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

REVISED CURRICULAM

M. PHARM.
SPECIALIZATION: PHARMACEUTICS

FOUR SEMESTER PROGRAMME

Effective from Academic Year 2012-13

The M. Pharm. (Pharmaceutics) course was introduced in 2005 at C.U. Shah College of Pharmacy by SNDT Women's University. The course is devised with a focus on the aptitude, talents and job potential for women in pharmaceutical industry and research and development institutes.

This is a four-semester programme with the following specific features:

1. Emphasis on advanced formulation design and development techniques including controlled release, Novel Drug delivery Systems and various strategies for drug targeting.
2. Applications of modern analytical techniques like spectroflurometry, infrared spectrophotometry, NMR, Spectromentry HPLC, HPTLC, X-ray diffraction analysis and spectral analysis.
3. Thrust on good manufacturing practices, quality audits, documentation and validation with a view to create total quality consciousness.
4. Packaging and product development courses designed to teach current trends in formulation and packaging of pharmaceuticals and newer drug delivery systems.
5. Understanding of Regulatory affairs, New Drug Application and patenting procedures.
6. 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.
7. One month in plant training in industry to correlate theory with professional practice.
8. 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.

PROGRAM OUTCOMES:

After successful completion of the program, the learners will be able to

1. Apply the principles of formulation development for developing therapeutically effective and safe drug delivery systems.
2. Analyze, criticize, organize, improvise and manage documentation related to formulation development and evaluation.
3. Sustain in the field of academia, pharmaceutical industry and also opt for higher education in pharmacy.

SCHEME: M.Pharm. In Pharmaceutics

Semester	Subject Code	Subject	Hours/ Week		Credits		Marks	
			TH	PR	TH	PR	TH	PR
First	1101	Advanced Pharmaceutics I	4	-	4	-	100	-
	1102	Physical Pharmaceutics	4	-	4	-	100	-
	1103	Modern Analytical Techniques I	4	-	4	-	100	-
	1104	Total Quality Management	4	-	4	-	100	-
	1201	Advanced Pharmaceutics I	-	8	-	4	-	100
	1203	Modern Analytical Techniques I	-	8	-	4	-	100
		Total	**16**	**16**	**16**	**8**	**400**	**200**
Second	2101	Advanced Pharmaceutics II	4	-	4	-	100	-
	2102	Industrial pharmacy	4	-	4	-	100	-
	2103	Modern Analytical Techniques II	4	-	4	-	100	-
	2104	Packaging Development	4	-	4	-	100	-
	2201	Advanced Pharmaceutics II	-	8	-	4		100
	2203	Modern Analytical Techniques II	-	8	-	4		100
		Total	**16**	**16**	**16**	**8**	**400**	**200**

Semester	Subject Code	Subject	Hours/ Week		Credits		Marks	
			TH	**PR**	**TH**	**PR**	**TH**	**PR**
Third	**3101**	Computing & Statistics	4	-	4	-	100	-
	3102	Pharmacokinetics & Biopharmaceutics	4	-	4	-	100	-
	3103	Research Methodology	4	-	4	-	100	-
	3104	Research Seminar	4	-	**2**	**-**	**50**	-
	3105	Research Project	-	16	-	8	200	-
	3106	Industrial Training	**One Month**		**2**		**50**	
		Total	**16**	**16**	**24**	**-**	**600**	-
Fourth	4101	Research Project (Thesis +Viva)	**32**	**-**	20	**-**	500	-
	4102	Research Colloquim	-	-	4	-	100	-
		Total	**72**	**-**	**24**	**-**	**600**	**-**
		Grand Total			**80**	**16**	**2000**	**400**

ABBRIVATIONS:

SEMESTER NUMBER	SPECIALIZATION	SUBJECT NUMBER
S1	PH	1
SEMESTER 1	PHARMACEUTICS	SUBJECT NUMBER 1

Examination Pattern for M. Pharm in Pharmaceutics

Semester I

Subject Code		SUBJECT	Exam Dur. (hr)	Theory				Exam Dur. (hr)	Practicals			
Theory	Practical			Int.	Ext.	Total	Credits		Int.	Ext.	Total	Credits
1101	1201	Advanced Pharmaceutics-I	2	50	50	100	4	6	50	50	100	4
1102	-	Physical Pharmacy	2	50	50	100	4					
1103	1203	Modern Analytical Techniques-I	2	50	50	100	4	-	50	50	100	4
1104	-	Quality Management & Drug Regulatory Affairs	2	50	50	100	4	6	-	-	-	-

Semester I : Total credits = 24

Semester- II

Subject Code		SUBJECT	Exam Dur. (hr)	Theory				Exam Dur. (hr)	Practicals			
Theory	Practical			Int.	Ext.	Total	Credits		Int.	Ext.	Total	Credits
2101	2201	Advanced Pharmaceutics II	2	50	50	100	4	6	50	50	100	4
2102	-	Industrial pharmacy	2	50	50	100	4	-	-	-	-	-
2103	2203	Modern Analytical Techniques II	2	50	50	100	4	6	50	50	100	4
2104	-	Packaging Development	2	50	50	100	4	-	-	-	-	-

Semester II : Total credits = 24

Semester III

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

Semester III: Total credits = 24

Semester IV

Subject Code		SUBJECT	Exam Dur. (hr)	Theory				Exam Dur. (hr)	Practicals			
Theory	Practical			Int.	Ext.	Total	Credits		Int.	Ext.	Total	Credits
4101		Research Project (Thesis)	-	200	200	400	12	-	-	-	-	-
4102		Research Colloquium	-	100		100	4		-	-	-	-
		Viva	-	-	100	100	8		-	-	-	-
		Total	-	300	300	600	24					

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**

The students will be awarded grades based on their performance as per the university rules.

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Semester I

M.Pharm–1101: Advanced Pharmaceutics I

SEMESTER		**SUBJECT**			
I		Advanced Pharmaceutics I Theory			
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: The subject is concerned with the advances in formulation development of Pharmaceutical dosage forms & new drug delivery carriers. The subject encompasses from the development of formulations, selection of various excipients, design of novel carrier system to complete evaluation of the drug delivery systems. Learning these techniques learner will be able to develop and evaluate advanced pharmaceutical dosage forms.

Learning Outcomes: The learners will be able to:

1. Understand the advances in formulation development of pharmaceutical dosage forms and new drug delivery carriers and advancements in coating technologies.
2. Select various excipients and polymers, design and development of novel pharmaceutical carrier systems as well as advanced pharmaceutical dosage forms such as tablets, capsules and injectables and evaluate them.

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

Module 1	**Selection of Pharmaceutical Excipients & Study of Polymers**	**1 credit**
Objectives	• To give an insight in selection of excipients in development of various pharmaceutical dosage forms. • To enable the learner to understand the basic principles of conventional polymers and polymers used for controlled release drug delivery system. • To study the regulatory, safety, specifications and evaluation techniques for various excipients as per the pharmacopoeial and pharmaceutical guidelines and their applications in the dosage forms. 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
	• **Excipients in pharmaceutical formulations**: Introduction to excipients and their importance in pharmaceutical and cosmetic industry; Functional excipients used in tablet manufacturing such as directly compressible excipients and super disintegrants; Novel surfactants, solubilizers and stabilizers in disperse systems, taste masking excipients, colours, flavours, sweetening agents, gel and film forming agents, solvents- Evaluation methods, quality control, regulatory aspects and material safety data sheets. • **Polymers in drug delivery systems:** Types of polymers-biodegradable, non-biodegradable and bio-erodible. Methods of polymerization, Homo and hetero polymers block co-polymers, Molecular weight of polymers, Characteristics of polymers, crystallinity, phase transition, polymer stabilization. Polymer testing, analysis, polymer solubility; Polymers for controlled release drug delivery like hydrogels, microparticles, nanoparticles, bioadhesive polymers, transport of small molecules in polymers, biodegradation of polymers, compatibility and biocompatibility of polymers; applications of polymers in biomedicine (e.g. in-situ/embedded systems), bio responsive polymers.	(6) (6)
Assigned writing & Exercise activities	• The assignments will be given to the students based on the selection, screening & properties of excipients • The students will be asked to collect data on various polymers available in the market & comment on the suitability in the pharmaceutical dosage forms.	(2)
Tutorial	• Topics pertaining to the study of pharmaceutical excipients & study of polymers will be assigned to the students & they will present the same	(1)
Assigned Reading/ References	1. Rowe, R. C., Sheskey, P. J., & Owen, S. C. (Eds.) Handbook of pharmaceutical excipients (6th ed.). London: Pharmaceutical Press and A.A.P.S., 2009 2. Lloyed, J.B., "Soluble polymers as targetable drug carriers", In: Drug delivery systems: fundamentals and techniques, edited by Johnson, P. and Lloy-Jones, J.G., Ellis Horwood, New York, 1991. 3. David K Platt, Biodegradable Polymers, iSmithers Rapra Publishing, 2006. 4. Catia Bastioli, Handbook of biodegradable polymers, iSmithers Rapra Publishing, 2005.	

Module 2	**Principles and Techniques of Solid Dosage Forms and Coating Technology**	**1 credit**
Objectives	• To enable learner to understand the recent advances in tablet and capsule technology. • To provide insight to oral controlled release drug delivery system and machinery used for the same. • To provide overview of advances in various types of coating techniques and various coating equipments. 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 and oral controlled release drug delivery systems:** Recent advances in tablet and capsule technology like double compression, direct compression, lubrication and binding agents, extrusion and spheronization, oral drug delivery systems, e.g., matrix controlled, osmotic pressure controlled, membrane permeation controlled, pH controlled, ion-exchange controlled, gel diffusion controlled, hydro-dynamically balanced systems, modulation of GI transit time, gastro-retentive systems. • **Coating of solid dosage forms**: Aqueous and non-aqueous film coating, polymers, process controls, coating equipment, coating pans, Accela-cota, Hi-coater, Dria-Coater and metering devices, spray systems, particle coating methods; advances in microencapsulation techniques.	(6) (6)
Assigned writing	• The assignments will be given to the students based on the tablet technology, coated tablets, Processing, Automation.	(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. Robert, W. M., & Aloysius, O. A., Pharmaceutical Dosage Forms—Tablets Vol 3 (Revised and expanded). (H. A. Lieberman, L. Lachman, & J. B. Schwartz, Eds.) Informa Health Care., 2008 2. Lachman, L., Lieberman, H. A., & Kanig, J. L.. The Theory and Practice of Industrial Pharmacy (3rd ed.). Mumbai: Varghese Publishing House. ,1991. 3. Rawlins, E. A. Bentley's text book of Pharmaceutics (8th ed.). London: Bailliere Tindal., 1995. 4. Rubinstein, M. H.,Tablets. In M. E. Aulton, Pharmaceutics: the science of dosage form design, London: ELBS Longman Group Ltd., 1988. 5. Rudnic, E. M., & Schwartz, J. D., Remington: The Science and Practice of Pharmacy, (A. R. Gennaro, Ed.) Philadelphia: Lippincott Williams & Wilkins, 2006 6. Saha, S., & Shahiwala, A. F.,Multifunctional coprocessed excipients for improved tabletting performance . Expert Opinion on Drug Delivery, 6 (2), 2009.

Module 3	**Classification of Pharmaceutical Carriers and Controlled Release Drug Delivery Systems**	**1 credit**
Objectives	• To give introduction to specialized pharmaceutical disperse phase systems. • To familiarize the learner with the recent advances in particulate drug delivery systems. • To provide an insight to formulation and evaluation of small volume and large volume parenterals. • To study the recent advances in injectable controlled release formulation, long acting contraceptives and implants 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
	• **Particulate Drug Carriers**: Liposomes, Niosomes, Nanoparticles, Solid lipid nanoparticles, Liposopheres and Microspheres, Dendrimers and Quantum dots **(Seminar)**	(4)
	• **Colloidal and disperse systems**: Novel emulsions like multiple emulsions, microemulsions, nanoemulsions, injectable emulsions. Suspensions, reconstituted suspensions nanosuspensions, and gels; quality assurance of dispersed systems. **(Seminar)**	(4)
	• **Parentral dosage forms**: Current trends in Formulation, Stabilization and Manufacture of small and large volume parenterals, Aseptic processing and Barrier isolator technology, Evaluation and quality control; Parenteral controlled release formulations, implantable drug delivery systems.	(4)
Assigned writing & Activities	• The assignments will be given to the students based on the novel drug delivery carriers and understanding of literature update. Discussion on recent research articles in International Journal of Pharmaceutics, Nanomedicine will be done as Case studies.	(2)
Tutorial	• Topics pertaining to the study of pharmaceutical carriers and principles related to various Controlled Release drug delivery systems will be assigned to the students followed by presentation and discussion.	(1)

Assigned Reading/ **References**	1. Vyas, S.P. and Khar, R.K., "Targeted and controlled drug delivery novel carriers", ISBN 81-239-0799-0, CBS, 1st edition, 38-79, 2002. 2. Sharma A., Sharma U., "Liposomes in drug delivery: progress and limitations", Int. J. Pharma., 1997, 154(2), 123- 140. 3. Riaz M., "Liposomes: preparation methods", Pak. J. Pharma. Sci., 1996, 19(1), 65-77. 4. Sharma S., Sharma N., Kumar S., Gupta G., "Liposomes: A review", J. Pharm. Res., 2009, 2(7), 1163-1167. 5. Jain S., Jain N., "Liposomes as drug carriers", In: Controlled and novel drug delivery, Jain N., CBS Publishers and Distributors, 1997, 304-305. 6. Davis, S.S. and Illum, L., "Colloidal delivery systems- opportunity and challenges, in site specific drug delivery cell biology", In Medical and Pharmaceutical aspect, John Wiley and Sons, Chichester, 93-100, 1986. 7. Thassu D. "Nanoparticulate Drug Delivery System" Vol. 166, Marcel Dekker Series, 2007. 8. Hauss D.,"Oral Lipid Based Formulation Enhancing The Bioavailability Of Poorly Water Soluble Drugs", Vol. 170, 2007. 9. Macnally E., "Protein Formulation & Delivery", 2nd Edition, Vol. 175, 2008

Module 4	**Project and Seminar**	**1 credit**
	• The learners will give one seminar based on principles, theory and the application of advanced drug delivery systems based on the above topics	(15)

M.Pharm–1201: Advanced Pharmaceutics I (Practical)

SEMESTER		**SUBJECT**			
I		Advanced Pharmaceutics I Practical			
WEEKLY ASSIGNMENT		**CREDITS**		**MARKS.**	
TH	**PR**	**TH**	**PR**	**TH**	**PR**
	8		4		100

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

Objective: To enable learner to understand the practical aspects in formulation development and evaluation of Pharmaceutical dosage forms & new drug delivery carriers. The Subject encompasses from the development of formulation, selection of various excipients & novel carrier systems. Using these techniques learners will be able to develop and evaluate various novel pharmaceutical drug delivery systems.

Learning Outcomes: The learners will be able to:

1. Understand the practical aspects in formulation development and evaluation of pharmaceutical dosage forms and new pharmaceutical drug delivery carriers.
2. Identify most appropriate excipients to be used in designing dosage forms by understanding their characteristics and evaluation.

Pre-assessment : Determination of entry level knowledge of student based on development, optimization& evaluation of Pharmaceutical dosage forms based on the Pharmacopeial guidelines

Module 1	**Selection of Pharmaceutical Excipients & Study of oral & topical dosage forms**	**1 credit**
Objectives	• To give an insight into selection of excipients in development of various pharmaceutical dosage forms. • To enable the learner to understand the basic principles of conventional polymers and polymers used for oral drug delivery system. • To study various evaluation techniques for various oral & topical dosage forms as per the pharmaceutical guidelines and their applications in the dosage forms. The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report and journal writing.	

Contents	Experiments	Hrs
	Development, Optimization and Evaluation of sustained release tablets. Development, Optimization and Evaluation of floating tablets. Development, Optimization and Evaluation of Pediatric Oral Suspension. Demonstration of Rotary tablet punch machine. Development, Optimization and Evaluation of Topical gel. Development & evaluation of Dental gel.	(6) (6) (4) (2) (6) (3)
Assigned Writing/ **Practical Activities**	Experiments pertaining to the current advances in rate & controlled release delivery systems will be assigned to the students & they will perform the same. Experimental work performed by the student will be documented and submitted in the form of Journal.	(3)
Assigned Reading/ **References**	1. Raymond C., Rowe, Paul J., Sheskey, Paul J. Weller, "Handbook of Pharmaceutical Excipients" 5th edition, Pharmaceutical Press, 2009 2. Lachman, Lieberman, "Pharmaceutical dosage forms: Dispersed systems" Vol. I and II , 2nd edition Basel Marcel Dekker 2008. 3. Nicholas P. Chezerisionoff, "Product design and testing polymeric materials", Marcel. Dekker, Technology & Engineering, 1990. 4. Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms", Volume 110, New York Marcel Dekker, 2001, CRC. 5. Lisbeth, Illum & Stanley S. Davis: "Polymers in Controlled Drug Delivery", Wright, Bristol, 1987.	
Module 2	**Study of recent advances in Parenteral dosage forms**	**1credit**
	Experiments	Hrs
	• Development and Evaluation of Subcutaneous Implants • Aseptic processing technique for Parentral Dosage Forms • Development, Optimization and Evaluation of Long Acting Oily Injection • Development, Optimization and Evaluation of Aqueous Injectable Suspension	(6) (6) (6) (6)

	• Development & Evaluation of Dry Powder Injection	(3)
Assigned writing& Tutorial	• Experimental work will be compiled by the student in the prescribed format in the journal & assessed by the supervisor. • 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. Lisbeth, Illum & Stanley S. Davis: "Polymers in Controlled Drug Delivery", Wright, Bristol, 1987. 2. K.E.Avis, "Pharmaceutical Dosage Forms: Parental Medication", Vol. I & II, Marcel Dekker Inc., N.Y. ,2008 3. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y.,2009 4. Rodriguez, F, "Principles of Polymer system", 3rd Edition, Mcgraw-Hill, New York, NY. 1989	

Module 3	**Study of Pharmaceutical Carriers and Controlled Release Drug Delivery Systems**	**1 credit**
Objectives	• To introduce specialized pharmaceutical dispersed systems. • To study recent advances in particulate drug delivery systems. • The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report.	
	Experiments	Hrs
	• Development and Evaluation of Multiple emulsion.	(4)
	• Development and evaluation of Microemulsions	(4)
	• Development and evaluation of Nanoemulsions	(4)
	• Development, Optimization and Evaluation of Polymeric Microspheres	(6)
	• Development, Optimization and Evaluation of Lipospheres	(6)
	• Development and Evaluation of Nanoparticles	(3)

Assigned Writing & Exercise	• The students will submit all the above formulations in a suitable packaging & submit all the experimental work in the form of compiled Journal.	(3)
Assigned Reading/ References	1. Nicholas P. Chezerisionoff, "Product design and testing polymeric materials", Marcel. Dekker, Technology & Engineering, 1990. 2. Raymond C., Rowe, Paul J., Sheskey, Paul J. Weller, "Handbook of Pharmaceutical Excipients" 4th edition, Pharmaceutical Press, 2003 3. Chien W., "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y. 4. Park K., "Controlled Drug Delivery – Challenges and Strategies", CRC, Washington, DC, 1997. 5. Thassu D. "Nanoparticulate Drug Delivery System" Vol 166, 2007. 6. Hauss D.,"Oral Lipid Based Formulation Enhancing The Bioavailability Of Poorly Water Soluble Drugs", Vol 170, 2007. 7. Macnally E. ,"Protein Formulation & Delivery", 2nd Edition, Vol 175, 2008	
Module 4	**Experiments**	**1Credit**
Objectives	1 Screening & selection of various film forming polymers 2. Comparison of Coated & Uncoated dosage forms 3. Evaluation of directly compressible excipients formulations	
	• Evaluation of various film forming polymers • Evaluation of Marketed coated & uncoated tablets • Development & Evaluation of tablets by directly compressible excipients • Study of film coating of tablets	8 8 8 3.
Assigned Writing & Exercise	• The students will submit all the above formulations in a suitable packaging & submit all the experimental work in the form of compiled Journal.	(3)

Assigned Reading/ **References**	1. Lerk C., Bolhuis G., "Comparative evaluation of excipients for direct compression-I". Pharm weekbl, 108, 448-469, 1973 2. Enézian M., "Direct compression of tablets using microcrystalline cellulose", Pharm Acta Helv*;* 47, 321–363, 1972. 3. Jantzen G. M., Robinson J. R., "Sustained and Controlled-release drug delivery systems in modern pharmaceutics", Banker G., Rhodes, C. edt., Marcel Dekker Inc. New York, 3rd ed, (34) 196-211, 1996. 4. Venkatraman S., Davar N., Chester A., Kleiner L., "An overview of controlled-release systems in handbook of pharmaceutical controlled release technology", Wise, D. L. edt, Marcel Dekker Inc.,4th ed, 233 (35), 2000. 5. Chiao C. L., Robinson J.R., "Sustained release drug delivery systems", 2nd ed, 36, 244-258, 1995. 6. Qiu Y., Zhang G., "Research and development aspects of oral controlled-release dosage forms", Handbook of Pharmaceutical Controlled Release Technology, Marcel Dekker Inc. New York, 465-503, 2000.

M.Pharm–1102: Physical Pharmacy

SEMESTER		**SUBJECT**			
I		Physical Pharmacy			
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 cover the fundamental physicochemical principles of pharmacy and to learn the importance of formulation design performance and stability studies.

Learning Outcomes: To enable the learners to:

1. Understand the need of preformulation studies in pharmacy, study of fundamental physicochemical properties of materials such as crystal characteristics, particles size etc., need and methods of solubility enhancement in pharmaceutical product development.
2. Understand drug dissolution and diffusion principles in biological systems, physical and chemical stability protocols as per ICH Guidelines

Pre-assessment: Determination of entry level knowledge of student based on physicochemical properties of actives & final formulations.

Module 1	**I. Preformulation, Drug Product Design and Solubilization Techniques**	**1 credit**
Objectives	To enable learner to : • Understand the need of Preformulation studies in pharmacy. • Study concepts, applications and protocols for Preformulation studies. • Study different mechanisms for enhancing solubility and correlate solubility with in-vitro bioavailability. • Understand various pro-drugs and drug carriers and kinetics of drugs release from controlled release drug delivery system	

Contents	Topics Covered	Hrs
	• **Preformulation**: Concepts and application in formulation: pH-pKa, correlation, partition coefficient, drug excipients compatibility studies, phase equilibria and phase rule, biopharmaceutical factors affecting formulations; protocol for preformulation studies • **Techniques of Solubilization**: Mechanisms for enhancing solubility such as chemical modification, micellar solubilization, cosolvency, complexation, hydrotrophy, and dielectric constant modification. • **Rheology:** Types of Flow, Thixotropy & dilatancy, flow properties, Rheological Measurement, Applications of rheology in pharmacy.	(6) (3) (3)
Assigned writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the need of Preformulation studies, drug product design and study of different solubilization techniques will be assigned to the students & they will present the same.	(3)
Assigned Reading/ References	1. J. T. Carstensen, "Pharmaceutical Preformulation", Informa Health care, 1998. 2. Mark Gibson, Pharmaceutical Pre formulation, Interpharm CRC, 2008 3. Martin A., "Physical Pharmacy", 6th edition, Williams Lippincott and Wilkins, 2010 4. Moji C. Adeyeye, "Preformulation Solid Dosage Form Development", Vol 178, 2008 5. Water insoluble Drug formulation, Rong Liu, CRC Press, 2008	
Module 2	**II. Principles and Techniques of Crystallography, Particle Size and Surface Area & Protein Binding**	**1 Credit**
Objectives	• To give an insight to various factors affecting crystal characteristics and study of crystal morphology. • To learn about concepts and applications of particles size analysis and study of various particle size analyzers. • To provide basic principles involved in complexation and protein binding and study of evaluation and applications of complexes. • 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
	• **Crystallography:** Crystal morphology, factors affecting crystal characteristics, supersaturation theory and its limitations, super solubility curves; nucleation mechanisms, crystal growth and various types of crystallizers; amorphous solids, and liquid crystals; polymorphism, surface characteristics; analytical methods, e.g., thermal analysis and X-ray diffraction. • **Particle size and surface area:** Concept and applications: statistical diameters, specific surface area; modern methods of analysis including Coulter Counter, SEM, TEM, methods based on photon correlation spectroscopy and laser diffraction spectroscopy **(Seminar).** • **Complexation and protein binding:** Classification, examples and applications of complexes, methods of analysis. Complexation with cyclodextrins. Protein binding: Concept and application. Drug-receptor interactions.	(5) (4) (3)
Assigned writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the principles and techniques of crystallography, particle size and surface area & protein binding will be assigned to the students & they will present the same.	(3)
Assigned Reading/ References	1. ICH Guidelines Q4B on Dissolution Testing 2. G.S.Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y. 3. Martin A., "Physical Pharmacy", 6th edition, Williams Lippincott and Wilkins, 2010	

Module 3	2 Diffusion, Dissolution And Dissolution Testing &Stability Studies	1 credit
Objectives	To enable learners to: • Understand drug dissolution and diffusion principles in biological systems • Study thermodynamics and different laws governing diffusion. • Study devices for dissolution rate testing and apparatus for in-vitro, in-vivo correlation. • Understand physical & chemical stability protocols as per ICH Guidelines.	

	• To provide an insight into accelerated stability testing and study of calculations of overages in details.	
Contents	**Topics Covered**	Hrs
	• **Diffusion, dissolution and dissolution testing:** Steady state diffusion-procedure and applications, drug dissolution, drug release, diffusion principles in biological systems, thermodynamics of diffusion, Fick's second 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 drug delivery systems, in vitro-in vivo correlation. • **Chemical Kinetics & Drug stability:** Pathways for drug degradation, Rate & order of reaction, Factors affecting reaction kinetics stability testing, programme, Accelerated studies and shelf- life assignment, ICH guidelines	(7) (5)
Assigned writing &Tutorials	• The assignments will be given to the students based on the above topics. • Topics pertaining to the diffusion, dissolution and dissolution testing & stability studies will be assigned to the students & they will present the same.	(3)
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. ICH Guidelines Q4B on Dissolution Testing available at http://www.ich.org.	
Module 4	**3 Project and Seminar**	**1 credit**
Objectives	The learners will give one seminar in each semester on literature update on preformulation, dissolution methods, drug stability, crystallography, General principles, theory and the application of topic covered in the above modules	(15)

M.Pharm. 1103: Modern Analytical Techniques I

SEMESTER		**SUBJECT**			
I		Modern Analytical Techniques I Theory			
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

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.

Learning Outcomes: To enable learner to:

1. Understand the principles and use various analytical techniques such as UV spectrophotometer, spectroflurometer, IR spectroscopy, etc. in determining purity of compounds, quantitative as well as qualitative evaluation of drugs.
2. Use the thorough knowledge of these instrumental techniques confidently 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	• To make students familiar with the principles of quantitative estimation using UV-visible spectrometry • To enable students to use spectrometers with proper understanding • To make students competent for the basic quality control requirements or needs of industries • To make students familiar with the principles of quantitative estimation of moisture in various pharmaceutical products and commonly used solvents using simple instrumental techniques • To enable students to use Karl Fischer method of analysis with proper understanding • To make students familiar with the principles of quantitative estimation of solubility of a compound • 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	(7)

	Woodward rules • **Determination of Water** Importance of determination of water or moisture content. Various methods 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	• To make students familiar with the principles of selective quantitative estimation using instrumental methods • To enable students to use spectrofluorometer with proper understanding • To make students competent for the basic quality control requirements of industries • To make students familiar with the principles of absorption and emission spectrometry • To enable students to use atomic absorption spectrometer with proper understanding and make them competent for quality control activities of industry • 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,	(7)

	fluoresamine, o-phthaladehyde and Br-MMC. Fluorescent indicators. Quenching Methods and fluoroimmuno assays • **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 Journals like Analytical Chemistry, Analytical Communications, 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 • ii) 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,		(7)

	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 (IEF), Immuno-electrophoresis and applications of electrophoresis.	(3) (2)
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–1203: Modern Analytical Techniques I Practical

SEMESTER		**SUBJECT**			
I		Modern Analytical Techniques I- Practical			
WEEKLY ASSIGNMENT		**CREDITS**		**MARKS**	
TH	**PR**	**TH**	**PR**	**TH**	**PR**
-	8	-	4	-	100

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

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

Learning Outcomes: The learner will be able to:

1. Use different analytical instruments used for qualitative and quantitative analysis of drugs and formulations as per pharmacopoeial requirements
2. Identify structure of any given compounds by determination of functional groups, nature of given compound (amorphous, crystalline) as well as polymorphic forms by use of analytical instruments such FTIR, DSC, etc.

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

Module 1	**UV –Visible spectrometry (Fundamental Aspects)**	**1 credit**
Objectives	1. To learn fundamental aspects of quantitative and qualitative estimation using UV-visible spectrometry 2. To study Beer Lambert Law	
Contents	**Experiments**	(30)
	1. Calibration of UV –Visible spectrometer for absorbance 2. Determination of wavelength of maximum absorption (λmax) of a compound 3. Determination of cut-off wavelength of commonly used solvents for	(4) (4)

	UV spectroscopy 4. Determination of E(1%, 1cm) and molar absorptivity of a substance 5. Determination of range of linearity in accordance with Beer Lambert Law 6. Determination of Limit of Quantitation (LOQ) and Limit of Detection (LOD) of compounds in UV range	(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 2 Analysis of an active ingredient from its formulations such as tablets, capsules, suspensions, ointments and injections 3 Analysis of binary mixtures by simultaneous equation method 4 Standardization of Karl Fischer reagent 5 Quantitative estimation of moisture by using Karl Fischer reagent 6 Recording of a thermograph using differential scanning calorimeter	(6) (8) (6) (2) (2) (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. • 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) (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, MD 20852, 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–1104: Total Quality Management

SEMESTER		**SUBJECT**			
I		Total Quality Management			
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.

Learning Outcomes: The learners will be able to:

1. Understand basic principles of TQM and building quality in products using current guidelines of GLP and GMP, factors controlling four M's for quality variation in various pharmaceutical products and documentation according to revised Schedule M.
2. Deal with regulatory aspects of pharmaceuticals and bulk drug manufacturing and include applications for INDA, ANDA and Clinical Trials approval, risks associated with different occupational hazards in pharmaceutical industries and safety procedures and waste disposal techniques to be followed in pharmaceutical industries.

Pre-assessment: Determination of entry level knowledge of student based on Good laboratory practices, Good manufacturing practices, Sch.M & WHO guidelines.

Module 1	**I. To understand basic principles of total quality management and its importance in pharmacy.**	**1 credit**
Objectives	• To understand basic principles of TQM and to built quality in products. • To study current guidelines of GLP and GMP. • To enable learners to understand factors controlling four M's for quality variation in various pharmaceutical products. • To develop an understanding of documentation required as per revised Schedule M. • 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, Philosophy of GMP's ISO. Four M's responsible for Quality variation in pharmaceutical products. • Concepts of GLP's and GCP, Quality control laboratory responsibilities, Good Laboratory Practices, routine controls on instruments and reagents. Standard test procedures, non-clinical testing, controls on animal house, Data generation and storage. • Documentation and its importance, Manufacturing documents, Standard Operating Procedures, Finished product release documentation.	(5) (5) (3)
Assigned writing &Tutorials	• The assignments will be given to the students based on the above topics. • Topics pertaining to the total 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. Willig, J.R. Stoker, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y. ,1997 2. A. A. Signore and T. Jacobs, "Good Design Practices for GMP Pharmaceutical Facilities" Taylor & Francis Group, 2005 3. Anne Marie Dixon, "Environmental Monitoring & Clean Rooms & Controlled Environments", Vol. 164, 2006.	

Module 2	**II. To understand quality audit and quality review procedure.**	**1 credit**
Objectives	• To develop an understanding of quality review and quality audit in pharmaceutical industries. • To introduce sampling plans and develop statistical methods of data generated. • To study in detail validation of various systems 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

	• Quality Audits: Auditing of manufacturing processes and facilities, Quality Review, Compliance reports and handling of Non –compliance. • ICH guidelines: Q1-Q10, Guidelines with special reference to quality by design and risk management. • Sampling plans and methods. Statistical analysis of data generated. • Validation of manufacturing processes, Equipment, Environment and Water supply systems and analytical methods.	(4) (4) (2) (2)
Assigned Writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the understanding of quality audit and quality review procedure 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 Dekker1999. 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. Internal Quality Audits, Issue 2, Oxford house, 1996	

Module 3	**III. Regulatory aspects of pharmaceuticals, US-FDA and WHO approval, INDA and ANDA applications. Patent search, infringement and its applications.**	**1 credit**
Objectives	• To deal with regulatory aspects of pharmaceuticals and bulk drug manufacturing and include applications for INDA, ANDA and clinical trial approval • To study in detail patent search, patent infringement and applications for Indian and International patents. • The learners will be assigned reading from books and related published articles from journals followed by interactive discussion / submission of report • To make learners understand risks associated with different occupational hazards in pharmaceutical industries.	

	• To familiarize learners with the safety procedures and waste disposal techniques to be followed. • 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 pharmaceuticals and bulk drug manufacture, US-FDA and WHO Approval, Overview of INDA, NDA, ANDA. Generics, Super generics & Biosimilars. Clinical trial approval, dossier preparation in CTD format. • Intellectual Property Rights, Patent search and awareness, Patent filling procedures and applications, Patent infringement. • To learn safety procedures of pharmaceutical industries**.** • Occupational health hazards, fire hazards, safety procedures, • Safety exercises and waste disposal and security in plant.	(6) 6)
Assigned Writing & Tutorials	• The assignments will be given to the students based on the above topics, • Topics pertaining to the application of regulatory aspects and patents 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., 15th Edition, 2003. 2. Indian Patents Act 2005 available at http://www.ipindia.nic.in/ipr/patent/patents.htm 1. SIGAR. Pharmacovigilance Education and Certification—Report on a Feasibility Survey. Pharmacopeia & Drug Safety. 1995. 2. Talbot JCC. Drug safety—a shared responsibility, Edinburgh: Churchill Livingstone;. Spontaneous reporting,1991 3. Report of CIOMS (Council for International Organizations of Medical Sciences) Working Group III, Guidelines for Preparing Core Clinical-Safety Information on Drugs, Geneva. 1995.	
Module 4	**Project Seminar**	**1 credit**

Objectives	• The seminar will be given to the student based on above topics in Total Quality Management & they will present the same	15

Semester II

M.Pharm–2101: Advanced Pharmaceutics II

SEMESTER		**SUBJECT**			
II		Advanced Pharmaceutics II- Theory			
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: To make the learner understand the developments in design, development and evaluation of advanced drug delivery systems. **Learning Outcome:** The learner will be able to: 1. Understand the developments in design and development of novel and advanced drug delivery systems using specialized excipients and approaches 2. Identify and understand the evaluation of novel and advanced drug delivery systems		
Pre assessment: Determination of entry level knowledge of student about recent advances in new drug delivery systems & pharmaceutical market trend based on quizzes, question & answers		
Module 1	**I. To study concepts of rate controlled and site specific drug delivery systems**	**1 credit**
Objectives	• To study site specific drug delivery systems to increase therapeutic efficacy of drug with minimum side-effects. • To enable the learners to understand physiology of eye and develop advancements in ocular controlled drug delivery systems. • To enable the learners to understand in detail 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 system. • **Site Specific and Target Oriented Drug Delivery Systems:** Introduction, rationale, biological processes in drug targeting, chemical targeting, prodrugs approach; targeted and site-specific drug delivery systems, e.g., tumor targeting, drug-carrier delivery systems. • **Ocular delivery of drug:** Introduction, physiology of the eye, ocular controlled drug delivery systems. • **Transdermal drug delivery systems (TDDS):** Introduction, anatomy of the skin, biochemistry of the skin, mechanisms and types of rate controlled transdermal drug delivery systems, recent developments e.g. transferosomes, evaluation of TDDS, e.g.. In-vitro skin permeation, in vivo transdermal bioavailability, optimization of the drug delivery systems.	(3) (3) (3) (3) (1)
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 followed by presentation and discussion.	(3)
Assigned reading/ References	1. S.D. Bruck, *"*Controlled Drug Delivery*"*, Vol.1 (Basic Concepts) CRC Press, 1983. 2. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y. 1992 3. Micheal Roberts, "Dermal Absorption & Toxicity Assessment", 2nd Edition, Vol 177, 2007 4. Micheal Rathbone, "Modified Drug Release Drug Delivery Technology", 2nd Edition, Vol 1, 2008. 5. Hauss D."Oral Lipid Based Formulation Enhancing The Bioavailability Of Poorly Water Soluble Drugs", Vol. 170, 2007.	

Module 2	**II. To study buccal, nasal, pulmonary drug delivery Systems**	**1credit**
Objectives	• To enable the learners to understand anatomy and physiology of buccal	

	and nasal mucosa and lungs. • To enable the learners to understand recent developments in buccal, nasal and pulmonary drug delivery systems and its applications. • 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
	• **Buccal Drug Delivery Systems:** Introduction, anatomy, physiology of Buccal mucosa, drug delivery systems for buccal applications. • **Nasal Drug Delivery Systems:** Introduction, physiological aspects, mechanisms and pathways, drug delivery systems. • **Pulmonary Drug Delivery Systems:** Introduction, anatomy of the lungs, physiology of airways, Factors affecting Pulmonary deposition and pulmonary clearance, design considerations; medical devices for the delivery of therapeutic aerosols to the lungs, metered dose inhalers, dry powder inhalers, Nebuilizers; therapeutic applications of aerosols.	(4) (4) (4)
Assigned writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the current advances in buccal, nasal & pulmonary delivery systems will be assigned to the students followed by presentation and discussion.	(3)
Assigned reading/ References	1. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y. 2. Rolland A., "Pharmaceutical Particulate Carriers", New York: Marcel Dekker, Inc.1993 3. Cohen, S. and Bernstein, H., "Microparticulate systems for the delivery of proteins and vaccines". Marcel Dekker, New York Inc., 2000	

Module 3	**III. To study rectal and vaginal drug delivery system.**	**1 credit**

Objectives	• To teach basic principles regarding the physiology of rectum, vagina and uterus. • To study in detail rectal and vaginal controlled buccal, nasal, pulmonary 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
	• **Rectal drug delivery systems:** Historical aspects, benefits and advantages, limitations, physiological aspects; controlled drug delivery to rectum. • **Intravaginal drug delivery systems:** Anatomy and Physiology, Factors affecting absorption and localization, vaginal delivery systems: Vaginal sponges, vaginal rings and hydrogels. • **Intrauterine devices (IUDs):** Introduction, anatomy of uterus, development of medicated IUDs, Copper IUD, and hormone releasing IUD, comparative efficacy of medicated and non medicated IUDs; prospects for intrauterine contraception, long acting contraceptive formulations.	(4) (4) (4)
Assigned writing & Tutorial	• The assignments will be given to the students based on above targeted drug delivery systems, their applications. • Topics pertaining to the current advances in rectal & vaginal delivery systems will be assigned to the students & they will present the same.	(3)
Assigned reading/ References	1. J. Kreuter, "Colloidal Drug Delivery Systems", Marcel Dekker, Inc., New York, 1994. 2. Langer, ed., "Biodegradable polymers as drug delivery systems", Marcel Dekker Inc. New York, 1996.	
Module 4	**IV. To study peptide based drug delivery system & Project & Seminar**	**1 credit**
Objectives	• To enable the learners to understand the structural complexity and challenges to peptides and protein delivery of drugs and develop recent developments in peptide based drug delivery systems.	

	• 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
	• **Delivery of peptide based pharmaceuticals:** Introduction, structural complexity and challenges to peptides and protein delivery of drugs, peptide-based drug delivery systems. • Gene delivery, Vaccine delivery and Antibody conjugated drug delivery systems. • Project & Seminar	(2) (2)
Assigned writing &Tutorial	Topics pertaining to the current advances of peptide based drug delivery system will be assigned to the students followed by presentation and interactive session. The assignments will be given to the students based on the above topics.	(3)
Assigned reading/ References	1. Robinson J.R and Lee V.L, "Controlled Drug delivery fundamentals and applications", 2nd edition, Marcel Dekker, Inc., New York, 1987. 2. Rudnic, E. M., & Schwartz, J. D. "Remington: The Science and Practice of Pharmacy", 20th ed., Vol. 1,Philadelphia: Lippincott Williams & Wilkins.2000. 3. MChaubal, "Excipients development for Pharmaceutical Biotechnology, and Drug Delivery System", Informa Healthcare, 2006. 4. Macnally E.,"Protein Formulation & Delivery", 2nd Edition, Vol. 175, 2008. 5. Rey,"Freeze Drying Lyophilization Of Pharmaceutical & Biological Products", 3rd Edition, 2010	

M.Pharm–2201: Advanced Pharmaceutics II (Practicals)

SEMESTER		**SUBJECT**			
II		Advanced Pharmaceutics II- Theory			
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 30 instructional hrs/module.

Objective: To enable the learners to understand the practical aspects in formulation development of Pharmaceutical dosage forms & new drug delivery carriers. The subject encompasses the development of formulation, selection of various excipients & evaluation of novel carrier system. Using these techniques learner will be able to develop and evaluate various advanced pharmaceutical dosage forms.

Learning Outcomes: The learner will be able to:

1. Understand the practical aspects in formulation development of pharmaceutical dosage forms and novel drug delivery carriers.
2. Encompass the development of formulations, selection of various excipients and evaluation of novel carrier systems

Pre assessment: Determination of entry level knowledge of student about formulation aspect , drug delivery systems, packaging requirement based on quizzes, question & answers

Module 1	**Design, Development and Evaluation of oral, nasal, buccal, vaginal & rectal Drug Delivery Products**	**1 credit**
Objectives	• To give an insight in selection of excipients in development of various pharmaceutical dosage forms. • To give the learner hands on training in design and development of the oral & buccal, nasal, vaginal and rectal drug delivery systems. • To study various evaluation techniques for oral, nasal, buccal and rectal 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, Preparation and evaluation of following drug delivery system: • Osmotically controlled release tablets containing osmogens ($NaCl/NaHCO_3$) and determination of dissolution kinetics • Orodispersible tablets • Nasal gels, Microemulsions for Nasal delivery • Buccal drug delivery systems • Preparation and evaluation of rectal drug delivery systems • Preparation and evaluation of vaginal drug delivery systems	(4) (4) (6) (4) (6) (4)
Assigned writing & Tutorial	• The documentation of experimental work will be done by the students and the compiled work will be submitted by student in form of journal • Experimental work pertaining to the current advances in rate & controlled release delivery systems will be assigned to the students & they will perform the same and the product and documentation records will be evaluated.	(2)
Assigned Reading/ References	1. Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms" New York Marcel Dekker Volume 110, 2001, CRC. 2. Lachman, L., Lieberman, H. A., & Kanig, J. L., The Theory and Practice of Industrial Pharmacy (3rd ed.). Mumbai: Varghese Publishing House, 1991 3. Ray and Weller, Handbook of Pharmaceutical Excipients, Pharmaceutical Press, 2009. 4. Nicholas P. Chezerisionoff, Product design and testing polymeric materials. 5. Micheal Roberts, "Dermal Absorption & Toxicity Assessment", 2nd Edition, Vol 177, 2007. 6. Langer, ed., Biodegradable polymers as drug delivery systems, Marcel Dekker Inc. New York,2000 7. *Bruck* S.D. , "*Controlled Drug Delivery*(Basic Concepts)", Vol.1, Marcel Dekker Inc., New York, CRC Press, 2005	
Module 2	**Study of recent advances in Parentral dosage forms and**	**1credit**

	pulmonary drug delivery systems	
Objectives	• To enable learner to understand practical aspects of advances in Parenteral drug delivery systems. • To give the learner hands on training on newer technologies used for parenteral delivery. • To enable learner to understand the of pulmonary drug delivery systems • The enable learners to understand documentation and maintenance of record all the experiments in the prescribed format in the journal.	
Contents	**Experiments**	Hrs
	Development, Preparation and evaluation of following drug delivery system: • Dry powder Inhaler Formulations • Gelatin Microspheres for Pulmonary Delivery • Polymeric nanoparticles for Parenteral Delivery • Preparation of Nanocarriers by Various high shearing devices & study of their limitations • Demonstration of High Pressure Homogenizer • Demonstration of lyophilizer	(6) (6) (6) (6) (2) (2)
Assigned writing & Tutorial	• The documentation of experimental work will be done by the students and the compiled work will be submitted by student in form of journal • Experimental work pertaining to the Nanoparticles, biphasic drug delivery systems will be assigned to the students & they will perform the same and the product and documentation records will be evaluated.	(2)

Assigned Reading/ **References**	1. Rodriguez, F. "Principles of Polymer Systems", 2nd edition, Mcgraw-Hill, New York, NY,1983 2. Lisbeth, Illum & Stanley S. Davis: "Polymers in Controlled Drug Delivery", Wright, Bristol, 1987. 3. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y. 4. *Cohen, S. and Bernstein, H.*, "*Microparticulate systems* for the delivery of proteins and vaccines". *Marcel Dekker*, New York Inc., 2000. 5. S.D. *Bruck*, "*Controlled Drug Delivery"*, Vol.1 (Basic Concepts) CRC Press, 2005. 6. *Kreuter* J., "*Colloidal Drug Delivery Systems", Marcel Dekker, Inc*., New York, 1994. 7. Rey," Freeze Drying Lyophilization Of Pharmaceutical & Biological Products", 3rd Edition, 2010 8. Kevin L. Williams "Drugs And Pharmaceutical Sciences Endotoxins: Pyrogens, Lal Testing And Depyrogenation", Vol 167, Third Edition, 2007.	
Module 3	**Study of Ophthalmic and trandermal Drug Delivery Systems**	**1 credit**
Objectives	• To introduce the learners to ophthalmic systems. • To enable learners to understand the practical aspects of recent advances in trandermal and topical drug delivery systems. • The enable learners to understand documentation and maintenance of records all the experiments in the prescribed format in the journal.	
Contents	**Experiments**	Hrs
	To design, develop and evaluate the following drug delivery systems: • Ophthalmic drug delivery systems • Transdermal drug delivery systems and study of their Diffusion kinetics • Solid Lipid Nanoparticles for Topical Delivery • Nanoemulsions for Topical delivery.	(8) (8) (6) (6)

Assigned writing & Tutorial	• The documentation of experimental work will be done by the students and the compiled work will be submitted by student in form of journal • Experimental work pertaining to the demonstration of sophisticated equipments, optimization of proces parameters, scale up issues, batch reproducibility will be assigned to the students & they will perform the same the experiment and documentation records will be evaluated.	(2)
Assigned Reading/ References	1. Yie W. Chien, "Novel Drug Delivery Systems", Drugs and Pharm. Sci. Series, Vol. 14, Marcel Dekker Inc., N.Y. 2. K. *Park, Controlled drug delivery: Challenges and strategies*. , ACS, Washington, DC (1997). 3. Robinson J.R and Lee V.L, "Controlled Drug delivery fundamentals and applications", 2nd edition, Marcel Dekker, Inc. , *New York* , 1987. 4. Ray and Weller, Handbook of Pharmaceutical Excipients, Pharmaceutical Press 5. Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms" New York Marcel Dekker Volume 110, 2001, CRC.	
Module 4	Evaluation Techniques for New Drug Delivery Systems	1 Credit
Objectives	1. To understand various evaluation parameters for Carriers 2. Comparison of In-vitro & in-vivo data 3. To understand the concepts of Stability studies	
Contents	**Experiments**	**Hrs**
	• Demonstration of Particle size analyser and determination of Zeta Potential • Demonstration of pelletization and coating of pellets. • Demonstration of spray dryer. • Correlation of In-vitro & in-vivo data for various formulations • Concept of Stability studies according to ICH guidelines on any one developed formulation. • Accelerated stability studies	4 4 4 4 6 6

Assigned writing	The documentation of experimental work will be done by the students and the compiled work will be submitted by student in form of journal	(2)
Assigned Reading/ References	1. Jantzen G. M., Robinson J. R., "Sustained and Controlled-release drug delivery systems in modern pharmaceutics", Banker G., Rhodes, C. edt., Marcel Dekker Inc. New York, 3rd ed, (34) 196-211, 1996. 2. Venkatraman S., Davar N., Chester A., Kleiner L., "An overview of controlled-release systems in handbook of pharmaceutical controlled release technology", Wise, D. L. edt, Marcel Dekker Inc.,4th ed, 233 (35), 2000. 3. Chiao C. L., Robinson J.R., "Sustained release drug delivery systems", 2nd ed, 36, 244-258, 1995.	

M.Pharm–2102: Industrial Pharmacy

SEMESTER		**SUBJECT**			
I		Industrial Pharmacy			
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 train students in various process operations carried out during development of various pharmaceutical dosage forms.

Learning Outcomes: The learner will be able to:

1. Understand various unit operations and processes carried out during development of various pharmaceutical dosage forms.
2. Gain knowledge of the newer techniques and pharmaceutical process parameters and operations

Pre assessment: Determination of entry level knowledge of student about various unit operations, processing parameters, new techniques such as pelletization based on quizzes, question & answers.

Module 1	**I. Unit Operations**	**1 credit**
Objectives	• To introduce factors affecting size reduction and study in details various types of mills used in industry and laws governing and power requirement of a mill. • To enable learner to understand the basic principles of theory of mixing, filtration, drying mechanism and rate of drying. • To introduce learner to different industrial equipments such as mixers, filters and various types of dryers currently used in industry.	
Contents	**Topics Covered**	Hrs

	• **Size reduction**: Definition, objectives of size reduction, factors affecting size reduction, laws governing energy and power requirements of a mill, various types of mills including equipments for nanosizing, colloid mill, high pressure homogenization, microfluidizers, and ultrasonicators. • **Mixing:** Theory of mixing and types of mixers including high speed mixers, ultrasonic mixers, industrial mixers-Nauta mixer and RMG, Diosna. • **Filtration and centrifugation:** Theory of filtration, filter media, industrial filters including filter press, rotary filer, edge filter, cartridge filters, and membrane filters, ultra filtration, reverse osmosis; factors affecting filtration, optimum-cleaning cycle in batch filters, Principles of centrifugation, industrial centrifugal filters and centrifugal sedimenters, ultracentrifugation. • **Drying:** Introduction, mode of heat transfer, internal mechanism of moisture flow, psychrometry, drying mechanisms, drying methods for pharmaceutical granulation and equipments. Moisture content and mechanism of drying, rate of drying and time of drying, calculations, classification and types of dryers, dryers used in pharmaceutical industries and special drying methods, e.g., tray dryers, fluidized bed dryers, spray dryer, tunnel, microwave, granulators-cum-driers IR dryers.Freeze dryer and Lyophilization.	(3) (3) (3) (3)
Assigned writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to unit operations carried out in pharmaceutical industries will be assigned to the students followed by presentation and discussion.	(3)
Assigned Reading/ References	1. Rubinstein, M. H,. Tablets. In M. E. Aulton (Ed.), Pharmaceutics: the science of dosage form design (pp. 304-321). London: ELBS Longman Group Ltd., 1988. 2. Rudnic, E. M., & Schwartz, J. D. ,Remington: The Science and Practice of Pharmacy, A. R. Gennaro, Ed., Philadelphia: Lippincott Williams & Wilkins. 2006. 3. Robert, W. M., & Aloysius, O. A, Pharmaceutical Dosage Forms—Tablets Vol. 1(H. A. Lieberman, L. Lachman, & J. B. Schwartz, Eds.), Informa Health Care, 2008 4. Swarbrick J., "Encyclopedia of Pharmaceutical technology", 2nd edition, Volumes: 1 to 19, Marcel Dekker, 2004. 5. L.V. Allen, Jr., N.G. Popovich, H.C. Ansel, W. Kluer, "Pharmaceutical Dosage Forms and Drug Delivery Systems". Lippincott Williams & Wilkins, 2005.	

Module 2	**II. Advanced tableting, pelletization and capsulation technology**	**1 credit**
Objectives	• To enable the learner to understand the improved tablet production systems, improvements in unit operations and role of computers in process control and tablet tooling. • To introduce the learners to pelletization technology and equipments used in pelletization and train students in recent advances in capsule technology. • 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
	• **Principles of improved tablets production system design:** Introduction, benefits of improved tablet production system, material, processing step combination or elimination, unit operation improvements, Role of computer process control and tablet tooling. • **Pelletization technology:** Introduction, pelletization process and formulation, equipments for pelletization spheronizers. • **Capsulation Technology:** Advances in capsulation technology: Hard and gelatin capsules, manufacture and machines.	(5) (3) (4)
Assigned writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to advances in tableting, pelletization & capsulation technology carried out in pharmaceutical industries will be assigned to the students and presentation & discussion will be made on the same.	(3)
Assigned Reading/ References	1. Carstensen, Thuro J., "Pharmaceutical principles of solid dosage forms" New York Marcel Dekker Volume 110, 2001, CRC 2. Lachman, L., Lieberman, H. A., & Kanig, J. L. The Theory and Practice of Industrial Pharmacy (3rd ed.). Mumbai: Varghese Publishing House,1991. 3. Rubinstein, M. H. ,Tablets. In M. E. Aulton (Ed.), Pharmaceutics: the science of dosage form design, London: ELBS Longman Group Ltd.,	

	1988. 4. Rudnic, E. M., & Schwartz, J. D. (2000). Remington: The Science and Practice of Pharmacy (20th ed., Vol. 1). (A. R. Gennaro, Ed.) Philadelphia: Lippincott Williams & Wilkins. 5. Lisbeth, Illum & Stanley S. Davis," Polymers in Controlled Drug Delivery", Wright, Bristol, 1987.	

Module 3	**III. Pilot plant scale up studies & Automated Process control systems**	**1 credit**
Objectives	• To introduce concept of pilot plant for development and control of various dosage forms for transition from laboratory to routine processing in full scale production facility. • To introduce the learners to concepts in batch scale and process modification and develop pilot plant study design for various dosage forms. • To enable learners to understand the automated process control systems and its parameters. • To introduce the learners to computer-aided manufacturing and robotics and preventive maintenance of plant and machinery efficiency.	
Contents	**Topics covered**	Hrs
	• Pilot plant scale up techniques : Introduction, concepts of pilot plant for development and control: Planning, size, organization and personnel; basic considerations in developing the process for production of dosage forms, GMP considerations, transfer of analytical methods to Quality Assurance, product consideration; pilot study design for solid dosage forms, liquid orals and semi-solids. • Automated Process control systems: Process variables, temperature, pressure, flow rates and vacuum levels and their measurements. Elements of automatic process control, Introduction to Computer Aided Manufacturing (CAM), robotics. • Engineering: Preventive maintenance assessing plant and machinery efficiency and life, material handling, transfer, transport and conveyance of bulk materials.	(5) (3) (2)

	• Production management, Planning and work flow sheet	(2)
Assigned writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining applications of Pilot plant scale up studies & Automated Process control systems in pharmaceutical industries will be assigned to the students & they will present the same.	(3)
Assigned Reading/ References	1. Ira R. Berry, Robert A. Nash, "Pharmaceutical process validation", Marcel Dekker, New York.1993. 2. Encyclopedia of Pharmaceutical technology, Volumes: 1 to 19,2000. 3. Rudnic, E. M., & Schwartz, J. DRemington: The Science and Practice of Pharmacy (A. R. Gennaro, Ed.) Philadelphia: Lippincott Williams & Wilkins, 2006.	

Module 4	**IV. Parentral Dosage form processing , Project and seminar**	**1 credit**
Objectives	• To develop an understanding of environmental controls and design considerations for Parentral production and study recent advances in manufacturing of small and large volume Parentral. • The learners will have to give one seminar in each semester, on topic suggested by his/her supervisor.	(15)
Contents	**Topics Covered**	Hrs
	• **Parentral technology:** Environmental controls and design considerations for Parentral production facility, processing and manufacturing of small and large volume Parentral, Barrier isolator technology. • **Project & Seminar**	(5) (10)

Assigned writing **&** **Tutorial**	• The assignments will be given to the students based on the above topics. • Topics pertaining to recent advancements in parentral dosage forms will be assigned to the students & they will present the same.	(6)
Assigned Reading/ References	1. Avis K.E, "Pharmaceutical Dosage Forms: Parental Medication", Vol. I Marcel Dekker Inc., N.Y.2000 2. Xiaoling L., Jasti B.R., "Design of Controlled Release Drug Delivery Systems", 3rd edition, McGraw-Hill.,2005. 3. M.J. Rathbone, J. Hadgraft, M.S. Roberts, "Modified-Release Drug Delivery Technology" Marcel Dekker Inc., N.Y,1998	

M.Pharm–2103: Modern Analytical Techniques II

SEMESTER		**SUBJECT**			
I		Modern Analytical Techniques II Theory			
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: The subject of Analytical techniques II consists of the basic principles and advances of various techniques of chromatographic separation of mixtures of organic compounds. Using these techniques the learner can elucidate the structure of separated constituents.

Learning Outcomes: The learner will be able to:

1. Understand the basic principles and advances of various techniques of chromatographic separation of mixtures of organic compounds
2. Elucidate the structure of separated constituents after chromatography

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. J. Holler, S. R. Crouch Douglas A. Skoog, Principles of Instrumental Analysis, Brooks/Cole Pub Co; 6th edition, 2006 6. David Watson Pharmaceutical analysis: a textbook for pharmacy students & pharmaceutical chemists Elsevier/Churchill Livingstone, 2005	
Module 2	**Principles and techniques of column chromatography**	**1 credit**

Objectives	• To enable the learners to understand the basic principles of various techniques of column chromatography • To enable the learners to understand the basic principles, techniques and instrumentation of High performance liquid chromatography (HPLC) • To enable the learners to understand the basic principles, techniques and instrumentation of Gas chromatography (GC) • To enable the learners to understand the basic principles, techniques and instrumentation of Size exclusion chromatography • To enable the learners to understand the basic principles, techniques and instrumentation of Ion pair chromatography • 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 charge. • The students will be asked to collect data on various stationery phases and mobile phases used for column chromatographic techniques.	(2)
Tutorial	• Topics pertaining to various techniques of column chromatography will 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 practice Blackie Academic & Professional Publisher, 1995 5. HPLC: High Performance Liquid Chromatography: Volume 2, P.D. Sethi and Rajat Sethi, CBS Publisher, 2008 6. P.D.Sethi , Rajat Sethi, HPLC: Quantitative Analysis of Pharmaceutical Formulations, CBS Publishers, 2007. 5. F. James Holler, Stanley R. Crouch Douglas A. Skoog. Principles of Instrumental Analysis, , Publisher: Brooks/Cole Pub Co; 6th edition, 2006 6. Gas Chromatography: Analytical Chemistry by open learning series, 2 Edition Wiley Publishers 1995. 7. Frank A. Settle , Brian D. Lamp , David L. McCurdy, Mark F, Vitha , Brian W. Gregory, Yinfa Ma Instrumental Methods of Analysis Wiley-Interscience; 8th edition, 2011.	

Module 3	**Structure elucidation of organic compounds- Theory and 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 3rd edition , W.H. Freeman & Company; 1991 3. Analytical Chemistry by open learning series, 2nd 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**
	• 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–2203: Modern Analytical Techniques II (Practicals)

SEMESTER		SUBJECT			
I		Modern Analytical Techniques II			
WEEKLY ASSIGNMENT		**CREDITS**		**MARKS.**	
TH	**PR**	**TH**	**PR**	**TH**	**PR**
-	8	-	4	-	100

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

Learning Outcomes: The learner will be able to:

1. Develop various analytical methods for quantitative estimation of drugs from formulations
2. Identify impurities in synthetic samples and/or plant extracts and implement pharmacopoeial requirements

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-Verlag Berlin–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.	(6)

	• 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) (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-Verlag Berlin–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, Harcourt Brace College 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, Harcourt Brace College 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 2. Identification of different functional groups by PNMR. 3. Identification of different types of carbons and carbon containing groups by 13 CNMR 4. Identification of Molecular ion peak, base peak in a mass spectrum of small molecular weight organic compounds. 5. Structure elucidation of some small molecular weight organic molecules by UV, IR, NMR and MS spectral data.	(6) (6) (4) (6) (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–2104– Packaging Development

SEMESTER		**SUBJECT**			
I		Packaging Development			
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 study the protective function of commonly used packaging materials, their limitations and possible interactions with various drugs.

Learning Outcome: The learner will be able to:

1. Understand the importance of packaging in pharmaceutical product development
2. Gain knowledge of protective function of commonly used packaging materials, their limitations and possible interactions with various drugs and help in choosing appropriate pharmaceutical packaging

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	• To enable the learner to understand various types of glass used in packaging and manufacturing of glass containers. • To understand classification of plastics, additives used in fabrication process • To study different types of metal containers used in pharmaceutical packaging • Evaluation of glass, plastic and metal containers as per the pharmacopeial guidelines. • To introduce the learner to container specifications for sterile dosage forms. • To introduce the learner to various types of flexible packaging • 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.	(3)
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, Project & 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 • Project & Seminar Based on New Packaging Aspect In Pharma Industry	(5) (10)

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	

Semester III

M.Pharm–3101: Computer & Statistics I

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

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

Learning Outcome: The learner will be able to:

1. Use of computer systems to access and retrieve information and develop an understanding of various application softwares with respect to pharmaceutical sciences for drug discovery, drug design, formulation development, production and Quality Assurance, QSAR for drug modelling and simulation of data
2. Understand concept of statistics as applied to pharmaceutical data, to analyze and interpret the data and factorial designs

Pre-assessment: Determination of entry level knowledge of student 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.	(3)
	• Modeling and simulation of data with application in pharmacokinetics	(3)

Assigned writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the basics of computers will be assigned to the students & they will present the same.	(3)
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**	Hrs
	• 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 softwares. • 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 computer applications in pharmacy will be assigned to the students & they will present the same.	(3)
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 and applications of statistics in pharmacy will be assigned to the students & discussed.		(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, 2008.		

Module 4	IV. Application of Statistics	1 credit	
Objectives	• To develop understanding of analysis of variance by studying randomized & factorial designs and teach various non-parametric tests. • To present statistical application in design of pharmaceutical & biomedical experiments		
Content	**Topics Covered**		
	• 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		(4)

	Runs test, Spearman's rank correlation. • Role of statistics in design of pharmaceutical and biomedical experiments specially controlled clinical trials.	(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 in pharmacy will be assigned to the students & they will present the same	(3)
Assigned Reading/ References	1. Martin, Bland., "An Introduction to Medical Statistics", 3rd edition, ELBS, Oxford University Press, 2009 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-MPH-2: Computer & Statistics I (Practicals)

The course is divided into 3 non creditable modules each with 10 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)	(4) (4)

	• 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.	(8)
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 software such as - QSAR, CADD, Pharmacokinetics, Factorial design with respect to pharmaceutical sciences.	
Contents	**Experiments**	(20)
	• Introduction to Internet, Use of Internet and www	(6)
	• Applications of Software-QSAR, CADD, Pharmacokinetics, Factorial design.	(4)
	• Using search engines like Google, Yahoo etc, Using advanced search techniques. Literature search using various search engines like google, pubmed, science direct, freepatentsonline.	(6)
Assigned Writing/ Practical Activities	• Experiments involving applications of software-QSAR, CADD, pharmacokinetics, factorial design for data interpretation would be assigned to the learners and they would perform and enter the same in their work books.	(4)

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 an understanding of features and functions & application of 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) (8)
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.	(4)
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–3102 Biopharmaceutics & Pharmacokinetics

SEMESTER		**SUBJECT**			
I		Biopharmaceutics & Pharmacokinetics			
WEEKLY ASSIGNMENT		**CREDITS**		**MARKS.**	
TH	**PR**	**TH**	**PR**	**TH**	**PR**
4	-	4	0	100	0

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

Objectives: The primary goal of biopharmaceutics and pharmacokinetics are to quantify drug absorption, distribution, biotransformation and excretion in intact living animal or man to use this information to predict the effect of alternation in dosage regime, routes of administration and physiological state on the accumulation and disposition.

Learning Outcomes: The learner will be able to:

1. quantify drug absorption, distribution, biotransformation and excretion and determine the pharmacokinetic parameters
2. calculate dosage regimens, identify drug, physiological and formulation factors that affect pharmacokinetics and dosage regimens

Pre assessment: Determination of entry level knowledge of student about dose calculation studies, Pharmacological factors & formulation factors affecting dose regimen studies based on quizzes, question & answers

Module 1	**I. To study basic concepts of bioavailability and multiple dose regime.**	**1 credit**
Objectives	• To introduce the learner to basic concepts of bioavailability and strategies to enhance bioavailability. • To introduce concepts of therapeutic drug monitoring and study in detail various parameters in multiple dose regimes. • 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
	• **Bioavailability and Bioequivalence:** Biopharmaceutical classification of drugs, absorption of permeability and solubility limited drugs, Biowavers for	(4)

	bioequivalence studies, strategies to enhance bioavailability. • **Therapeutic response and Toxicity:** Concentration and response, Therapeutic concentration range, therapeutic index, therapeutic window, factors affecting plasma concentration and toxicity. • **Multiple Dose Regimen:** Drug level-time relationship, steady state, plateau value, mean residence time, time to reach plateau, bolus and infusion, practical issues, drug accumulation, average amount and concentration at plateau, accumulation index, maintenance dose, loading dose, maintenance of dose in therapeutic range.	(4) (4)
Assigned writing &Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the concepts of bioavailability and multiple dose regime will be assigned to the students & they will present the same	(3)
Assigned Reading/ References	1. Malcolm Rowland, Thomas N. Tozer., Clinical Pharmacokinetics: Concept and Application; 3rd Edn. B. I. Lea & Febiger, 1989. 2. Leon Shargel, Susanna Wu-Pong, Andrew B. C. Yu. Applied Biopharmaceutics and pharmacokinetics, 3rd edition, McGraw-Hill, Medical Pub. Division, 2005 3. Milo Gibaldi and Donald Perrier, "Pharmacokinetics", Marcel Dekker, 1982	

Module 2	**II. To study concepts of pharmacokinetics**	**1.Credit**
Objectives	• To enable learner to understand various physiologic and pharmaceutical factors affecting bioavailability. • To quantify drug absorption, distribution, biotransformation processes. • To study pharmacokinetics. • To resolve the observed kinetic profile into their component parts and analysis and interpretation of data generated. • 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
	• **Biopharmaceutics and kinetics of drug absorption:** Zero-order	(4)

	Absorption Model, First-Order, Absorption Model, Significance of Absorption Rate constants. • **Drug distribution and protein binding:** Physiologic Factors, Calculation of Apparent Volume of Distribution, Protein Binding of Drugs, Kinetics of Protein Binding, Determination of Binding Constants and Binding Sites, Graphic Methods, Clinical Significance of Drug-Protein Binding. • **Drug elimination and clearance concepts:** Drug elimination, Drug clearance, physiologic approach to clearance, Renal clearance, Renal drug excretion, Drug clearance, Determination of renal clearance, Relationship of Clearance Elimination Half-Life and Volume of Distribution, Hepatic Elimination of Drugs, Fraction of drug excreted unchanged (fe) and Fraction of drug metabolized, (1-fe), Clinical focus, Pharmacokinetics of drugs and metabolites, enzymes involved in the biotransformation of drugs, Drugs biotransformation reactions, Route of drug administration and extra hepatic Drug metabolism, First-Pass effects, Hepatic clearance, Significance of drug metabolism.	(4) (4)
Assigned writing & Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the concepts in pharmacokinetics will be assigned to the students followed by presentation and disscussion.	(3)
Assigned Reading/ References	1. LaDu, BN, Mandel, HG & Way, EL, "Fundamentals of Drugs Metabolism and Disposition", Williams & Wilkins, Baltimore, 1972. 2. T. Z. Csáky, "Intestinal Absorption and Malabsorption. Raven Press, N.Y., 1975. 3. Shargel, "Generic Drug Product Development Specialty Dosage Form", 1st Edition, 2010	

Module 3	**III. Study of Compartmental and non-compartmental modeling**	**1 credit**
Objectives	• To enable learner to understand the concepts of one compartment open model and various factors affecting it. • To introduce the learner to two compartment and three compartment open i.v.and oral models.	

	• Application of statistical moment in non compartmental analysis. • 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
	• **Compartmental Modeling:** One compartment open model: I.V. and oral route of administration, volume of distribution, elimination half-life, first order elimination, fraction of drug remaining, renal clearance, total clearance, Calculation of elimination rate constant from urinary excretion data. Multi-compartment Modeling: Two compartment open IV and oral administration models, and three compartment model concepts. • **Non compartment Analysis:** Based on statistical moments, Bioavailability, clearance, Half-life, Absorption kinetics, Apparent volume of distribution etc, Steady state concentration.	(6) (6)
Assigned writing &Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the concepts Compartmental & Non compartmental modelling will be assigned to the students & they will present the same	
Assigned Reading/ References	1. J. T. Carstensen, "Theory of Pharm.Systems", Vols. 1-3, Academic Press, New York, 1996 2. D.J. Cutler,"Pharmaceutical Product Development: *In vitro - In vivo* Correlation". Informa Health Care, 1978. 3. Malcolm Rowland, Thomas N. Tozer., "Clinical Pharmacokinetics: Concept and Application"; 3rd Edition, B. I. Lea & Febiger, 1989 4. Shargel, "Generic Drug Product Development Specialty Dosage Form", 1st Edition, 2010.	

Module 4	**IV. Study of concepts of non-linear pharmacokinetics and pharmacokinetics in clinical studies**	**1 credit**
Objectives	• To introduce the students with non-linear pharmacokinetics. • To study applications of pharmacokinetics in various clinical studies.	

	• Therapeutic drug monitoring and interpretation of data analysis. • 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
	• **Non-linear Pharmacokinetics:** Saturable enzymatic elimination process, drug elimination by capacity limited pharmacokinetics, mixed drug elimination, time dependent pharmacokinetics, bioavailability of drugs that follow non-linear Pharmacokinetics due to protein binding (e.g. Phenytoin) • **Application of Pharmacokinetics in Clinical Situation:** Individualization of dosing regimen, Variability in clinical Response and Drug Pharmacokinetics with Special Reference to Renal and Hepatic Diseases, Genetic factors, age and weight, diseases, altering/affecting the pharmacokinetic parameters, therapeutic drug monitoring, conversion from IV dose to oral dosing, determination of dose, frequency of drug administration and route of administration, dosing of drugs in infants, elders and patients.	(6) (6)
Assigned writing &Tutorial	• The assignments will be given to the students based on the above topics. • Topics pertaining to the concepts of non-linear pharmacokinetics and pharmacokinetics in clinical studies will be assigned to the students & they will present the same.	(3)
Assigned Reading/ References	1. J. T. Carstensen, "Drug Stability: Principles and Practices", Drugs and Pharm.Sci., Series, vol. 43, Marcel Dekker Inc., N.Y.1995 2. Lisbeth lliun and Stanley S. Davis: "Polymers in Controlled Drug Delivery", Wright Bristol 1987. 3. Chilukuri D.," Pharmaceutical Product Development: In Vitro-In Vivo Correlation", Vol 165, 2007. 4. Sarfaraz K. Niazi," Handbook Of Bioequivalence Testing", Vol 171, 2007	

M.Pharm–3102: Biopharmaceutics & Pharmacokinetics (Practicals)

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

<table>
<tr><td colspan="3">Objective: The quantify drug absorption, distribution, biotransformation and excretion in intact living animal or man using various mathematic models & softwares & to use this information to predict the effect of alternation in dosage regime, routes of administration and physiological state on the accumulation and disposition.</td></tr>
<tr><td colspan="3">Pre-assessment: Determination of entry level knowledge of student about dose calculation studies, Pharmacological factors & formulation factors affecting dose regimen studies based on quizzes, question & answers</td></tr>
<tr><td>Module 1</td><td>Calculation of pharmacokinetic parameters after oral administration in one compartment open model & absorption studies – in vitro and in – vitro and in – situ.</td><td>-</td></tr>
<tr><td>Objectives</td><td>• To quantify drug absorption, distribution, biotransformation processes using mathematic model.
• To study pharmacokinetics.
• To resolve the observed kinetic profile into their component parts and analysis and interpretation of data generated.</td><td></td></tr>
<tr><td>Contents</td><td>Experiments</td><td>(20)</td></tr>
<tr><td></td><td>• To study one compartment open model after intravenous bolus administration.
• To calculate pharmacokinetic parameters using supplied data after oral administration in one compartment open model
• Absorption studies – in vitro and in – vitro and in – situ.</td><td>(4)
(4)
(6)</td></tr>
<tr><td>Assigned Writing/
Practical Activities</td><td>• Experiments involving study hydrodynamic model of one compartment open model after intravenous bolus administration would be assigned to the learners and they would perform and enter the same in their work books.</td><td>(6)</td></tr>
<tr><td>Assigned Reading/
References</td><td>1. LaDu, BN, Mandel, HG & Way, EL, “Fundamentals of Drugs Metabolism and Disposition”, Williams & Wilkins, Baltimore, 1972.
2. T. Z. Csáky, “Intestinal Absorption and Malabsorption. Raven Press, N.Y., 1975.
3. Shargel, “Generic Drug Product Development Specialty Dosage Form”, 1st Edition, 2010</td><td></td></tr>
</table>

	4. M. Rowland, T.N. Tozer, "Clinical Pharmacokinetics: Concept and Applications", 3rd Ed. B.I.Lea & Febiger, 1989. 5. M. Gibaldi and D. Perrier, "Pharmacokinetics". M. Dekker, 1982.	

Module 2	**IV. Study of Plasma Protein Binding & Data Interpretation using statistical analysis tests**	-
Objectives	• To study plasma protein binding of drug & understand various physiologic and pharmaceutical factors affecting bioavailability. • To understand data interpretation using statistical analysis tests.	
Contents	**Experiments**	(20)
	• To study plasma protein binding of drug using egg albumin • To study erythrocyte binding of drug using blood • To perform statistical analysis of given Pharmaceutical data.	(6) (4) (6)
Assigned Writing/ Practical Activities	• Illustrative examples of statistical analysis of given pharmaceutical data would be assigned to the learners and they would perform and enter the same in their work books.	(4)
Assigned Reading/ References	1. D.J. Cutler,"Pharmaceutical Product Development: In vitro-In vivo Correlation". Informa Health Care, 1978. 2. Malcolm Rowland, Thomas N. Tozer., "Clinical Pharmacokinetics: Concept and Application"; 3rd Edition, B. I. Lea & Febiger, 1989 3. Shargel, "Generic Drug Product Development Specialty Dosage Form", 1st Edition, 2010. 4. S. Niazi, "Handbook of Bioequivalence testing". Informa Health Care, 2005.	
Module 3	**V. Statistical Data Analysis by application of experimental designs & analysis of variance**	-
Objectives	• To introduce use of parametric tests for sampling theory. • To design suitable methodology using experimental designs & perform	

	analysis of variance for arriving at statistical inferences	
Contents	**Experiments**	(20)
	• To study examples based on sampling theory & parametric tests used for the same. • To perform analysis of variance for arriving at statistical inferences when samples are from same population or from different population. • To design suitable methodology using experimental designs based on replication, randomization & local control.	(6) (6) (4)
Assigned Writing/ Practical Activities	• Illustrative examples involving sampling theory & parametric tests & designing of suitable methodology using experimental designs would be assigned to the learners and they would perform and enter the same in their work books.	(4)
Assigned Reading/ References	1. M. Rowland, T.N. Tozer, "Clinical Pharmacokinetics: Concept and Applications", 3rd Ed. B.I.Lea & Febiger, 1989. 2. L. Shargel, S. Wu-Pong, B. C Andrew, "Applied Biopharmaceutics and pharmacokinetics", 3rd Ed. McGraw-Hill Medical Pub. Division, 2010. 3. M. Gibaldi and D. Perrier, "Pharmacokinetics". M. Dekker, 1982.	

3103 : 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.

Learning Outcomes: The learner will be able to:

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

Module 1	**Introduction of Research Methodology**	**1 credit**

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 A. Research Process: To determine what type of research to be done, plan of research work B. 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**
	C. **Implementation and Documentation** D. 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 e) Introduction of software used in data analysis.	**5**
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 writing, documentation, organization of reference material, bibliography, end note.	**3**
Recommended books	**1.** B.D. John, A.L. Brown and R.R. Cocking, 1999. "How People Learn: brain, mind, experience and school". Washington, DC: National Academy Press. **2.** J.R. Fraenkel, N.E. Wallen, 2008. "How to Design and Evaluate Research in Education*", 7th Ed*. Boston: McGraw-Hill. **3.** K.E. David, 2009. Curriculum Development for Medical Education: *A Six-Step Approach,* 2nd Ed. The John Hopkins University Press. ISBN 0-8018-9367-4. **4.** N. Peter, 2009. "Leadership: Theory and Practice*." 3rd*	

Ed. Thousand Oaks: Sage Publications.

5. G. Bordage, B. Dawson, 2003. Experimental study design and grant writing in eight steps and 28 questions. *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.

3104: Research Seminar

SEMESTER III		**SUBJECT Research Seminar**			
WEEKLY ASSIGNMENT		**CREDITS**		**MARKS.**	
TH	**PR**	**TH**	**PR**	**TH**	**PR**
2	**--**	**2**	**--**	**50**	--
Learning Outcomes: The learner will be able to: **1.** collect and collate scientific data on recent topics in Pharmaceutics and prepare presentations **2.** Develop aptitude, attitude, communication, presentation and soft skills					

3105: Research Project

SEMESTER III		**SUBJECT** Research Project			
WEEKLY ASSIGNMENT		**CREDITS**		**MARKS.**	
TH	**PR**	**TH**	**PR**	**TH**	**PR**
	24	-	8	200	--
Learning Outcomes: The learner will be able to: 1. apply knowledge for development and evaluation of conventional, novel and modified drug delivery systems 2. present the research and develop aptitude, attitude, communication, presentation and soft skills					

3106: Industrial Training

SEMESTER III		**SUBJECT:**Industrial Training			
ONE MONTH		**CREDITS**		**MARKS.**	
TH	**PR**	**TH**	**PR**	**TH**	**PR**
		2		**50**	
Learning Outcomes: The learner will be able to: **1.** gain knowledge during hands on training in the pharmaceutical industry for better understanding of career prospects and avenues available **2.** Understand the working of various departments of the pharmaceutical industry					

Semester IV

4101 and 4102: Research Project

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

Learning Outcoems: The learner will be able to:

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