GUJARAT TECHNOLOGICAL UNIVERSITY

CHEMICAL TECHNOLOGY (36)

SUBJECT NAME: PROCESS TECHNOLOGY OF DRUGS & INTERMEDIATES (DE-VII)

SUBJECT CODE: 2173602

B.E. VIIth SEMESTER

Type of Course: Chemical Technology

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

Rationale: The main objective of this subject is to study the catalytic reactions of enzymes, Chiral technology, separation technology in pharmaceutical industry, design & development of safe process, optimization organic process & reactions.

Teaching and Examination Scheme:

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

L-Lectures; T-Tutorial/TeacherGuidedStudentActivity;P-Practical;C-Credit;ESE-EndSemesterExamination; PA-Progressive Assessment, ALA- Active Learning Assignment, OEP- Open Ended project

Contents:

Sr. No.	Topic	Teaching Hours	Module Weightage (%)
01	**Raw materials** : Raw materials for Pharmaceutical Industry	2	3
02	**Enzymes**: Enzymes as catalyst (a) in Synthesis for Pharmaceuticals (b) Introduction to Principle of enzymes catalyst, Lipases & esterase are for hydrolytic conversion. Lipases & esterase's in organic solvents, other hydrolytic reactions, Enzyme-catalyzed C-X bond synthesis, Enzyme-catalyzed reduction, Chiral Technology, Chemical Development of enantiomerically pure products, resolution, chiral synthesis etc.	18	30
03	**Separation techniques in Pharmaceutical industry**: Separation (a) aspect of Chemical Purification & process separation technology (b), Introduction to Separation technology; choosing a separation process, Adsorption Separation methods, Simulated moving bad (SMB) chromatography; Large scale chromatography; homogeneous, Heterogeneous catalyst & phase transfer catalyst	8	13
04	**The Design & Development of Safe Chemical Processes**: Introduction, the chemical process life-cycle, Legislative requirements for safe process development & scale up,	16	27

	Development technologies for safe Process design, Unit operations posing particular hazards during development, Strategies for chemical hazards assessment, Hazards of gas & vapor generation, Identification of highly-energetic materials, Small scale screening tests: case studies, Flammability issues associated with chemical manufacture, Gas & Vapor pressure systems, Process control considerations & safety critical systems, GMP in chemical development.		
05	**Optimization of Organic Reactions & Processes** : Introduction the purpose of chemical development, Discovering the best synthetic route; Selecting the best route for scale-up, Choice of raw materials, reagents etc; case studies, the investigative approach to chemical development, Effect of process variables on yield & quality of products; Quality control in process analysis as an aid to optimization, Designing a robust process & preventing scale-up problems, Solvent effects, Work up & product isolation, Selecting the parameters to vary, Planning for scale up, Design of environmentally friendly processes, Effluent minimization & control, Statistical methods of optimization	16	27

Suggested Specification table with Marks (Theory):

Unit No	Unit Title	Distribution of Theory Marks (%)					
		R Level	U Level	A Level	N Level	E Level	Total
1	Raw materials	1.8	0.3	0.3	0.3	0.3	3
2	Enzymes	18	3	3	3	3	30
3	Separation techniques in Pharmaceutical industry	7.8	1.3	1.3	1.3	1.3	13
4	The Design & Development of Safe Chemical Processes	16.2	2.7	2.7	2.7	2.7	27
5	Optimization of Organic Reactions & Processes	16.2	2.7	2.7	2.7	2.7	27

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

Reference Books:

1. Enzymes in Industry Prod & App Wolfgang Aehle, Wiley VCH Publication, 2003
2. Industrial Pharmaceutical Biotechnology. Heinrich Klefenz, Wiley-VCH Publication, 2002
3. Process Integration in Biochemical Engineering, T.Scheper, Springer Publication, 2003.
4. Principles of Research & Chemical Development in the Pharmaceutical Industry,Oligan Repic, Wiley Interscience 1998
5. From Bench to Market the Evolution Chemical Synthesis, Romano Di Fabio, Oxford University Press, 2000.
6. Industrial Bio transformations, A. Liese, Wiley – VCH 2000
7. Pollution Prevention through Process Integration (Systematic Design Tools), Mahmound M. Academic Press, 1997.
8. Practical Process Research & Development, Neal G. Anderson, Academic Press, 2000

9. Fine Chemicals Manufacture – Tech & Engg, A.Cybulski, Elsevier Publication, 2000
10. Mixing Equipment (Impeller type),AIChE Publication 2001
11. Chemical Process Quantitative Risk Analysis, AIChE Publication, 2000
12. Strategies for Organic Drug Synthesis & Design, & Daniel Led nicer, John Willey & Sons Inc. New York., 2nd Ed, 1998.
13. Organic Chemistry of Drug Synthesis: Vol.1 to 6, Daniel Lednicer, John Wiley & Sons Inc.
14. Burger's Medicinal Chemistry & Drug Discovery: Vol. 1 to 6, A. Burger & M.E.Wolff, John Wiley & Sons – New Jersey,6th Ed, 2003
15. Foye's Principles of Medicinal Chemistry, W.O. Foye, Lippincott Williams & Wilkins-Philadelphia, Oxford, 6th Ed, 2008
16. Text book of Medicinal & Pharmaceutical Chemistry, Charles Owens Wilson Lippincott Williams & Wilkins – Philadelphia. 1962
17. Organic Synthesis – The Disconnection Approach, Warren S., John Wiley & Sons – Chichester.,1st Ed., 2005
18. Pharmaceutical Substances: Synthesis, Patents, Applications (N-Z), A. Kleemann, Georg Thieme Verlag,Stuttgart.4th Ed, 2001
19. Textbook of Medicinal & pharmaceuticals Chemistry, Wilson & Gisvold ., Williams & Wilkins,1st Ed, 2004.

Course Outcomes:

1. To know the catalytic reactions of enzymes, Chiral technology,separation technology in pharmaceutical industry, design & development of safe process , optimization organic process & reactions.
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.	Synthesis of drugs involving two or more steps with (a). analysis of raw materials and product synthesized. (b). in process control & reaction monitoring (3 synthesis)
2.	Synthesis of drug intermediates (4 exercises)
3	Any innovative modifications in the process of drug synthesized (2 examples) and no repetition of the same from previous years.

Major Equipment:

Glasswares, heating mantles / water baths, weighing scale, mechanical stirrers,oven , sieves, tablet punching machines, tablet disintegration equipment, tablet dissolution test equipment, UV spectro photometer, Melting / boiling point apparatus 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. Literature survey on Simulated moving bed (SMB) chromatography; Large

scale chromatography; homogeneous, Heterogeneous catalyst & phase transfer catalyst

2. Literature survey of chiral synthesis
3. Design of Pharma formulation industry .
4. PPT on effluent treatment challenges in Pharma industry
5. Drug purification by chromatography

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.