

Subject Code: 2SC2020305	Subject Title: Pharmaceutical Microbiology
COURSE TYPE: CORE COURSE	

Course Objective:

The course provides knowledge of microbes, interaction of microbes and humans. It also gives basic knowledge of sterility in Pharmaceuticals. It also covers drug design, discovery and other methods used in Pharmaceutical Microbiology.

Teaching scheme (hours) per week		Credit			Theory Marks		Practical Marks		Total
Theory	Practical	Theory	Practical	Total	Uni. Assessment	Cont. Assessment	Uni. Assessment	Cont. Assessment	
4	-	4	-	4	60	40	-	-	100

Unit	Content	Lectures	Weightage
1	Biology of Microorganisms 1. Introduction to Pharmaceutical Microbiology 2. Fundamental features of Microbiology: Microbial cultivation, Enumeration of microorganisms, pharmaceutical important of major categories of microorganisms. 3. Detection, identification, and characterization of organisms of pharmaceutical and medical significance 4. Medical significance of fungi, Fungal species identification methods, Antifungal therapy, Some clinically important fungi, Antibiotic production by fungi 5. Principles of microbial pathogenicity and epidemiology: Introduction, Portals of entry, Consolidation, Manifestation of disease, Damage to tissues, Recovery from infection: exit of microorganisms, Epidemiology of infectious disease.	15	25%
2	Prescribing therapeutics, Contamination and Infection control 1. Laboratory evaluation of antimicrobial agents 2. Bacterial resistance to antibiotics: Resistance to β-lactam antibiotics, glycopeptide antibiotics, tetracycline antibiotics, fluoroquinolone antibiotics, chloramphenicol and anti-mycobacterial therapy, Multiple drug resistance, Clinical resistance— MIC values, breakpoints, phenotype and outcome 3. Clinical uses of antimicrobial drugs: Principles of use of antimicrobial drugs, Clinical use, Antibiotic policies 4. Microbial spoilage, infection risk and contamination control	15	25%

	5. Chemical disinfectants, antiseptics and preservatives		
3	Pharmaceutical Production 1. Sterile pharmaceutical products 2. Principles of good manufacturing practice 3. Sterilization procedures and sterility assurance 4. The wider contribution of microbiology to the pharmaceutical sciences	15	25%
4	1. Drug Discovery and Development: Drug discovery process, Target Identification, Target Validation, Drug interactions with targets or receptors, preclinical and clinical development of drug, rational drug designing, Pharmacodynamics, Pharmacokinetics, and Toxicology 2. Regulatory practices of Pharmaceuticals: Brief Introduction to IP, BP, USP, FDA, GMP, GLP, ISO, WHO. 3. Factory and hospital hygiene: Introduction, Control of microbial contamination during manufacture: general aspects, Manufacture of sterile products, Aseptic areas: additional requirements.	15	25%

Learning Outcome:

Development of knowledge of Biopharmaceuticals, their development, designing, formulation and manufacturing
 .Generation of knowledge Regulatory processes of various commercialized Biopharmaceuticals

Reference Books:

1. Hugo and Russell's, Pharmaceutical Microbiology, Wiley India Pvt. Ltd.
2. Quality Assurance in Microbiology by Rajesh Bhatia
3. Drugs from discovery to approval by Rick Ng, WILEY-LISS
4. Pharmaceutical Microbiology by Ashutosh Kar