SPECIALISATION: PHARMACEUTICS AND PHARMACEUTICAL TECHNOLOGY
SEMESTER - II
SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK		CREDITS	
		T	P	T	P
221	Fundamentals of Pharmaceutics - II	3	---	4	---
222	Pharmaceutical Product Development - I	3	---	4	---
223	Pharmaceutical Technology - I	3	---	4	---
224	Pharmaceutical Biotechnology	3	---	3	---
225	Pharmaceutics and Pharmaceutical Technology Practical - II	---	18	---	6
226	Subject Seminar	6	---	---	3
	TOTAL	18	18	15	9

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
221	Fundamentals of Pharmaceutics - II	3	80	20	--	--
222	Pharmaceutical Product Development -I	3	80	20	--	--
223	Pharmaceutical Technology -I	3	80	20	--	--
224	Pharmaceutical Biotechnology	3	80	20	--	--
225	Pharmaceutics and Pharmaceutical Technology Practical -II	12	--	--	80	20
226	Subject Seminar	--	--	--	--	100
	TOTAL		320	80	80	120

SUBJECT : Fundamentals of Pharmaceutics II
SUBJECT CODE : 221
RATIONALE : This unit discusses advanced concepts of drug development process with emphasis on drug excipients interactions which influence stability of dosage forms. Principle theories of in vitro dissolution testing of dosage forms is integral part of product development and characterization, with the background of BCS classification and SUPAC guidelines. Applied pharmacokinetics throws light on special therapeutic categories like pediatrics, geriatrics, Chrono pharmacotherapy and obesity, which is useful in F&D.

COURSE OBJECTIVES: At the end of the course the student should be able to:
1. Describe importance of drug development process, with each stage of development.
2. Know the role of excipients in biopharmaceutics of each dosage form.
3. Know about interactions of key excipients and their combinations.
4. Understand fundamentals of in vitro dissolution testing and instrumentation.
5. Apply principles of pharmacokinetics in dosage form design.

LEARNING OUTCOMES: At the end of the course the student will be able to:
1. Identify safe excipients for products.
2. Develop new dissolution methods for drug products.
3. Develop and select correct dissolution medium for relevant dosage forms.
4. Co relate BCS with predictions and interpretation of dissolution results.
5. Manage dissolution data and apply mathematical treatment.
6. Understand pharmacokinetics of special group of patients.

PREREQUISITES: **Fundamentals of Pharmaceutics I**

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
221	Fundamentals of Pharmaceutics - II	3	---	3	4	20	--	80	--	100

Course content: 221 Fundamentals of Pharmaceutics - II

1	Preformulation • Various stages of drug product development and their significance • Drug- excipient interactions –Physical, Chemical and Therapeutic manifestations.	30
2	Dissolution: • Theories of dissolution, release rates and constants. • Comparison of dissolution principles of conventional release and controlled release products. • Dissolution data handling and correction factors (Similarity and dissimilarity) • Selection of dissolution medium and conditions including special cases. • Dissolution equipments • Dissolution: New BCS and Modified BCS. • SUPAC guidelines for dosage forms.	35
3	Applications of pharmacokinetics • Multiple dosing and dosage regimen • Influence of dosage regimen on concentration time profile • Factors affecting steady state concentration of drug • Concept of loading and maintenance dose • Problems with renal impairment • Influence of overnight no dose period • Chrono pharmacokinetics and its significance • Forensic pharmacokinetics and its significance • Pharmacokinetics in Geriatric and Pediatric patients • Pharmacokinetics in obese patients	35

SUBJECT : Pharmaceutical Product Development –I
SUBJECT CODE : 222

RATIONALE : This unit discusses how systematically generic product development is carried out with QBD approach. The detailed discussion of principles of product development and challenges in for each dosage forms make F& D very clear to the students. The functional characterization methods and instruments for the same are necessary to know for stable product and its effective qualification.

COURSE OBJECTIVES: At the end of the course the student should be able to:

1. Discuss QBD principles for product development.
2. Understand principles of dosage form development for all types of products.
3. Derive key parameters to prove product standards.
4. Describe instabilities and stability test parameters.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Design the steps of generic product development based on process variables and formulation variables.
2. Determine screening criteria for successful products.
3. Design dosage form development of all types of dosage forms.
4. Identify factors influencing development of successful drug product.

PREREQUISITES: Principles of physical pharmaceutics.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
222	Pharmaceutical Product Development -I	3	---	3	4	20	--	80	--	100

Course content:

222 Pharmaceutical Product Development - I

1	Generic product development: Significance, development stages and scope (National and International) Innovators' product characterization and its importance, Case study.	10
2	QBD: Brief discussion of application in product development with examples.	15
3	Solid oral dosage forms: Conventional tablets (coated and uncoated) and all other types of tablets, Capsules (HGC and SGC): • Principles and challenges in formulation development • Characterization standards • Stability testing (ICH) • Regulatory requirements (National and International)	20
4	Liquid orals: Solutions, Suspensions , Emulsions, Antacids and Dry syrups) • Principles and challenges in formulation development	10

	• Characterization standards • Stability testing (ICH)	
5	Topical liquid formulations: Suspensions, Emulsions. • Principles and challenges in formulation development • Characterization standards • Stability testing (ICH)	05
6	Sterile pharmaceuticals: SVP, LVP, Parenteral suspensions, emulsions, Dry powder for injection., Ophthalmic (Eye drops, eye ointments and gels) • Principles and challenges in formulation development • Characterization standards • Stability testing (ICH)	10
7	Semisolids: Ointments (different types and methods) and Gels. • Principles and challenges in formulation development • Characterization standards • Stability testing (ICH)	10
8	Pharmaceutical aerosols: All types • Principles and challenges in formulation development • Characterization standards • Stability testing (ICH)	10
9	Cosmeceuticals and Nutraceuticals: Brief introduction	10

SUBJECT : Pharmaceutical Technology –I
SUBJECT CODE : 223

RATIONALE: This unit discusses factors affecting design of pharmaceutical plant, production planning and material control. Further, advanced technologies of product manufacturing with their characteristic features are discussed with emphasis on equipments and machines used. The branded technologies are also discussed. Drug device combinations and other medical devices are also of importance.

COURSE OBJECTIVES: At the end of the course the student should be able to:
1. Understand supply chain management.
2. Discuss various techniques of granulation and compression.
3. Know tablet tooling and its applications.
4. Understand importance of particle engineering.

LEARNING OUTCOMES: At the end of the course the student will be able to:
1. Plan production and material supply.
2. Compare and contrast different granulation methods.
3. Make choice of correct taste masking techniques for solid orals.
4. Use branded technology for manufacture.
5. Handle aseptic processing.
6. Applications of advanced parenteral techniques.

PREREQUISITES: Basic methods of manufacturing.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
223	Pharmaceutical Technology -I	3	---	3	4	20	--	80	--	100

Course content:

223 Pharmaceutical Technology -I

1	Production planning: • Plant lay out-Factors affecting lay out- significant features designing different departments—Regulatory requirement of plant design. • Production planning • Supply chain management, Material management, Waste management	15
2	Advancement in production technology (Commercial methods and equipments and Automation):	75
	Solid oral dosage forms: Tablets and Capsules • Granulation technology- PAT in wet granulation, Roller compaction, Mini and Micro granulation, Fluid bed processing, Pelletisation techniques, Hot melt extrusion, Foam granulation, Continuous granulation, Effervescent granulation.	30

	• Taste masking techniques • Tablet tooling-Types of tooling its applications. • Coating technology – Pan coating, Fluid bed coating, and Dry coating. Film coating, Hot melt coating, Spray coating, • Milling techniques-dry and wet and its importance, Nano milling, Spherical crystallization, Importance and methods of particle engineering. • Branded technologies—Glatt technology, Procell technology, Granurex technology, MicroPx ™ Technology, PDG technology (Pneumatic dry granulation technology), • HGC and SGC: Liquid filling in HGC, Soft gel technology, Capsule filling machines. • Microencapsulation	
	Liquid orals: Homogenization techniques, Nano and Micro systems.	20
	Sterile dosage forms: FFS technology, Clean in place and clean out of place process, Lyophilization process, Aseptic processing, Prefilled syringes, Needle free injections.	25
3	Drug device combinations: Classification and examples.	10

SUBJECT : Pharmaceutical Biotechnology
SUBJECT CODE : 224

RATIONALE: This unit discusses the applications of biotechnological methods to develop biopharmaceuticals and immunological products. This is a complementary subject to dosage form development and pharmaceutical microbiology,

COURSE OBJECTIVES: At the end of the course the student should be able to:
1. Understand principle methods of biotechnology.
2. Apply these methods to develop biopharmaceuticals.
3. Know importance of microbes in industrial microbiology.

LEARNING OUTCOMES: At the end of the course the student will be able to:
1. Identify and differentiate different microbes of interest.
2. Apply principles of genetic engineering for healthcare products.

PREREQUISITES: Basic microbiology.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
224	Pharmaceutical Biotechnology	3	---	3	3	20	--	80	--	100

Course content:

224 Pharmaceutical Biotechnology

1	Brief introduction of importance of bacteria, virus, bacteriophage, yeast, animal cell, plant cell, mutants & vectors in genetic engineering.	10
2	Brief overview of methods in biotechnology. Nucleic acid isolation, genetic recombination, cloning methods, gene expression methods. Protein and Peptide Assembly.	15
3	Brief introduction of importance of microorganism in industrial microbiology	25
4	Immunobiotechnology: Hybridoma, vaccines, viral & bacterial peptides, genetically engineered production of lymphokines.	25
5	Biopharmaceuticals:	25
	Introduction of major areas for biotechnological applications in pharmaceutical industry.	
	Classification & description of biopharmaceutical products and their applications.	

SUBJECT : Pharmaceutics and Pharmaceutical Technology Practical – II
SUBJECT CODE : 225
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
225	Pharmaceutics and Pharmaceutical Technology Practical –II	--	18	18	6	---	20	---	80	100

Course content:

1. Data management of Biopharmaceutics and Pharmacokinetics, Mathematical calculations.
2. Preparation, evaluation of different dosage forms and to Study effect of formulation parameters.
3. Study of different packaging of existing market products.
4. Comparative evaluation of market brands of different dosage forms.

Books Recommended

1. Banker & Rhodes; Modern Pharmaceutics, 4th Edition, Marcel Dekker Inc., New York.
2. Swarbrick and Boylan; Encyclopedia of Pharmaceutical Technology Vol. 1 to 22,
3. Remington's Pharmaceutical Sciences, Lippincott, Williams and Wilkins
4. Umesh Banakar; Pharmaceutical Dissolution Testing, Marcel Dekker Inc., New York.
5. Jens Thur Carstensen; Pharmaceutical Preformulation , Informa Healthcare
6. Wilkinson JB, Moore RJ ; Harry's Cosmeticology, 7th Ed. Chemical Publish
7. Lieberman and Lachman ;Pharmaceutical Dosage Forms: Tablets Vol: 1-3
8. Lieberman and Lachman ; Pharmaceutical Dosage Forms: Parenteral Vol: 1-3
9. Lieberman and Rieger; Pharmaceutical Dosage Forms: Disperse Systems Vol: 1-3
10. W. A. Jenkins and K. R. Osborn; Packaging Drugs and Pharmaceutical Techonomic publishing company, Lancaster.
11. Peter Elsner & Howard Maibach; Cosmeceuticals, Marcel Dekker Inc, New York.

BOOKS RECOMMENDED:

1. Krieg Noel R. Ed. ; "Bergeys Manual Of Systematic Bacteriology Vol-1", Williams And Wilkins Publication
2. Krieg Noel R. Ed.; "Bergeys Manual Of Systematic Bacteriology Vol-2", Williams And Wilkins Publication
3. Krieg Noel R. Ed.;"Bergeys Manual Of Systematic Bacteriology Vol-3",Williams And Wilkins Publication
4. Krieg Noel R. Ed.;"Bergeys Manual Of Systematic Bacteriology Vol-4,Williams And Wilkins Publication
5. Casida L.E.; Industrial Microbiology", New Age International Publication
6. Purohit S ; "Pharmaceutical Microbiology", Ab Grobias Publication
7. Sambhamurthy K.; "Pharmaceutical Biotechnology", New Age International Publication.
8. Stanbury Peter F. ; "Principles Of Fermentation Technology", Aditya Books Publication

SUBJECT : Subject seminar
SUBJECT CODE : 226

RATIONALE: This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES : At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: None
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
226	Subject seminar	6	----	6	3	-----	100	-----	-----	100

SPECIALISATION:
PHARMACEUTICS AND PHARMACEUTICAL TECHNOLOGY
SEMESTER-III
SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT Hrs/WK		CREDITS	
		Theory	Practical	Theory	Practical
231	Drug Delivery Systems	4	---	4	---
232	Pharmaceutical Product Development - II	3	---	3	---
233	Pharmaceutics and Regulatory Affairs	2	---	2	---
234	Pharmaceutical Technology - II	3	---	3	--
235	Pharmaceutics and Pharmaceutical Technology Practical – III	---	18	---	6
236	Synopsis (Introduction To Dissertation) & Viva Voce	---	---	3	---
237	Subject Seminar	6	---	---	3
	TOTAL	18	18	15	9

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	DURATION OF EXAM (HRS)	MARKS			
			THEORY		PRACTICAL	
			University level evaluation	Institute level evaluation	University level evaluation	Institute level evaluation
231	Drug Delivery Systems	3	80	20	--	--
232	Pharmaceutical Product Development - II	3	80	20	--	--
233	Pharmaceutics and Regulatory Affairs	3	80	20	--	--
234	Pharmaceutical Technology - II	3	80	20	--	--
235	Pharmaceutics and Pharmaceutical Technology Practical – III	12	--	--	80	20
236	Synopsis (Introduction To Dissertation) & Viva Voce	--	80	20	--	--
237	Subject Seminar	--	--	--	--	100
	TOTAL		400	100	80	120

SUBJECT : Drug Delivery System
SUBJECT CODE : 231

RATIONALE : The course discusses suitability of drug candidates for modified drug delivery and suitability of new drug delivery systems for conventional drug molecules. Physiological and physicochemical factors affecting design of delivery systems is also discussed. Classification of drug delivery systems according to route of administration and mathematical computation of drug release rate and release mechanisms are also included.

COURSE OBJECTIVES: At the end of the course the student should be able to:

1. Discuss biopharmaceutics of CRDDS.
2. Describe pharmacokinetic profiles of drugs to predict fate of dds.
3. Understand different approaches for controlled release of drug.
4. Understand objectives of DDS for any route of administration.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Apply pharmacokinetic parameters for designing dds.
2. Mathematically compute release rate from dds.
3. Predict release profiles and mechanism of drug release from dds.
4. Use clear objectives for designing any dds through any route of administration.

PREREQUISITES: Pharmaceutical technology for different dosage forms.

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
231	Drug Delivery System	4	--	4	4	20	--	80	--	100

Course content:

231 Drug Delivery System

1	Biopharmaceutical and pharmacokinetic aspect of CRDDS.	10
2	Mathematical modeling for NDDs: Dissolution controlled, diffusion controlled, erodible systems and osmotic pumps. Transdermal delivery. Factorial design-application in designing controlled release formulations.	20
3	Biological barriers affecting effective drug delivery through various routes. Principles of development (Objectives, limitations ,suitable drug candidates), formulation approaches (technology used), Characterization, and branded technologies of:	70
	a) Oral drug delivery system: GIT, Oral pulsatile systems, Gastro retentive systems, Osmotic systems, SEDDS, SMEDDS, and Colon DDS.	15
	b) Parenteral controlled drug delivery systems	05
	c) Targeted drug delivery system/ Site specific drug delivery	05
	d) Drug delivery to brain	05

	e) Drug delivery system for Protein & Peptides	05
	f) Pulmonary DDS	10
	g) Drug delivery to oral cavity	08
	h) Trans mucosal DDS: Buccal dds, Ocular dds, Recta dds, vaginal dds.	07
	i) Transdermal DDS: Transdermal patches, Iontophoresis, Sonophoresis, and Phonophoresis.	10

SUBJECT : Pharmaceutical Product Development - II
SUBJECT CODE : 232

RATIONALE : This unit discusses formulation strategies of drug delivery systems. It emphasizes on biopharmaceutical parameters governing ADME of drugs through each route of administration. Understanding of biological barriers results in choosing correct approach for. It also gives details about all possible techniques to enhance bioavailability of drug which enables to choose the suitable one. Assessment of biopharmaceutical properties facilitates characterization and screening of different formulations of. Applications of polymers and factors affecting choice of polymers is essential for designing.

COURSE OBJECTIVES: At the end of the course the student should be able to:

1. Understand pros and cons of each route of administration.
2. Understand role of biological barriers.
3. Discuss various techniques to enhance bioavailability.
4. Describe different methods of assessment of biopharmaceutics.
5. Understand role of polymers and functional classification of polymers.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Compare and contrast the routes of administration for.
2. Make choice of correct approach to overcome biological barriers from each route.
3. Make choice of suitable technology for drug candidate for improved bioavailability.
4. Perform in vitro and ex-vivo methods of determination of biopharmaceutical properties of formulations.
5. Screen formulations before in-vivo studies.
6. Make choice of polymers to design economical and effective controlled release formulations.

PREREQUISITES:

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
232	Pharmaceutical Product Development - II	3	-	3	3	20	--	80	--	100

COURSE CONTENT:

232 Pharmaceutical Product Development - II

1	Biopharmaceutical parameters of drug delivery Comparison of routes of administration; Physiological and formulation factors affecting bioavailability through each route.	25
2	Pharmacokinetics and Biopharmaceutics in drug research.	10
3	Objectives and Approaches of different bioavailability enhancement techniques.	15
4	Assessment of biopharmaceutical properties Introduction	25

	Measurement of key biopharmaceutical properties. Release of drug from dosage form into solution-Mechanisms Stability aspects of drug in physiological fluid. Permeability study: Partition co-efficient, Cell culture study, Tissue techniques, Perfusion studies, Assessment of permeability in humans.	
5	Applications of Polymers in drug delivery. Functional classification of polymers with characteristic features Basic properties of biodegradable and non-biodegradable polymers. Brands available and their applications	25

SUBJECT : Pharmaceutics and Regulatory Affairs
SUBJECT CODE : 233
RATIONALE : It is necessary to register the drug products in different countries' authorities, state level, national level, EU AND US FDA in particular. This unit acquaints students for literature resources as guidance for F&D. Further, types of documents and its components are discussed which is integral part of product development. Computation of results of QC, in-vitro testing, in-vivo testing and IVIVC, with correct interpretation is integral part of dossier preparation for any product registration, it is detailed here country wise.

COURSE OBJECTIVES: At the end of the course the student should be able to:
1. Use literature resources thoroughly for F&D.
2. Update himself with latest regulatory aspects of F&D, nationally and internationally.
3. Know about set of documents for each stage of F&D.

LEARNING OUTCOMES: At the end of the course the student will be able to:
1. Use drug and excipients s' regulatory requirements effectively in F&D.
2. Prepare documents as per different guidelines.
3. Manage results of each batch of formulations and properly interpret the same.

PREREQUISITES: NONE
TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
233	Pharmaceutics and Regulatory Affairs	2	-	2	2	20	--	80	--	100

Course content:

233 Pharmaceutics and Regulatory Affairs:

1	Introduction to applications of guidelines provided by : ICH , WHO, US FDA, Inactive ingredient guide, International pharmaceutical excipients committee, Cosmetic toiletries and fragrance association, COLIPA guidelines, Orange book, Six sigma concept, PAT (Process analytical techniques), Schedule M (D & C ACT) In formulation development with examples.	25
2	Regulatory requirements of dosage form quality standards in different countries. (US FDA, and EU): For Solid oral dosage forms.	25
3	Regulatory requirements of stability testing, Dissolution methods, In vivo testing and IVIVC in different countries (US FDA and EU) for solid oral dosage forms.	25
4	Documentation in pharmaceutical industry: IPQC and QC reports and their significance, BMR records, Stability testing protocols, Dossier preparation for product registration, Brief discussion of GMP and Validation of pharmaceutical processing.	25

SUBJECT : Pharmaceutical Technology - II
SUBJECT CODE : 234

RATIONALE : This unit details the factors to be considered for scale up batch manufacturing. Technology transfer of any dosage form necessitates understanding of mathematical equations and quantification of parameters for successful large scale manufacturing. It also discusses different packaging materials with their pros and cons, testing integrity of package and innovations. Environment controls in pharmaceutical industry with emphasis on air and water control systems is also discussed at length.

COURSE OBJECTIVES: At the end of the course the student should be able to:

1. Understand principles of scaling up of pharmaceuticals and.
2. Understand role of packaging of pharmaceuticals.
3. Understand air handling systems.
4. Understand importance of water quality in industry.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Apply scale up techniques scientifically for effective production of pharmaceuticals.
2. Make correct choice of pharmaceutical packaging.
3. Know operations of air handling and water handling systems.

PREREQUISITES: NONE

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		T	P	T	P	
234	Pharmaceutical Technology - II	3	-	3	3	20	--	80	--	100

Course content:

234 Pharmaceutical Technology -II

1	Scale up techniques: Introduction Scale up considerations for manufacturing of: Tablets, Capsules (HGC and SGC), Liquids and Semisolids pharmaceuticals. Scale up considerations for Nanosystems and Particulate dds systems Scale up considerations for Biotechnology products	30
2	Packaging of different class of dosage forms Selection criteria for product packaging, packaging material & stability of product, labeling and Screening of packaging material.	25
3	Environment control in pharmaceutical industry. a) An introduction to environmental control and monitoring b) High Purity Water Systems • Types or qualities of water • Determining the quality of the required water • Steps for producing WFI water Monitoring high purity water systems	45

	c) Effects of environmental conditions on product Stability d) Environmental Monitoring • Microbiological Environmental Monitoring methods and standards. • Roll of Personnel in environment monitoring, Working in Clean Zones, Cleanroom Garments, Personal Hygiene and Personal Responsibility, General Rules when Working in Cleanrooms and other Controlled Environments e) Aseptic Techniques f) Pharmaceutical Cleanrooms and Clean Zones: Classification of Pharmaceutical Cleanrooms, Design of Pharmaceutical Cleanrooms, Measuring Cleanliness within Pharmaceutical Cleanrooms, Particle Counting, Microbial Monitoring	

SUBJECT : Pharmaceutics and Pharmaceutical Technology Practical – III
SUBJECT CODE : 235

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
235	Pharmaceutics and Pharmaceutical Technology Practical –III	--	18	18	6	--	20	--	80	100

235 Pharmaceutics and Pharmaceutical Technology Practical – III

1	To study scale-up process. (Preparation of small batches up to 2-5 Kg.)
2	Preparation and evaluation of Modified release dosage forms:
	Microspheres
	Coated pellets
	Coated tablets
	Topical gels and transdermal dosage forms
	Mucoadhesive dosage forms
	Floating tablets
	Capsule dosage form
	Mouth dissolving tablets
	Buccal tablets
3	Data management and mathematical modeling.
4	In vitro and Ex vivo study of .DDS

BOOKS RECOMMENDED:

1.	Banker & Rhodes; Modern Pharmaceutics 4th Edition,
2.	Donal L. Wise; Handbook of Pharmaceutical Controlled release Technology, Marcel Dekker
3.	N. K. Jain ; Controlled and Novel Drug Delivery, CBS Publishers
4.	Robinson and Lee ; Controlled Drug Delivery, Marcel Dekker
5.	Lieberman and Lechman; Pharmaceutical Dosage Forms: Tablets Vol:1-3
6.	Lieberman and Lechman; Pharmaceutical Dosage Forms: Parenteral Vol:1-3
7.	Lieberman and Rieger; Pharmaceutical Dosage Forms: Disperse Systems Vol:1-3
8.	Swarbric and Boylan ; Encyclopedia of Pharmaceutical Technology, Vol1-22,
9.	Cartensen; Drug stability, Marcel Dekker.
10.	Kenneth A. Connors; Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists, 2nd Ed. (Illustrated) Wiley-Interscience
11.	N. K. Jain ; Progress in Control and Novel Drug Delivery, CBS Publishers
12.	Vyas and Khar ; Targeted and Controlled Drug Delivery, CBS P publishers
13.	Ghosh and Pfizer ; Drug Delivery to Oral Cavity , Marcel Dekker

14.	Gupta and Kompella ; Nanoparticle Technology in Drug Delivery , Marcel Dekker Inc
15.	Guy and Hadgraft ; Trandermal Drug Delivery, Marcel Dekker Inc
16.	Mitra ; Ophthalmic Drug Delivery System, Marcel Dekker Inc
17.	Chien ; Novel Drug Delivery Systems, Marcel Dekker Inc
18.	Malmsten ; Surfactant and Polymers in Drug Delivery, Marcel Dekker Inc
19.	Bret Berner and Steven dinh ; Electronically Controlled Drug Delivery
20.	Vincent Lenaerts, Robert Gurny (Editor), Hardcover ; Bioadhesive Drug Delivery Systems , CRC Pr
21.	Edith Mathiowitz (Editor), Donald E. Chickering (Editor), Claus-Michael Lehr (Editor); Bioadhesive Drug Delivery Systems: Fundamentals, Novel Approaches, and Development, Marcel Dekker Inc
22.	W. Mark Saltzman; Drug Delivery: Engineering Principles for Drug Therapy , Oxford Uni Pr
23.	Steven M. Dinh (Editor), Puchun Liu (Editor); Advances in Controlled Drug Delivery: Science, Technology, and Products (Illustrated) , Amer Chemical Society
24.	Glen Kwon (Editor); Polymeric Drug Delivery Systems, Informa Healthcare
25.	Russell O. Potts (Editor), Richard H. Guy (Editor); Mechanisms of Transdermal Drug Delivery, Marcel Dekker Inc
26.	Hans Bisgaard (Editor), Gerald C. Smaldone (Editor), Christopher O'Callaghan (Editor); Drug Delivery to the Lung (Illustrated)
27.	Hardcover, Informa Healthcare
28.	Isaac Ghebre-Sellassie (Editor); Multiparticulate Oral Drug Delivery, Informa Healthcare
29.	Dennis M. Brown; Drug Delivery Systems in Cancer Therapy, Humana Pr Inc
30.	Guru V. Betageri, Daniel L. Parson, Scott A. Jenkins, Daniel L. Parsons; Liposome Drug Delivery Systems, Technomic Pub Co
31.	XIAOLING LI, Bhaskara R. Jasti (Editor); Design Of Controlled Release Drug Delivery Systems, McGraw-Hill
32.	Raphael M. Ottenbrite, Raphael M. Ottenbrite (Editor), Sung Wan Kim (Editor); Polymeric Drugs and Delivery Systems, Technomic Pub Co

SUBJECT : Subject Seminar
SUBJECT CODE : 237

RATIONALE : This unit is complementary to compensate the boundryless content of theory syllabus. It includes all aspects of core subject specialization which tangentially touch the content of syllabus. (It does not include routine syllabus topics) All research and reviewed articles along with reference books are taken as basis for preparing a seminar. Innovative topics are ensured in each session.

COURSE OBJECTIVES: At the end of the course the student should be able to:

1. Develop knowledge to refer literature for given topic. Literature search include key words, Library use and internet use.
2. Develop presentation skills.
3. Get peripheral knowledge of the subject with current perspective.

LEARNING OUTCOMES: At the end of the course the student will be able to:

1. Find any reference related to the theme.
2. Have presentation skills in terms of precise and contented, relevant presentation.
3. Identify current perspectives related to the subject.

PREREQUISITES: None

TEACHING AND EVALUATION SCHEME:

SUB CODE	TITLE OF SUBJECT	TEACHING SCHEME			CREDITS	EVALUATION SCHEME				TOTAL MARKS
						INTERNAL		EXTERNAL		
		T	P	TOTAL HRS		Theory	Practical	Theory	Practical	
237	Subject Seminar	6	-	6	3	---	100	---	---	100

SPECIALIZATION:
PHARMACEUTICS AND PHARMACEUTICAL TECHNOLOGY
SEMESTER-IV
SCHEME OF TEACHING

SUB CODE	NAME OF SUBJECT	CONTACT HOURS PER WEEK	CREDITS
241	Dissertation (Project Work)	36	12
242	Viva- Voce	---	12

SCHEME OF EXAMINATION

SUB CODE	NAME OF SUBJECT	UNIVERSITY LEVEL EVALUATION
241	Dissertation	100
242	Viva- Voce	100
	TOTAL	200