

Subject Code: BP303T	Subject Title: PHARMACEUTICAL MICROBIOLOGY - Theory
Pre-requisite Subject	- NONE -

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:

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

Teaching Scheme (Hours per week)				Evaluation Scheme (Marks)		
Lecture	Tutorial	Practical	Credit	Theory(T)		Total Marks
				University Assessment	Continuous Assessment	
						Theory
3	1	-	4	75	25	100

	Subject Contents		
Sr. No	Topic	Total Hours	Weight (%)
1	Unit -I • 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). • Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.	10	23
2	Unit -II • Identification of bacteria using staining techniques (simple, Gram’s &Acid fast staining) and biochemical tests (IMViC). • Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization. • Evaluation of the efficiency of sterilization methods. Equipments employed in large scale sterilization. • Sterility indicators.	10	23
3	Unit- III • Study of morphology, classification, reproduction/replication and cultivation of	10	23

	Fungi and Viruses. • Classification and mode of action of disinfectants • Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions • Evaluation of bactericidal & bacteriostatic. • Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.		
4	Unit-IV • Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification. • Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. • Assessment of a new antibiotic.	8	16
5	Unit-V • 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. • 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.	7	15

Recommended Books: (Latest Editions)

1. W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London.
2. Prescott and Dunn., Industrial Microbiology, 4th edition, CBS Publishers & Distributors, Delhi.
3. Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
4. Malcolm Harris, Balliere Tindall and Cox: Pharmaceutical Microbiology.
5. Rose: Industrial Microbiology.
6. Probisher, Hinsdill et al: Fundamentals of Microbiology, 9th ed. Japan
7. Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
8. Peppler: Microbial Technology.
9. I.P., B.P., U.S.P.- latest editions.
10. Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
11. Edward: Fundamentals of Microbiology.
12. N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
13. Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly company