**Paper No. - MICC 414** **(Generic Elective)**

# Pharmaceutical Microbiology

**Credit – 04** **Max. Marks -100**

**Unit I: Principles of Antimicrobial chemotherapy. (0.8 Credit)**

Introduction and selection of antimicrobial agents

Concept of Bioassay, therapeutic index, MIC and $LD_{50}$

Penetrating defenses, as cellular permeability barriers, Cellular transport system and drug diffusion.

Definition and classification of antibiotics, with respect to their mechanism of action. Antibacterial spectrum, Structural activity and relationship (SAR), acquisition of drug resistance, pharmacokinetics and adverse drug effect β- Lactum(Penicillin, Amoxicillin, cefuroxime), aminoglycosides (Streptomycin, Gentamicin), Tetracyclines (Tetracyclin, doxicyclin) , Macrolides (Erythromycin, Azethreomycin), Peptide antibiotics (Bacitracin, polymixin, ), Sulphonamides (sulfamethoxazole), co-trimoxazole and quinolones (ciprofloxacin) Chloramphenicol, trimethoprim.

**Unit II: Molecular aspects of Antimicrobial Chemotherapy. (0.8 Credit)**

Definition, classification, Mechanism of action and examples of chemical disinfectants, antiseptic and preservatives.

Definition, classification, Mechanism of action and examples of antiviral (Acyclovir, zidovudine), Antifungal (amphotericin B, Fluconazole) and Antitumor (Bleomycin, ductinomycin ) antibiotics.

Drug delivery system in gene therapy. Approaches and safety considerations associated with gene therapy. Immunological problems associated to gene therapy. Pre-requisites and candidate diseases for human gene therapy.Drug carrier, Macromolecular, cellular, and synthetic Viral and non viral mediated gene delivery.

Introduction, concept and types of drug targeting, cellular level events of drug targeting, targeting ligands, blood cell receptors for endogenous compounds/ ligands, carrier and vesicular system for targeting, specialized liposomes for cellular drug targeting.

**Unit III: Microbial Production and spoilage of Pharmaceutical Products. (0.8 Credit)**

Manufacturing procedure and in-process control of Pharmaceutical products: Bacterial and Viral vaccine, sterile injectables, Solid dosage forms, liquid orals and Ointments

New Vaccine production: DNA vaccines, synthetic, peptide vaccines, multivalent subunit vaccines, edible vaccines and their trials.

Microbial production and applications of therapeutic / diagnostic enzymes: Asparaginase, Streptokinase, beta lactamases

Microbial production contamination and spoilage of Pharmaceutical products (sterile injectables, ophthalmic preparations and implements) and their sterilization

Applications of Biosensors in pharmaceutical industries.

**Unit IV: Regulatory Practices and Policies in Pharmaceutical Industries. (0.8 Credit)**

FDA, Govt. regulatory practices and polices.

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Concept of R & D and Financing R and D, Quality control and market planning.
Significance of IP, BP and USP.
Reimbursement of drugs, Biological and legislative aspects.
Rational drug design (Quantitative structure activity relation QSAR of drug) and computational aspect of drug design.
Screening and utilization of bioactive phytochemicals.
Patenting of drugs and Biological products

**Unit V: Quality Assurance and Validation. (0.8 Credit)**
Regulatory aspects of QC, QA, and QM.GMP , GLP and CMP in Pharma Industry. ISO, WHO, USFDA certification.Microbial Limit test of Pharma products. Sterility testing ,pyrogen testing and LAL test of Sterile Pharma products. Sterilization- heat, D- value, Z-value and survival curve, radioactive, gaseous and filtration. Chemical and biological indicators.Designing layout for microbiology laboratory.

## REFERENCES


1. Pharmaceutical Microbiology- Edited by W. B. Hugo & A.R. Russel Sixth Edition. Blackwell Scientific Publications.
2. Lippincott's illustrative Reviews: Pharmacology Edition: 02 Maryjnycck by Lippincott's review Publisher Pheladelphia 1997.
3. Principles of medicinal chemistry Vol. 1 by Kadam S.S., Mahadik K.R., Bothra K.G. Edition: 18, Nirali Publication.
4. Pharmacognosy by GokhleS.D., KoKateC.K.. Edition: 18, Nirali Publication.
5. Biotechnology – Expanding Horizon by B.D. Singh ., First Edition, Kalyani Publication, Delhi.
6. Analytical Microbiology- Edited by Fredrick Kavanagh volume I &II. Academic Press New York.
7. Pharmaceutical Biotechnology by S. P. Vyas& V.K. Dixit. CBS publishers & distributors, New Delhi.
8. Quniolinone antimicrobial agents- Edited by David C. Hooper, John S. Wolfson. ASM WashingtonDC.
9. Quality control in the Pharmaceutical industry - Edited by Murray S. Cooper Vol. 2, Academic Press New York.
10. Biotechnology- Edited by H.J. Rhem& Reed, vol 4 VCH publications, Federal Republic of Germany.
11. Good manufacturing practices for Pharmaceuticals. By Sydney H. Willing, Murray M. Tuckerman, Willam S. Hitchings IV. Second edition Mercel Dekker NC New York.


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