

Objective: Application of Microbes in production of pharmaceutically active compounds.

Credits Earned: 6 Credits

Course Outcomes: After completion of this course, student will be able to

- Identify different antimicrobial agents and it's mode of action.
- Process involved in Drug discovery and development
- Regulatory guidelines in pharmaceuticals product.

Pre-requisite of course: N.A.

Teaching and Examination Scheme

Teaching Scheme (Hours)			Credits	Theory Marks			Tutorial/ Practical Marks		Total Marks
Theory	Tutorial	Practical		ESE (E)	Mid Sem (M)	Internal (I)	Viva (V)	Practical (PR)	
5	0	2	6	50	30	20	25	25	150

Contents:

Unit	Topics	Contact Hours
1	Antibiotics and Synthetic antimicrobial agents: Antibiotics- β -lactam, aminoglycosides, tetracyclines, macrolides Antifungal antibiotics - Griseofulvin Antiviral drugs: Amantidines; Nucleoside analogues, Interferons, Peptide antibiotics Synthetic antibiotics - Sulphonamides; Chloramphenicol; Quinolone.	15
2	Mechanism of Action of Antibiotics: Inhibition of cell wall synthesis, Nucleic acid and Protein synthesis. Mode of Action of chemical antimicrobial agents. Study of resistance of microbes to antimicrobial agents.	15
3	Microbial contamination and control Microbiological Contamination: Product recalls; microbial limit standards. Preservation of microbial product: Type of Preservatives. The test methods for evaluation of formulations such as Preservative Efficacy Testing and Stability of Drugs & Stability Testing. Microbiological control: Risk Assessment, Disinfectants: Factors in Choice and Use of Disinfectants. Qualification of Disinfectants Test Methods and Validation of disinfectants.	18
4	Regulatory Aspects of Pharmaceuticals Quality assurance and Quality control of microbial contaminants in pharmaceutical industries with respect to FDA and WHO (GMP and GLP). Their maintenance and requirement criteria as per Indian Pharmacopeia.	12
	Total Hours	60

Microbiology**References:**

1. Hugo, WB and Russell, AD. *Pharmaceutical Microbiology*, (2003). Blackwell Science, Oxford, UK.
2. Sandle, T, *Pharmaceutical Microbiology*, (2016) Elsevier, 80 High Street, Sawston, Cambridge, CB22 3HJ, UK.
3. Krogsgaard L, Lilijefors T. and Madsen, U. *Textbook of Drug Design and Discovery*, (2004). Taylor and Francis, London.
4. Geoffrey Hanlon and Norman Hodges. *Essential Microbiology for pharmacy and pharmaceutical science*. (2013).Wiley Blackwell.
5. S. P. Vyas & V. K. Dixit. *Pharmaceutical Biotechnology*. (2003) CBS Publishers & Distributors, New Delhi.
6. Bhatia R and Ichhpujani RL. *Quality Assurance in Microbiology*. (1995). CBS Publishers, New Delhi.
7. Gregory Gregoriadis. *Drug Carriers in biology & Medicine*. (2001). Academic Press New York.
8. Davis, B. D., Dulbecco, R, Eisen, H. N., Ginsberg, R. S. *Microbiology*. (1990). Harper and Row Publishers, Singapore.

Instructional Method:

- d. The course delivery method will depend upon the requirement of content and need of students. The teacher in addition to conventional teaching method by black board, may also use any of tools such as demonstration, role play, Quiz, brainstorming, etc.
- e. The internal evaluation will be done on the basis of continuous evaluation of students in the class-room in the form of attendance, assignments, verbal interactions etc.
- f. Students will use supplementary resources such as online videos, NPTEL videos, e-courses, Virtual Laboratory.

List of Practical

1	Antibiotic sensitivity assay
2	Microbial examination of Non-sterile products
3	Sterility testing of different locations of production area and packaging area
4	Bio burden estimation of package material or medical devices
5	To check the effect of preservative in different formulations
6	To check the effect of disinfectant
7	To prepare various pharmaceutical formulations: Ointment, Emulsion, Chemical Depilatory
8	To formulate liposomes