B.Sc. III Year **Semester – V**

BIM -S501
SEC-3 PHARMACEUTICAL MICROBIOLOGY

MM : 100
Time : 3 hrs
L Credit
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Sessional : 30
ESE : 70
Pass Marks : 40

Total Hours: 60

Learning objectives:

- Students will learn about the basics of pharmaceutical microbiology and important microorganisms playing a role in pharmaceutics.
- To understand different products of microbial origin playing a key role in pharmaceutical applications.
- To understand the role of secondary metabolites in the pharmaceutical industry.
- To understand good practices and regulation involved in utilizing microbial product for pharmaceutical applications

Learning outcomes:

At the end of course students will be able to

- Describe how antibiotic work and resistance develop in microorganisms.
- Suggest good practices and regulation involved in utilizing microbial products for pharmaceutical applications.
- Design microbiology laboratory and explain the safety measures used in microbiology laboratory.
- Determine antibiotic sensitivity, MIC, MBC and other quality parameters of microbiology laboratory.

UNIT - I

Pharmaceutical premises: selection of area for a pharmaceutical premise, different components of a premise, Govt. norms for a premise. **(08 Lectures)**

UNIT - II

Good manufacturing practices (GMP) and its organization, good laboratory practice (GLP), cGMP; Operation of quality control (QC) and quality assurance (QA) units. **(12 Lectures)**

UNIT - III

Sterile area and its maintenance, environmental monitoring, types of environmental monitoring, methods of sterilization in pharma, disinfectants and antiseptics, evaluation of disinfectants. **(16 Lectures)**

UNIT - IV

Routine tests: antibiotic assay, microbial limit test (MLT), pyrogen tests (in rabbit, *in vitro*, endotoxin tests), preservative efficacy test.**(10 Lectures)**

UNIT - V

Safety in microbial laboratory: Biosafety cabinets ; Occurrence of laboratory infections: tuberculosis and serum Hepatitis in lab workers; Routes of infection in laboratory (infection through mouth, skin, respiratory tract)

(14 Lectures)

Suggested Reading

1. Dubey R.C. and Maheshwari, D.K. *A Textbook of Microbiology*. 3rd ed., S. Chand & Co, Ram Nagar, New Delhi, p. 1034. ISBN 81-219-2620-3
2. SS Purohit and AK Saluja. Pharmaceutical Microbiology, Agrobios (India), ISBN-13-9788177541939
3. CKJ Paniker. Test Book of Microbiology, Orient Longman