GUJARAT TECHNOLOGICAL UNIVERSITY, AHMEDABAD, GUJARAT

COURSE CURRICULUM
COURSE TITLE: PHARMACEUTICAL TECHNOLOGY
(COURSE CODE: 3360507)

Diploma Programme in which this course is offered	Semester in which offered
Chemical Engineering	Sixth

1. RATIONALE

Gujarat is having more than 30 percent of pharmaceutical production capacity of India. Medicinal product manufacturing requires special considerations like sterilization, clean facility development and maintaining strict standards during formulating different dosage. The content of this subject is designed to enable diploma chemical engineers to develop the skills required for working in manufacturing of bulk drugs and formulations in special considerations to comply with standards.

2. COMPETENCY

The course content should be taught and curriculum should be implemented with the aim to develop required skills in the students so that they are able to acquire following competency:

- **Supervise production of drugs following standards for quality and cleanliness.**

3. COURSE OUTCOMES (COs)

The theory should be taught and practical should be carried out in such a manner that students are able to acquire required learning outcomes in cognitive, psychomotor and affective domain to demonstrate following course outcomes:

i. Identify appropriate methods in medicine production.
ii. Apply various methods of sterilization.
iii. Use design parameters for clean facilities
iv. Produce different dosage forms.
v. Identify appropriate packaging materials.

4. TEACHING AND EXAMINATION SCHEME

Teaching Scheme (In Hours)			Total Credits (L+T+P)	Examination Scheme				
				Theory Marks		Practical Marks		Total Marks
L	T	P	C	ESE	PA	ESE	PA	150
3	0	2	5	70	30	20	30	

Legends: L - Lecture; **T** - Tutorial/Teacher Guided Student Activity; **P** - Practical; **C** - Credit; **ESE** - End Semester Examination; **PA** - Progressive Assessment

5. COURSE CONTENT DETAILS

Unit	Major Learning Outcomes (In Cognitive Domain)	Topics and Sub-topics
Unit – I Basics of Pharmaceutical Technology	1a. Describe the characteristics of the Pharmaceutical industries compared to other industries	1.1 Characteristics of Pharmaceutical industries
	1b. Explain the concept of product standards 1c. Distinguish the different methods of production 1d. Compare API and formulation production	1.2 Product Standards: IP, BP, USP 1.3 Methods of production, Chemical synthesis, Isolation from plants, isolation from animals 1.4 Fermentation 1.5 API and Formulation
Unit – II Sterilization	2a. Justify the need for in the sterilization pharmaceutical industry 2b. Compare methods of Sterilization, with their benefits and limitations 2c. Describe the sterile facilities	2.1 sterility and requirement of sterility, Concept of sterilization 2.2 Methods of Sterilization with, applications, , Heat sterilization, (a)Steam sterilization, (b) Dry heat sterilization, Radiation sterilization Gas sterilization, Filtration sterilization 2.3 Sterile facilities : preparation area, compounding area, ware housing
Unit – III Clean Facilities	3a. Describe the important design parameters for various processes	3.1 Design parameters for clean facilities : Air change rate, Pressurization, Temperature control, Humidity control
	3b. Describe Architectural design issues	3.2 Architectural design issues : Facility Layout, Air locks and Pass through, windows, Gowning room
	3c. Select material of construction 3d. Explain the concept of clean construction	3.3 Material of construction for wall, doors, ceilings, floors 3.4 Clean construction
	3e. Describe HEPA filters	3.5 HEPA filters
Unit – IV Dosage forms	4a. Describe features of different types of solid dosage forms 4b. Describe the excipients in solid dosage forms	4.1 Solid dosage forms : Tablets, Coated tablets, Gelatine capsules, Chewable tablets, Gum based tablets 4.2 Excipients in solid dosage forms
	4c. Describe features of the semi-solid dosage forms 4d. Describe the features of different types of Gels 4e. Differentiate between Gels, Commercial Gelling agents	4.3 Semi-Solid dosages : Ointments and creams, 4.4 Bases for ointments and creams, 4.5 Packaging and storage of ointments and creams 4.6 Types of Gels, Commercial Gelling agents
	4e. Distinguish various liquid dosage forms	4.7 Liquid dosage forms: Solutions, Suspensions, Emulsions

Unit	Major Learning Outcomes (In Cognitive Domain)	Topics and Sub-topics
Unit – V Manufacturing and Packaging	5a. Differentiate between the manufacturing of tablets and capsules	5.1 Manufacturing, tablets and capsules
	5b. Describe packaging and storage of ointments and creams	5.2 Packaging and storage of ointments and creams
	5c. Describe the critical aspects of liquid manufacturing 5d. Describe the salient features of different types of packaging materials 5e. Describe the process of maintaining the quality control of packaging materials.	5.3 Critical aspects of liquid manufacturing: particle size of raw materials, parameters of compounding, uniformity, stability problems 5.4 Packaging materials: General considerations, Glass, Plastic and metal 5.5 Quality control of packaging materials

6. SUGGESTED SPECIFICATION TABLE WITH HOURS and MARKS (THEORY)

Unit	Unit Title	Teaching Hours	Distribution of Theory Marks			
			R Level	U Level	A Level	Total Marks
I	Basics of Pharmaceutical Technology	06	4	4	2	10
II	Sterilization	07	3	3	6	12
III	Clean Facilities	07	3	3	6	12
IV	Dosage forms	13	7	7	7	21
V	Manufacturing and Packaging	09	5	5	5	15
Total		**42**	**22**	**22**	**26**	**70**

Legends: R = Remember**, U** = Understand**, A=** Apply and above Level (Bloom's revised 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.

7. SUGGESTED PRACTICAL / EXERCISES

The practical/exercises should be properly designed and implemented with an attempt to develop different types of skills **(outcomes in psychomotor and affective domain)** so that students are able to acquire the competencies/programme outcomes. Following is the list of practical exercises for guidance.

Note*: Here only outcomes mainly in psychomotor domain are listed as practical/exercises. However, if these practical/exercises are completed appropriately, they would also lead to development of certain outcomes in affective domain which would in turn lead to development of* ***Course Outcomes*** *related to affective domain. Thus over all development of* ***Programme Outcomes (****as given in a common list at the beginning of curriculum document for this programme) would be assured.*

Faculty should refer to that common list and should ensure that students also acquire outcomes

in affective domain which are required for overall achievement of Programme Outcomes/Course Outcomes.

S. No.	Unit No.	Practical/Exercise (Outcomes in Psychomotor Domain)	Approx. Hours Required
1	I	Separate medicine from plant extract	2
2	I	Synthesise pharmaceutical ingredient in laboratory conditions	2
3	I	Prepare pharmaceutical product by fermentation	4
4	II	Preserve milk by application of heat sterilization	2
5	II	Prepare chart of sterilization techniques	2
6	III	Prepare chart of clean facility development	2
7	IV	Prepare tablets	2
8	IV	Demonstrate some excipients	2
9	IV	Prepare ointment product	2
10	IV	Prepare cream product	2
11	IV	Prepare solution product	2
12	IV	Prepare suspension product	2
13	IV	Prepare an emulsion product	2
14	V	Prepare some packaging materials/Demonstrate packaging process for some drug	2
		Total	**30**

8. SUGGESTED STUDENT ACTIVITIES

Following is the list of proposed student activities. These could be individual and group based.

i. Explore internet, visit websites of reputed pharmaceutical companies and prepare ppt presentations on different topics (in group of four-five) and present in class
ii. Study (in group of four-five) the design of some real pharmaceutical production plant and identify good features of design and also weaknesses in it, present in class to have a group discussion.
iii. Survey market for different types of packaging available for pharmaceutical items and identify their features (commercial as well medicinal), further explore packaging processes required for such type of packaging.

9. SPECIAL INSTRCTIONAL STRATEGY (If Any)

i. Show animations/ videos and drawings/models of pharmaceutical production processes
ii. Arrange visit to nearby API production plants and formulation plants
iii. Arrange expert lectures.

10 SUGGESTED LEARNING RESOURCES

A) Books

S. No.	Title of Books	Author	Publication
1	Pharmaceutical Process Engineering	Hickey, Anthony J.;David Ganderton	Marcel Dekker Inc. USA, 2001
2	Pharmaceutical Manufacturing handbook	Gad, Shayne Cox	John Wiley and Sons, 2008
3	Good pharmaceutical Manufacturing practice	Sharp, John	CRC press, New York, 2005

B) Major Equipment/Materials with Broad Specifications

i. Glassware: Conical flask, burette, pipette, round bottom flask, measuring cylinder, beaker
ii. Glass Assembly: Round bottom flask, condenser, Separating funnel
iii. Burner
iv. Weight balance (minimum 0.1gm)
v. Heating and cooling bath
vi. Refrigerator

C) Software/Learning Websites

i. www.pharmaceuticalonline.com
ii. www.pharmaceutical-technology.com
iii. www.pharmamanufacturing.com
iv. www.worldpharmaceuticals.net

11. COURSE CURRICULUM DEVELOPMENT COMMITTEE

Faculty Members from Polytechnics

- **Prof. N. N. Hansalia**, Lecturer in Chemical Engineering, Government Polytechnic, Rajkot
- **Prof R. P. Hadiya**, Lecturer in Chemical Engineering, Government Polytechnic, Rajkot
- **Prof (Smt.) K. J. Sareriya**, Lecturer in Chemical Engineering, Government Polytechnic, Rajkot
- **Prof M. R. Aacharya**, Lecturer in Chemical Engineering, Government Polytechnic, Gandhinagar.

Coordinator and Faculty Members from NITTTR Bhopal

- **Dr. Bashirullah Shaikh**, Assistant Professor, Department of Applied Sciences.
- **Dr. Joshua Earnest**, Professor, Department of Electrical & Electronics Engineering.