixture by planar chromatography i.e. adsorption and partition. • The students will be asked to collect data on various stationary phases and mobile phases used for planar chromatographic techniques. 	(2)
Tutorial	<ul style="list-style-type: none"> • Topics pertaining to various techniques of planar chromatography will be assigned to the students & they will present the same. 	(1)
Assigned Reading/ References	<ol style="list-style-type: none"> 1. E. Stahl, Thin-Layer Chromatography, A Laboratory Handbook. 2nd Edition Springer-Verlag Berlin–Heidelberg–New York 1969. 2. Wagner & S. Bladt, Plant Drug Analysis by H., 2nd Edition, Springer 2001. 3. Jiri Gasparic and Jaroslav Churacek, A Laboratory Handbook of paper and thin layer chromatography, Ellis Horwood limited 1979. 4. P.D. Sethi, HPTLC Quantitative Analysis of Pharmaceutical Formulations. CBS Publishers and Distributors, New Delhi, 1996. 5. F. James Holler, Stanley R. Crouch Douglas A. Skoog. Principles of Instrumental Analysis, , Publisher: Brooks/Cole Pub Co; 6th edition, 2006 6. Analytical Chemistry by open learning series, Wiley Publisher, 2nd Edition 7. David G. Watson Pharmaceutical analysis: a text book for pharmacy students and pharmaceutical chemists Elsevier/Churchill Livingstone, 2005 	
Module 2	Principles and techniques of column chromatography	1 credit

Objectives	<ol style="list-style-type: none"> 1. To enable the learners to understand the basic principles of various techniques of column chromatography 2. To enable the learners to understand the basic principles, techniques and instrumentation of High performance liquid chromatography (HPLC) 3. To enable the learners to understand the basic principles, techniques and instrumentation of Gas chromatography (GC) 4. To enable the learners to understand the basic principles, techniques and instrumentation of Size exclusion chromatography 5. To enable the learners to understand the basic principles, techniques and instrumentation of Ion pair chromatography 6. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion/submission of report 	
Contents	Topics covered	Hrs
	<p>General principles, theory and the application of column chromatographic techniques:</p> <ul style="list-style-type: none"> • Techniques, instrumentation and Applications of High performance liquid chromatography (HPLC) – Theory of HPLC - Van Deemter Equation, various detectors used, derivatisation in HPLC. (5) • Techniques, instrumentation and Applications of Gas chromatography (GC) - Theory of GC, packed column, Capillary column, carrier gases used. (5) • Techniques, instrumentation and Applications of Size exclusion chromatography and ion pair chromatography. (2) 	
Assigned writing	<ul style="list-style-type: none"> • The assignments will be given to the students to collect and compile information about different mechanisms of separation of components in a mixture by column chromatography i.e. partition, molecular size, ionic charge. • The students will be asked to collect data on various stationary phases and mobile phases used for column chromatographic techniques. 	(2)

Tutorial	<ul style="list-style-type: none"> • Topics pertaining to various techniques of column chromatography will be assigned to the students & they will present the same. 	(1)
Assigned Reading/References	<ol style="list-style-type: none"> 1. Bernard Fried, Joseph Sherma, Thin-layer chromatography 4th Edition Marcel Dekker 2005 2. Instrumental methods of Analysis by Higuchi, CBS Publishers. 1997 3. High Performance Liquid Chromatography: Analytical Chemistry by open learning series, Wiley Publisher, 2nd Edition 1992. 4. W. John Lough, High performance liquid chromatography: fundamental principles and practice Blackie Academic & Professional Publisher, 1995 5. HPLC: High Performance Liquid Chromatography: Volume 2, by P.D. Sethi and Rajat Sethi CBS Publisher, 2008 6. P.D. Sethi, Rajat Sethi, HPLC: Quantitative Analysis of Pharmaceutical Formulations, CBS Publishers 2007. 7. F. James Holler, Stanley R. Crouch Douglas A. Skoog. Principles of Instrumental Analysis, Publisher: Brooks/Cole Pub Co; 6th edition, 2006 8. Gas Chromatography: Analytical Chemistry by open learning series, 2 Edition Wiley Publishers 1995. 9. Frank A. Settle, Brian D. Lamp, David L. McCurdy, Mark F. Vitha, Brian W. Gregory, Yinfa Ma Instrumental Methods of Analysis Wiley-Interscience; 8th edition, 2011 	

Module 3	Structure elucidation of organic compounds-Theory and Problemsolving	1 credit
Objectives	<ul style="list-style-type: none"> • To enable the learner to understand the basic principles of structure elucidation of organic compounds. • To enable the learner to understand the basic principles, techniques and instrumentation of Mass spectrometry- (MS) 	

Assigned Reading/References	<ol style="list-style-type: none"> 1. R.M. Silverstein, G.C., Bassler, T.C. Morrill Spectroscopic identification of organic compounds John Wiley and Sons, New York, 5th Edition. 1991. 2. William. Kemp Organic Spectroscopy 3 edition. W.H. Freeman & Company; 1991 3. Analytical Chemistry by open learning series, 2 Edition Wiley Publishers. 4. J.R. Dyer, Applications of absorption Spectroscopy of Organic compounds Prentice Hall, London 2009 	
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Module 4	Project and Seminar	1 credit
Objectives	<ul style="list-style-type: none"> • The learners will give one seminar in each semester based on principles, theory and the application of topics suggested based on the above module 	(15)

M.Pharm–2201: Analytical Techniques II (Practicals)

The course is divided into **4** modules of **one credit each** with 30 instructional hrs/module.

Objective:		
<ol style="list-style-type: none"> 1. To give hands on training to learners for techniques of qualitative and quantitative techniques of planar and Column chromatography 2. To develop various analytical methods with optimization of parameters 3. To perform quantitative estimation of drugs from formulations 4. To identify impurities in the synthetic samples and/or plant extracts. 5. To understand and implement pharmacopoeial requirements wherever necessary 		
Learning Outcomes: The learner will be able to:		
<ol style="list-style-type: none"> 1. Develop various analytical methods for quantitative estimation of drugs from formulations using HPLC and other chromatographic methods 2. Identify impurities in synthetic samples and/or plant extracts and implement pharmacopoeial requirements 		
Pre-assessment		
<ol style="list-style-type: none"> 1. To assess the entry level knowledge of learners about basic planar chromatographic techniques. 2. To assess the entry level knowledge of learners about stationary phases and mobile phases used for TLC, PC and HPTLC. 		
Module 1	Techniques of planar chromatography-I-TLC,PC	1 credit
Objectives	<ol style="list-style-type: none"> 1. To enable the learners to understand and perform the techniques and instrumentation of thin layer chromatography (TLC) 2. To enable the learners to understand and perform the techniques and instrumentation of Preparative TLC 	
Contents	Experiments	Hrs
	<ul style="list-style-type: none"> • Development of suitable solvent system for the separation of mixtures of organic compounds. • Development of suitable solvent system for the separation of herbal extracts. • Quantitative separation of components of a mixture by Preparative thin layer chromatography. • Use of various derivatising agents for detection of compounds by TLC 	 (8) (8) (6)

	<ul style="list-style-type: none"> Separation of sugars/ amino acids by Thin layer chromatography. 	(4)
Assigned Writing/ Practical Activities	<ul style="list-style-type: none"> Experiments involving the qualitative and quantitative separation of organic mixtures and plant extracts by TLC would be assigned to the learners and they would perform and enter the same in their work books. 	(4)
Assigned Reading/ References	<ol style="list-style-type: none"> Thin-Layer Chromatography, A Laboratory Handbook by E. Stahl, Second Edition, Springer-Verlag Berlin–Heidelberg–New York 1969. Plant Drug Analysis by H. Wagner & S. Bladt, Second Edition, Springer. A Laboratory Handbook of paper and thin layer chromatography by Jiri Gasparic and Jaroslav Churacek, Publisher-Ellis Horwood limited. Manual of HPTLC applicator, scanner and photodocumentation system by CAMAG 	
Module 2	Techniques of planar chromatography–II-PC, HPTLC.	1 credit
Objectives	<ol style="list-style-type: none"> To enable the learners to understand and perform the techniques and instrumentation of Paper chromatography (PC) To enable the learner to understand and perform the basic techniques and instrumentation of High performance thin layer chromatography (HPTLC) 	
Contents	Experiments	Hrs
	<ul style="list-style-type: none"> Development of suitable solvent system for the separation of mixtures of organic compounds. 	(6)
	<ul style="list-style-type: none"> Development of suitable solvent system for the separation of herbal extracts. 	(6)
	<ul style="list-style-type: none"> Use of various derivatising agents for detection of compounds by PC. 	(4)
	<ul style="list-style-type: none"> Separation of sugars/ amino acids by Paper chromatography. 	(4)
	<ul style="list-style-type: none"> Demonstration and hands on training on High performance thin layer chromatography (HPTLC). 	(4)

	<ul style="list-style-type: none"> Separation of some mixtures of organic compounds by HPTLC using TLC applicator, Scanner and TLC plate visualiser 	(4)
Assigned Writing/ Practical Activities	<ul style="list-style-type: none"> Experiments involving the qualitative and quantitative separation of organic mixtures and plant extracts by PC and HPTLC would be assigned to the learners and they would perform and enter the same in their work books. 	(2)
Assigned Reading/ References	<p>5. Thin-Layer Chromatography, A Laboratory Handbook by E. Stahl, Second Edition, Springer-Verlag Berlin–Heidelberg–New York 1969.</p> <p>6. <u>Plant Drug Analysis</u> by <u>H. Wagner & S. Bladt</u>, Second Edition, Springer.</p> <p>7. A Laboratory Handbook of paper and thin layer chromatography by Jiri Gasparic and Jaroslav Churacek, Publisher-Ellis Horwood limited.</p> <p>8. Manual of HPTLC applicator, scanner and photodocumentation system by CAMAG</p>	
Assigned Reading/ References	<p>1. A Laboratory Handbook of paper and thin layer chromatography by Jiri Gasparic and Jaroslav Churacek, Publisher-Ellis Horwood limited</p> <p>2. Pharmacopoeia of India, Govt. of India, Ministry of Health.</p> <p>3. British Pharmacopoeia, ministry of health and social welfare, UK.</p> <p>4. HPLC: High Performance Liquid Chromatography: Volume 2, by <u>P.D. Sethi</u> and <u>Rajat Sethi</u>.</p> <p>5. Instrumental Methods of Chemical analysis by G. W. Ewing McGraw-Hill Book Co., Inc., New York.</p> <p>6. Principles of Instrumental Analysis, Douglas A. Skoog, F. James Holler and Timothy A. Nieman, Fifth edition, Harcourt Brace College publishers.</p>	
Module 3	Techniques of column chromatography- HPLC, GC, Flash chromatography, Supercritical fluid chromatography.	1 credit
Objectives	<p>1. To perform quantitative and qualitative estimation using High Performance liquid chromatography (HPLC) and Gas chromatography (GC).</p> <p>2. To perform selective quantitative estimation of drugs from their mixture.</p>	
Contents	Experiments	Hrs

	<ol style="list-style-type: none"> Demonstration of High performance thin layer chromatography. (2) Plotting of a standard curve for caffeine / betaine / catechin by HPLC. (6) Quantitative estimation of caffeine in cola drinks and tea extract by HPLC. (4) To check the effect of alteration of various parameters on retention times (RT) of compounds by HPLC. (4) Determination of HETP value, selectivity factor, tailing factor by HPLC. (4) Demonstration of Gas liquid chromatography. (2) Demonstration of flash chromatography. (2) Demonstration of Supercritical fluid extraction chromatography. 	
Assigned writing & Tutorial	Experiments involving the qualitative and quantitative separation of organic mixtures and plant extracts by HPLC and/or GC would be assigned to the learners and they would perform and enter the same in their work books.	(2)
Assigned Reading/ References	<ol style="list-style-type: none"> A Laboratory Handbook of paper and thin layer chromatography by Jiri Gaspari and Jaroslav Churacek, Publisher-Ellis Horwood limited Pharmacopoeia of India, Govt. of India, Ministry of Health. British Pharmacopoeia, ministry of health and social welfare, UK. HPLC: High Performance Liquid Chromatography: Volume 2, by <u>P.D. Sethi</u> and <u>Rajat Sethi</u>. Instrumental Methods of Chemical analysis by G. W. Ewing McGraw-Hill Book Co., Inc., New York. Principles of Instrumental Analysis, Douglas A. Skoog, F. James Holler and Timothy A. Nieman, Fifth edition, Harcourt Brace College publishers. 	

Module 4	Structure elucidation of organic compounds - Problems solving	1 credit
Objectives	<ul style="list-style-type: none"> To identify functional groups in compounds by chemical studies. To identify functional groups in compounds by spectral studies. To elucidate the structure of simple organic molecules using chemical and spectral studies. 	
Contents	Experiments	Hrs

	1. Identification of various functional groups (amine, nitro, aldehyde, keto, carboxylic, hydroxyl, etc.) by UV and IR	(6)
	2. Identification of different functional groups by ¹³ C NMR.	(6)
	3. Identification of different types of carbons and carbon containing groups by ¹³ C NMR	(4)
	4. Identification of Molecular ion peak, base peak in a mass spectrum of small molecular weight organic compounds.	(6)
	5. Structure elucidation of some small molecular weight organic molecules by UV, IR, NMR and MS spectral data.	(6)
Assigned Writing & Exercise	1. Problems pertaining to the structure elucidation of organic molecules with different functional groups would be assigned to the learners. 2. The problems will be solved by learners using the given spectral data for various drugs, structures will be deduced and the results will be entered in their workbooks	(2)
Assigned Reading/References	1. Spectroscopic identification of organic compounds by R.M. Silverstein, G.C., Bassler, T.C. Morrill, Pub: John Wiley and Sons, NY. 2. Spectroscopic identification of organic compounds by John Dyer, Willy, NY. 3. Organic Spectroscopy by William. Kemp, NY. W.H. Freeman & Company; 3 edition (March 1991) 4. Analytical Chemistry by open learning series 5. Applications of absorption Spectroscopy of Organic compounds by J.R. Dyer (Prentice Hall, London)	

M.Pharm–2102-Product Development–II

SEMESTER	SUBJECT
I	Product Development–II

WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	0	4	0	100	0

The course is divided into 4 modules of one credit each with 15 instructional hrs/module.

<p>Objective: To make the learner understand the developments in design, development and evaluation of advanced drug delivery systems.</p> <p>Learning Outcomes: The learner will be able to:</p> <ol style="list-style-type: none"> 1. Understand the various aspects in formulation development of pharmaceutical dosage forms and novel drug delivery carriers. 2. Encompass the development of formulations, selection of various excipients, selection of routes of administration and evaluation of novel pharmaceutical carrier systems <p>Pre-assessment: Determination of entry level knowledge of student on advanced drug delivery systems in form of quizzes, question & answers.</p>		
Module 1	I. To study concepts of rate controlled and site specific drug delivery systems and particulate carrier systems	1 credit
Objectives	<ul style="list-style-type: none"> • To study site specific drug delivery systems to increase therapeutic efficacy of drug with minimum side-effects. • To introduce the learner to specialized pharmaceutical dispersed systems. • To study recent advances in particulate drug delivery systems. • To enable learners to understand the physiology of eye and develop advancements in ocular controlled drug delivery systems. • To enable learner to understand biochemistry and anatomy of skin, recent developments in transdermal drug delivery systems and evaluate TDDS as per regulatory guidelines. • The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics Covered	Hrs.

	<ul style="list-style-type: none"> • Conceptsandsystemsdesignforratecontrolleddelivery:Rate preprogrammed,ActivationmodulatedandFeedbackregulateddrugdelivery systems. • Particulatecarriersystems: microspheres,liposomesandnanocarriers. • Sitespecificdrugdelivery:Activeandpassivetargeting, monoclonal antibodiesfordrugtargeting. <p>1 Oculardeliveryofdrug:Anatomy&physiologyofeye,development of ocular controlled release therapeutic systems, safety & toxicity evaluation.Assignedreading. (3)</p> <p>2 Transdermaldrugdelivery:Permeationthroughskin,permeation enhancers,technologiesfordevelopingtransdermaldrugdeliverysystemslike gels,patchesandsprays andevaluationthereof. (3)</p>	(3)
Assigned Writing & Tutorial	<ul style="list-style-type: none"> • Theassignments willbe given to thestudents basedon theabovetopics. • Topicspertainingtothecurrentadvancesinrate&controlledrelease deliverysystems will be assignedto thestudents&theywill present thesame. 	(3)
Assigned reading/ References	<ol style="list-style-type: none"> 1. YieW.Chien,“NovelDrugDeliverySystems”,DrugsandPharm.Sci.Series, Vol. 14, Marcel Dekker Inc., N.Y,1992. 2. RobinsonJ.RandLeeV.L,“ControlledDrugdeliveryfundamentalsandapplications”,2ndedition, MarcelDekker,Inc.,<i>NewYork</i>,1987. 3. S.D. Bruck, “<i>Controlled Drug Delivery</i>”, Vol.1 (Basic Concepts) CRC Press.1983. 4. Davis, S.S. and Illum, L., “Colloidal delivery systems- opportunity and challenges, in site specific drug delivery cell biology”, John Wiley and Sons, Chichester, , 1986. 5. Vyas, S.P. and Khar, R.K., “Targeted and controlled drug delivery novel carriers”, CBS, 1st edition, 2002. 6. Micheal Roberts, “Dermal Absorption & Toxicity Assessment”, 2nd Edition, Vol 177, 2007. 7. G.S.Banker&C.T.Rhodes,“ModernPharmaceutics”,DrugsandPharm.Sci. 	

	Series, Vol. 7, Maracel Dekker Inc., N. Y. 1994. 8. Jain S., Jain N., "Liposomes as drug carriers", In: Controlled and novel drug delivery", CBS Publishers and Distributors, 1997.	
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Module 2	II. Advances in Oral Drug Delivery Systems	1 credit
Objectives	<ul style="list-style-type: none"> To enable the learner to understand the recent advances in Oral Drug Delivery Systems. To provide an insight to concepts and various types of oral controlled release drug delivery system and evaluation methods for the same. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion/ submission of report 	
Contents	Topics Covered	Hrs
	<ul style="list-style-type: none"> Oral Drug Delivery Systems: Osmotic pressure controlled, membrane permeation controlled, pH controlled, Ion-exchange controlled, gel diffusion controlled and hydro dynamically balanced systems, modulation of gastrointestinal transit time and release kinetics and evaluation thereof. 	(12)
Assigned Writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the product development stages & market need of the formulations will be assigned to the students & they will present the same. 	(3)
Assigned reading/ References	<ol style="list-style-type: none"> Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms" New York Marcel Dekker Volume 110, 2001. Lachman, L., Lieberman, H. A., & Kanig, J. L. "The Theory and Practice of Industrial Pharmacy" 3rd edition, Mumbai: Varghese Publishing House, 1991 	

	<p>3. Rawlins, E. A. (1995). Bentley's textbook of Pharmaceutics, 8th edition, London: Bailliere Tindal.</p> <p>4. Micheal Rathbone, "Modified Drug Release Drug Delivery Technology", 2nd Edition, Vol 1, 2008.</p> <p>5. Chilukuri D., "Pharmaceutical Product Development: In Vitro-In Vivo Correlation", Vol 165, 2007.</p> <p>6. Rubinstein, M. H., Aulton M. E., "Pharmaceutics: the science of dosage form design", pp. 304-321., London: ELBS Longman Group Ltd. 1988.</p> <p>7. Robinson J.R and Lee V.L, "Controlled Drug delivery fundamentals and applications", 2nd edition, Marcel Dekker, Inc., New York, 1987.</p> <p>8. Rolland A., "Pharmaceutical Particulate Carriers", New York: Marcel Dekker, Inc. 1993</p> <p>9. Rudnic, E. M., & Schwartz, J. D. "Remington: The Science and Practice of Pharmacy", Philadelphia: Lippincott Williams & Wilkins. 2006.</p> <p>10. Saha, S., & Shahiwala, A. F. "Multifunctional coprocessed excipients for improved tableting performance", 2nd edition, 2009</p>	
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Module 3	III. To study mucosal and intrauterine drug delivery systems	1 credit
Objectives	<ul style="list-style-type: none"> • To enable the learners to understand the anatomy and physiology of buccal and nasal mucosa and lungs. • To enable the learners to understand the recent developments in mucosal drug delivery systems and its applications. • To provide insight into rectal and vaginal drug delivery systems and recent developments in medicated IUDS, hormone-releasing IUDS and prospects for intrauterine contraception. • The learners will be assigned reading from books and related published articles from journals followed by interactive discussion/submission of report 	

Contents	Topics Covered	Hrs
	<ul style="list-style-type: none"> Mucosal drug delivery systems: Mechanism of transmucosal permeation and mucosal membrane models, Buccal, Nasal, Pulmonary, Rectal and Vaginal drug delivery systems. Intrauterine drug delivery systems: Medicated IUDs, copper IUD, Hormone releasing IUD, long acting contraceptive formulations. 	(6) (6)
Assigned Writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the mucosal & intrauterine drug delivery systems will be assigned to the students & they will present the same. 	(3)
Assigned reading/ References	<ol style="list-style-type: none"> Kreuter J., "Colloidal Drug Delivery Systems", Marcel Dekker, New York, 1994. Langer, ed., Biodegradable polymers as drug delivery systems, Marcel Dekker Inc. New York 	

Module 4	IV. To study recent advancements in Parenteral drug delivery systems & Project & Seminar	1 credit
Objectives	<ul style="list-style-type: none"> To develop an understanding of environmental controls and design considerations for Parenteral production. To enable learners to understand the recent advances in manufacturing of small and large volume parenterals. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics covered	hrs
	<ul style="list-style-type: none"> Parenteral drug delivery systems: Injectable controlled release formulations, long acting depot formulations, implantable drug delivery. The Seminar topic will be given to the student based on the above content & they have to present the same 	(4) (8)
Assigned Writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. 	(3)

	<ul style="list-style-type: none"> Topics pertaining to the product development stages & market need of parental formulations will be assigned to the students & they will present the same. 	
Assigned reading/References	1. K.E.Avis, "Pharmaceutical Dosage Forms: Parental Medication", Vol.I Marcel Dekker Inc., N.Y, 2008. 2. S.Turco and R.E.King, "Sterile Dosage Forms", 2nd edition, 1998.	

M.Pharm-2103: Quality Management-II

SEMESTER		SUBJECT			
I		Quality Management-II			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	0	4	0	100	0

The course is divided into 4 modules of **one credit each** with 15 instructional hrs/module.

<p>Objective:</p> <ol style="list-style-type: none"> 1. To learn of concepts of TQM in totality. 2. To study in detail ICH Guidelines with special reference to quality by design and risk management 3. To study the concepts of patent search, patent infringement and applications for Indian and International patents. <p>Learning Outcomes: The learner will be able to:</p> <ol style="list-style-type: none"> 1. Understand the aspects in formulation development of pharmaceutical dosage forms and novel drug delivery carriers using guideline of GLP and GMP 2. Apply the Regulatory aspects of pharmaceutical and bulk drug manufacture to built quality in products. 3. Develop an understanding of quality review and quality audit in pharmaceutical industries. 		
<p>Pre-assessment: Determination of entry level knowledge of student based on regulatory aspects in pharmacy practice in form of quizzes, question & answers.</p>		
Module 1	I. Study of basic principles of Regulatory aspects of pharmaceutical and bulk drug manufacture, ICH guidelines and its importance in pharmacy.	1 credit
Objectives	<ul style="list-style-type: none"> • To enable the learner to understand Regulatory aspects of pharmaceutical and bulk drug manufacture to built quality in products and provide brief Overview of worldwide regulatory agencies and authorities. • To study recent amendments to Drugs and Cosmetics Act and other relevant Rule of regulatory authorities. • To study current guidelines of GLP and GMP. • To study in detail ICH Guidelines with special reference to quality by design and risk management. • The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics Covered	Hrs

	<ul style="list-style-type: none"> Regulatory aspects of pharmaceutical and bulk drug manufacture, Overview of world wide regulatory agencies and authorities. 	(3)
	<ul style="list-style-type: none"> Recent amendments to Drugs and Cosmetics Act and other relevant Rules like Schedule M, Schedule Y, Consumer Protection Act, Environmental Protection Act, Factories Act. 	(3)
	<ul style="list-style-type: none"> Certification and licensing procedures, WHO-GMP, US-FDA, EU and ISO Certification. 	(3)
	<ul style="list-style-type: none"> ICH guidelines: Q1-Q10, Guidelines with special reference to quality by design and risk management. 	(3)
Assigned writing & Tutorials	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the regulatory aspects of pharmaceutical and bulk drug manufacture will be assigned to the students & they will present the same. 	(3)
Assigned Reading/References	<ol style="list-style-type: none"> S.H. Willig, M.M. Tuckerman and W.S. Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y. A. A. Signore and T. Jacobs, "Good Design Practices for GMP Pharmaceutical Facilities" Taylor & Francis Group. ICH Guidelines available at: http://www.ich.org 	

Module 2	II. Study of Regulatory aspects of pharmaceuticals, US-FDA and WHO approval, INDA and ANDA applications. Patent search, infringement and its applications and Present status and scope of Pharmaceutical Industry in India.	1 credit
Objectives	<ol style="list-style-type: none"> To enable the learner understand the regulatory aspects of pharmaceuticals and bulk drug manufacturing and include applications for INDA, ANDA and clinical trial approval To study the concepts of patent search, patent infringement and applications for Indian and International patents. 	

	<p>3. To familiarize the learner with concepts of Intellectual property rights and its applications.</p> <p>4. To introduce the learner to the concepts of Generics, Supergenerics and Biosimilars and understand Dossier preparation in CTD format.</p> <p>5. To discuss present status and scope of pharmaceutical industry in India</p> <p>6. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion/submission of report.</p>	
Contents	Topics Covered	hrs
	<p>1. Intellectual property rights, Patent search and awareness, filing procedures, patent infringement and application for Indian and International patents.</p> <p>2. Overview of Drug approval process, applications for INDA, NDA and ANDA, Generics, Supergenerics and Biosimilars Clinical trial approval, Dossier preparation in CTD format.</p> <p>3. Present status and scope of Pharmaceutical Industry in India, Globalization of drug industry, Mergers & Acquisitions, Introduction to export of drugs and import policy.</p>	(4) (4) (4)
Assigned writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the regulatory aspects of pharmaceuticals will be assigned to the students & they will present the same. 	(3)
Assigned Reading/References	<p>1. Carlton F, Agallaco J, "Validation of aseptic Pharmaceutical Processes", 1st edition, New York, Marcel Dekker.</p> <p>2. Loftus, B. T., Nash, R. A., ed. Pharmaceutical Process Validation. vol. New York: Marcel Dekker, 1993.</p> <p>3. ICH Guidelines available at: http://www.ich.org</p> <p>4. Indian Patents Act 1970 available at http://www.patentoffice.nic.in/ipr/patent/patents.htm</p>	

Module 3	III. Study of quality audit and quality review procedure, Outsourcing and Sampling plans.	1 credit
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Objectives	<ul style="list-style-type: none"> To develop an understanding of quality review and quality audit in pharmaceutical industries. To introduce outsourcing, sampling plans and develop statistical methods of data generated. To study validation of various systems in pharmaceutical industry. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics covered	Hrs
	<ul style="list-style-type: none"> Outsourcing: Manufacturing Packaging, Analytical testing, Loan licensing, Contract manufacture, Audits thereof 	(4)
	<ul style="list-style-type: none"> Quality Audits: Auditing of manufacturing processes and facilities, Quality Review, Compliance reports and handling of Non –compliance. 	(4)
	<ul style="list-style-type: none"> Sampling plans, Methods and Statistical analysis of data generated. 	(4)
Assigned writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the quality audit and quality review procedure, outsourcing and sampling plans will be assigned to the students & they will present the same. 	(3)
Assigned Reading/ References	<ol style="list-style-type: none"> Malik V., “Drugs and Cosmetics Act”, Eastern Book Co., 1940 Loftus, B.T., Nash, R.A., ed. “Pharmaceutical Process Validation”, vol. 57, New York: Marcel Dekker, 1993. 	

Module 4	IV. Understanding of Occupational health hazards, Plant security, Internal security and safety procedures to be followed in pharmaceutical industries. & Project & Seminar	1 credit
Objectives	<ul style="list-style-type: none"> To make learner understand the risks associated with different occupational hazards in pharmaceutical industries. To teach safety procedures and safety exercises to be followed. 	

	<ul style="list-style-type: none"> To introduce the learner to plant security, security of site and internal security in pharmaceutical industries. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics Covered	Hrs
	<ul style="list-style-type: none"> Safety in plant, safety exercises. Chemical and Fire hazards Class I, II & III. Occupational health hazards. Plant security, Security of site, Internal security and current issues. The student has to present the seminar on the basis of topics covered. 	(2) (2) (8)
Assigned Writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the risks associated with different occupational hazards & safety procedures to be followed will be assigned to the students & they will present the same. 	(3)
Assigned reading/ References	<ul style="list-style-type: none"> Loftus, B.T., Nash, R.A., ed. "Pharmaceutical Process Validation", vol. 57, New York: Marcel Dekker, 1993. 	

M.Pharm–2104–Packaging Development

SEMESTER		SUBJECT			
II		Packaging Development			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	8	4	4	100	100

The course is divided into 4 modules of **one credit each** with 15 instructional hrs/module.

Objective:

- To study the protective function of commonly used packaging materials, their limitations and possible interactions with various drugs
- To evaluate glass, plastic and metal containers as per the pharmacopeial guidelines.

<p>3. To understand requirement and specification of caps and closure system, and labels and labeling concepts.</p> <p>Learning Outcome: The learner will be able to:</p> <ol style="list-style-type: none"> 1. Understand the importance of packaging in pharmaceutical product development. 2. Gain knowledge of protective function of commonly used packaging materials, their limitations and possible interactions with various drugs and help in choosing appropriate pharmaceutical packaging 		
<p>Pre assessment: Determination of entry level knowledge of student about pharmaceutical packaging requirements based on quizzes, question & answers.</p>		
Module 1	I. Pharmaceutical containers and its specifications	1 credit
Objectives	<ol style="list-style-type: none"> 1. To enable the learner to understand various types of glass used in packaging and manufacturing of glass containers. 2. To understand classification of plastics, additives used in fabrication process 3. To study different types of metal containers used in pharmaceutical packaging 4. Evaluation of glass, plastic and metal containers as per the pharmacopeial guidelines. 5. To introduce the learner to container specifications for sterile dosage forms. 6. To introduce the learner to various types of flexible packaging 7. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics Covered	hrs

	<ul style="list-style-type: none"> • Glass containers for Pharmaceuticals: Glass types, their manufacture chemical composition, Performance testing and quality control, Defects. (3) • Plastics containers for pharmaceuticals: Classification of plastics, plastic polymers and their physio-chemical, mechanical and biological properties: Additives and fabrication processes, plastic containers for Parenteral and transfusion sterile drip kits. Quality control testing and biological toxicity. (3) • Metal containers: Aluminum and tin plated drums collapsible tubes. Aerosol containers, Lacquering, coating and lining. (2) • Flexible packaging: Types of films, Co-extruded films, foils, coating and laminates, shrink and stretch films, blisters including ALU-ALU blisters and Strip Packaging. (2) 	
Assigned writing & Tutorial	<ul style="list-style-type: none"> • The assignments will be given to the students based on the above topics. • Topics pertaining to pharmaceutical containers used in pharmaceutical industries will be assigned to the student followed by presentation and interactive session. 	(2)
Assigned Reading/References	<ol style="list-style-type: none"> 1. Hanlon J., Robert J. Kelsey, "Handbook of Package Engineering" 2nd Edition, McGraw-Hill, New York. 1984 2. Paine A., "Packaging User's Handbook", Springer, 1990 3. K. Avis, Liberman and Lachman, Pharmaceutical Dosage Forms: Parenterals, Vol. I, Marcel Dekker, Expanded and revised edition, 2008. 	

Module 2	II. Study of secondary packaging systems and its specifications	1 credit
Objectives	<ul style="list-style-type: none"> • To enable learner to understand requirement and specifications of caps and closure system, and labels and labeling concepts. • To understand the design of corrugated systems used in pharmaceutical packaging. • Evaluation of all secondary packaging systems. 	

Contents	Topics Covered	hrs
	<ul style="list-style-type: none"> • Paper and paperboard: Types of paper, folding cartons, quality control testing of paper and paperboard and their common defects 	(3)
	<ul style="list-style-type: none"> • Corrugated and solid fibre boards and boxes: Types of corrugation, methods, types of box design and Quality control. 	(3)
	<ul style="list-style-type: none"> • Caps and Closures: Types of caps, closures, liners, child resistant caps. Elastomeric closures for parenterals, classification of Elastomers, physical chemical and biological properties and their quality control. 	(3)
	<ul style="list-style-type: none"> • Labels and labeling: Types of labels, adhesives, inject and bar coding and printing of labels, Quality control and common defects in printing of labels. 	(3)
Assigned writing & Tutorial	<ul style="list-style-type: none"> • The assignments will be given to the students based on the above topics. • Topics pertaining to secondary packaging systems used in pharmaceutical industries will be assigned to the students followed by presentation and interactive session. 	(3)
Assigned Reading/References	<ol style="list-style-type: none"> 1. Friedman W.F., Kipnees J.J., "Industrial Packaging". New York: Wiley, 1960. 2. Paine A., "Packaging User's Handbook", Springer, 1990 	

Module 3	III. Selection of pharmaceutical packaging based on product package compatibility, environmental conditions and handling conditions.	1 credit
Objectives	<ul style="list-style-type: none"> • To enable the learner to understand various laboratory testing methods for packaging systems. • To study tamper evident packaging systems • To determine product packaging compatibility 	

	<ul style="list-style-type: none"> To determine packaging selection criteria. 	
Contents	Topics Covered	hrs
	<ul style="list-style-type: none"> Transitworthiness of package: Hazards, mechanical, climatic protection during transit, Laboratory testing methods. 	(4)
	<ul style="list-style-type: none"> Product–Package compatibility: Stability of product, package selection and development criterion, Line clearance and packaging operation in pharma industry. 	(4)
	<ul style="list-style-type: none"> Tamper evident and child resistant packaging systems: Various types and their mechanisms. 	(4)
Assigned writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to product package compatibility, environmental conditions and handling conditions in pharmaceutical industries will be assigned to the students & they will present the same. 	(2) (1)
References	<ol style="list-style-type: none"> Ross, C.F., “Packaging of Pharmaceuticals”, Newnes-Butterworths (London), 1975. Friedman W.F., Kipnes J.J., “Industrial Packaging”. New York: Wiley, 1960. 	

Module 4	IV. Packaging Machinery & Seminar	1 credit
Objectives	<ul style="list-style-type: none"> To enable learner to understand the concepts in packaging machinery required for filling of liquid dosage forms and packaging systems for solid dosage forms. To understand concepts in sealing and capping machinery. To introduce learner to packaging controls as per schedule M 	
Contents	Topics Covered	hrs
	<ul style="list-style-type: none"> Packaging Machinery: Including strip packaging, and blister packing, form fill and seal machines, blow form and fill machines liquid and solid filling 	(9)

	<p>machines, capping machines packaging operations and packaging controls as per schedule M</p> <ul style="list-style-type: none"> • Project&SeminarBasedonNewPackagingAspectInPharmaIndustry 	(3)
Assigned writing & Tutorial	<ul style="list-style-type: none"> • The assignments will be given to the students based on the above topics. • Topics pertaining packaging machinery in pharmaceutical industries will be assigned to the students & they will present the same. 	(3)
Assigned Reading/References	<ol style="list-style-type: none"> 1. Hanlon J., Robert J. Kelsey, "Handbook of Package Engineering" 2nd Edition, Mcgraw-Hill, New. York. 1984 2. Yam, K L., "The Wiley Encyclopedia of Packaging Technology" 3rd. Edition, 2009. 3. W. F. Friedman and J.J. Kipnees, <i>Industrial Packaging</i>. New York: Wiley, 1960. 4. Ross, C. F. <i>Packaging of Pharmaceuticals</i>, Newnes-Butterworths(London), 1975 	

M.Pharm–2204-Packaging and Product Development–II(Practicals)

The course is divided into **4** modules of **one credit each** with 30 instructional hrs/module

Objective:

1. To provide hands-on training and enable the learner to understand the practical aspects in formulation development of Pharmaceutical dosage forms;
2. To use new drug delivery systems and selection, testing, quality control and evaluation of commonly used packaging materials, their limitations and possible interactions with various drugs and formulation.

Learning Outcome: The learner will be able to:

1. Perform various quality control tests on packaging materials, analyze and interpret the results.
2. Understand the importance of packaging in pharmaceutical product development and select appropriate packaging materials

<p>3. Gain knowledge of protective function of commonly used packaging materials, their limitations and possible interactions with various drugs and help in choosing appropriate pharmaceutical packaging</p>		
<p>Pre-assessment: Determination of entry level knowledge of student based on commonly used packaging materials used in pharmacy in form of quizzes, question & answers.</p>		
<p>Module 1</p>	<p>I. Pharmaceutical containers: Study of primary and secondary packaging systems their specification evaluation</p>	<p>1 credit</p>
<p>Objectives</p>	<ul style="list-style-type: none"> • To provide hands on training on various types of glass used in packaging • Evaluation of glass, plastic and metal containers as per the pharmacopeial guidelines. • Evaluation of paper and corrugated systems used in pharmaceutical packaging • The enable learner to understand documentation and maintenance of record all the experiments in the prescribed format in the journal. 	
<p>Contents</p>	<p style="text-align: center;">Experiments</p>	<p>Hrs</p>
	<ul style="list-style-type: none"> • To perform quality control tests on glass ampoules as per IP and USP (4) • To perform quality control tests on glass vials as per IP and USP. (4) • To perform quality control tests on glass bottles as per IP and USP (4) • To perform quality control tests on paper as per IS Standards (4) • To perform quality control tests on paper board as per IS Standards (3) • To perform quality control tests on corrugated fibre board (3) • Determination of wax content of wax paper. (2) • Determination of polyethylene content of polyethylene coated paper (2) 	
<p>Assigned Writing/ Practical Activities</p>	<ul style="list-style-type: none"> • Experiments pertaining to the study and evaluation of packaging systems and its specifications will be assigned to the students & they will perform the same and documentation records will be evaluated. • Experimental work performed by the student will be submitted in the form of Journal (2) 	<p>(2)</p> <p>(2)</p>

References	<ol style="list-style-type: none"> 1. Hanlon J., Robert J. Kelsey, "Handbook of Package Engineering" 2nd Edition, Mcgraw-Hill, New. York. 1984 2. Paine A., "Packaging User's Handbook", Springer, 1990. 3. Ross, C.F., "Packaging of Pharmaceuticals", Newnes-Butterworths (London), 1975. 4. Friedman W.F., Kipnees J.J., "Industrial Packaging". New York: Wiley, 1960. 5. Yam, K.L., "The Wiley Encyclopedia of Packaging Technology" 3rd. Edition, 2009. 	
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Module 2	Selection of pharmaceutical packaging based on product package compatibility, environmental conditions.	1 credit
Objectives	<ol style="list-style-type: none"> 1. To study the requirement of caps and closure systems. 2. To study identification and evaluation of plastics for Parenteral and flexible packaging systems. 3. To introduce container specification for sterile dosage forms. 4. To enable learners to understand documentation and maintenance of record all the experiments in the prescribed format in the journal. 	
Contents	Experiments	hrs
	<ol style="list-style-type: none"> 1. Identification of HDPE, LDPE, PVC, Polystyrene, PET Plastics. (4) 2. To perform quality control tests on plastic containers IP (4) 3. Determination of water vapour transmission of given plastic. (4) 4. To perform quality control tests on rubber closures for Injectable preparation IP. (4) 5. Determination of preservative uptake by rubber closure. (4) 6. Testing of Aluminium collapsible tubes: quality control tests, product package compatibility, stress testing. (6) 	
Assigned Writing/ Practical Activities	<ol style="list-style-type: none"> 1. Experiments pertaining to the selection and evaluation of pharmaceutical packaging will be assigned to the students & they will perform the same. (2) 	(2)

	2. Experimental work performed by the student will be documented and submitted in the form of Journal	
References	<ol style="list-style-type: none"> 1. <i>Friedman W.F., Kipnees J.J., "Industrial Packaging". New York: Wiley, 1960.</i> 2. Paine A., "Packaging User's Handbook", Springer, 1990. 3. Ross, C. F. Packaging of Pharmaceuticals, Newnes-Butterworths (London), 1975 	

Module 3	Study of Pharmaceutical Carriers and Controlled Release Drug Delivery Systems	1 credit
Objectives	<ul style="list-style-type: none"> • To give the learner hands on training in design and development of specialized pharmaceutical dispersed systems, particulate drug delivery systems and oral controlled release systems. • To study various evaluation techniques for oral, topical and dispersed dosage forms as per the pharmacopeia and regulatory guidelines • To enable learners to understand documentation and maintenance of record all the experiments in the prescribed format in the journal 	
Contents	Experiments	Hrs

	<ul style="list-style-type: none"> • Development, Optimization and Evaluation of Sustained release tablet. (6) • Development, Optimization and Evaluation of Paediatric Oral Suspension. (4) • Development, Optimization and Evaluation of Topical gel (4) • Development and Evaluation of Subcutaneous Implants (4) • Development, Optimization and Evaluation of Lipospheres (4) • Development, Optimization and Evaluation of polymeric Microspheres (4) 	
Assigned Writing/ Practical Activities	<ul style="list-style-type: none"> • Experiments pertaining to the study of pharmaceutical carriers and controlled release drug delivery systems will be assigned to the students & they will perform the same. (2) • Experimental work performed by the student will be submitted in the form of Journal (2) 	
References	<ol style="list-style-type: none"> 1. Bruck S.D. , “<i>Controlled Drug Delivery (Basic Concepts)</i>”, Vol.1, Marcel Dekker Inc., New York, CRC Press, 2005 2. Rolland A., “<i>Pharmaceutical Particulate Carriers</i>”, New York: Marcel Dekker, Inc. 1993 3. Lachman, L., Lieberman, H. A., & Kanig, J. L. (1991). <i>The Theory and Practice of Industrial Pharmacy</i> (3rd ed.). Mumbai: Varghese Publishing House. 4. Ray and Weller, <i>Handbook of Pharmaceutical Excipients</i>, 5th edition, Pharmaceutical Press, 2009. 5. Rodriguez, F, <i>Principles of Polymer system</i>. 6. Lachman, Lieberman, <i>Pharmaceutical dosage forms: Dispersed systems Vol. I, II</i>, Marcel-Dekker, 2008. 7. Nicholas P. Chezerisionoff, <i>Product design and testing polymeric materials</i>, 	

	<p>8. Langer,ed.,Biodegradablepolymersasdrugdeliverysystems, Marcel Dekker Inc. New York, 2002.</p> <p>9. YieW.Chien,“NovelDrugDeliverySystems”,DrugsandPharm. Sci.Series,Vol.14,MarcelDekker Inc.,N.Y.1985.</p>	
Module4	ConceptsinpreparationandevaluationofNanocarrierSystemsand stability studies	1 Credit
Objectives	<p>1.Tounderstandpreparationandvariousevaluationparametersfor Nanocarrier Systems</p> <p>2.Comparisonof<i>In-vitro</i> &<i>in-vivo</i>data</p> <p>3</p>	
Contents	Experiments	Hrs
	<ul style="list-style-type: none"> • DemonstrationofParticlesizeanalyser • DeterminationofzetaPotentialofnanocarriers • Demonstrationofhighpressure homogeniser • Preparationofmicroemulsion,multipleemulsionandnanoparticles • Correlationof<i>In-vitro</i>&<i>in-vivo</i>data forvarious formulations • ConceptofStabilitystudiesaccordingtoICHguidelinesonanyone developed formulation. 	<p>2</p> <p>2</p> <p>2</p> <p>8</p> <p>4</p> <p>8</p>
Assigned Writing/ Practical Activities	<ul style="list-style-type: none"> • Experimentspertainingtothestudyofpharmaceuticalcarriersand controlled release drug delivery systems will be assigned to the students & they will perform the same. • Experimentalwork performedbythestudent willbe submitted in theformofJournal 	(4)
References	<p>1. Bruck S.D. ,“Controlled Drug Delivery(BasicConcepts)”, Vol.1, Marcel Dekker Inc., New York, CRC Press, 2005</p> <p>2. Rolland A.,“Pharmaceutical Particulate Carriers”,. New York:MarcelDekker,Inc.1993</p>	10.

	<ol style="list-style-type: none"> 3. Lachman, L., Lieberman, H. A., & Kanig, J. L. (1991). The Theory and Practice of Industrial Pharmacy (3rd ed.). Mumbai: Varghese Publishing House. 4. Ray and Weller, Handbook of Pharmaceutical Excipients, 5th edition, Pharmaceutical Press, 2009. 5. Rodriguez, F, Principles of Polymers system. 6. Lachman, Lieberman, Pharmaceutical dosage forms: Dispersed systems Vol. I, II, Marcel-Dekker, 2008. 7. Nicholas P. Cheremisinoff, Product design and testing polymeric materials, 8. Langer, ed., Biodegradable polymers as drug delivery systems, Marcel Dekker Inc. New York, 2002. 9. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N. Y. 1985. 	
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Semester III

M.Pharm–3101–Computer& Statistics

SEMESTER		SUBJECT			
I		Computer&Statistics			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	4	4	0	100	0

Thecourseisdivided into4 modules of **onecrediteach**with15 instructional hrs/module.

Objective:		
<ol style="list-style-type: none"> 1. Tomakelearners understandbasicsof computersand useofcomputersinPharmacypractice 2. Tousecomputersindrugdiscovery,formulationdevelopment,production&Quality Assurance 		
LearningOutcome: Thelearnerwillbeableto:		
<ol style="list-style-type: none"> 1. Use of computer systems to access and retrieve information and develop an understanding ofvariousapplicationsoftwareswithrespecttopharmaceuticalsciencesfordrugdiscovery, drug design, formulation development, production and Quality Assurance, QSAR for drug modelling and simulation of data 2. Understand concept of statistics as applied to pharmaceutical data, to analyze and interpret the data and factorial designs 		
Pre-assessment: Determinationofentrylevelknowledgeofstudentonapplicationsofcomputers in pharmacybasedon quizzes,question &answers.		
Module 1	I. Basics ofcomputers	1 credit
Objectives	Tointroduceuseofcomputersystemtoaccessandretrieveinformation& developanunderstandingofvariousapplicationsoftwarewithrespecttopharmaceuti cal sciences.	
Contents	Topics Covered	hrs

	<ul style="list-style-type: none"> Application of computers in pharmaceutical sciences, stores management, inventory control, drug information systems and hospital information systems Access to and retrieval of information: Smart search using internet, use of search engines and websites, drug information sources. Computer applications in pharmacy, with special reference to formulation development, production, quality assurance, and validation. Modeling and simulation of data with application in pharmacokinetics 	(3) (3) (3) (3)
Assigned Writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the need of computer to retrieve information will be assigned to the students & they will present the same. 	(3)
Assigned Reading/References	<ol style="list-style-type: none"> Bansal, Mohan, medical Informatics: A Primer, 4th edition, Tata McGraw Hill, New Delhi. 2007 Subramanian N. Introduction to Computers and Fundamentals of Computer Sciences, Tata McGraw-Hill, New Delhi, 1990 	

Module 2	II. Applications in Pharmacy	1 credit
Objectives	<ul style="list-style-type: none"> To enable learner to use computers in pharmacy with reference to drug discovery, formulation development, production & Quality Assurance. To introduce computer-aided drug design & QSAR for drug modeling and simulation of data 	
Contents	Topics Covered	
	<ul style="list-style-type: none"> Introduction to computer-aided drug design (CADD), QSAR various software's and molecular modeling in CADD Importance and generation of physico-chemical descriptors using various software's. 	(3) (3) (3)

	<ul style="list-style-type: none"> Correlation methods and generation of molecular models using computer software's. Interpretation and statistical significance of molecular models developed using softwares. Structure based and pharmacophore based drug designing using CADD. Importance of docking studies in drug development. 	(3)
Assigned Writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the applications of computers in pharmacy will be assigned to the students & they will present the same. 	(2) (1)
Assigned Reading/References	<ol style="list-style-type: none"> R.D. Lele, "Computers in Medicine", Tata McGraw-Hill, New Delhi, 1999 Fassett, Willam and Christanson Dale "Computer Application in Pharmacy", 4th edition, Lea & Febiger, 1986 C.N. Madu, "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Edition. Chi Publishers Inc, 2003. 	

Module 3	III. Concept of Statistics	1 credit
Objectives	<ul style="list-style-type: none"> To study in detail laws of probability and hypothesis testing and understand different types of distribution. To understand concept of statistics as applied to pharmaceutical data, to analyze and interpret the data. 	
Contents	Topics Covered	Hrs
	<ul style="list-style-type: none"> Probability: Laws of probability, types of distribution. 	(4)
	<ul style="list-style-type: none"> Hypothesis testing: Types of errors, tests for significance: one-tailed and two-tailed tests, t test, z test, chi-square test. 	(4)
	<ul style="list-style-type: none"> Correlation and regression: definition and calculation of correlation coefficient, regression coefficient, least square, method, linear regression. 	(4)

Assigned Writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the concepts of statistics will be assigned to the students & they will present the same. 	(3)
Assigned Reading/References	<ol style="list-style-type: none"> Daniel W., "Biostatistics: A Foundation for Analysis in the Health Sciences", John Wiley and Sons, 1998 Mahajan B.K., "Methods in Biostatistics", 4th edition, Jaypee Publications, New Delhi. 	

Module 4	IV. Application of Statistics	1 credit
Objectives	<ul style="list-style-type: none"> To develop understanding of analysis of variance by studying randomized & factorial designs and teach various non-parametric tests. To present statistical application in design of pharmaceutical & biomedical experiments 	
Content	Topics Covered	Hrs
	<ul style="list-style-type: none"> Analysis of variance: Completely randomized design, randomized complete block design, Factorial design, and response surface graphs. 	(4)
	<ul style="list-style-type: none"> Non-parametric tests: The sign test, The Mann-Whitney U test, The Run test, Spearman's rank correlation. 	(4)
	<ul style="list-style-type: none"> Role of statistics in design of pharmaceutical and biomedical experiments specially controlled clinical trials. 	(4)
Assigned Writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the above topics. Topics pertaining to the applications of statistics will be assigned to the students & they will present the same. 	(3)
Assigned Reading/References	<ol style="list-style-type: none"> Martin, B., "An Introduction to Medical Statistics", 3rd edition, ELBS, Oxford University Press. Murray Rand Stephens L., "Outline of Theory and Problems of Statistics", Tata McGraw-Hill, New Delhi. 1998. 	

	3. Bolton, "Pharmaceutical Statistics Practical & Clinical Application", Vol 135, Marcel Dekker, 2004.	
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M.Pharm-3201: Computer & Statistics I (Practicals)

The course is divided into 3 non creditable modules each with 20 instructional hrs/module.

Objective:		
<ol style="list-style-type: none"> 1. To make learners understand basics of computers and use of computers in Pharmaceutical applications & data retrieving. 2. To develop an understanding of various application softwares such as-QSAR, CADD, Pharmacokinetics, Factorial design with respect to pharmaceutical sciences 		
Learning Outcome: The learner will be able to:		
<ol style="list-style-type: none"> 1 Use of computer systems to access and retrieve information and develop an understanding of various application software 2 Understand concept of statistics as applied to pharmaceutical data, to analyze and interpret the data and factorial designs 		
Pre-assessment: The entry level knowledge of the student about the handling of computers & data interpretation will be determined		
Module 1	1. Basics of computers	-
Objectives	<ul style="list-style-type: none"> • To introduce use of computer system to access and retrieve information. • To develop an understanding of various application software with respect to pharmaceutical sciences. 	
Contents	Experiments	(20)
	<ul style="list-style-type: none"> • Major Commands For Windows Operating System • Introduction To Word Processing (MS word) • Presentation Tool: Introduction to presentation tool, features and functions, Creating presentation, Customizing presentation, Showing 	(6) (4) (6)

	presentation. Tools used may be Microsoft PowerPoint, OpenOffice or similar tool.	
Assigned Writing/ Practical Activities	<ul style="list-style-type: none"> Experiments involving Windows Operating System & features involving Word Processing (MS Word) & Presentation Tool would be assigned to the learners and they would perform and enter the same in their work books. 	(4)
Assigned Reading/ References	<ol style="list-style-type: none"> R.D. Lele, "Computers in Medicine", Tata McGraw-Hill, New Delhi, 1999 Fassett, Willam and Christanson Dale "Computer Application in Pharmacy", 4th edition, Lea & Febiger, 1986 	

Module 2	II. Use of internet & application of softwares in data interpretation	-
Objectives	<ul style="list-style-type: none"> To introduce Internet & search engines like Google, Yahoo etc, & other advanced search techniques to access and retrieve information. To develop an understanding of various application software such as - QSAR, CADD, Pharmacokinetics, Factorial design with respect to pharmaceutical sciences. 	
Contents	Experiments	(20)
	<ul style="list-style-type: none"> Introduction to Internet, Use of Internet and www Application of Software - QSAR, CADD, Pharmacokinetics, Factorial design. Using search engines like Google, Yahoo etc, Using advanced search techniques. Literature search using various search engines like google, pubmed, sciencedirect, free patent online. 	(6) (6) (6)
Assigned Writing/	<ul style="list-style-type: none"> Experiments involving applications of software - QSAR, CADD, pharmacokinetics, factorial design for data interpretation would be assigned to the learners and they would perform and enter the same in their work books. 	(2)

Practical Activities		
Assigned Reading/References	<p>1. C.N. Madu,. “Statistics as easy as one, two, three with Microsoft Excel for Windows”, 1st Edition. Chi Publishers Inc, 2003.</p> <p>2. Fassett, Willam and Christanson Dale “Computer Application in Pharmacy”, 4th edition, Lea & Febiger, 1986</p>	

Module 3	III. Statistical Data Analysis & Application of Spreadsheet to Pharmacy	-
Objectives	<ul style="list-style-type: none"> To introduce use of statistical data analysis to access and retrieve information. To develop an understanding of features and functions & application of spreadsheet to pharmaceutical sciences. 	
Contents	Experiments	(20)
	<ul style="list-style-type: none"> Spreadsheet Tool: Introduction to spreadsheet application, features and functions, Using formulas and functions, Data storing, Features for Statistical data analysis, Generating charts/ graph and other features. Tools used may be Microsoft Excel, Open office or similar tool. 	(8)
	<ul style="list-style-type: none"> R-Project: Statistical package. 	(6)
Assigned Writing/ Practical Activities	<ul style="list-style-type: none"> Experiments involving the understanding of features and functions & application of spreadsheet would be assigned to the learners and they would perform and enter the same in their work books. 	(6)

Assigned Reading/ References	<ol style="list-style-type: none">1. Fassett, Willam and Christanson Dale "Computer Application in Pharmacy", 4th edition, Lea & Febiger, 19862. C.N. Madu. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Edition. Chi Publishers Inc, 2003.3. R.D. Lele, "Computers in Medicine", Tata McGraw-Hill, New Delhi, 1999.	
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M.Pharm–3102:Validation

SEMESTER		SUBJECT			
I		Validation			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	-	4	-	100	-

The course is divided into 4 modules of **one credit each** with 15 instructional hrs/module.

<p>Objective:</p> <ol style="list-style-type: none"> In the subject of Validation, the learners learn and understand the basic principles and methods of validation of equipment, processes and personnel of pharmaceutical industries Using these techniques the learner are made aware of functioning and requirements in the field of Quality assurance. <p>Learning Outcome: The learner will be able to:</p> <ol style="list-style-type: none"> Understand the principles and methods of validation To apply validation to different processes for mixing, granulation, drying, compression, filtration, filling, etc. <p>Pre-assessment: The entry level knowledge of student about the various processes involved in various departments of Pharmaceutical industry will be determined based on quizzes, question & answers.</p>		
Module 1	Validation of Equipment and Sterilization processes	1 credit
Objectives	<ul style="list-style-type: none"> To enable the learners about the concept of Validation To enable the learner to understand the principles and methods of validation To enable the learner to understand various processes and their validation methods To enable the learner to understand the validation of sterilization methods 	

	<ul style="list-style-type: none"> The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics covered	hrs
	<ul style="list-style-type: none"> Qualification, validation and calibration of equipment. Validation of processes like mixing, granulation, drying, compression, filtration, filling, etc. Validation of sterilization, methods and equipment, dry heat sterilization, autoclaving, membrane filtration. 	(2) (4) (4)
Assigned writing & Exercise Activities	<ul style="list-style-type: none"> The assignments will be given to the students based on calibration and validation of equipment and processes as per ICH guidelines and international norms. The students will be asked to collect data on methods of validation of equipment and processes used in Pharma industries & comment on their applicability. 	(3)
Tutorial	<ul style="list-style-type: none"> Topics pertaining to the validation of equipment, sterile and non sterile processes used in Pharma industries will be assigned to the students & they will present the same 	(2)
Assigned Reading/References	<ol style="list-style-type: none"> Process validation in manufacturing of Biopharmaceuticals-Guidelines current practices, and industrial case studies by Anurag Singh Rathod, Gail Sofer, G.K. Sofer. Informa Healthcare Publisher 2005. Remington's the science and practice of pharmacy 21st Edition by Alfonso R. Gennaro. Lippincott Williams & Wilkins Publisher 2006. 	

Module 2	Validation of Analytical processes and personnel	1 credit
Objectives	<ul style="list-style-type: none"> To enable the learner to apply the concept of Validation To enable the learner to understand the principles and methods of validation of personnel 	

	<ul style="list-style-type: none"> To enable the learners to understand validation methods of analytical processes To enable the learners about procedures of audits The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics covered	hrs
	<ul style="list-style-type: none"> Validation and audits of analytical procedures such as HPLC, UV, GC, HPTLC. Validation of personnel handling the analytical instruments 	(5) (5)
Assigned writing	<ul style="list-style-type: none"> The assignments will be given to the students based on validation of personnel and analytical processes as per ICH guidelines and international norms. The students will ask to collect data on methods of validation of analytical processes and personnel used in Pharma industries & comment on their applicability. 	(3)
Tutorial	<ul style="list-style-type: none"> Topics pertaining to the validation of Analytical processes and personnel used in Pharma industries will be assigned to the students & they will present the same 	(2)
Assigned Reading/ References	<p>1. Pharmaceutical Process Validation by Robert A. Nash, Alfred H. Wachter Marcel Dekker Publisher 3rd edition 2003.</p> <p>2. Process validation in manufacturing of Biopharmaceuticals-Guidelines current practices, and industrial case studies by Anurag Singh Rathod, Gail Sofer, G.K. Sofer. Informa Healthcare Publisher 2005.</p>	

Module 3	Validation of Air and Water handling system in Pharmaceutical Industries and Hospitals	1 credit
Objectives	<ul style="list-style-type: none"> To enable the learner to understand the principles and methods of validation of air handling equipment To enable the learners to understand validation of water supply system 	

	<ul style="list-style-type: none"> To enable the learners about security measures to be taken for protecting the electronic data. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Topics covered	hrs
	<ul style="list-style-type: none"> Validation of air handling equipment and facilities in sterile and non-sterile areas. 	(4)
	<ul style="list-style-type: none"> Validation of water supply system, demineralized, distilled and water for injection. 	(4) (2)
	<ul style="list-style-type: none"> Validation and security measures for electronic data processing. 	
Assigned writing	<ul style="list-style-type: none"> The assignments will be given to the students based on validation of air handling equipment, water supply system and electronic data processing as per ICH guidelines and international norms. The students will ask to collect data on methods of validation of air handling equipment, water supply system and electronic data processing and security measures used in Pharma industries & comment on their applicability. 	(3)
Tutorial	<ul style="list-style-type: none"> Topics pertaining to the validation of validation of air handling equipment, water supply system and electronic data processing used in Pharma industries will be assigned to the students & they will present the same 	(2)
Assigned Reading/ References	<ol style="list-style-type: none"> Remington's the science and practice of pharmacy 21st Edition by Alfonso R. Gennaro. Lippincott Williams & Wilkins Publisher 2006. Pharmaceutical Process Validation 3rd edition by Robert A. Nash, Alfred H. Wachter, Marcel Dekker Publisher 3rd edition 2003. 	

Module 4	Project and Seminar	1 credit
Objectives	<ul style="list-style-type: none"> The learners will give one seminar in each semester based on principles, theory and the application of topics suggested based on the above module 	(15)

M.Pharm–3202:Validation(Practicals)

The course is divided into 3 non-creditable modules with 20 instructional hrs/module.

<p>Objective:</p> <ol style="list-style-type: none"> 1. In the subject of Validation, the learners learn and understand the basic principles and methods of validation of equipment, processes and personnel of pharmaceutical industries. 2. Using these techniques the learners can be aware of functioning and requirements in the field of Quality assurance. <p>Learning Outcome: The learner will be able to:</p> <ol style="list-style-type: none"> 1. Understand the principles and methods of validation of equipments and sterilization with respect to sterilization method. 2. Perform validation on various equipments such as glassware, autoclave, oven, tablet press and membrane filters. 		
<p>Pre-assessment</p> <p>The entry level knowledge of student about the equipments used and various processes involved in various departments of Pharmaceutical industry and hospitals will be determined based on quizzes, question & answers.</p>		
Module 1	Validation of Equipment and Sterilization processes	Hrs
Objectives	<ul style="list-style-type: none"> • To enable the learners about the concept of Validation • To enable the learner to understand the basic principles and methods of validation • To enable the learners to understand various processes in various departments of Pharmaceutical industry and hospitals and their validation methods • To enable the learners to understand the validation of sterilization methods • The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Experiments	Hrs
	<ul style="list-style-type: none"> • Validation of equipments: <ol style="list-style-type: none"> a. Glassware- volumetric flasks, cylinder, beakers etc 	(5)

	<ul style="list-style-type: none"> b. Autoclave c. Hotair Oven d. Membrane Filters e. Powdermixer (Dry) f. Tabletcompression machine g. Validationofsterilizationprocesses: <ul style="list-style-type: none"> a. Moistheatsterilizationprocesses b. DryHeat sterilizationprocesses c. Chemicalsterilization processes d. Membranefiltrationsprocesses 	(3) (8)
Assigned Writing/ Practical Activities	<ul style="list-style-type: none"> • Theassignmentswillbe given tothestudentsbasedonthe experiments pertaining to calibration and validation of equipment and processes as per ICH guidelines and international norms. • The students will ask to collect data on methods of validation of equipmentandprocessesusedinPharmaindustries&commentontheir applicability. 	(4)
Assigned Reading/ References	<ol style="list-style-type: none"> 1. Anurag Singh Rathod, Gail Sofer, G.K. Sofer.Process validation in manufacturing of Biopharmaceuticals-Guidelines current practices, and industrial case studies. Informa Healthcare 2005. 2. AlfonsoR.Gennaro.Remington'sthescienceandpracticeofpharmacy 21st Edition. Lippincott Williams & Wilkins2006. 3. RobertA.Nash,AlfredH.Wachter.PharmaceuticalProcessValidation 3rd edition. Marcel Dekker Publisher 2003. 4. F.J. Carleton and J.P. Agalloco, Validation of Pharmaceutical Process (Sterile Products), Second Edition Revised & Expanded, Marcel Decker Inc. 	
Module2	Validationof Analyticalprocessesand personnel	-
Objectives	<ul style="list-style-type: none"> • Toenable thelearnerstoapplythe concept of Validation • Toenablethelearnerstounderstandtheprinciplesandmethodsof validation of personnel 	

	<ul style="list-style-type: none"> To enable the learners to understand validation methods of analytical processes To enable the learners about various procedures of audits The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report 	
Contents	Experiments	Hrs
	<ul style="list-style-type: none"> Validation of Analytical Instruments <ul style="list-style-type: none"> a. HPLC b. GC c. HPTLC 	(15)
Assigned writing & Tutorial	<ul style="list-style-type: none"> The assignments will be given to the students based on the experiment pertaining to validation of personnel and analytical processes as per ICH guidelines and international norms. The students will ask to collect data on methods of validation of analytical processes and personnel used in Pharma industries & comment on their applicability. 	(5)
Assigned Reading/ References	<ol style="list-style-type: none"> Robert A. Nash, Alfred H. Wachter Pharmaceutical Process Validation 3rd edition, Marcel Dekker Publisher 2003. Anurag Singh Rathod, Gail Sofer, G.K. Sofer. Process validation in manufacturing of Biopharmaceuticals-Guidelines current practices, and industrial case studies. Informa Healthcare 2005. Manohar A. Potdar. cGMP :Current Good Manufacturing Practices for Pharmaceuticals/ Hyderabad, PharmaMed Press, 2008 	
Module 3	Validation of Air and Water handling system in Pharmaceutical Industries and Hospitals	-

Objectives	<ul style="list-style-type: none"> • Toenablethelearnerstounderstandtheprinciplesandmethodsof validation of air handling equipment • Toenable thelearners tounderstand validation of watersupplysystem • Toenablethelearnersaboutsecuritymeasurestobetakenforprotecting the electronic data. • Thelearnerswillbeassignedreadingfrombooksandrelatedpublished articlesfromjournals followedbyinteractivediscussion/submissionofreport 	
Contents	Experiments	Hrs
	<ol style="list-style-type: none"> 1. Validationofcleaningarea 2. Cleaningvalidationof oneequipment 	
Assigned Writing & Exercise	<ul style="list-style-type: none"> • Theassignmentswillbegiventothestudentsbasedonvalidationofair handlingequipment,watersupplysystemandelectronicdataprocessingasper ICH guidelines and international norms. • The students will ask to collect data on methods of validation of air handling equipment, water supply system and electronic data processing and securitymeasures used in Pharmaindustries& comment on theirapplicability 	(2)
Assigned Reading/ References	<ol style="list-style-type: none"> 1. AlfonsoR.Gennaro.Remington'sthescienceandpracticeofpharmacy 21stEdition Lippincott Williams & Wilkins 2006. 2. RobertA.Nash,AlfredH.Wachter,PharmaceuticalProcessValidation 3rd edition, Marcel Dekker Publisher 2003. 3. Anurag Singh Rathod, Gail Sofer, G.K. Sofer, Process validation in manufacturing of Biopharmaceuticals-Guidelines current practices, and industrial case studies. Informa Healthcare 2005. 4. ManoharA.Potdar.cGMP:CurrentGoodManufacturingPracticesfor Pharmaceuticals/Hyderabad,PharmaMedPress,2008 	

SEMESTER		SUBJECT			
I		ResearchMethodology			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4	--	4	--	100	--

1. **Objective:** To inculcate an understanding of research methodology and study various aspects and ethics associated with it.
2. To study principles of Instructional design through active and collaborative learning.
3. To understand problem identification, its implementation and evaluation and also introduce various research funding agencies for pharmacy.
4. To introduce different methods of assessment and concepts of basic research and give a brief overview of formation of research problem.
5. To study in detail concepts of mathematical modeling and types involved in processes of formulation of model based on simulation.
6. To understand experimental modeling, general model of process and introduce risk assessment and uncertainty associated with experimental modeling.
7. To inculcate an understanding of research deliverables in form of various publications, thesis writing and presentations.
8. To develop a learning of principles on ethical consideration involving research and issues related to plagiarism.

Learning Outcomes: The learner will be able to:

1. Understand problem identification, its implementation and evaluation and also introduce various research funding agencies for pharmacy.
2. Introduced different methods of assessment and concepts of basic research and give a brief overview of formation of research problems.
3. Apply concepts of mathematical and experimental modeling and types involved in processes of formulation of model based on simulation.

Module 1	Introduction of Research Methodology	1 credit
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Objectives	<ol style="list-style-type: none"> 1. To inculcate an understanding of research methodology 2. To understand various principles of learning & theory based on it. 3. To know various government & other research funding agencies. 4. To understand various methods and sources of literature 	
Contents	Topics Covered	15
	<p>Learning and instruction</p> <p>Principles of Instructional design and learning theory, Merrill's five principles and Gagne's condition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learning model of Kolb.</p>	5
	<p>Basics of Research</p> <p>Definition, objectives, motivation, types of research and approaches: descriptive research, conceptual, theoretical, applied and experimental.</p>	6
	<p>Literature review</p> <p>Important methods and sources to search for literature (Primary and secondary sources), referencing and search from Journals and Patents, Literature search using internet and web based interfaces, suitable search engines, advanced search techniques & data bases.</p> <p>Review and compilation of the collected matter</p>	3
	Funding & Scholarship	1

	Agencies funding research in pharmaceutical sciences, Scholarship, types of scholarships in education.	
Module2	Basics of Research	1 credit
Objectives	<ol style="list-style-type: none"> 1. To learn about various assessment techniques. 2. To understand basics of research. 3. To study various research problems & develop research plan 4. To learn planning, execution and implementation of the schedule 	
	Assessment Definition and methods, Georges Millers pyramid, Assessment, measurement and tests, Types of numbers, Formative and summative assessment.	3
	Formation of Research Problem Research Process: To determine what type of research to be done, plan of research work Selection of research area, prioritization of research. Objectives and scope of work, Developing Research Plan and Schedule: Scheduling Constraints, steps, problems in scheduling, limitations.	6
	Implementation and Documentation Collecting the requisites of the experiments to be performed, maintaining the records of all the experiments, maintenance of equipments/instruments and logbooks for all the instruments, to come out with innovative ideas.	6
Module3	Mathematical Modelling & Analysis of Data	1 credit

<p>Objectives</p>	<ol style="list-style-type: none"> 1. To acquaint research students with various mathematical&experimentalmodelingtechniques used to draw conclusions in Experimental Research. 2. To be able to identify, analyze and solve problems related to research using software. 3. Tostudythevarioussoftwareusedinpharmacyfor dataanalysis. 	
	<p style="text-align: center;">MathematicalModelingand Simulation</p> <p>Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, differenceequations,partialdifferentialequations,graphs, simulation: concept, types (quantitative , experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement</p>	<p>5</p>
	<p style="text-align: center;">ExperimentalModeling</p> <p>a) Definition of experimental design, examples, single factor experiments blocking and Nuisance factors, guidelines for designing experiments.</p> <p>b) General model of process: Input factors/ variables, Output parameters / variables controllable/uncontrollablevariables,dependent/ independent variables, experimental validity.</p>	<p>5</p>
	<p style="text-align: center;">Analysis ofdata</p> <p>a)Types of data: parametric and nonparametric,descriptive and inferential data,</p>	<p>5</p>

	<p>b) Collection of data: normal distribution, calculation of co-relation coefficient</p> <p>c) Dataprocessing:analysis,erroranalysis,meaning,and differentmethods:analysisofvariance,significanceof variance, analysis of covariance, multiple regression, testing linearity/nonlinearity of model, testing adequacy of model.</p> <p>d) Testtobeusedin dataexploration andtheirchoice</p> <p>e) Introductionofsoftwareusedindataanalysis.</p>	
Module4	EthicsInPharmacy&Research Deliverables	1 credit
	<ul style="list-style-type: none"> • Tolearntechniquesusedintheprofessional presentations. • Tolearnaboutresearchpublications,thesiswriting and presentations. • Tounderstandethicalconsiderationinvolving researchandissues relatedtoplagiarism. 	
	<p>ResearchDeliverables</p> <p>a) VariousFormsofPublication:Thesis,Paper,Research proposal</p> <p>b) Thesis Writing: Introduction, Literature Review or State-of-the-Art, Research Approach (methodology), Results or findings, Discussions, Conclusions, Scope for future work References, Appendices,</p> <p>c) Presentation:Poster,thesis,proposal,and paper</p>	6
	<p>Ethical issues inresearch</p> <p>Historical perspectives, General principles on ethical consideration involving human participation,Generalethicalevaluationofdrugs/device/diagnostics/vaccines/herbalremedies.</p>	6

	Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good Clinical Practices norms, Ethical principles related to animal experiments.	
	<p>Plagiarism</p> <p>Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript writing, documentation, organization of reference material, bibliography, end note.</p>	3
Recommended books	<ol style="list-style-type: none"> 1. B.D. John, A.L. Brown and R.R. Cocking, 1999. "How People Learn: brain, mind, experience and school". Washington, DC: National Academy Press. 2. J.R. Fraenkel, N.E. Wallen, 2008. "How to Design and Evaluate Research in Education", 7th Ed. Boston: McGraw-Hill. 3. K.E. David, 2009. Curriculum Development for Medical Education: A Six-Step Approach, 2nd Ed. The John Hopkins University Press. ISBN 0-8018-9367-4. 4. N. Peter, 2009. "Leadership: Theory and Practice." 3rd Ed. Thousand Oaks: Sage Publications. 5. G. Bordage, B. Dawson, 2003. Experimental study design and grant writing in eight steps and 28 questions. <i>Medical Education</i>, 37(4): 376-385. 6. B.J. Avolio, F.O. Walumbwa, T.J. Weber, 2009. Leadership: Current theories, research, and future directions. <i>Annual Review of Psychology</i>, 60: 421-449. 7. C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers. 8. D. Montgomery, 2000. "Design of Experiments". 5th Ed. Wiley Interscience. 9. K.P. Willkinson, L. Bhandarkar, "Formulation of Hypothesis". 3rd Ed. Himalaya publishing, Mumbai. 10. Schank Fr, 2008. "Theories of Engineering Experiments". 2nd Ed. Tata McGraw Hill. 11. D.C. Montgomery, 2009. "Introduction to SQC" 6th Ed. John Willy & sons. 	

M.Pharm-3104:-ResearchSeminar

LearningOutcomes:Thelearnerwillbeableto:

1. CollectandcollatescientificdataonrecenttopicsinPharmaceuticsandprepare presentations
2. Developaptitude,attitude,communication,presentationandsoftskills

SEMESTER		SUBJECT			
III		ResearchSeminar			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
2	--	2	--	50	--

M.Pharm-3105:-ResearchProject

LearningOutcomes:Thelearnerwillbeableto:

1. applyknowledgefordevelopmentandevaluationofconventional,novelandmodified drug delivery systems
2. presenttheresearchanddevelopaptitude,attitude,communication,presentationandsoft skills

SEMESTER		SUBJECT			
III		ResearchProject			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
	24	-	8	200	--

M.Pharm-3106-:IndustrialTraining

LearningOutcomes:Thelearnerwillbeableto:

1. gainknowledgeduringhandsontraininginthepharmaceuticalindustryforbetter understanding of career prospects and avenues available
2. Understandtheworkingofvariousdepartmentsofthepharmaceuticalindustry

SEMESTER		SUBJECT			
III		IndustrialTraining			
ONE MONTH		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
		2		50	

Semester IV

M.Pharm-4101-: Research Project and M.Pharm-4102-: Research Colloquium

Learning Outcomes: The learner will be able to:

1. apply knowledge for development and evaluation of conventional, novel and modified drug delivery systems
2. present the research and develop aptitude, attitude, communication, presentation and soft skills

SEMESTER		SUBJECT			
IV		Research Project			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
-	36	20	--	500	--

SEMESTER		SUBJECT			
IV		Research Colloquium			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
	--	4	--	100	--