S.N.D.T. WOMEN'S UNIVERSITY

MUMBAI

M. PHARM. SYLLABUS

SPECIALIZATION: QUALITY ASSURANCE

FOUR SEMESTER PROGRAMME

Effective from Academic Year 2012-13

The M. Pharm. (Quality Assurance) course, a very unique one was introduced in India for the FIRST TIME in 1989 at C.U. Shah College of Pharmacy, by SNDT Women's University after due sanction from the University Grants Commission and AICTE. The course is devised with a focus on the aptitude, talents and job potential for women in pharma industry and research and development institutes.

This four semester programme has the following specific features.

1) Emphasis on modern analytical techniques like spectroflurometry, infrared spectrophotometry, NMR, Spectromentry HPLC, X-ray diffraction analysis and spectral analysis.

2) Thrust on good manufacturing practices, quality audits, documentation and validation with a view to create total quality consciousness.

3) Packaging and product development courses designed to teach current trends in formulation of pharmaceuticals and newer drug delivery systems.

4) Understanding of Regulatory affairs, New Drug Application and Patenting procedures.

5) Students work on a research project for two semesters and submit a dissertation at the end of fourth semester for which they are evaluated by subject experts.

6) One month in plant training in industry to correlate theory with professional practice.

7) Guest lectures and seminars are routinely arranged where visiting faculty impart insights in state-of-art technology and current advances in pharmaceutical sciences.

ADMISSION CRITERIA:

Only Female candidates shall be admitted as per rules of Directorate of Technical Education, Maharashtra: (a) Non Sponsored Seats (b) Sponsored Seats (c) Seats for reserved Category candidates. Admission will be given on purely merit basis to candidates with valid GPAT/CET score. Any additional rules prescribed by the AICTE or SNDT Women's University will be applicable.

SCHEME: M.Pharm (Quality Assurance)

Sem	Subject Code	Subject	Hours/ Week TH	Hours/ Week PR	Credits TH	Credits PR	Marks TH	Marks PR
First	S1-MQA-1	Analytical Techniques I	4	8	4	4	100	100
	S1-MQA-2	Product Development I	4	-	4	-	100	-
	S1-MQA-3	Biological Evaluation	4	8	4	4	100	100
	S1-MQA-4	Quality Management I	4	-	4	-	100	-
		Total	**16**	**16**	**16**	**8**	**400**	**200**
Second	S2-MQA-1	Analytical Techniques II	4	8	4	4	100	100
	S2-MQA-2	Quality Management II	4	-	4	-	100	-
	S2-MQA-3	Product Development II	4	-	4	-	100	-
	S2-MQA-4	Packaging	4	8	4	4	100	100
		Total	**16**	**16**	**16**	**8**	**400**	**200**
Third	S3 – MQA-1	Industrial Training	**One Mnth**		**2**		**50**	
	S3- MQA-2	Computing & Statistics	4	4	4	-	100	-
	S3- MQA-3	Validation	4	4	4	-	100	-
	S3- MQA-4	Research Methodology	4	-	4	-	100	-
	S3- MQA-5	Research Seminar	4	-	**2**	**-**	**50**	-
	S3- MQA-6	Research Project	-	8	8	-	200	-
		Total	**16**	**16**	**24**	**-**	**600**	-
Fourth	S4 - MQA-1	Research Project	**32**	**-**	12	**-**	300	-
		Research Colloquiam	-	-	4	-	100	-
		& Viva	-	-	8	-	200	-
		Total	**72 Or 80 (?)**	-	**24**	-	**600**	-

		Grand Total			**80**	**16**	**2000**	**400**

Examination Pattern for M. Pharm in Quality Assurance

Semester I

SR. NO	SUBJECT	Exam Dur.	Theory				Exam Dur.	Practicals			
			Int.	Ext.	Total	Credits		Int	Ext.	Total	Credits
1	Modern Analytical Techniques-I	3	**50**	**50**	100	**4**	6	**50**	**50**	100	**4**
2	Product Development	3	**50**	**50**	100	**4**	-	-	-	-	-
3	Biological Evaluation	3	**50**	**50**	100	**4**	6	**50**	**50**	100	**4**
4	Quality Management-I	3	**50**	**50**	100	**4**	-	-	-	-	-

Semester I : Total credits = 24

Semester- II

SR. NO	SUBJECT	Exam. Dur.	Theory				Exam. Dur.	Practicals			
			Int.	Ext.	Total	Credits		Int.	Ext.	Total	Credits
1	Modern Analytical Techniques-II	3	**50**	**50**	100	**4**	6	**50**	**50**	100	4
2	Product Development-II	3	**50**	**50**	100	**4**	6	-	-	-	-
3	Drug Regulatory Affairs and Intellectual Property Rights.	3	**50**	**50**	100	**4**	-	-	-	-	-
4	Packaging Development	3	**50**	**50**	100	**4**	-	**50**	**50**	100	4

Semester II : Total credits = 24

Semester III

SR. NO	SUBJECT	Exam Dur.	Theory				Exam Dur.	Practicals			
			Int.	Ext.	Total	Credits		Int	Ext.	Total	Credits
1	Computing & Statistics	3	**50**	**50**	100	**4**					
2	Validation	3	**50**	**50**	100	**4**					
3	Research Methodology	3	**50**	**50**	100	**4**	6	-	-	-	-
4	Research Seminar	1	**25**	**25**	**50**	**2**	**1**	-	-	-	-
5	Research Project	-	-	-	-	-	-	-	-	200	**8**
6	Industrial Training				**50**	**2**					

Semester III: Total credits = 24

Semester IV

SR. NO	SUBJECT	Exam Dur.	Theory				Exam Dur.	Practicals			
			Int.	Ext.	Total	Credits		Int	Ext.	Total	Credits
1	Research Project (Thesis)				300	12	-	-	-	-	-
2	Colloquia				100	4	1	-	-	-	-
3	Viva	-	-	-	200	8	1	-	-	-	-

Semester IV: Total credits = 24

Semester I+ II + III + IV = 96 Credits Course

SEMESTER III & IV

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 student 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	**75**
Presentation/ communication	**50**
Result/ conclusion	**75**

Research Colloquium	**100**
Viva voce and external assessment	**200**
Total marks	**600**

Semester I

M.Pharm. S1-MQA-1: Analytical Techniques I

SEMESTER	SUBJECT
I	Analytical Techniques I

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

Objectives: Analytical techniques have become an integral part of pharmaceutical and other industries. Thorough knowledge of these techniques is essential for the following reasons.

1. To understand importance of various analytical techniques in determining purity of compounds
2. To carry out quantitative estimation of drugs from formulations and plant extracts
3. To carry out qualitative estimation of compounds for correct identification
4. To elucidate the structure of compounds from the analytical data
5. To isolate and identify the impurities in the sample
6. To monitor chemical reactions using analytical data

The knowledge of these techniques would make students confident while working with R & D and Quality Control departments of 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. To assess the knowledge of students about role of water as an impurity
3. To know the fundamental concepts of solubility and role of solubility in Pharmacy

Module 1	**Spectroscopy & Phase Analysis**	**1 credit**
Objectives	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
	• **Ultraviolet-Visible Spectrometry** **General Principles of Spectrometry:** Line spectrum, band spectrum, absorption spectroscopy, emission spectroscopy, electromagnetic spectrum, meaning of various terms like absorbance, transmittance, absorptivity, molar absorptivity, $E^{1\%}_{1cm}$ and λmax. 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 λmax values for important functional groups. • **Derivative UV Spectrometry** Principle and applications of derivative UV spectrometry, analysis of a binary and a multi-component system, background effect, background correction methods, difference spectrometry, difference derivative spectrometry **Problems based on** Beer- Lambert law, Conversion of transmittance to absorbance and vice versa, calculation of λmax values base on Fieser Woodward rules • **Determination of Water** Importance of determination of water or moisture content. Various methods	(7)

	used for determination of water and moisture content in pharmaceutical products by industries. Composition of Karl-Fischer reagent, its standardization and reactions involved in determination of water • **Phase Solubility Analysis** Importance of phase solubility analysis, various phase solubility diagrams, different regions in the diagram and their significance. Applications of phase solubility diagrams.	(2) (2)
Assigned writing & Exercise activities	• To make students write answers to the commonly asked questions on the topic • To prepare tables and summarize formulae required for solving problems • To draw neat ray diagrams • To solve numerical problems • To write down reactions involved in estimation of moisture • To draw phase solubility diagrams	
Tutorial	• To carry out literature survey to compile names of drugs analyzed by the learnt techniques • To find updates in the learnt techniques	(4)
Assigned Reading/ References	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.	

Module 2	**Spectrofluorimetry, Atomic Absorption And Emission Spectrometry & X-Ray Diffraction Analysis**	**1 credit**
Objectives	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 4. 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
	• **Spectrofluorimetry** Principle, definition and types of luminescence, Resonance 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. Analysis of directly fluorescing substances – inorganic species, vitamins, alkaloids, steroids and medicinal agents Analysis of indirectly fluorescing substances -by derivatization Derivatising agents for metals, non-metals and organic compounds. Use of derivatising agents such as – salicylaldehyde, 8-hydroxyquinoline, dansyl chloride, disyl chloride, NBD chloride, fluoresamine, o-phthaladehyde and Br-MMC. Fluorescent indicators. Quenching Methods and fluoroimmuno assays	(7)

	• **Atomic Absorption And Emission Spectrometry** 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 Turbulent flow burners, laminar flow burners , Applications • **X-Ray Diffraction Analysis** Principle, Bragg's Law, instrumentation, sources of X-rays, Applications	(4) (2)
Assigned writing & Exercise activities	• 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	• 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	1. Principles of Instrumental Analysis: Douglas A. Skoog(Author), F. James Holler, Stanley R. Crouch, 6th edition, Publisher: Brook, 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, January, Popular Prakashan Pvt. Ltd., Mumbai, 2010. 4. Published articles pertaining to the learnt techniques in reputed 5. Journals like Analytical Chemistry, Analytical Communications, 6. The Analyst, Indian Drugs, etc.	

Module 3	X-Ray Diffraction Studies, Thermal Analysis & Electrophoresis	1 credit	
Objectives	• To make students familiar with the principles of qualiitative 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 an unique technique for analysis of charged molecules and proteins • To understand use of electrophoresis in formulations		
Contents	**Topics covered**		Hrs
	• **IR Spectrometry** Principle, types of vibrations, Instrumentation with respect to sources, monochromators-prisms and gratings, detectors-thermocouple, bolometer, Golay cell, pyroelectric detector, Sample preparation techniques, Michelson interferometer, FT-IR, applications, various regions in IR spectrum and their use for characterization of functional groups. Problems based on functional group characterization and structure elucidation based on wave numbers • **Thermal Analysis** Thermogravimetry (TG), Differential thermal Analysis (DTA), Differential Scanning Calorimeter (DSC) Principle, technique, instrumentation, applications, differential thermogram / DSC curve • **Electrophoresis** Theory and principles, Zeta potential, classification, instrumentation, moving boundary electrophoresis, Zone Electrophoresis (ZE), Isoelectric focusing		(7) (3) (2)

	(IEF), Immuno-electrophoresis and applications of electrophoresis.	
Assigned writing & Exercise activities	• To make students write answers to the commonly asked questions on the topic • To draw neat diagrams and write definitions and equations involved in the chapter • To elucidate structure of a molecule based on IR data	
Tutorial	• To carry out literature survey to compile names of drugs analyzed by IR spectrometry, X-ray crystallography and by electrophoresis • To compile different applications of electrophoresis • To find updates in the learnt techniques	(3)
Assigned Reading/ References	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.	

Module 4	**Project and Seminar**	**1 credit**	
	Presentation on some recent research /seminars based on the above topics		(15)

M.Pharm–S1-MQA-1: Modern Analytical Techniques I Practical

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

<table>
<tr><td colspan="3">Objective:
• 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 learners to understand pharmacopoeial requirements</td></tr>
<tr><td colspan="3">Pre-assesment:
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</td></tr>
<tr><td>Module 1</td><td>UV –Visible spectrometry
(Fundamental Aspects)</td><td>1 credit</td></tr>
<tr><td>Objectives</td><td colspan="2">1. To learn fundamental aspects of quantitative and qualitative estimation using UV-visible spectrometry</td></tr>
</table>

	2. To study Beer Lambert Law	
Contents	**Experiments**	(30)
	1. Calibration of UV –Visible spectrometer for absorbance 2. Determination of wavelength of maximum absorption (λmax) of a compound 3. Determination of cut-off wavelength of commonly used solvents for 4. UV spectroscopy 5. Determination of $E_{1cm}^{1\%}$ and molar absorptivity of a substance 6. Determination of range of linearity in accordance with Beer Lambert Law 7. Determination of Limit of Quantitation (LOQ) and Limit of Detection (LOD) of compounds in UV range	(4) (4) (6) (6) (4) (4)
Assigned Writing/ Practical Activities	• 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	1. Practical Pharmaceutical Chemistry: A. H Beckett and J. B. Stenlake, 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	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)
Assigned Writing/ Practical Activities	• Experiments pertaining to the selective quantitative estimation of bulk drugs and the drugs from marketed formulations by UV-visible spectrometry would be assigned to the students and they would perform the same and document in the journals.	(2)
	• Students would be asked to find various methods for determination of moisture content. They would be asked to interprete thermograph obtained by using Differential Scanning Calorimeter.	(2)
Assigned Reading/ References	1. Practical Pharmaceutical Chemistry: A. H Beckett and J. B. Stenlake, 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. T.Vogel's Textbook of Quantitative Chemical Analysis, 6th Edition, Prentice Hall, 2000	

Module 3	**Spectrofluorimetry, Atomic Absorption spectrometry (Flame Photometry) and electrophoresis**	**1credit**
Objectives	1. To perform quantitative and qualitative estimation using spectrofluorimetry and flame photometry 2. To enable students perform selective quantitative estimation of drugs from their mixture 3. To enable learners analyze proteins using electrophoresis	
Contents	**Experiments**	Hrs
	1. Plotting of absorption spectrum 2. Plotting of emission spectrum 3. Plotting of a standard curve for quinine sulphate 4. Analysis of any one fluorescent compound Development, Optimization and Evaluation of Long Acting Oily Injection 5. Analysis of a mixture of alkali halides 6. Analysis of proteins using electrophoresis	(4) (4) (4) (6) (6) (3)
Assigned writing& Tutorial	• Experiments pertaining to the selective quantitative estimation of drugs from the marketed formulations by spectrofluorimetry and flame photometry would be assigned to the students and they would perform the same and enter it in their work books • . Estimation of proteins by electrophoresis	(2) (1)
Assigned Reading/ References	1. A.H. Beckett and J.B. Stenlake, Practical Pharmaceutical chemistry, Part 1 & 2, Athlone Press, London. 2. Pharmacopoeia of India,6th Edition, Govt. of India, Ministry of Health & welfare, 2010. 3. British Pharmacopoeia, General Medicine Commision, UK., 2011. 4. United State Pharmacopeia, 34th Edition, Convention, Inc., Rockville, MD20852, 2011. 5. Vogel's Textbook of Quantitative Chemical Analysis, 6th Edition, Prentice Hall, 2000	

Module 4	**IR Spectrometry**	**1 credit**
Objectives	• To identify functional groups in compounds. • To monitor chemical reactions • To identify impurities in the sample	
Contents	**Experiments**	Hrs
	1. Calibration of IR spectrometer with polystyrene film 2. IR spectrum of a neat liquid 3. Preparation of KBr pellet for any one solid sample 4. Preparation of a 'mull' for samples with different functional groups such as amine, nitro, aldehyde, keto, carboxylic, hydroxyl, etc. 5. To monitor chemical reaction using IR spectrometry 6. To identify impurities in the sample	(6) (6) (6) (4) (4) (2)
Assigned Writing & Exercise	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	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 S1-MQA-2: Product Development I

SEMESTER		**SUBJECT**			
I		**Product Development 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: 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			
Pre-assessment: Determination of entry level knowledge of student about concepts and applications for preformulation studies , various formulation aspects & stability studies based on quizzes, question & answers.			
Module 1	**I.**	**Preformulation, Chemical Kinetics and Drug Stability**	**Instr. hrs**
Objectives	1. To enable the learner to understand the need of preformulation studies in pharmacy. 2. To study concepts, applications and protocols for preformulation studies. 3. To understand physical & chemical stability protocols as per ICH Guidelines. 4. To provide an insight into accelerated stability testing and study of calculations for shelf life in details.		

Contents	Topics Covered	Hrs
	• **Preformulation Studies**: pka and solubility kinetics, pH profile, partition coefficient, crystal morphology, polymorphism, powder flow, surface characteristics, dissolution, solublization techniques, drug –excipients compatibility studies, protocol for performulation 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	• 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	• 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	1. Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms" , Volume 110, Marcel Dekker New York, 2001, CRC 2. Ray and Weller, "Handbook of Pharmaceutical Excipients", Pharmaceutical Press, 2009. 3. Lachman, Lieberman, "Pharmaceutical dosage forms: Dispersed systems", Vol. I, II, Marcel-DekkerNew York, 2008. 4. Lisbeth, Illum & Stanley S. Davis, "Polymers in Controlled Drug Delivery", Wright, Bristol, 1987. 5. ICH Guidelines available at: http://www.ich.org	

Module 2	**II. Principles and Techniques of Solid Dosage Forms and Coating Technology & Study of Pharmaceutical polymers**	**1 credit**
Objectives	1. To enable learner to understand about recent advances in tablet and capsule technology. 2. To provide an insight to oral controlled release 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 release 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
	• **Solid dosage forms**: Recent advances in tablet and capsule technology like double compression, direct compression, capsule filling machine, Novel tableting excipients binding agents, super disintegrants, lubricants and diluents	(4)
	• **Coating of solid dosage forms**: Various types of functional coatings, polymers, Advances in process controls, coating equipments, coating pans, Accela cota, Hi-coater, Driacoater, fluid bed coating equipments e.g. Glatt & Kugel coaters. Coating application and metering equipment, particle coating methods, pelletization. Technology.	(4)
	• **Pharmaceutical polymers:** Biodegradable & non biodegradable polymers block copolymers, stimuli sensitive polymers, mucoadhesive polymers	(4)

Assigned writing	• The assignments will be given to the students based on the various solid dosage forms available and coating of solid dosage froms using various polymers.	(2)
Tutorial	• 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	1. Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms", Volume 110, New York Marcel Dekker, 2001, CRC. 2. Lachman, L., Lieberman, H. A., & Kanig, J. L. "The Theory and Practice of Industrial Pharmacy" 3rd edition. Mumbai, Varghese Publishing House.1991. 3. Rawlins, E. A., "Bentley's text book of Pharmaceutics" 8th edition, London: Bailliere Tindal.1995. 4. Rubinstein, M. H. M. E. Aulton,"Pharmaceutics: the science of dosage form design", 3rd edition, pp. 304-321, London: ELBS Longman Group Ltd.,1988 5. Rudnic, E. M., & Schwartz, J. D. "Remington: The Science and Practice of Pharmacy"Philadelphia: Lippincott Williams & Wilkins.2006. 6. Saha, S., & Shahiwala, A. F., "Multifunctional coprocessed excipients for improved tabletting performance" . Expert Opinion on Drug Delivery ,pp 197-208, 2009. 7. David K Platt, Biodegradable Polymers, iSmithers Rapra Publishing, 2006. 8. Catia Bastioli, Handbook of biodegradable polymers, iSmithers Rapra	•

Module 3	III) Drug Dissolution and Diffusion Studies& Study of Pharmacokinetic modeling	1 credit
Objectives	1. To enable the learner to understand drug dissolution and diffusion principles in biological systems. 2. To study thermodynamics and different laws governing diffusion. 3. To learn about the dissolution rate testing devices. 4. To understand effect of environmental factors in dissolution testing. 5. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report. 6. To enable learner to understand the concepts of one compartment open model and determine various factors affecting it. 7. To understand concepts of *in vivo - in vitro* Correlation 8. To introduce two compartments and three compartment open IV models. 9. To familiarize learners with application of statistical moment in non compartmental analysis. 10. To study Non-linear pharmacokinetics.	
Contents	**Topics Covered**	Hrs
	• **Dissolution Studies:** Steady state diffusion-procedure and applications, drug dissolution, drug release, diffusion principles in biological systems, thermodynamics of diffusion, Fick's law. Devices for dissolution rate testing viz., forced convection, non-sink devices, and continuous flow through methods; effect of environmental factors in dissolution testing; test apparatus for various drug delivery systems. • **Pharmacokinetics:** Compartmental & Non compartmental analysis, Pharmacokinetic modeling approaches, Biopharmaceutical classification of drugs, absorption, permeability and solubility limited drugs, Biowavers for bioequivalence studies, Concepts of *in vitro & in-vivo* Correlation, One and Two Compartmental Modeling, Statistical Moment Analysis, Non-linear kinetics.	(3) (9)

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	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	• 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–S1-MQA-3: Biological Evaluation

SEMESTER		**SUBJECT**			
I		Biological Evaluation			
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: This paper is designed to give insight of different procedures of biological evaluation of drugs, pharmacological aspects of new therapies, toxicological studies on drugs and Bio- safety studies.		
Pre-assessment: The entry level knowledge of student about the pharmacology, microbiology and bioassays will be determined based on quizzes, question & answers.		
Module 1	**Pre-clinical drug evaluation**	**1 credit**
Objectives	This module is designed to expand student's knowledge regarding ➢ NCE Development ➢ Testing of NCE (animal/microbiological) ➢ Clinical Trials	
Contents	**Topics Covered**	Inst. hrs
	1. New Drug Discovery and development process **2.** Pre-clinical drug evaluation of NCE, NBE and Biological as per Schedule Y and ICH guidelines: single dose, repeat dose toxicity studies, safety pharmacology, genetic toxicology, reproduction toxicity studies (including segment I, II, and III), and carcinogenicity studies. **3.** Clinical Trials, Phase I, II & II **4.** After completion of this module student will have better	(3) (5) (3) (3)

	understanding different phases of clinical trials as well as Schedule Y and ICH guidelines.	
Assigned writing & Exercise activities	• 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	• Topics pertaining to the study of toxicity studies will be assigned to the students & they will present the same	(2)
Assigned Readings/ References	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	This module is designed to gain understanding of ➢ 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 2. Radioimmunoassay: General principles, scope and limitation.	(3)

	Radioimmunoassay of some drugs like insulin, digitalis etc. Fluoroimmunoassay,*Fluorescent Labelling* 3. Molecular biology of receptors such sodium, calcium and potassium ion channels as well as GPCR. 4. After completion of this module student will be able to evaluate different methods bioassay, different labeling techniques as well as molecular targeting.	(4) (4)
Assigned writing & Exercise activities	• Assignments will be given to the students based on different topics such as Different types of labeling and Bioassays • Students will be asked to present molecular structures of various receptors.	(3)
Tutorials	• Topics pertaining to the study of molecular biology will be assigned to the students & they will present the same	(1)
Assigned Reading	1. H. Gerard Vogel,"Drug discovery and evaluation: Pharmacological assays ",2nd edition, Springer Publication, New York, 2002. 2. Strachan T., Andrew P., "Human Molecular Genetics", 2nd Edition, Wiley-Liss Publication, New York, 1999. 3. Sudebry P., "Human Molecular Genetics", 2nd Edition, Prentice Hall Publication, USA , 2002.	
Module 3	**Microbiological evaluation and Pyrogen Science**	**1 credit**
Objectives	This module provides learners with advanced knowledge of ➢ Methodologies of microbial limit tests ➢ Principles of sterility tests ➢ Importance of pyrogen testing ➢ Methods of pyrogen testing	
Contents	**Topics Covered**	

	1. Microbiological limit tests 2. Sterility tests: Methodology & Interpretation 3. Tests for effectiveness of antimicrobial preservatives. 4. Chemistry and properties of bacterial Pyrogens and endotoxins, 5. Mechanism of action of Pyrogens and Pharmaceutical aspects of the same. 6. Pyrogen test of IP compared to that of BP & USP, Interpretation of data, and comparison of LAL and official pyrogen tests. 7. After completion of this module student will be able analyze and interpret results of various microbiological tests such as sterility test.	(2) (3) (2) (2) (2) (2)
Assigned writing & Exercise activities	• 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	1. Bengt L and 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", 3 rd 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–S2-MQA-3: Biological Evaluation (Practicals)

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

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.		
Pre-assessment: The entry level knowledge of student about the pharmacology, microbiology and bioassays will be determined based on quizzes, question & answers.		
Module 1	**Introduction to Animal Models**	**Credit 1**
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. **2.** To Study Effect of diazepam on muscle grip by rota-rod apparatus **3.** To Study Effect of diazepam on behavioral activity by hole-board technique and elevated plus maize. **4.** To Study of chlorpromazine induced catatonia. **5.** Effect of analgesic by hot plate technique	**(**4) (4) (6) (4) (6)
Assigned writing & Exercise	• Experiments pertaining to the different animal models will be assigned to the students & they will perform the same. • Experimental work performed by the student will be	(3) (3)

activities	submitted for of Journal	
Assigned Reading	1. H. Gerard Vogel, "Drug discovery and evaluation: Pharmacological assays", 2nd edition, Springer Publication, New York,2007 2. S.K.Kulkarni , "Handbook of Experimental Pharmacology" 3. 1st edition, Vallabh Prakashan, Delhi,2000.	
Module 2	**Microbiological testing of various formulations.**	**Credit 1**
Objective	Microbiological testing of variousformulationsforms important part of pharmacological screening. This module aims to provide hands on training in carrying out industry oriented pharmaceutical microbiological testing.	
Contents	**Experiments**	
	1.Effectiveness of antimicrobial agent by cup plate method 2.Effectiveness of antimicrobial agent using Ditch plate method 3.To perform Sterility test of given sample. 4.To determine minimum inhibitory concentration of given antibiotic 5.To perform the Microbial limit test of the given sample	(4) (6) (4) (6) (4)
Assigned writing & Exercise activities	1. Experiments pertaining to the microbiological screening will be assigned to the students & they will perform the same. 2. Experimental work performed by the student will be submitted in the for of Journal	(3) (3)
Assigned Reading/ References	1. Indian Pharmacopeia, Published by Health and Welfare Ministry, by Govt. of India, 6th Edition, 2010. 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. 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.	
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. 2. Demonstration of various routes of administration 3. Demonstration of Bioanlayser 4. Demonstration of Blood Cell Counter 5. Demonstration of Water Maize Apparatus	(4) (4) (6) (4) (6)
Assigned writing & Exercise activities	• 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	1. Updated Manual book of instruments 2. S.K.Kulkarni , "Handbook of Experimental Pharmacology" ,1st edition, Vallabh Prakashan, Delhi, 2000.	
Module 4	**Development of Protocols & Data Handling**	**Credit 1**
Objectives	• 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 2. Development of Protocols for various Pharmacological activities like Anti-inflammatory, Wound healing, Anti-diabetic etc. 3. Development of Protocols for Toxicity Studies. 4. Development of Protocols for gamma scintigraphic imaging 5. Interpretation of Hematological & Biochemical data	(4) (6) (6) (4) (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 S1-MQA4: 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.		
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	1. To enable learners to understand basic principles of TQM to built quality in products. 2. To study current guidelines of GLP and GMP. 3. To familiarize learners 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	
Contents	**Topics Covered**	Hrs

	• 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, controls on animal house, site, Data generation and storage.	(5) (5) (3)
Assigned writing & Tutorials	• 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	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**	**1credit**
Objectives	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. 2. **Premises: Plant layout:** Controls of contamination and Environmental controls. 3. **Equipment:**Selection, purchase specifications, Preventive maintenance and Calibration. 4. **Materials:** API's and raw materials, purchase specifications, Selection of vendors, Material management, Warehousing, Good Warehousing Practices. 5. **Manufacturing methods**, Production controls and In process controls, Line clearance.	(3) (3) (2) (2) (2)
Assigned Writing & Tutorial	• 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	1. Carlton F, Agallaco J, "Validation of aseptic Pharmaceutical Processes ", 1st edition, New York, Marcel Dekker. 2. Loftus, B. T., Nash, R. A., ed. Pharmaceutical Process Validation. vol. 57.New York: Marcel Dekker (993. 3. 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	• To develop an understanding of documentation required as per revised Schedule M. • To enable learners 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 learners to distribution and supply chain management. • To enable learners 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
	• **Documentation and its importance:** Manufacturing documents, Standard Operating Procedures, Finished product release document. • **Distribution and supply chain management:** Handling of returned goods, Recovered materials and Reprocessing. Waste disposal and Treatment of Effluent. • Complaints and recalls, evaluation of complaints, Recall procedures, related records and documents.	(6)
Assigned Writing & Tutorials	• 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/ References	1. Malik, V, Drugs and Cosmetics Act, 1940, Eastern Book Co. 2. 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. 3. SIGAR. Pharmacovigilance Education and Certification—Report on a Feasibility Survey. Pharmacoepia & Drug Safety. 1995. 4. Talbot JCC. *Drug safety—a shared responsibility*.Edinburgh: Churchill Livingstone;. Spontaneous reporting,1991 5. Report of CIOMS (Council for International Organisations of Medical Sciences) Working Group III, Guidelines for Preparing Core Clinical-Safety Information on Drugs, Geneva. 1995	
Module 4	**IV Project & Seminar**	**1 credit**
Objectives	1. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / , presentation of seminar &submission of report	

Semester II

M.Pharm–S2-MQA-1: Analytical Techniques II

SEMESTER		**SUBJECT**			
I		**Modern Analytical Techniques II**			
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.		
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	• 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

	General principles, theory and the applications of planar chromatographic techniques • Techniques and instrumentation of thin layer chromatography (TLC) • Techniques and instrumentation of Paper chromatography (PC) • Techniques and instrumentation of High performance thin layer chromatography(HPTLC) • Applications of TLC, PC, HPTLC • Comparison of planar chromatography and column chromatography	(4) (2) (2) (2) (2)
Assigned writing & Exercise activities	• 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 stationery phases and mobile phases used for planar chromatographic techniques.	(2)
Tutorial	• Topics pertaining to various techniques of planar chromatography will be assigned to the students & they will present the same.	(1)
Assigned Reading/ References	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 textbook for pharmacy students and pharmaceutical chemists Elsevier/Churchill Livingstone, 2005	

Module 2	**Principles and techniques of column chromatography**	**1 credit**
Objectives	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
	General principles, theory and the application of column chromatographic techniques: • Techniques, instrumentation and Applications of High performance liquid chromatography (HPLC) – Theory of HPLC-Van Deemter Equation, various detectors used, derivatisation in HPLC. • Techniques, instrumentation and Applications of Gas chromatography (GC)-Theory of GC, packed column, Capillary column, carrier gases used. • Techniques, instrumentation and Applications of Size exclusion chromatography and ion pair chromatography .	(5) (5) (2)
Assigned writing	• 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	(2)

	charge. • The students will be asked to collect data on various stationery phases and mobile phases used for column chromatographic techniques.	
Tutorial	• Topics pertaining to various techniques of column chromatographywill be assigned to the students & they will present the same.	(1)
Assigned Reading/ References	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 practiceBlackie 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 MaInstrumental Methods of Analysis Wiley-Interscience; 8th edition, 2011	

Module 3	**Structure elucidation of organic compounds- Theory and Problem solving**	**1 credit**

Objectives	• To enable the learners to understand the basic principles of structure elucidation of organic compounds. • To enable the learners to understand the basic principles, techniques and instrumentation of Mass spectrometry- (MS) • To enable the learners to understand the basic principles, techniques and instrumentation of NMR spectroscopy • To enable the learners to understand the basic principles, techniques and instrumentation of PNMR, ^{13}CNMR, COSY, 2-D-NMR. • 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
	• General principles, theory and the application of structure elucidation of organic compounds • Theory, principle, instrumentation, different types of Mass spectrometry • Innovative technique-Tandem Mass spectroscopy • Nuclear magnetic resonance - Theory, principle of NMR spectroscopy, instrumentation, different types of NMR, PNMR, ^{13}CNMR, COSY, 2-D-NMR. • Problem solving in structure elucidation of organic compounds using UV, IR, NMR and MS.	(5) (5) (3)
Assigned writing	• The assignments will be given to the students to collect and compile information about different methods used for determination of structure of an organic compound. • The students will be asked to collect data on various chemical and spectral techniques used for structure elucidation.	(2)
Tutorial	• Topics pertaining to various techniques used for structure elucidation such as MS, NMR will be assigned to the students & they will present the same.	(1)

Assigned Reading/ References	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	

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 module		(15)

M.Pharm–S2-MQA-1: Analytical Techniques II (Practicals)

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

Objective: 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		
Pre-assessment 1. To assess the entry level knowledge of learners about basic planar chromatographic techniques. 2. To assess the entry level knowledge of learners about stationery phases and mobile phases used for TLC, PC and HPTLC.		
Module 1	**Techniques of planar chromatography-I - TLC, PC**	**1 credit**
Objectives	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
	• 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 • Separation of sugars/ amino acids by Thin layer chromatography.	(8) (8) (6) (4)

Assigned Writing/ Practical Activities	• 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	1. Thin-Layer Chromatography, A Laboratory Handbook by E. Stahl, Second. Edition, Springer-VerlagBerlin–Heidelberg–New York 1969. 2. Plant Drug Analysis by H. ***Wagner*** & S. Bladt, Second Edition, Springer. 3. A Laboratory Handbook of paper and thin layer chromatography by Jiri Gasparic and Jaroslav Churacek, Publisher-Ellis Horwood limited. 4. Manual of HPTLC applicator, scanner and photodocumentation system by CAMAG	
Module 2	**Techniques of planar chromatography – II - PC, HPTLC.**	**1 credit**
Objectives	1. To enable the learners to understand and perform the techniques and instrumentation of Paper chromatography (PC) 2. To enable the learners to understand and perform the basic techniques and instrumentation of High performance thin layer chromatography (HPTLC)	
Contents	**Experiments**	Hrs
	• Development of suitable solvent system for the separation of mixtures of organic compounds. • Development of suitable solvent system for the separation of herbal extracts. • Use of various derivatising agents for detection of compounds by PC. • Separation of sugars/ amino acids by Paper chromatography. • Demonstration and hands on training on High performance thin layer chromatography (HPTLC). • Separation of some mixtures of organic compounds by HPTLC using TLC applicator, Scanner and TLC plate visualiser	(6) (6) (4) (4) (4) (4)

Assigned Writing/ Practical Activities	• 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	5. Thin-Layer Chromatography, A Laboratory Handbook by E. Stahl, Second. Edition, Springer-VerlagBerlin–Heidelberg–New York 1969. 6. Plant Drug Analysis by H. ***Wagner***& S. Bladt, Second Edition, Springer. 7. A Laboratory Handbook of paper and thin layer chromatography by Jiri Gasparic and Jaroslav Churacek, Publisher-Ellis Horwood limited. 8. Manual of HPTLC applicator, scanner and photodocumentation system by CAMAG	
Assigned Reading/ References	1. A Laboratory Handbook of paper and thin layer chromatography by Jiri Gaspari and Jaroslav Churacek, Publisher-Ellis Horwood limited 2. Pharmacopoeia of India, Govt. of India, Ministry of Health. 3. British Pharmacopoeia, ministry of health and social welfare, UK. 4. HPLC: High Performance Liquid Chromatography: Volume 2, by P.D. Sethi and Rajat Sethi. 5. Instrumental Methods of Chemical analysis by G. W. Ewing Mcgraw-Hill Book Co., Inc., NewYork. 6. Principles of Instrumental Analysis, Douglas A. Skoog, F. James Holler and Timothy A. Nieman, Fifth edition, HarcourtBraceCollege publishers.	
Module 3	**Techniques of column chromatography- HPLC, GC, Flash chromatography, Super critical fluid chromatography.**	1credit
Objectives	1. To perform quantitative and qualitative estimation using High Performance liquid chromatography (HPLC) and Gas chromatography (GC). 2. To perform selective quantitative estimation of drugs from their mixture.	
Contents	Experiments	Hrs

	1. Demonstration of High performance thin layer chromatography. 2. Plotting of a standard curve for caffeine / betaine/ catechin by HPLC. 3. 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. 5. Determination of HETP value, selectivity factor, tailing factor by HPLC. 6. Demonstration of Gas liquid chromatography. 7. Demonstration of flash chromatography. 8. Demonstration of Supercritical fluid extraction chromatography.	(2) (6) (4) (4) (4) (4) (2) (2)
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	1. A Laboratory Handbook of paper and thin layer chromatography by Jiri Gaspari and Jaroslav Churacek, Publisher-Ellis Horwood limited 2. Pharmacopoeia of India, Govt. of India, Ministry of Health. 3. British Pharmacopoeia, ministry of health and social welfare, UK. 4. HPLC: High Performance Liquid Chromatography: Volume 2, by P.D. Sethi and Rajat Sethi. 5. Instrumental Methods of Chemical analysis by G. W. Ewing Mcgraw-Hill Book Co., Inc., NewYork. 6. Principles of Instrumental Analysis, Douglas A. Skoog, F. James Holler and Timothy A. Nieman, Fifth edition, HarcourtBraceCollege publishers.	

Module 4	**Structure elucidation of organic compounds- Problem solving**	**1 credit**
Objectives	• 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 PNMR.	(6)
	3. Identification of different types of carbons and carbon containing groups by 13 CNMR	(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 work books	(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–S2-MQA2- 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.

Objective: To make the learner understand the developments in design, development and evaluation of advanced drug delivery systems.		
Pre-assessment: Determination of entry level knowledge of student on advanced drug delivery systems in form of quizzes, question & answers.		
Module 1	**I. To study concepts of rate controlled and site specific drug delivery systems and particulate carrier systems**	**1 credit**
Objectives	• To study site specific drug delivery systems to increase therapeutic efficacy of drug with minimum side-effects. • To introduce the learners 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 learners 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.
	• **Concepts and systems design for rate controlled delivery:** Rate preprogrammed, Activation modulated and Feed back regulated drug delivery systems.	(3) (3)

	• **Particulate carrier systems:** microspheres, liposomes and nanocarriers. • **Site specific drug delivery:** Active and passive targeting, monoclonal antibiodies for drug targeting. 1 **Ocular delivery of drug:** Anatomy & physiology of eye, development of ocular controlled release therapeutic systems, safety & toxicity evaluation.Assigned reading. 2 **Transdermal drug delivery:** Permeation through skin, permeation enhancers, technologies for developing transdermal drug delivery systems like gels, patches and sprays and evaluation thereof.	(3) (3)
Assigned Writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the current advances in rate & controlled release delivery systems will be assigned to the students & they will present the same.	(3)
Assigned reading/ References	1. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y,1992. 2. Robinson J.R and Lee V.L, "Controlled Drug delivery fundamentals and applications", 2nd edition, Marcel Dekker, Inc. , ***New York*** , 1987. 3. S.D. *Bruck*, "*Controlled Drug Delivery"*, 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, "Modern Pharmaceutics", Drugs and Pharm. 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.	

Module 2	**II. Advances in Oral Drug Delivery Systems**	**1credit**
Objectives	• 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
	• **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 gastro intestinal transit time and release kinetics and evaluation thereof.	(12)
Assigned Writing & Tutorial	• 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	1. Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms" New York Marcel Dekker Volume 110, 2001. 2. Lachman, L., Lieberman, H. A., & Kanig, J. L. "The Theory and Practice of Industrial Pharmacy" 3rd edition, Mumbai: Varghese Publishing House,1991 3. Rawlins, E. A. (1995). Bentley's text book of Pharmaceutics, 8th edition, London: Bailliere Tindal. 4. Micheal Rathbone, "Modified Drug Release Drug Delivery	

	Technology", 2nd Edition, Vol 1, 2008. 5. Chilukuri D.," Pharmaceutical Product Development: In Vitro-In Vivo Correlation", Vol 165, 2007. 6. Rubinstein, M. H.,. Aulton M. E., "Pharmaceutics: the science of dosage form design", pp. 304-321., London: ELBS Longman Group Ltd. 1988. 7.Robinson J.R and Lee V.L, "Controlled Drug delivery fundamentals and applications", 2nd edition, Marcel Dekker, Inc., New York, 1987. 8. Rolland A., "Pharmaceutical Particulate Carriers",. New York: Marcel Dekker, Inc.1993 9. Rudnic, E. M., & Schwartz, J. D. "Remington: The Science and Practice of Pharmacy",Philadelphia: Lippincott Williams & Wilkins.2006. 10. Saha, S., & Shahiwala, A. F. "Multifunctional coprocessed excipients for improved tabletting performance", 2nd edition, 2009	

Module 3	**III. To study mucosal and intrauterine drug delivery systems**	**1 credit**
Objectives	• 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

	• **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	• 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	1. Kreuter J.,"Colloidal Drug Delivery Systems", Marcel Dekker, New York, 1994. 2. Langer, ed., Biodegradable polymers as drug delivery systems, Marcel Dekker Inc. New York	

Module 4	**IV. To study recent advancements in Parentral drug delivery systems & Project & Seminar**	**1 credit**
Objectives	• 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 parentrals. • 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
	• **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 sames	(4) (8)
Assigned Writing &	• The assignments will be given to the students based on the above topics.	(3)

Tutorial	• 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.	

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.

Objective: Learning of concepts of TQM in totality.		
Pre-assessment: Determination of entry level knowledge of student based on regulatory aspects in pharmacy practice in form of quizzes, question & answers.		
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	• 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
	• Regulatory aspects of pharmaceutical and bulk drug manufacture, Overview of worldwide regulatory agencies and authorities. • Recent amendments to Drugs and Cosmetics Act and other relevant Rules like Schedule M, Schedule Y, Consumer Protection Act, Environmental Protection Act, Factories Act. • Certification and licensing procedures, WHO-GMP, US-FDA, EU and	(3) (3) (3)

	ISO Certification. • ICH guidelines: Q1-Q10, Guidelines with special reference to quality by design and risk management.	(3)
Assigned writing & Tutorials	• 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	1. 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. 2. A. A. Signore and T. Jacobs, "Good Design Practices for GMP Pharmaceutical Facilities" Taylor & Francis Group. 3. 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.**	**1credit**
Objectives	1. To enable the learner understand the regulatory aspects of pharmaceuticals and bulk drug manufacturing and include applications for INDA, ANDA and clinical trial approval 2. To study the concepts of patent search, patent infringement and applications for Indian and International patents. 3. To familiarize the learner with concepts of Intellectual property rights and its applications. 4. To introduce the learner to the concepts of Generics, Super generics and Biosimilars and understand Dossier preparation in CTD format.	

	5. To discuss present status and scope of pharmaceutical industry in India 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
	1. Intellectual property rights, Patent search and awareness, filing procedures, patent infringement and application for Indian and International patents. 2. Overview of Drug approval process, applications for INDA, NDA and ANDA, Generics, Super generics and Biosimilars Clinical trial approval, Dossier preparation in CTD format. 3. Present status and scope of Pharmaceutical Industry in India, Globalization of drug industry, Mergers & Acquisitions, Introduction to export of drugs and import policy.	(4) (4) (4)
Assigned writing & Tutorial	• 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	1. Carlton F, Agallaco J, "Validation of aseptic Pharmaceutical Processes", 1st edition, New York, Marcel Dekker. 2. Loftus, B. T., Nash, R. A., ed. Pharmaceutical Process Validation. vol. New York: Marcel Dekker, 1993. 3. ICH Guidelines available at: http://www.ich.org 4. Indian Patents Act 1970 available at http://www.patentoffice.nic.in/ipr/patent/patents.htm	

Module 3	**III. Study of quality audit and quality review procedure, Outsourcing and Sampling plans.**	**1 credit**

Objectives	• To develop an understanding of quality review and quality audit in pharmaceutical industries. • To introduce outsourcing, samplings 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
	• Outsourcing: Manufacturing Packaging, Analytical testing, Loan licensing, Contract manufacture, Audits thereof • Quality Audits: Auditing of manufacturing processes and facilities, Quality Review, Compliance reports and handling of Non –compliance. • Sampling plans, Methods and Statistical analysis of data generated.	(4) (4) (4)
Assigned writing & Tutorial	• 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	1. Malik V., "Drugs and Cosmetics Act", Eastern Book Co., 1940 2. Loftus, B. T., Nash, R. A., ed. "Pharmaceutical Process Validation", vol. 57,NewYork: 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	• To make learner understand the risks associated with different occupational hazards in pharmaceutical industries. • To teach safety procedures and safety exercises to be followed.	

	• 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
	• 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	• 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	• Loftus, B. T., Nash, R. A., ed. "Pharmaceutical Process Validation", vol. 57,NewYork: Marcel Dekker, 1993.	

M.Pharm–S2-MQA4– 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.		
Pre assessment: Determination of entry level knowledge of student about pharmaceutical packaging requirements based on quizzes, question & answers.		
Module 1	**I. Pharmaceutical containers and its specifications**	**1 credit**
Objectives	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

	• Glass containers for Pharmaceuticals**:** Glass types, their manufacture chemical composition, Performance testing and quality control, Defects. • 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. • Metal containers: Aluminum and tinplate drums collapsible tubes. Aerosol containers, Lacquering, coating and lining. • Flexible packaging: Types of films, Co-extruded films, foils, coating and laminates, shrink and stretch films, blisters including ALU- ALU blisters and Strip Packaging.	(3) (3) (3) (2) (2)
Assigned writing & Tutorial	• 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	• 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 ad revised edition, 2008	

Module 2	**II. Study of secondary packaging systems and its specifications**	**1credit**

Objectives	• 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
	• Paper and paperboard: Types of paper, folding cartons, quality control testing of paper and paperboard and their common defects • Corrugated and solid fibre boards and boxes: Types of corrugation, methods, types of box design and Quality control. • 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. • 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) (3) (3) (3)
Assigned writing & Tutorial	• 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	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	• To enable the learner to understand various laboratory testing methods for packaging systems. • To study tamper evident packaging systems • To determine product packaging compatibility • To determine packaging selection criteria.	
Contents	**Topics Covered**	hrs
	• Transit worthiness of package: Hazards, mechanical, climatic protection during transit, Laboratory testing methods. • Product–Package compatibility: Stability of product, package selection and development criterion, Line clearance and packaging operation in pharma industry. • Tamper evident and child resistant packaging systems: Various types and their mechanisms.	(4) (4) (4)
Assigned writing & Tutorial	• 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	1) Ross, C. F., "Packaging of Pharmaceuticals", Newnes-Butterworths (London), 1975. 2) *Friedman* W. F., Kipnees J. J., "*Industrial Packaging"*. New York: Wiley, 1960.	

Module 4	**IV. Packaging Machinery & Seminar**	**1 credit**
Objectives	• 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
	• Packaging Machinery**:** Including strip packaging, and blister packing, form fill and seal machines, blow form and fill machines liquid and solid filling machines, capping machines packaging operations and packaging controls as per schedule M	(9)
	• Project & Seminar Based on New Packaging Aspect In Pharma Industry	(3)
Assigned writing & Tutorial	• 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	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, *Industrial Packaging*. New York: Wiley, 1960. 4. Ross, C. F. Packaging of Pharmaceuticals, Newnes-Butterworths (London), 1975	

M.Pharm–S2-MQA2- Packaging and Product Development – II (Practicals)

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

Objective: To provide hand on training and enable the learners to understand the practical aspects in formulation development of Pharmaceutical dosage forms; 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.		
Pre-assessment: Determination of entry level knowledge of student based on commonly used packaging materials used in pharmacy in form of quizzes, question & answers.		
Module 1	**I. Pharmaceutical containers: Study of primary and secondary packaging systems their specifications evaluation**	**1 credit**
Objectives	• 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 learners to understand documentation and maintenance of record all the experiments in the prescribed format in the journal.	
Contents	**Experiments**	Hrs
	• 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)

Assigned Writing/ Practical Activities	• 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) (2)
References	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.	

Module 2	**Selection of pharmaceutical packaging based on product package compatibility, environmental conditions.**	**1credit**
Objectives	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. The enable learners to understand documentation and maintenance of record all the experiments in the prescribed format in the journal.	
Contents	**Experiments**	hrs
	1. Identification of HDPE, LDPE, PVC, Polystyrene, PET Plastics. 2. To perform quality control tests on plastic containers IP 3. Determination of water vapour transmission of given plastic. 4. To perform quality control tests on rubber closures for Injectable preparation IP. 5. Determination of preservative uptake by rubber closure. 6. Testing of Aluminium collapsible tubes: quality control tests, product	(4) (4) (4) (4) (4) (6)

	package compatibility, stress testing.	
Assigned Writing/ Practical Activities	1. Experiments pertaining to the selection and evaluation of pharmaceutical packaging will be assigned to the students & they will perform the same. 2. Experimental work performed by the student will be documented and submitted in the form of Journal	(2) (2)
References	1. *Friedman* W. F., Kipnees J. J., "*Industrial Packaging"*. New York: Wiley, 1960. 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	• 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 disperse phase dosage forms as per the pharmacopeia and regulatory guidelines • The enable learners to understand documentation and maintenance of record all the experiments in the prescribed format in the journal.	
Contents	**Experiments**	Hrs

	• Development, Optimization and Evaluation of Sustained release tablet. • Development, Optimization and Evaluation of Paediatric Oral Suspension. • Development, Optimization and Evaluation of Topical gel • Development and Evaluation of Subcutaneous Implants • Development, Optimization and Evaluation of Lipospheres • Development, Optimization and Evaluation of polymeric Microspheres	(6) (4) (4) (4) (4) (4)
Assigned Writing/ Practical Activities	• 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. • Experimental work performed by the student will be submitted in the form of Journal	(2) (2)
References	1. *Bruck*S.D. , "*Controlled Drug Delivery*(Basic Concepts)", Vol.1, Marcel Dekker Inc., New York, CRC Press, 2005 2. *Rolland* A.,"*Pharmaceutical Particulate Carriers*",. *New York*: *Marcel Dekker*, *Inc*.1993 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 Polymer system. 6. Lachman, Lieberman, Pharmaceutical dosage forms: Dispersed systems Vol. I, II, Marcel-Dekker, 2008. 7. Nicholas P. Chezerisionoff, 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.	
Module 4	**Concepts in preparation and evaluation of Nanocarrier Systems and stability studies**	**1 Credit**
Objectives	1 To understand preparation and various evaluation parameters for Nanocarrier Systems 2.Comparison of *In-vitro*&*in-vivo* data 3	
Contents	**Experiments**	**Hrs**
	• Demonstration of Particle size analyser • Determination of zeta Potential of nanocarriers • Demonstration of high pressure homogeniser • Preparation of microemulsion, multiple emulsion and nanoparticles • Correlation of *In-vitro*&*in-vivo* data for various formulations • Concept of Stability studies according to ICH guidelines on any one developed formulation.	2 2 2 8 4 8
Assigned Writing/ Practical Activities	• 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. • Experimental work performed by the student will be submitted in the form of Journal	(4)
References	1. *Bruck*S.D. , "*Controlled Drug Delivery*(Basic Concepts)", Vol.1, Marcel Dekker Inc., New York, CRC Press, 2005 2. *Rolland* A.,"*Pharmaceutical Particulate Carriers*",. *New York*: *Marcel Dekker, Inc.*1993 3. Lachman, L., Lieberman, H. A., & Kanig, J. L. (1991). The Theory and Practice of Industrial Pharmacy (3rd ed.). Mumbai: Varghese	10.

	Publishing House. 4. Ray and Weller, Handbook of Pharmaceutical Excipients, 5th edition, Pharmaceutical Press, 2009. 5. Rodriguez, F, Principles of Polymer system. 6. Lachman, Lieberman, Pharmaceutical dosage forms: Dispersed systems Vol. I, II, Marcel-Dekker, 2008. 7. Nicholas P. Chezerisionoff, 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.	

Semester III

M.Pharm–S3-MQA-2– Computer & Statistics

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

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

Objective: To make learners understand basics of computers and use of computers in Pharmacy practice		
Pre-assessment: Determination of entry level knowledge of student on applications of computers in pharmacy based on quizzes, question & answers.		
Module 1	**I. Basics of computers**	**1 credit**
Objectives	To introduce use of computer system to access and retrieve information & develop an understanding of various application software with respect to pharmaceutical sciences.	
Contents	**Topics Covered**	hrs
	• Application of computers in pharmaceutical sciences, stores management, inventory control, drug information systems and hospital information systems	(3)
	• Access to and retrieval of information: Smart search using internet, use of search engines and web sites, drug information sources.	(3)
	• 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)
Assigned	• The assignments will be given to the students based on the above	(3)

Writing & Tutorial	topics. • Topics pertaining to the need of computers to retrieve information will be assigned to the students & they will present the same.	
Assigned Reading/ References	1. Bansal, Mohan, medical Informatics: A Primer,4th edition, Tata McGraw Hill, New Delhi.2007 2. Subramanian N. Introduction to Computers and Fundamentals of Computer Sciences, Tata McGraw-Hill, New Delhi, 1990	

Module 2	**II. Applications in Pharmacy**	**1credit**
Objectives	• 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**	
	• 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. • 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) (3) (3) (3)
Assigned Writing & Tutorial	• 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	1. R.D.Lele, "Computers in Medicine", Tata McGraw-Hill, New Delhi, 1999 2. Fassett, Willam and Christanson Dale "Computer Application in Pharmacy", 4th edition, Lea & Febiger, 1986 3. 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	• 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
	• Probability: Laws of probability, types of distribution. • Hypothesis testing: Types of errors, tests for significance: one-tailed and two- tailed tests, t test, z test, chi-square test. • Correlation and regression: definition and calculation of correlation coefficient, regression coefficient, least square, method, linear regression.	(4) (4) (4)
Assigned Writing & Tutorial	• 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	1. Daniel W., "Biostatistics: A Foundation for Analysis in the Health Sciences", John Wiley and Sons, 1998 2. Mahajan B.K., "Methods in Biostatistics", 4th edition, Jaypee Publications, New Delhi.	

Module 4	**IV. Application of Statistics**	**1 credit**

Objectives	• To develop understanding of analysis of variance by studying randomized & factorials designs and teach various non-parametric tests. • To present statistical application in design of pharmaceutical & biomedical experiments	
Content	**Topics Covered**	Hrs
	• Analysis of variance: Completely randomized design randomized complete block design, Factorial design, and response surface graphs. • Non-parametric tests: The sign test, The Mann-Whitney U test, The Runs test, Spearman's rank correlation. • Role of statistics in design of pharmaceutical and biomedical experiments specially controlled clinical trials.	(4) (4) (4)
Assigned Writing & Tutorial	• 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	1. Martin, B., "An Introduction to Medical Statistics", 3rd edition, ELBS, Oxford University Press. 2. Mirray R and 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.	

M.Pharm–S3-MQA-2: Computer & StatisticsI (Practicals)

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

Objective: To make learners understand basics of computers and use of computers in Pharmaceutical applications & data retrieving.		
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	• 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)
	• 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 presentation. Tools used may be Microsoft Power Point, Open Office or similar tool.	(6) (4) (6)
Assigned Writing/ Practical Activities	• 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	1. R.D.Lele, "Computers in Medicine", Tata McGraw-Hill, New Delhi, 1999 2. 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	• 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 softwaresuch as - QSAR, CADD, Pharmacokinetics, Factorial design with respect to pharmaceutical sciences.	
Contents	**Experiments**	(20)
	• Introduction to Internet, Use of Internet and www • Applications 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, science direct, freepatentsonline.	(6) (6) (6)
Assigned Writing/ Practical Activities	• Experiments involving applications of software-QSAR, CADD, pharmacokinetics, factorial designfor data interpretation would be assigned to the learners and they would perform and enter the same in their work books.	(2)
Assigned Reading/ References	1. C.N. Madu,. “Statistics as easy as one, two, three with Microsoft Excel for Windows”, 1st Edition. Chi Publishers Inc, 2003. 2. Fassett, Willam and Christanson Dale “Computer Application in Pharmacy”, 4th edition, Lea & Febiger, 1986	

Module 3	**III. Statistical Data Analysis & Application of Spreadsheet to Pharmacy**	**-**
Objectives	• To introduce use of statistical data analysis to access and retrieve information. • To develop anunderstanding of features and functions &applicationof spreadsheet to pharmaceutical sciences.	
Contents	**Experiments**	(20)
	• 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. • R-Project: Statistical package.	(8) (6)
Assigned Writing/ Practical Activities	• 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	1. Fassett, Willam and Christanson Dale "Computer Application in Pharmacy", 4th edition, Lea & Febiger, 1986 2. 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.	

M.Pharm–S3-MQA-3: 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.

Objective: 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.		
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.		
Module 1	**Validation of Equipment and Sterilization processes**	**1 credit**
Objectives	• To enable the learners about the concept of Validation • To enable the learners to understand the principles and methods of validation • To enable the learners to understand various processes 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	**Topics covered**	hrs

	• 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	• 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 ask to collect data on methods of validation of equipment and processes used in Pharma industries & comment on their applicability.	(3)
Tutorial	• 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	1. 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. 2. 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	• To enable the learners to apply the concept of Validation • To enable the learners to understand the principles and methods of validation of personnel • 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
	• Validation and audits of analytical procedures such as HPLC, UV, GC, HPTLC. • Validation of personnel handling the analytical instruments	(5) (5)
Assigned writing	• 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	• 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	1. Pharmaceutical Process Validation by Robert A. Nash, Alfred H. Wachter Marcel Dekker Publisher 3rd edition 2003. 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.	

Module 3	**Validation of Air and Water handling system in Pharmaceutical Industries and Hospitals**	**1 credit**
Objectives	• To enable the learners to understand the principles and methods of validation of air handling equipment • To enable the learners to understand validation of water supply system • 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
	• Validation of air handling equipment and facilities in sterile and non-sterile areas. • Validation of water supply system, demineralized, distilled and water for injection. • Validation and security measures for electronic data processing.	(4) (4) (2)
Assigned writing	• 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	• 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	1. Remington's the science and practice of pharmacy 21st Edition by Alfonso R. Gennaro. Lippincott Williams & Wilkins Publisher 2006. 2. 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	• 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–S3-MQA-3: Validation (Practicals)

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

<table>
<tr><td colspan="3">Objective:
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 learners can be aware of functioning and requirements in the field of Quality assurance.</td></tr>
<tr><td colspan="3">Pre-assessment
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.</td></tr>
<tr><td>Module 1</td><td>Validation of Equipment and Sterilization processes</td><td>Hrs</td></tr>
<tr><td>Objectives</td><td>• To enable the learners about the concept of Validation
• To enable the learners 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</td><td></td></tr>
<tr><td>Contents</td><td>Experiments</td><td>Hrs</td></tr>
<tr><td></td><td>• Validation of equipments:
a. Glassware-volumetric flasks, cylinder, beakers etc
b. Autoclave
c. Hot air Oven
d. Membrane Filters
e. Powder mixer (Dry)</td><td>(5)</td></tr>
</table>

	f. Tablet compression machine g. Validation of sterilization processes: a. Moist heat sterilization processes b. Dry Heat sterilization processes c. Chemical sterilization processes d. Membrane filtrations processes	(3) (8)
Assigned Writing/ Practical Activities	• The assignments will be given to the students based on the 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 equipment and processes used in Pharma industries & comment on their applicability.	**(4)**
Assigned Reading/ References	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. Alfonso R. Gennaro. Remington's the science and practice of pharmacy 21st Edition. Lippincott Williams & Wilkins2006. 3. Robert A. Nash, Alfred H. Wachter.Pharmaceutical Process Validation 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.	
Module 2	**Validation of Analytical processes and personnel**	-
Objectives	• To enable the learners to apply the concept of Validation • To enable the learners to understand the principles and methods of validation of personnel • 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
	• Validation of Analytical Instruments a. HPLC b. GC c. HPTLC	(15)
Assigned writing& Tutorial	• 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	1. Robert A. Nash, Alfred H. WachterPharmaceutical Process Validation3rd edition, Marcel Dekker Publisher 2003. 2. Anurag Singh Rathod, Gail Sofer, G.K. Sofer. Process validation in manufacturing of Biopharmaceuticals-Guidelines current practices, and industrial case studies. Informa Healthcare 2005. 3. 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	• To enable the learners to understand the principles and methods of validation of air handling equipment • To enable the learners to understand validation of water supply system • 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	**Experiments**	**Hrs**
	1. Validation of cleaning area 2. Cleaning validation of one equipment	
Assigned Writing & Exercise	• 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	**(2)**
Assigned Reading/ References	1. Alfonso R. Gennaro.Remington's the science and practice of pharmacy 21st Edition Lippincott Williams & Wilkins 2006. 2. Robert A. Nash, Alfred H. Wachter,Pharmaceutical Process Validation 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. Manohar A. Potdar. cGMP : Current Good Manufacturing Practices for Pharmaceuticals/Hyderabad, PharmaMed Press, 2008	

S3-MQA-4: Research Methodology

SEMESTER		SUBJECT			
I		Research Methodology			
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.

Module 1	**Introduction of Research Methodology**	**1 credit**
Objectives	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**
	Learning and instruction 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.	**5**
	Basics of Research Definition, objectives, motivation, types of research and approaches: descriptive research, conceptual, theoretical, applied and experimental.	**6**
	Literature review 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. Review and compilation of the collected matter	**3**
	Funding & Scholarship Agencies funding research in pharmaceutical sciences, Scholarship, types of scholarships in education.	**1**
Module 2	**Basics of Research**	**1credit**
Objectives	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 log books for all the instruments, to come out with innovative ideas.	**6**
Module 3	**Mathematical Modelling & Analysis of Data**	**1 credit**
Objectives	**1.** To acquaint research students with various mathematical & experimental modeling techniques used to draw conclusions in Experimental Research. **2.** To be able to identify, analyze and solve problems related to research using software. **3.** To study the various software used in pharmacy for data analysis.	

	Mathematical Modeling and Simulation Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, difference equations, partial differential equations, graphs, simulation: concept, types (quantitative , experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement	**5**
	Experimental Modeling a) Definition of experimental design, examples, single factor experiments blocking and Nuisance factors, guidelines for designing experiments. b) General model of process: Input factors/ variables, Output parameters / variables controllable / uncontrollable variables, dependent / independent variables, experimental validity.	**5**
	Analysis of data a) Types of data: parametric and nonparametric, descriptive and inferential data, b) Collection of data: normal distribution, calculation of co-relation coefficient c) Data processing: analysis, error analysis, meaning, and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regression, testing linearity/nonlinearity of model, testing adequacy of model. d) Test to be used in data exploration and their choice	**5**

	e) Introduction of software used in data analysis.	
Module 4	**Ethics In Pharmacy & Research Deliverables**	**1 credit**
	• To learn techniques used in the professional presentations. • To learn about research publications,thesis writing and presentations. • To understand ethical consideration involving research and issues related to plagiarism.	
	Research Deliverables a) Various Forms of Publication: Thesis, Paper, Research proposal 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, c) Presentation: Poster, thesis, proposal , and paper	**6**
	Ethical issues in research Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines/ herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good Clinical Practices norms, Ethical principles related to animal experiments.	**6**
	Plagiarism Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscript	**3**

	writing, documentation, organization of reference material, bibliography, end note.	
Recommended books	**1.** B.D. John, A.L. Brown and R.R. Cocking, 1999. "How People Learn: brain, mind, experience and school". Washington, DC: NationalAcademy 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 JohnHopkinsUniversity 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. *Medical Education, 37*(4): 376-385. **6.** B.J. Avolio, F.O. Walumbwa, T.J. Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*: 421-449. **7.** C.R. Kothari, 2004. "Research Methodology". 2nd Ed. New Age International (p) Limited, Publishers. **8.** D. Montgomary, 2000. "Design of Experiments". 5th Ed. Wiley Interscience. **9.** K.P. Willkinsion, 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.	

S3-MQA5: Research Seminar

SEMESTER		SUBJECT			
III		Research Seminar			
WEEKLY ASSIGNMENT		CREDITS		MARKS.	
TH	PR	TH	PR	TH	PR
4 (or 2?)	--	2	--	50	--

S3-MQA-6: Research Project

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

S3-MQA-1: Industrial Training

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

Semester IV

S4-MQA-1: Research Project

SEMESTER		SUBJECT			
III		Research Project			
WEEKLY ASSIGNMENT		**CREDITS**		**MARKS.**	
TH	**PR**	**TH**	**PR**	**TH**	**PR**
36 **(or 32?)**	--	24	--	600	--