

# LJ UNIVERSITY

## LJ INSTITUTE OF PHARMACY

### SEMESTER: V

**Subject Name: Pharmaceutical Microbiology**

**Subject Code: BP501TP**

**Scope:** To study all categories of microorganisms especially for the production of alcohol antibiotics, vaccines, vitamins enzymes

**Objectives:** Upon completion of the course the student shall 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.

**Teaching scheme and examination scheme:**

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	1	4	8	75	25	35	15

Sr. No.	Course Contents	Hours
1	<b>Introduction:</b> history of microbiology, its branches, scope and its importance. <b>Introduction to Prokaryotes and Eukaryotes :</b> Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses. <b>Isolation and preservation methods:</b> Isolation and preservation methods for pure cultures, cultivation of anaerobes, quantitative measurement of bacterial growth (total & viable count).	10
2	<b>Study of different types of Microscopy:</b> phase contrast microscopy, dark field microscopy and electron microscopy Identification of bacteria using staining techniques (simple, Gram's & Acid fast Staining) and biochemical tests (IMViC).	8
3	<b>Sterilization:</b> 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. Equipment employed in large scale Sterilization. Sterility indicators. <b>Disinfectants:</b> Classification and mode of action of disinfectants Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and Bactericidal actions. Evaluation of bactericidal & Bacteriostatic. <b>Sterility Testing:</b> Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.	12
4	<b>Aseptic Area:</b> Designing of aseptic area, laminar flow equipment; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.	08

	<b>Microbiological Assay:</b> Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids. Assessment of a new Antibiotic.	
5	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.	07
<b>Total Hours</b>		45

## Practical

1. Introduction and study of different equipments and processing, e.g., B.O.D. incubator, laminar flow, aseptic hood, autoclave, hot air sterilizer, deep freezer, refrigerator, microscopes used in experimental microbiology.
2. Sterilization of glassware, preparation and sterilization of media.
3. Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.
4. Staining methods- Simple, Grams staining and acid fast staining (Demonstration with practical).
5. Isolation of pure culture of micro-organisms by multiple streak plate technique and other techniques.
6. Microbiological assay of antibiotics by cup plate method and other methods
7. Motility determination by Hanging drop method.
8. Sterility testing of pharmaceuticals.
9. Bacteriological analysis of water
10. Biochemical test.

### Recommended Books:

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. Pepler: 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