GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Engineering
Subject Code: 3173621
Semester-VII
Subject Name : Drug Delivery, Biotechnology, Validation Requirements and Regulatory Affairs

Type of Course: Chemical Technology

Prerequisite: Studied department electives of previous semesters. Basic knowledge of Pharmaceutics & Organic chemistry is required**.**

Rationale: The main objective of this subject is to study various Drug delivery methods, Fermentation technology, Genetic Engineering and Validation requirements.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks				Total Marks
				Theory Marks		Practical Marks		
L	T	P	C	ESE (E)	PA (M)	ESE Viva(V)	PA (I)	
3	0	2	4	70	30	30	20	150

Content:

Sr. No.	Content	Total Hrs.
1	**Drug delivery system:** Performulation, Formulation, Evolution, Large scale manufacture and packing with focus on equipment with reference to Oral sustained and controlled release dosage forms, Aerosols, Introduction to Novel drug Delivery Systems Transdermal, Transmucosal (buccal, sublingual, nasal, vaginal, rectal), Ophthalmic Colloidal: Liposome's, nanoparticles, emulsion systems	13
2	Introduction to Radiopharmaceuticals and overview of cosmetic products	4
3	**Application of Biotechnology in foods, pharma:** Application of Biotechnology in foods, pharma, and other industries with specific reference to enzymes. Principles of surface and solid state fermentation, Design of different fermentors and the biochemical engineering aspects. Process control of fermentation. Fermentation technology of industrial chemicals, organic acids, amino acids, vitamins, polysaccharides, antibiotics, etc	8
4	Enzyme fermentation and technology including immobilization and enzyme reactors. Genetic engineering principles & techniques and its application in medicines, cloning and other fields.	4
5	Validation and Regulatory Requirements, cGMP and Quality assurance, Schedule M, Process& product validation and quality audits. Documentation	8
6	New drug application (NDA), generic products(ANDA), Schedule Y, DPCO, drugs and cosmetics act and rules including licensing intermediates industry, ICH guidelines.	8

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Suggested Specification table with Marks (Theory): (For BE only)

Distribution of Theory Marks					
R Level	U Level	A Level	N Level	E Level	C Level
20	20	10	10	5	5

Legends: R: Remembrance; U: Understanding; A: Application, N: Analyze and E: Evaluate C: Create and above Levels (Revised Bloom's Taxonomy)

Reference Books:

1. Phamaceutical Dosage Forms Ans Drug Delivery Systems , Ansel ,Philadelphia Fea & Febiger , 1985
2. Introduction to pharmaceutical Dosage Forms Henry ,Ansel , Kimpton Publishers , 1976
3. Pharmaceutical: The Science of Dosage Form Design Aulton , B.I Naverly Pvt . Ltd, 1995
4. Modern pharmaceutics G.S.Bnaker New York , Marcel Dekker 1990
5. Fundamentals of Pharmacy ,Blome H.E. Philadelphia Fea & Febiger , 1985
6. Pharmaceutical production Facilities Design & Application ,G.C.Cole New York EIIis Horwood 1990
7. Pharmaceutical Dispensing ,Martin E.W.Easton Husa, Mack Pub. Co 1971
8. Law of Drugs Medicines & Cosmetics, K.K. Singh , L.R. Bugga Beotra's ,Law Book co. Pvt. Ltd., Allahabad.
9. Pharmaceutical Production Facilities Design & Applications , G.C.Cole , New York EIIis Horwood 1990
10. Drug Delivery Device : Fundamentals & Applications , Tyle ,New York , Marcel Dekker 1988
11. Encyclopedia of pharmaceutical Technology , J.Swarbrick , New York , Marcel Dekker , 1993
12. Pharmaceutial Sciences , A.R.Gennaro Remington, Mac Pub . Co . Easton , Pennsylvania 1990
13. Indian Pharmacopiea , British Pharmacopoiea , United States Pharmacopoiea.
14. Principles of fermentation technology, Stanbury P. F. and Whitaker A.
15. Basic bioreactor design, Riet K. V. and Tramper J.23. Elements of biotechnology, Gupta P.K.
16. Industrial fermentations: Underkofler L. A. and Hickey R. J. Vol. I and II

List of experiments:

1. Cyclo addition reaction
2. Preparation of 5-phenyl azo salicylic acid
3. Preparation of ortho & para nitro phenol & isolation by steam distillation
4. Synthesis of dihydropyrimidinone
5. Preparation of Phenyl benzoate by Schotten-Baumann reaction.
6. Disintegration test for solid dosage forms
7. Dissolution test for solid dosage forms

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Course Outcomes:

Sr. No.	CO statement	Marks % weightage
1	To describe the pre formulation & formulation methods of various drug delivery system, radiopharmaceuticals, cosmetic products, fermentation technology, genetic engineering, validation requirements & regulatory requirements.	33
2	To illustrate various drug delivery systems, fermentation process, genetic engineering, cGMP, Quality assurance, NDA and ANDA	24
3	To demonstrate the applications of new drug delivery systems, fermentation process, DNA technology, process& product validations, Drug& Cosmetic acts.	13
4	To analyse the new drug delivery methods, fermentation process, cloning methods, quality audits validation process and Drugs& Cosmetics act.	13
5	To explain the advantages & disadvantages of drug delivery systems, cosmetic products, enzyme fermentation, fermentation techniques, ICH guidelines, documentation.	10
6	To evaluate the novel drug delivery system, biochemical engineering applications, validation methods and regulatory methods.	7

Major Equipment:

1. Mechanical stirrer & heating mantle
2. Sieves
3. Vacuum pump
4. Dryer
5. Disintegration apparatus
6. Dissolution apparatus
7. UV spectroscope

List of Open Source Software/learning website:

1. Literature available in any laboratory manual of Pharmaceutical Industries.
2. Literature available on internet
3. Medical dictionaries
4. Delnet
5. Pharmacopoeia