

(B. Pharm.)
(Semester - III)

L	T	P	C
3	1	-	4

Course Code	BP303T
Course Title	Pharmaceutical Microbiology - Theory

Scope:

Study of all categories of microorganisms especially for the production of alcohol antibiotics, vaccines, vitamins, enzymes etc.

Objectives:

Upon completion of this course the student should be able to –

1. Understand methods of identification, cultivation and preservation of various microorganisms.
2. To understand the importance and implementation of sterilization in pharmaceutical processing and industry.
3. Learn sterility testing of pharmaceutical products.
4. Carried out microbiological standardization of Pharmaceuticals.
5. Understand the cell culture technology and its applications in pharmaceutical industries.

Course Learning Outcomes (CLO):

At the end of the course, students will be able to –

1. Understand fundamentals of pharmaceutical microbiology and cell culturing.
2. Identify various types of microorganisms.
3. Describe principle, operations and applications of various sterilization techniques.
4. Explain concept of disinfection, sterility testing, contamination and its prevention.
5. Practice aseptic processing for cultivation and isolation of microorganism.
6. Evaluate antibiotics, vitamins and amino acids by microbiological assay.

Syllabus:

Teaching hours: 45 Hours

UNIT I

10 Hours

Basics of Microbiology:

Introduction, history of microbiology, its branches, scope and its importance. Introduction to Prokaryotes and Eukaryotes. Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).

Types of Microscopy:

Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.

UNIT II

10 Hours

Identification of Bacteria:

Identification of bacteria using staining techniques (simple, Gram's & Acid fast staining) and biochemical tests (IMViC).

Sterilization:

Study of principle, procedure, merits, demerits and applications of physical, chemical, gaseous, radiation and mechanical method of sterilization and concept of D, Z and F Value. Evaluation of the efficiency of sterilization methods. Equipment employed in large scale sterilization. Sterility indicators.

UNIT III

10 Hours

Fungi and Viruses:

Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.

Disinfection:

Classification and mode of action of disinfectants, Factors influencing disinfection, antiseptics and their evaluation for bacteriostatic and bactericidal actions.

Sterility Testing:

Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.

UNIT IV

08 Hours

Aseptic Practice:

Designing of aseptic area, laminar flow equipment; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.

Microbiological Assay:

Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new antibiotic.

UNIT V

07 Hours

Contamination and Prevention:

Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage. Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.

Cell Culture:

Growth of animal cells in culture, general procedure for cell culture, Primary, established and transformed cell cultures. Application of cell cultures in pharmaceutical industry and research.

Tutorials

Teaching hours: 15 Hours

Tutorials will be based on above syllabus

Suggested Readings[^]: (Latest edition)

1. Denyer, Stephen P.; Hodges, Norman; Gorman, Sean P.; Gilmore, Brendan F. *Hugo and Russell's Pharmaceutical Microbiology*. Hoboken, NJ: Wiley-Blackwell
2. Prescott and Dunn's *Industrial Microbiology*. Delhi, India: CBS Publishers & Distributors.
3. Pelczar, Chan, Kreig. *Microbiology*. India: Tata McGraw-Hill Education

4. Malcolm, Harris. *Pharmaceutical Microbiology*. London, UK: Baillière, Tindall and Cox.
5. Rose Anthony H. *Industrial Microbiology*. London, UK: Butterworths
6. Frobisher, Hinsdill, Crabtree, Goodheart. *Fundamentals of Microbiology*. Japan: W.B. Saunders Company.
7. Carter, S.J. *Cooper and Gunn's Tutorial Pharmacy*. Delhi, India: CBS Publisher and Distribution.
8. Pepler, H. J.; Perlman, D. *Microbial Technology: Fermentation technology*. USA: Academic Press of University of Michigan.
9. Indian Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia
10. Ananthnarayan, Paniker. *Text Book of Microbiology*. Chennai, India: Orient-Longman Publisher.
11. Edward, Alcamo. *The Fundamentals of Microbiology*. USA: Jones & Bartlett Publishers
12. Jain N. K. *Pharmaceutical Microbiology*. Delhi, India: Vallabh Prakashan
13. Holt J. G.. *Bergey's Manual of Systematic Bacteriology*. Baltimore, MD, USA: Williams and Wilkins

L= Lecture, T= Tutorial, P= Practical, C= Credit

^ this is not an exhaustive list
