AMITY UNIVERSITY
UTTAR PRADESH

Annexure '**AAB-CD-01**

Course Title: **Fundamentals & Applications of Pharmaceutical Biotechnology**

Course Code: BIOT337
Credit Units: 4
Level: UG

L	T	P/ S	SW/F W	TOTAL CREDIT UNITS
3	0	0	2	4

#	Course Title	weightage	
1	**Course Objectives:** The objective of this course is to understand and apply the basic concepts of Pharmaceutical Biotechnology for Commercial Units. The students will understand various classes of biotech products, regulations governing production and marketing of biotech & pharmaceutical products. The student will gain insight into the working of biotechonology & pharmaceutical industries .		
2	**Prerequisites:** Human physiology, Cell biology and Molecular Biology, Chemistry		
3	**Student Learning Outcomes:** After completing this course, the student will be able to: • Describe the mechanism of drugs development and drug discovery • Acquired knowledge regarding basic pharmacology • Comprehensive knowledge regarding the development and use of vaccines		

	• Identify and appraise the guide lines and ethical concerns regarding the use of drugs		
Course Contents / Syllabus:			
4	**Module I Introduction to Pharmaceutical Biotechnology**	**30% Weightage**	
	Introduction to Different branches of Pharmacy , History of Pharmaceutical Biotehnology sector, Growth., Future of Pharmaceutical Industry and its Product, Types of drugs and formulations from natural and synthetic sources, Recombinant therapeutics,		
5	**Module II Pharmacodynamics & Pharmacokinetics**	**20 % Weightage**	
	Principles of pharmacodynamics, Drug receptor interaction, Potency and therapeutic index , Pharmacodynamic models and biomarkers , General principles of pharmacokinetics , Route and timing of administration, Plasma concentration and its relationship to drug actions, Principles of bioavailability/bioequivalence , Adverse drug reactions		•
6	**Module III Biological and novel therapies**	**25 % Weightage**	
	Vaccines: Definition and Development of Vaccine, Classification of vaccines, DNA Vaccine, Monoclonal Antibodies based pharmaceuticals, Interferons, interleukins, growth factors, gene therapy and immunotherapy, Bioreductive drugs, Cancer vaccines.		
7	**Module IV Quality Standards**	**25 % Weightage**	
	Good Manufacturing Practice (GMP's), Good Lab Practices, Regulatory Issues and Drug Product Approval for Biopharmaceuticals		
8	**Pedagogy for Course Delivery:**		

Pedagogy for Course Delivery:

Lectures: 39

SW: 15

Presentation/ Seminar: 4

Class Test: 02

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Assessment/ Examination Scheme:

Theory L/T (%)	Lab/Practical/Studio (%)	End Term Examination
100	0	70%

Theory Assessment (L&T):

Continuous Assessment/Internal Assessment						End Term Examination
Components (Drop down)	**Class Test 1**	**Class Test 2**	**Home Assignment**	**Presentation/ Seminar**	Attendance	
Weightage (%)	5	10	10	-	5	70

Lab/ Practical/ Studio Assessment:NA

	Continuous Assessment/Internal Assessment				End Term Examination			
Components (Drop down	**Performance**	**Lab record**	**viva**	**Attendance**	**Lab record**	**Performance**	**Viva**	**Total**

	Weightage (%)										

Text & References

- Biopharmaceuticals and industrial prospective. Gray Walsh & B. Murphy, *Kluwer publishers*

(1999). Biopharmaceuticals. Gray Walsh, *Wiley John & Sons, Inc*. (2003).

- The practice of Medicinal chemistry. Camille G. Wermuth, Academic Press, (2003).

Any other Study Material: