Title of the Course: PHARMACEUTICAL MICROBIOLOGY [T]

Course Code: MIC-622

Number of Credits: 4, Theory

Contact hours: 60

Effective from Academic Year: 2022-23

Prerequisites:	Students should have basic knowledge of industrial microbiology, fermentation technology, maintenance and identification of cultures.	
Objectives:	• To understand the role and importance of microorganisms in pharmaceutical industries. • To summarize the concept of aseptic handling and preparation of sterilized pharmaceuticals processing. • To examine the quality maintenance and manufacturing of pharmaceutical formulations. • To demonstrate microbiological standardization of pharmaceuticals.	
Content:		
1.	**Introduction to Pharmaceutical Microbiology**	**(20)**
1.1	**History of Pharmaceutical Microbiology:** Contributions of Louis Pasteur, Edward Jenner, Alexander Fleming, Joseph Lister, Paul Ehrlich, Selman Waksman Milestones and developments in pharmaceutical microbiology History of profession of Pharmacy in India in relation to pharmacy education.	**3**
1.2	**Organization structure and layout of a pharmaceutical Industry:** Organizational structure and different departments in pharmaceutical industries, Location and layout of a pharmaceutical plant, Features of a good layout. **Good Practices:** Good Manufacturing Practices (cGMP) and Good Microbiology Laboratory Practices in a pharmaceutical industry.	**5**
1.3	**Regulatory approvals for Pharmaceutical Industry Certification (Sections relevant to microbiology):** Central Drugs Standard Control Organization (CDSCO), USFDA, MHRA (Medicines and Healthcare Products Regulatory Agency), PGA (Pharmacy Guild of Australia), WHO, The pharmacy Act, Drugs and Cosmetics Act, FSSAI, The Food Safety and Standards Act. **Guidance Documents for a Pharmaceutical Industry:** Indian Pharmacopoeia, British Pharmacopoeia/ European Pharmacopoeia, US Pharmacopoeia, Japan Pharmacopoeia **Documentation and Data Integrity:** ALCOA Principle, and ALCOA Plus.	**5**

1.4	**Biosafety Levels in Pharmaceutical Industries:** Biosafety cabinets, Working of biosafety cabinets, Protective clothing, Specification for BSL1, BSL-2, BSL-3, and BSL-4, Importance of biosafety in manufacturing pharmaceutical products.	**4**
1.5	**Discarding biohazardous waste:** Methodology of Disinfection, Autoclaving and Incineration.	**3**
2.	**Microbiological Quality Control and Sterility Assurance**	**20**
2.1	Concepts of Qualification, Validation & Calibration of equipment and instruments in microbiology laboratory. **Classes and types of pharmaceutical products:** Sterile and non-sterile formulations. **Sampling practices:** General principles, sampling of raw material, intermediate, finished products, primary packaging material, water, compressed air, and nitrogen gas. **Environmental monitoring:** Utilities, settle plate technique, air sampling, surface monitoring, and monitoring of personal gear. **Testing of utilities:** compressed air, nitrogen.	**5**
2.2	**Microbiological methods for pharmaceutical analysis:** **Media**: Preparation, Growth promoting and inhibitory properties of media, Sample preparation. **Enumeration:** Standard plate count, Direct microscopic counts, membrane filtration technique, most probable number, turbidimetric methods, Bioburden Test. **Microbiological examination of non-sterile products:** Pour plate, Membrane Filtration, MPN, Tests for specific microorganisms - Total Aerobic Microbial Count (TAMC), Total Yeast and Mold Count (TYMC), Tests for *E. coli*, *Salmonella, Pseudomonas aeruginosa,* and *S. aureus*. **Sterility Testing:** Membrane Filtration and Direct Inoculation Method. **Rapid Microbiological Methods**: ATP bioluminescence, Impedance, and Chemiluminescence. **Antimicrobial Effectiveness Testing:** Bioassay	**5**
2.3	**Advanced Identification systems of Microorganisms:** Automated Microbiological Identification Systems (BBL crystal identification system, BioMerieux Vitek, and Biolog). **Culture maintenance:** Basic culture and preservation methods, Lyophilization, Cryopreservation.	**3**
2.4	**Endotoxins and Pyrogens:** LAL Assay. Principles of Gel Clot Method, chromogenic end-point method, Kinetic turbidimetric assay, and Kinetic chromogenic assay.	**4**

2.5	**Sterilization Methods:** Pharmaceutical products, Autoclave Validation. Manufacturing of aseptically filled and terminally sterilized products. **Testing of disinfectants:** Surface challenge test	**3**
3.	**Drug Development**	**(10)**
3.1	**Preclinical development:** Toxicity testing – acute, sub-acute and chronic toxicity	**2**
3.2	Clinical development: Clinical trials (I, II, III and IV), Ethics in pharmaceutical industries.	**2**
3.3	**Pharmacokinetics:** Absorption Distribution Metabolism Excretion (ADME) and Bioavailability studies	**2**
3.4	Role of FDA in drug development (INDA, NDA)	**2**
3.5	Carriers and delivery systems, targeted drug delivery, sustained release	**2**
4.	**Production and Applications of Microbially Derived Pharmaceutical Agents:**	**(10)**
4.1	**Vaccines:** AIDS/ Malaria/ Covid-19	**3**
4.2	**Antimicrobial:** Streptomycin (antibacterial), Atazanavir (antiviral), Artimisinin (antiprotozoal)	**4**
4.3	Pre-biotics or Pro-biotics	**3**
Pedagogy:	Lectures/tutorials/assignments	
References/ Readings	Anjaneyulu Y, & Marayya R, Quality Assurance & Quality Management in Pharmaceutical Industry, Pharma Book Syndicate. (2017) Baird R.M., Hodges N.A. & Denyer S.P. Handbook of Microbiological Quality Control in Pharmaceutical and Medical Devices, Taylor and Francis Inc. (2000) D'Souza J., Killedar S.G., Biotechnology and Fermentation Process, Nirali Prakashan. (2008) Hugo W.B. & Russel A.D., Pharmaceutical Microbiology, Blackwell Scientific publications, Oxford London. (2004) Jain N.K., Pharmaceutical Product Development, CBS Publication. (2007) Kokare C. Pharmaceutical Microbiology, Nirali Prakashan. (2016) Lachman L., Lieberman H.A., Kanig J.L., The Theory and Practice of Industrial Pharmacy, Varghese Publishing House. (1986) Loftus B.T. & Nash R.A., Pharmaceutical Process Validation, Drugs and Pharmaceutical Science Series, Volume 23, Marcel	

	Dekker Inc. (1984) Shargel L. & Andrew B.C., Applied Biopharmaceutics & Pharmacokinetics, McGraw Hill Education. (2016) Latest Pharmacopeias, Acts, and Guidelines (as listed in the syllabus) (2022)	
Course Outcomes	● Integrate and connect the importance of microbiology in pharmaceutical ● Apply the knowledge of good manufacturing practices. ● Appraise, evaluate and implement the rules and regulations pertaining to microbiological standards in industry. ● Develop microbially derived pharmaceutical product.	