GUJARAT TECHNOLOGICAL UNIVERSITY

CHEMICAL TECHNOLOGY (36)
DRUG DELIVERY, BIOTECHNOLOGY & VALIDATION REQUIREMENT
SUBJECT CODE: 2183601
B.E. 8TH SEMESTER

Type of Course: Chemical Technology

Prerequisite: Studied department electives of previous semesters. Basic knowledge of Chemical Engineering,Pharmaceutics, Biochemistry & Chemistry is required

Rationale: The main objective of this subject is to study the drug delivery system, application of Biotechnology, validation & regulatory requirements, new drug application.

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks						Total Marks
L	T	P	C	Theory Marks			Practical Marks			
				ESE (E)	PA (M)		ESE (V)		PA (I)	
					PA	ALA	ESE	OEP		
4	0	3	7	70	20	10	20	10	20	150

Content:

Sr. No.	Topic	Teaching Hours	Module Weightage (%)
01	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	20	33
	Introduction to Novel drug Delivery Systems: Transdermal, Transmucosal (buccal, sublingual, nasal, vaginal, rectal), Ophthalmic, Colloidal: Liposome's, nanoparticles, emulsion systems etc		
	Introduction to Radio pharmaceuticals, Overview of cosmetic products		
02	Application of Biotechnology in foods, pharma: Application of Biotechnology in foods, pharma, and other industries with special reference to enzymes Definitions, nomenclature and terminologies, isolation purification strain improvements, optimization of growth and product formation using industrially important micro organism Genetic engineering principles and technique Principles of surface and solid state fermentation, Design of different fermentors and the biochemical engineering aspects. Process control of fermentations. Fermentation technology of industrial chemicals, organic acids, amino acids, vitamins, polysaccharides, antibiotics, etc. Enzyme fermentation and technology including immobilization and enzyme reactors. Fermentative animals, and other developments	20	34

03	Validation and Regulatory Requirements: CGMP and Quality assurance, Schedule M	20	33
	Process, product validation and quality audits. Documentation		
	New drug application (NDA), generic products(ANDA), Schedule Y		
	DPCO, drugs and cosmetics act and rules including licensing intermediates industry		

Suggested Specification table with Marks (Theory):

Distribution of Theory Marks					
R Level	U Level	A Level	N Level	E Level	C Level
60	**10**	**10**	**10**	**10**	**-**

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

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

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

Course Outcomes:

1. To know the drug delivery system, application of Biotechnology, validation & regulatory requirements, new drug application
2. To carry out the synthesis of drug molecules and preparations of pharmaceutical formulations
3. To be able to apply this knowledge in API & Pharmaceutical Formulation industries
4. To build a bridge between theoretical and practical concept used in industry

List of Experiments:

1.	Minimum **5** experiments to illustrate the principles of green chemistry/technology. The experiments may include, greener version(S) of classical reactions such as, N-acetylation, O- acetylation, etherification, esterification, bromination, iodination, oxidation, reduction, rearrangement(S) such Beckmann etc , and use of ionic liqu0id as green solvents

Major Equipment:

Glasswares, heating mantles / water baths, weighing scale, mechanical stirrers, oven , oil bath, vacuum oven, UV spectro photometer etc

Open Ended Project fields:-

Students are free to select any area of science and technology based on chemical technology applications to define Projects.

Some suggested projects are listed below:

1. PPT on cGMP,
2. PPT on different validation in Pharmaceutical industries.
3. Literature survey on fermentation technology
4. PPT on NDA
5. PPT on validation system

List of Open Source Software/learning website:

1.Literature available under R&D of Pharmaceutical Industries.
2.Literature available on internet
3.Medical dictionaries
4.Delnet
5. Pharma journals./e-journals

ACTIVE LEARNING ASSIGNMENTS: Preparation of power-point slides, which include videos, animations, pictures, graphics for better understanding theory and practical work – The faculty will allocate chapters/ parts of chapters to groups of students so that the entire syllabus to be covered. The power-point slides should be put up on the web-site of the College/ Institute, along with the names of the students of the group, the name of the faculty, Department and College on the first slide. The best three works should submit to GTU.