



GUJARAT TECHNOLOGICAL UNIVERSITY

Bachelor of Engineering

Subject Code: 3173618

Semester-VII

Subject Name : Technology of Sterile Products & Pharmaceutical Packaging Technology

Type of Course: Chemical Technology

Prerequisite: Studied department electives of previous semesters. Basic knowledge of Pharmaceutics is required.

Rationale: The main objective of this subject is to study the technology of sterile products and to know about the pharmaceutical packaging technology

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks				Total Marks
L	T	P		Theory Marks		Practical Marks		
			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	Sterile Dosage Forms: Pre-formulation & Formulation: Evolution, Large scale manufacture & packing with focus on equipment with reference Parenterals & ophthalmic dosage forms. Layout design & Unit operations related to above dosage forms	12
2	Blood products, medical sutures, ligatures	3
3	Stability evaluation: Stability evaluation of pharmaceutical dosage forms	4
4	Pharmaceutical Packaging: Introduction to Packaging, classification of Packaging, essential requirements, Functions of Packaging, Importance / significance of Pharma Packaging, Properties of Ideal Package, Packaging formats in Pharma Industry, FDA Definitions.	6
5	Introduction to packaging material, classifications of packaging materials. Introduction to glass, plastic and metal as packaging material, types of glass, plastic & metal and their advantages & disadvantages; type of glass, plastic and metal containers and their evaluation methods. Introduction to ancillary packing materials. Introduction to Closures & sealing system, classification of contemporary closures by their utility, Special closures, sealing system, closure liners, tamper proof closures	10
6	Introduction of blister packing and strip packing, types of blisters, blister & strip packaging process, advantages & disadvantages, machinery used for blister and strip packing, other packages, child resistant packing. Introduction, Packaging of Sterile Pharmaceuticals, Packaging Components, Packaging of Ophthalmics, Selection of Packaging, packaging of aerosols. Defects in packaging, New trends in pharmaceutical packaging.	10



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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)

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. Remington's Pharmaceutical Sciences, A.R. Gennaro Mac Pub. Co. Easton, Pennsylvania, 1990
2. Indian pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia.
3. Pharmaceutical Dosage Forms Vol. I & II, Liebermann, New York, Marcel Dekker, 1996.
4. Pharmaceutical Unit Operations : Coating, K Avis, A Shukla and R Chang, Interpharm Press, 1998
5. Pharmaceutical Production Facilities: Design & Applications, G.C.Cole, New York Ellis Horwood 1990
6. Textbook of Pharmaceutics, A C Bentley, Oxford University Press, 1969.
7. D. A. Dean, Roy Evans, Ian Hall. Pharmaceutical packaging technology. Tylor and Francis.
8. Edward J. Bauer, Pharmaceutical Packaging Handbook. Bausch and Lomb, Rochester, New York, USA
9. Wilmer A. Jenkins, Kenton R. Osborn. Packaging drugs and pharmaceuticals.

Course Outcomes:

Sr. No.	CO statement	Marks % weightage
1	To describe the pre-formulation & formulation of sterile products, the pharmaceutical packaging materials, pharmaceutical packing, blood products, sutures and ligatures.	33
2	To illustrate the method of manufacturing of the sterile products, pharmaceutical packaging.	24
3	To demonstrate the layout design and unit operations in the sterile dosage forms and design of pharmaceutical packing.	13
4	To analyse the large scale manufacturing of sterile products, defects and the new trends in pharmaceutical packing	13
5	To explain the equipments used for large manufacture of sterile products, the machinery used for pharmaceutical packaging.	10
6	To evaluate the sterile dosage forms, stability of pharmaceutical dosage forms, and the packaging materials.	7

List of experiments:

1. Preparation of Benzoic acid ointment



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2. Preparation & Determination of moisture content for effervescent granules
3. Formulation of Antacid gel
4. Isolation of Casein from milk
5. Pre-formulation studies.
6. To study the preparation of parenterals.
7. To study the preparation of ophthalmic ointments
8. To study the preparation of eye drops.

Major Equipment:

1. Mechanical stirrer & heating mantle
2. Sieves
3. Vacuum pump
4. Dryer

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