SEMESTER S6

BIOPHARMACEUTICAL TECHNOLOGY

Course Code	PEBBT636	CIE Marks	40
Teaching Hours/Week (L: T:P: R)	3:0:0:0	ESE Marks	60
Credits	3	Exam Hours	2 Hrs. 30 Min.
Prerequisites (if any)	NIL	Course Type	Theory

Course Objectives:

1. The subject will give exposure of fundamental knowledge in biopharmaceutical Technology for students to make their career in pharmaceutical industries.

SYLLABUS

Module No.	Syllabus Description	Contact Hours
1	Introduction to Different Pharmacopoeia, IP, BP, EUP, USP, Quality Control Standards, Standard Operating Procedure, GMP, cGMP, Quality analysis: QC, QA, Documentation, Market complaint analysis. USFDA, WHO, Patenting of Pharmaceutical products. Role of regulatory authorities in the biopharmaceutical industry.	9
2	Production of Biopharmaceuticals: Drug Discovery Process, Sources of drugs: Plants, Animals and Microbes. Current status and future prospectus. Approaches in drug design. Impact of genomics and related technologies in drug discovery. Delivery of biopharmaceuticals. Packaging and transport of biopharmaceutical products.	9
3	Downstream process: Techniques used for the product purification (HPLC, HPTLC, Column Chromatography, Gel Filtration, Centrifugation) Immunogenicity of biopharmaceuticals: Immunogenicity, Immunogenicity valency, Methods of factors contributing to immunogenicity valency 10 (product-related factors, host-related factors), Consequence of immunogenicity to biopharmaceuticals; Measurement of immunogenicity	9

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4	ADME, Case studies, Erythropoietin, Insulin, Somatotropin, Interleukin-2, Interferon Granulocytemacrophage-CSF, DNase, Factor VIIA, Factor IX, Factor VIII, Activated protein C, Tissue plasminogen activator, Monoclonal antibodies, Biosimilars - Advances and challenges.	**9**

Course Assessment Method
(CIE: 40 marks , ESE: 60 marks)

Continuous Internal Evaluation Marks (CIE):

Attendance	Assignment/ Microproject	Internal Examination-1 (Written)	Internal Examination- 2 (Written)	Total
5	**15**	**10**	**10**	**40**

End Semester Examination Marks (ESE)

In Part A, all questions need to be answered and in Part B, each student can choose any one full question out of two questions

Part A	Part B	Total
• 2 Questions from each module. • Total of 8 Questions, each carrying 3 marks **(8x3 =24marks)**	• Each question carries 9 marks. • Two questions will be given from each module, out of which 1 question should be answered. • Each question can have a maximum of 3 sub divisions. **(4x9 = 36 marks)**	**60**

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Course Outcomes (COs)

At the end of the course students should be able to:

Course Outcome		Bloom's Knowledge Level (KL)
CO1	Understand the discovery and regulatory process of biopharmaceuticals	**K2**
CO2	Discern the production, processing, packaging and transport of drug molecules	**K2**
CO3	Ascertain the use of various therapeutic proteins, antibodies and vaccines	**K3**
CO4	Analyze case study and industrial production of therapeutic proteins	**K4**

Note*: K1- Remember, K2- Understand, K3- Apply, K4- Analyse, K5- Evaluate, K6- Create*

CO-PO Mapping Table:

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12
CO1	3	3										2
CO2	3	3										2
CO3	3	3										2
CO4	3	3	2									2

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Text Books				
Sl. No	**Title of the Book**	**Name of the Author/s**	**Name of the Publisher**	**Edition and Year**
1	Biopharmaceuticals: Biochemistry & Biotechnology", 2nd Edition	Gary Walsh	Wiley Publications	2018
2	An Essential Guide to Biopharmaceuticals	David Aebisher	Nova Publications.	2015
3	"Biopharmaceuticals, an Industrial Perspective, 1st Edition	Gary Walsh	Springer.	2015

Reference Books				
Sl. No	**Title of the Book**	**Name of the Author/s**	**Name of the Publisher**	**Edition and Year**
1	Modern Biopharmaceuticals: Recent Success Stories, 1st Edition	Jörg Knäblein	Wiley Blackwell Publications.	2020
2	Biopharmaceuticals: Challenges and Opportunities1st Edition	Dr. Basanta Kumara Behera	CRC Press.	2015

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