

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**  
**(Established by Govt. of A.P., Act. No. 30 of 2008)**  
**ANANTHAPURAMU – 515 002 (A.P) INDIA**

**Course Structure for B. Pharmacy - R13 Regulations**  
**B. Pharmacy**

**IV-II Semester**

S.No	Course code	Subject	Th	Tu/Drg/Lab	Credits
1.	13R00801	Novel Drug Delivery Systems	3	1 - -	3
2.	13R00802	Pharmaceutical Biotechnology	3	1 - -	3
3.	13R00803	<b>MOOC - I</b> (Intellectual Property Rights)	3	1 - -	3
4.	13R00804	<b>MOOC – II</b> (Biostatistics and Design of Experiments)	3	1 - -	3
5.	13R00805	Comprehensive Viva Voce	-	- - -	3
6.	13R00806	Project Work & Seminar	-	- - 20	12
			12	4 20	27

**Note:** MOOC-I - NPTEL (<http://nptel.iitm.ac.in>) General  
MOOC-II - NPTEL (<http://nptel.ac.in>) Biotechnology

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR  
ANANTHAPURAMU**

<b>Subject</b>	NOVEL DRUG DELIVERY SYSTEMS	<b>Code</b>	13R00801
<b>Course year</b>	B. Pharmacy IV year	<b>Semester</b>	II
<b>Theory</b>	3 hrs/week	<b>Tutorial</b>	1hr/week
<b>End exam</b>	70 marks	<b>Internal exam</b>	30 marks
<b>Credits</b>	3		

**Scope:** The novel drug delivery systems course provide the knowledge about various novel and targeted systems- formulation, evaluation and applications

**Objectives:** To learn the novel technologies in drug delivery systems

**Outcomes:** Student must able to formulate the drug delivery systems for drugs.

**UNIT I**

Concepts of controlled release, sustained release, extended release, timed release and delayed release. Rationale behind the design of above delivery systems. Factors influencing the design and performance of sustained and controlled release dosage forms.

**UNIT II**

**Oral Control Drug Delivery Systems:** Fundamentals, Dissolution Controlled, Diffusion Controlled, Ion Exchange Resins, Osmotic based systems, pH Independent Systems, altered density systems and use of polymers in controlled drug delivery.

**UNIT III**

**Targeted Drug Delivery Systems:** Fundamentals and applications, formulation and evaluation of nano particles, resealed erythrocytes and liposomes and niosomes.

**UNIT IV**

**Transdermal Drug Delivery Systems:** Fundamentals, permeation of drugs across the skin, types of TDDS, Materials employed and Evaluation of TDDS.

**UNIT V**

**Mucoadhesive Delivery Systems:** Mechanism of bioadhesion, mucoadhesive materials, formulation and evaluation of Buccal and Nasal drug delivery systems.

**Text Books:**

1. Robinson JR and Vincent HL. *Controlled drug delivery fundamentals and applications*, 2ed, marcel dekker 2005.
2. Yiew Chien, *Novel drug delivery systems*, 2<sup>nd</sup> ed, marcel dekker 2003.

**Reference Books:**

1. N.K. Jain, *Advances in Control & Novel drug delivery*, CBS Publishers.
2. Lippincott Williams and Wilkins, *Remington Pharmaceutical Sciences*
3. E.A Rawlkins, *Bentley's Text Book of Pharmaceutics*, Elbspubl

# JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

## ANANTHAPURAMU

<b>Subject</b>	PHARMACEUTICAL BIOTECHNOLOGY	<b>Code</b>	13R00802
<b>Course Year</b>	B.Pharmacy IV year	<b>Sem</b>	II
<b>Theory</b>	3hrs/week	<b>Tutorial</b>	1hr/week
<b>End exam</b>	70 Marks	<b>Internal exam</b>	30Marks
<b>Credits</b>	3		

**Scope:** To study the Fermentation, Recombinant and Enzyme Technology

**Objective:** To know the various technologies types, design, preparation and operation

**Outcome:** The Student has to know the Application of below mentioned technologies and uses of immunological preparations.

### UNIT I

**Fermentation Technology:** Isolation, Selection, Screening of Industrially important microbes, Strain improvement. Types, design & operation of Bioreactor. Types of fermentations, optimization of fermentation process, Principle and Procedure involving in downstream process and effluent treatment. **Specific Fermentations:** Selection of organism, fermentation & purification of antibiotics (penicillin, streptomycin, tetracycline, and erythromycin), vitamins (riboflavin and cyanocobalamine), lactic acid, alcohol and acetone.

### UNIT II

**Recombinant DNA Technology:** Introduction to r-DNA technology and genetic engineering, steps involved in isolation of enzymes, vectors, recombination and cloning of genes. Production of bio technology derived therapeutic proteins like humulin, humatrop, activase, intron a, monoclonal antibodies by hybridoma technique, recombivax HB (hepatitis b). Stem cells and their applications.

### UNIT III

**Immunology & Immunological Preparations:** Principles of Immunity, Humoral immunity, cell mediated immunity, antigen – antibody reactions, hypersensitivity and its applications. Active & passive immunizations vaccine preparation, standardization & storage of BCG, cholera, smallpox, polio, typhus, tetanus toxoid, immuno serum & diagnostic agents.

## **UNIT IV**

**Enzyme Technology:** Techniques of immobilization of enzymes, factors affecting enzyme kinetics, advantages of immobilization over isolated enzymes. Study of enzymes such as hyaluronidase, penicillinase, streptokinase, streptodornase, amylase, protease etc. immobilization of bacteria & plant cells.

## **UNIT V**

Introductory study & applications of bioinformatics, proteomics and genomics, Nanobiotechnology, Gene therapy.

### ***Text Books:***

- 1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2 nd Ed, Publ- Panima publication cooperation, New Delhi.*
- 2. P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press.*
- 3. J. D. Watson, Recombinant DNA technology. 2 nd Edition, W.H. Freemann 1992.*
- 4. S.P.Vyas and Dixit, Pharmaceutical Biotechnology, CBS Publishers New Delhi.*

### ***Reference Books:***

- 1. Prescott and Dunne, "Industrial Microbiology" MC Graw Hill Book Company.*
- 2. K. Kielslich "Biotechnology" Vol 6, Verlegchemic, Switzerland.*
- 3. PF Standury & A. Whitaker, "Principles of fermentation Technology" Pergamon Press, Oxford.*
- 4. A. Wiseman, Handbook of enzyme biotechnology. 3<sup>rd</sup> Edition Elis Horwood.*
- 5. Alexande M Moo-young, Comprehensive Biotechnology, Pergamon Press, New York.*

**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR**  
**ANANTHAPURAMU**

<b>Subject</b>	<b>MOOC – I Intellectual Property Rights</b>	<b>Code</b>	<b>13R00803</b>
<b>Course year</b>	B. Pharmacy IV year	<b>Semester</b>	II
<b>Theory</b>	3 hrs/week	<b>Tutorial</b>	1hr/week
<b>End exam</b>	70 marks	<b>Internal exam</b>	30 marks
<b>Credits</b>	3		

**SCOPE:** The course is designed to introduce fundamental aspects of Intellectual property Rights to students who are going to play a major role in development and management of innovative projects in industries. The course introduces all aspects of the IPR Acts. It also includes case studies to demonstrate the application of the legal concepts in Science, Engineering, Technology and Creative Design.

**UNIT I**

**OVERVIEW OF INTELLECTUAL PROPERTY**

Introduction and the need for intellectual property right (IPR),  
IPR in India – Genesis and Development,  
IPR in abroad,  
Some important examples of IPR

**UNIT II**

**PATENTS AND UTILITY MODELS**

**PATENTS:** Patent document, searching a patent, Drafting of a patent, Filing of a patent  
Macro-economic impact of the patent system, Patent and kind of inventions protected by a patent, Granting of patent, Rights of a patent  
Protecting your inventions – extension in patent protection  
The different layers of the international patent system (national, regional and international options)  
**UTILITY MODELS:** Differences between a utility model and a patent, Trade secrets and know-how agreements.

**UNIT III**

**COPYRIGHTS, TRADEMARKS AND GEOGRAPHICAL INDICATIONS**

**COPYRIGHTS:** Copyright, things covered by copyright, period of copyright, Rights covered by copyrights and protection of copyrights.  
**RELATED RIGHTS:** Related rights, Distinction between related rights and copyright  
**TRADEMARKS:** Trademark –Rights, kind of signs, types and function of trademarks  
Registration, period, extension and protection of trademark.  
Well-known marks and their protection, Domain name and its relation to trademarks.  
**GEOGRAPHICAL INDICATIONS**  
Geographical indication - its protection, reasons for protection

**UNIT IV**

**INDUSTRIAL DESIGNS AND NEW PLANT VARIETIES**

**INDUSTRIAL DESIGNS:** Protection, kinds of protection, needs for protection  
**NEW PLANT VARIETIES:** New varieties of plants – protection and extension  
Breeder – Rights and protection

**UNIT V**

**UNFAIR COMPETITION AND ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS**

**UNFAIR COMPETITION:** Unfair competition, Relationship between unfair competition and intellectual property laws.  
**ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS:** Infringement of intellectual property rights, Enforcement Measures and Emerging Issues in Science and technologies.  
Overview of Biotechnology and Intellectual Property Rights in Biotechnology Research.  
Management - Licensing and Enforcing Intellectual Property, Commercializing Biotechnology Invention and Case studies of Biotechnology.  
Case studies of patents in other areas – Pharmaceutical Research

## TEXT BOOKS

T. M Murray and M.J. Mehlman, Encyclopedia of Ethical, Legal and Policy issues in Biotechnology, John Wiley & Sons 2000

## REFERENCES

1. P.N. Cheremisinoff, R.P. Ouellette and R.M. Bartholomew, Biotechnology Applications and Research, Technomic Publishing Co., Inc. USA, 1985
2. D. Balasubramaniam, C.F.A. Bryce, K. Dharmalingam, J. Green and K. Jayaraman, Concepts in Biotechnology, University Press (Orient Longman Ltd.), 2002
3. Bourgagaize, Jewell and Buiser, Biotechnology: Demystifying the Concepts, Wesley Longman, USA, 2000.
4. AjitParulekar and Sarita D' Souza, Indian Patents Law – Legal & Business Implications; Macmillan India Ltd , 2006.
5. B.L.Wadehra; Law Relating to Patents, Trade Marks, Copyright, Designs & Geographical Indications; Universal law Publishing Pvt. Ltd., India 2000
6. P. Narayanan; Law of Copyright and Industrial Designs; Eastern law House, Delhi , 2010

NPTEL: <http://nptel.ac.in/syllabus/syllabus.php?subjectId=110999906>

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR  
ANANTHAPURAMU

<b>Subject</b>	MOOC – II Biostatistics and Design of Experiments	<b>Code</b>	13R00804
<b>Course year</b>	B. Pharmacy IV year	<b>Semester</b>	II
<b>Theory</b>	3 hrs/week	<b>Tutorial</b>	1hr/week
<b>End exam</b>	70 marks	<b>Internal exam</b>	30 marks
<b>Credits</b>	3		

**SCOPE:** Biostatistics is the application of statistics to different topics in biology including medicine, pharmacy, public health science, agriculture and fishery. It involves the analysis of data from experiments; its interpretation and drawing conclusion from the results. It involves the application of statistical theory to real-world problems, the practice of designing and conducting biomedical experiments and clinical trials. Design of experiments is planning experimental strategy, screening a large number of parameters and selecting the important ones, determining the minimum number of experiments and deciding on the mode and manner in which experiment have to be conducted. The course encompasses topics such as distribution of data, sample size, tests of significance, data reduction, regression analysis, comparison of performance of drugs in clinical trials, design of experiments, screening and second order designs.

**UNIT I**

Introduction to Statistics

Various Distributions: Normal Distribution, sample and Population, Z distribution.

**UNIT II**

Test of Significance, t- test, F test, ANOVA.

**UNIT III**

2 test/odds ratio, Non-Parametric test, other tests.

**UNIT IV**

Design of Experiments: Introduction to design of experiments, screening designs – Data Analysis.

**UNIT V**

Higher order Designs - Data analysis

Regression Analysis – Data reduction

**REFERENCES:**

1. 'Biostatistics', KS Negi, AITB Publishers, Delhi.
2. 'Fundamentals of Biostatistics', Irfan Ali Khan, Ukaaz Publications
3. 'Biostatistics for Pharmacy', Khan and Khanum, Ukaaz Publications
4. 'Basic statistics and Pharmaceutical applications', J.E, Demuth, Merce & Dekker.
5. 'Applied statistics' by S.C.Gupta & V.K.Kapoor
6. 'Fundamentals of mathematical statistics' by S.C.Gupta & V.K.Kapoor

NPTEL: <http://nptel.ac.in/courses/102106051/>