

Branch Name:	M.Sc. Biotechnology/ Microbiology
Program Code:	SC201/ SC202
Course Name:	Pharmaceutical Bioprocesses and Quality System
Course Code:	3SC2000203
Pre-requisite Course:	

Course Objectives:

- Develop understanding of microorganisms and their role in pharmaceutical sciences, including antimicrobial agents and resistance.
- Provide knowledge of antimicrobial evaluation, infection control, and contamination prevention.
- Familiarize students with clinical use of drugs, antibiotic policies, and challenges of multidrug resistance.
- Introduce principles of pharmaceutical production, including sterilization, GMP, and aseptic practices.
- Enhance understanding of drug discovery, pharmacology, and regulatory frameworks in the pharmaceutical industry.

Teaching and Examination Scheme:

Teaching Scheme (Hours per week)				Evaluation Scheme (Marks)				
Lecture (L)	Tutorial (T)	Practical (P)	Credit	Theory (Marks)		Practical (Marks)		Total (Marks)
				University Assessment	Continuous Assessment	University Assessment	Continuous Assessment	
4	--	--	4	50	50	--	--	100

Subject Contents:

Unit	Content	Lectures	Weightage
1	Biology of Microorganisms • Introduction to Pharmaceutical biology - Antibiotics: General properties of antibiotics. Antibacterial- β-lactam antibiotics, Amino glycosidic antibiotics, Macrolides, Tetracyclines, Sulfonamides, Polypeptide and glycopeptide, Chloramphenicol. - Antifungal- Nystatin, Griseofulvin, Amphotericin, Antiviral Ribavirin, Acyclovir, Ganciclovir, AZT, Antiprotozoal and Anti helminthic agents. - Mechanism of action of antibiotics – Bacterial cell wall, Cell membrane, Protein synthesis, Nucleic acid synthesis and antimetabolites- folate antagonism. Resistance- Mechanism of resistance against antibiotics.	15	25%
2	Prescribing therapeutics, Contamination and Infection control • Laboratory evaluation of antimicrobial agents • 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 • Clinical uses of antimicrobial drugs: Principles of use of antimicrobial drugs, Clinical use, Antibiotic policies • Microbial spoilage, infection risk and contamination control - Chemical disinfectants, antiseptics and preservatives	15	25%
3	Pharmaceutical Production • Sterile pharmaceutical products	15	25%

	- Principles of good manufacturing practice - Sterilization procedures and sterility assurance - The wider contribution of microbiology to the pharmaceutical sciences		
4	- 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 Regulatory practices of Pharmaceuticals: Brief Introduction to IP, BP, USP, FDA, GMP, GLP, ISO, WHO. - Factory and hospital hygiene: Introduction, Control of microbial contamination during manufacture: general aspects, Manufacture of sterile products, Aseptic areas: additional requirements.	15	25%

Text books:

- Prescot L.M., Jarley G.P Klein D.A —Microbiology Latest Edition Mc Graw Hill Company Inc b.
- Rawlins E.A. Bentley's Text Book of Pharmaceutics B ailliere Tindals 24-28 London Latest Edition
- Forbisher — Fundamentals of Microbiology Philidelphia W.B. Saunders. Latest Edition

Reference Books:

- Hugo and Russell's, Pharmaceutical Microbiology, Wiley India Pvt. Ltd.
- Quality Assurance in Microbiology by Rajesh Bhatia
- Drugs from discovery to approval by Rick Ng, WI LEY-LISS
- Pharmaceutical Microbiology by Ashutosh Kar
- Prescott L.M. Jarley G.P., Klein.D.A. — Microbiology.2nd edition WMC Brown Publishers, Oxford. Latest Edition e.
- War Roitt, Jonathan Brostoff, David male, — Immunology Latest Edition, Mosby-year book Europe Ltd, London.
- Pharmacopoeia of India, Govt of India, Latest Editions.

List of Open Source Software/learning website:

- <https://www.youtube.com/watch?v=iy3fjjHPt-U>

Course Learning Outcomes (CLO): On completion of this course, the students will be able to:

CLO	Description	Bloom's Taxonomy Level
CLO1	Define and explain the fundamental principles of pharmaceutical microbiology, including the role of microorganisms in drug development, health, and disease.	1 Remember 2 Understand
CLO2	Explain, apply, and analyze the classification, properties, and mechanisms of action of antimicrobial agents, including antibacterial, antifungal, antiviral, antiprotozoal, and antihelminthic drugs.	2 Understand 3 Apply 4 Analyze
CLO3	Apply, analyze, and evaluate antimicrobial resistance mechanisms, including multidrug resistance, and interpret clinical parameters such as MIC values, breakpoints, and therapeutic outcomes in prescribing practices.	3Apply 4 Analyze 5 Evaluate

CLO4	Explain, apply, analyze, and evaluate laboratory methods for antimicrobial testing, infection control strategies, microbial spoilage, and the use of disinfectants, antiseptics, and preservatives in pharmaceutical and healthcare settings.	2 Understand 3 Apply 4 Analyze 5 Evaluate
CLO5	Explain, apply, analyze, evaluate, and design pharmaceutical production processes, including sterile product manufacturing, implementation of Good Manufacturing Practices (GMP), sterilization techniques, and sterility assurance systems.	2 Understand 3 Apply 4 Analyze 5 Evaluate 6 Create
CLO6	Apply, analyze, evaluate, and design drug discovery and development strategies, including target identification and validation, pharmacodynamics, pharmacokinetics, toxicological evaluation, and regulatory compliance (FDA, WHO, GMP, GLP, ISO) for safe and effective therapeutics.	2 Understand 3 Apply 4 Analyze 5 Evaluate 6 Create

Mapping of CLO s with POs & PSOs

Course Learning Outcomes	Programme Outcomes (POs)																Programme Specific Outcome (PSOs)		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	PSO1	PSO2	PSO3
CLO1	1	1				2			1								1	2	3
CLO2	2	2				2			2								2	3	3
CLO3	2	2	1			2			2								3	3	3
CLO4	2	2	1			2			2				1				2	2	3
CLO5	2	2	3			2			2				3				1	2	3
CLO6	3	3	3			2			2				3				3	1	3

3: High, 2: Medium, 1: Low