MMB - E302
ELECTIVE - II PHARMACEUTICAL MICROBIOLOGY

L T Credit
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Learning objectives:

- Student will learn about the basics of pharmaceutical microbiology and important microorganism playing role pharmaceutically.
- To understand different products of microbial origin playing key role in pharmaceutical application.
- To understand role of secondary metabolites in pharmaceutical industry.
- To understand good practices and regulation involved in utilizing microbial product for pharmaceutical application

Learning outcomes:

At the end of course student will be able to

- Explain the different components of immune system and how they provide defense against infection.
- Describe how antibiotic work and resistance develop in microorganism.
- suggest good practices and regulation involved in utilizing microbial product for pharmaceutical application.
- Design microbiology laboratory and explain the safety measures used in microbiology laboratory.
- Determine antibiotic sensitivity, MIC, MBC and other quality parameter of microbiology laboratory.

UNIT – I

Non-medicinal antimicrobial agents:- Bacteriostatic and bactericidal agents, factors affecting antimicrobial activity;non medicinal antimicrobial chemicals - sanitizers, disinfectants, antiseptics, antimicrobial action of phenols and phenolic compounds, alcohols, halogens, heavy metals, dyes, aldehydes, detergents, sources and preservation of microorganisms

(11 Lectures)

UNIT – II

Medicinal antimicrobial agents: History of chemotherapy – plants and arsenicals as therapeutics, Paul Ehrlich and his contributions, selective toxicity and target sites of drug action in microbes. Development ofsynthetic drugs – Sulphanamides, antitubercular compounds, nitrofurons, nalidixic acid, metronidazole group of drugs.Routes of drug administration: Merits and Demerits, First pass metabolism, Transport of drugs, Bioavailability, Adverse drug reaction. **(11 Lectures)**

UNIT – III

The ecology of microorganisms affecting pharmaceutical industry – The atmosphere, water, skin & respiratory flora of personnel, raw-materials, packing, equipments, building, utensils; types of microorganisms occurring in pharmaceutical products;microbial contamination and spoilage of pharmaceutical products (sterile injectibles, non injectibles, ophthalmic preparations and implants);sterilisation method: Steam sterilization, dry heat, radiation, gaseous, filteration, biological indicators

(13 Lectures)

UNIT – IV

Antibiotic sensitivity and drug resistance–Antibiotics – History and definition of antibiotics as drugs, types of antibiotics and their classification. Non-medical uses of antibiotics, Drug resistance, mechanism of drug resistance in bacteria,nutritional mutants and their importance, vitamin assay, amino acid assay, assay for growth inhibiting substances – assay for non-medicinal antimicrobials ;drug sensitivity testing methods, determination of MIC, E-test; Introduction to pharmacokinetics.

(13 Lectures)

UNIT – V

Quality control, quality assurance and validation: Good manufacturing practices (GMP) and good laboratory practices (GLP) in pharmaceutical industry;regulatory aspects of quality control; Quality assurance and quality management in pharmaceuticals ISO, WHO and US certification;safety in microbiology laboratory, Enumeration of Microorganism, Pharmacopoeial methods for the detection of specified micro-organisms, Sterility testing, MLT, Endotoxin test (LAL test), pyrogen test.

(12 Lectures)

Suggested Reading

1. S.S.Purohit, Pharmaceutical Microbiology, AGROBIOS
2. 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
3. ChandrakantKokare. Pharmaceutical Microbiology, Nirali Publisher