Pharmaceutical Biotechnology (Theory)

Course code: BP403T

For B.Pharm IV semester students

As per the new PCI Syllabus 2026 (NEP 2020)

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Wiseleaf
Scientific Ventures Private Limited

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Edition: First Edition, September 2026

Language: English

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ISBN: 978-81-181068-0-7

9 788118 106807

MRP: 385/-

Published by: Wiseleaf Scientific Ventures Pvt. Ltd.

Address: Wework - Berger Delhi One Floor 19, C-001/A2, Sector 16b, Noida, Uttar Pradesh, 201301, India

Printed by: Patraloka | Prints and More

Immadihalli Main Rd, Immadihalli, Whitefield, Bengaluru, Karnataka 560066

Printed in India

Preface

Pharmaceutical biotechnology occupies the ground where molecular biology becomes medicine. A student meeting the subject in the fourth semester has learned anatomy, chemistry, and the classical pharmaceutics of small molecules, and now encounters a different kind of drug: the protein grown in a living cell, the antibody raised against a chosen target, the vaccine that trains an immune system, the gene delivered to correct a defect. This book was written to teach that field as one connected discipline rather than a list of techniques.

A single idea runs through every chapter, from the first page to the last: the arc from gene to product. To supply a human protein as a medicine, its gene is introduced into a host cell, the cell is grown so that it makes the protein, and the product is then recovered, purified, and proven identical in structure and activity to the natural molecule. The molecular biology and the pharmaceutics are two halves of one arc, and the book keeps both in view. Alongside it run three further threads that the reader will meet repeatedly: that every biotech medicine is inseparable from the analysis that characterizes it and the standard that releases it; that cells, microbes, and immune systems are harnessed as factories; and that each technology carries a ledger of benefit, risk, and ethics.

The book follows the BP403T syllabus unit by unit and covers every prescribed topic in full, from monoclonal antibodies and recombinant DNA technology through fermentation and industrial products to gene therapy, genomics, immunology, vaccines, and sera. It is written in a formal academic register, defines each term before using it, derives the mechanisms that examinations test rather than merely asserting them, and illustrates every method and classification with an original, print-ready figure or table. Each chapter opens with measurable learning outcomes tied to the Course Outcomes, and closes with a graded self-assessment of short-answer, long-answer, and multiple-choice questions with model answers written to the university marking pattern.

The aim throughout has been a book that serves three readers from the same pages: the first-time learner meeting the subject, the reviser consolidating it, and the examinee the night before the paper.

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Course Objectives

The objectives of this course are to:

1. Introduce the fundamental concepts of biological macromolecules, biosimilars, and modern vaccine technologies used in pharmaceutical biotechnology.
2. Explain the physicochemical and functional characterization methods used for the analysis and comparability assessment of biologics and biosimilars.
3. Develop understanding of upstream and downstream manufacturing processes involved in the production of biopharmaceuticals and vaccines.
4. Describe quality control, stability testing, and immunogenicity assessment procedures applied to biologics and vaccine products.
5. Familiarize students with regulatory frameworks and approval pathways governing biosimilars and vaccines in India and global markets.

Course Outcomes

Upon successful completion of this course, the student will be able to:

CO1. Explain the role of biotechnology in pharmaceutical sciences, including monoclonal antibodies and enzyme immobilization. *(Chapters 1–3)*

CO2. Apply genetic engineering and recombinant DNA technology for the production of biopharmaceuticals such as insulin, interferons, and vaccines. *(Chapters 4–6)*

CO3. Describe microbial biotransformation and analyze fermentation processes used in pharmaceutical industries. *(Chapters 7–9)*

CO4. Assess the role of bioinformatics and artificial intelligence in the Human Genome Project and personalized medicine. *(Chapters 10–11)*

CO5. Describe vaccine and sera development, including preparation, evaluation, standardization, and regulatory requirements, and critically evaluate challenges and emerging approaches. *(Chapters 12–13)*

Syllabus (BP403T · 45 hours)

Unit I (9 h): Introduction to biotechnology in pharmaceutical sciences; protein therapeutics; analytical characterization of proteins; monoclonal antibodies; antigens; enzyme immobilization; cell culture and immobilization techniques; pharmaceutical applications.

Unit II (9 h): Principles of genetic engineering; recombinant DNA technology; production of interferons, hepatitis-B vaccine, and insulin; polymerase chain reaction (PCR) and its applications; mutations and types of mutants.

Unit III (9 h): Microbial biotransformation; fermentation principles and process control; industrial production of alcohol, penicillins, citric acid, and vitamin B_{12}; blood products - collection, processing, and storage.

Unit IV (9 h): Gene therapy - types and methodologies; delivery systems; ethical concerns and challenges; Human Genome Project; role of bioinformatics and artificial intelligence in personalized medicine.

Unit V (9 h): Basics of immunology; types and generations of vaccines; immunization strategies; vaccine preparation, evaluation, and standardization; regulatory aspects; sera therapy; marketed products; challenges and newer approaches.

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Chapter 1. Foundations of Pharmaceutical Biotechnology and Protein Therapeutics

Learning outcomes

After this chapter the student will be able to:

1. *Define pharmaceutical biotechnology, state its scope, and trace the gene-to-product arc through the central dogma (DNA to RNA to protein). (CO1)*
2. *Distinguish a biotechnology-derived medicine from a traditional small-molecule drug across size, structure, route, manufacture, and immunogenicity. (CO1)*
3. *Classify protein therapeutics and give a named marketed example and clinical use for each class. (CO1; Objective 1)*
4. *Justify the use of proteins as drugs, weigh their advantages against their limitations, and define a biosimilar, explaining why it is "similar, not identical" to its reference product. (Objective 1)*
5. *Describe the four levels of protein structure and match each analytical method to the attribute it assesses. (Objective 2)*
6. *Explain the principle of comparability and how a biosimilar is characterized against its reference product. (Objective 2)*

Introduction

Pharmaceutical biotechnology is the branch of pharmaceutical science that uses living cells, or molecules derived from them, to manufacture and characterize medicines. The medicines it makes are called biopharmaceuticals or biologics: proteins and nucleic acids, or whole cells, produced by controlled biological systems rather than by stepwise chemical synthesis. Insulin for diabetes, erythropoietin for renal anaemia, clotting factors for haemophilia, and monoclonal antibodies for cancer and autoimmune disease all reach the patient through this route. The subject exists because a class of diseases could not be treated by the small organic molecules that fill the classical pharmacopoeia. A missing human protein cannot be replaced by a synthetic tablet of unrelated structure; it must be replaced by the protein itself, made faithfully and in quantity.

That single requirement organizes the whole discipline. To supply a human protein as a drug, its gene is introduced into a host cell, the cell is grown so that it reads the gene and secretes the protein, and the product is then recovered, purified and proven identical in structure and activity to the natural molecule. This is the throughline the book returns to in every chapter: **from gene to product.** The molecular biology (how a gene is expressed) and the pharmaceutics (how the product is purified and released) are two halves of one arc, and a B. Pharm graduate is expected to see both.

This opening chapter lays three foundations. The first is the definition and scope of the field and how its medicines differ from small-molecule drugs. The second is protein therapeutics, the largest class of biologics, organized by what the proteins do in the body. The third is analytical characterization, the set of methods that prove a protein drug is what it claims to be, because for a biologic the structure and the safety are inseparable from the analysis that demonstrates them.