B. Tech. Semester IV

Subject Name: Pharma Technology -API & Formulation **Subject Code:** BTCH14502

Type of course: Professional Elective Course

Prerequisite: Basic calculations in chemical engineering, Unit operations and unit processes.

Rationale: This course offers basic understanding of Pharmaceutical industries, API development and dosages.

Teaching and Examination Scheme:

TEACHING SCHEME				Theory Marks			Practical Marks		Total
L	T	P	C	TEE	CA1	CA2	TEP	CA3	100
3	0	0	3	60	25	15	--	--	

CA1: Continuous Assessment (assignments/projects/open book tests/closed book tests **CA2:** Sincerity in attending classes/class tests/ timely submissions of assignments/self-learning attitude/solving advanced problems **TEE:** Term End Examination **TEP:** Term End Practical Exam (Performance and viva on practical skills learned in course) **CA3:** Regular submission of Lab work/Quality of work submitted/Active participation in lab sessions/viva on practical skills learned in course

Content:

Sr. No.	Topics	Teaching Hrs.	Module % Weightage
1.	**Introduction to Pharmaceutical Industry** Classification of pharmaceutical dosage forms and routes of drug administration. Origin and Development of the Pharmacopoeia-IP/BP/USP, Introduction to monographs, Regulatory bodies. Active Pharmaceutical ingredients (APIs) & intermediates.	5	12
2.	**Unit Processes and unit operations involved in Pharma Industry :** Study of selected unit Processes and unit operations. Design, Working Principle, Validation and Cleaning Strategies, Powder Processing Area (PPA) – Conditions, Validation and Cleaning processes.	5	15
3	**Synthesis of selected API** Manufacturing of Insulin, Salicylic acid and Methyl Salicylate, Penicillin, Erythromycin and Streptomycin with due focus on major engineering problems, types of processes, scaleup and special considerations with respect to manufacturing facilities.	5	12
4	**Solid Formulation and Semisolids Formulation** Study of excipients used in Gastro Retentive, Mucoadhesive Systems and Colon Specific and Sustained Release pills, Pulsatile Drug Delivery Systems. Formulation and development of mouth dissolving Tablets, Taste Masking Formulation, Sublingual and Buccal Formulations. Basics of Process Automation of Solid Dosage Form Production. Semisolid Formulation with Special Reference to Penetration, Enhancers, Emulgels, Semisolids based on Liposomes, Niosomes.	7	15

5	**Liquid Formulations** Study of Multiple Emulsion, Micro Emulsion including Self Emulsified Drug Delivery Systems and Self Micro Emulsified Drug Delivery Systems. Study of Advances in Liquid Formulation of specific drugs	5	12
6	**Inhalation Aerosols** Basic Components of Aerosol Formulations. Types of inhalation products and their clinical Role, Therapeutic Aerosols, Metered Dose Inhalers, Dry powder Inhalers	4	10
7	**Regulatory aspects of pharmaceutical packaging, specification and quality**	5	12
8	**Current Good Manufacturing Practices, laboratory practices, distribution practices.**	9	12

Suggested Specification table with Marks (Theory/Practical):

% Distribution of Marks					
R Level	**U Level**	**A Level**	**N Level**	**E Level**	**C Level**
30	30	15	15	05	05

Legends: R: Remembrance, **U:** Understanding; **A:** Application, **N:** Analyze, **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 Text Books:

Sr. No.	Title of book /article	Author(s)	Publisher and details like ISBN	Year of publication	Publication Edition
1	Unit Processes in Pharmacy	Ganderton David	Elsevier Ltd.		
2	The Theory and Practice of Industrial Pharmacy	L. Lachman	CBS Publishers		
3	Modern Pharmaceutics	Gilbert and S. Banker, Christofer T. Rhodes	Marcel Decker Series		4th
4	Advanced Pharmaceutics: Physicochemical principles	Cherng-Ju uim	CRC Press –	2004	
5	Physical characterization of Pharmaceutical Solids - Volume 70	H. T. Brittain	Marcel-Decker Series		
6	The Wiley Encyclopedia of Packaging Technology	Kit L. Yam	Wiley ISBN: 9780470541388, 0470541385	2010	3rd
7	Fundamentals of Packaging Technology	Walter Soroka	Institute of Packaging Professionals	1995	4th

			ISBN: 9781930268258, 1930268254		
8	Good Pharmaceutical Manufacturing practice, Rational and compliance	John Sharp	CRC Press	2004	1st
9	Pharmaceutical Dosage Form And Drug Delivery Systems,	Howard C. Ansel, Nicholas G., Popovich, Lord V. Alien		1995	6th
10	Unit Processing of Organic Synthesis,	Groggins P. H	Tata-McGraw Hill, New Delhi,	2001	5th
11	Shreve's Chemical Process Industries	Austin G. T	McGraw-Hill	1994.	5th
12	Dryden's Outlines of Chemical Technology	Gopalarao. M. & Sitting M.	East-West Pub., New Delhi,	1997	2nd

Course Outcome:

Sr. No.	CO Statement After learning this subject, students will be able to	Marks % weightage
CO-1	Understand the role of unit operations in pharmaceutical manufacture	15
CO-2	Understand the mechanism of basic pharmaceutical units operation	20
CO-3	Understand the significance of particle size and particle shape in drug formulation.	20
CO-4	Interpret the key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices and Good Documentation Practices to offer customized solutions.	25
CO-5	Prepare and implement the check lists and SOPs for various Good Regulatory Practices	20

Mapping with POs:

	PO 1	PO 2	PO 3	PO 4	PO 5	PO 6	PO 7	PO 8	PO 9	PO1 0	PO1 1	PO1 2	PSO 1	PSO 2	PSO 3
CO-1	3	3	2	3	3	2	3	3	2	2	2	3	2	3	3
CO-2	3	3	2	1	1	3	3	3	3	2	2	3	2	3	3
CO-3	3	3	3	3	2	2	3	2	2	2	2	3	1	3	3
CO-4	2	2	1	3	3	3	2	3	2	3	3	3	3	2	2
CO-5	2	1	2	1	1	3	3	3	2	2	2	2	3	2	1
Rationale*	13	12	10	11	10	13	14	14	11	11	11	14	11	13	12

Rationale*: All COs are satisfying the well-defined POs & PSOs

SPECIMEN TASKS THAT CAN BE ASSIGNED: (CA2 component)

Sr No	Description
1	Prepare check lists/SOPs for various Good Regulatory Practices in pharma industry.
2	Technical report on any Pharma industry visit.

LIST OF PRACTICALS: NA

Major Equipment: NA

List of Open Source/learning website:

- **https://nptel.ac.in/courses/104102113**
- **https://nptel.ac.in/courses/103107127**