



**Gyanmanjari**  
Innovative University

**Course Syllabus**  
**Gyanmanjari Pharmacy College**  
**Semester-3(B.Pharm.)**

**Subject:** Pharmaceutical Microbiology (BPHBP13312)

**Type of course:** Major

**Prerequisite:** NA

**Rationale:** The course involves the study of microorganisms associated with the manufacture of pharmaceuticals e.g. minimizing the number of microorganisms in a process environment, excluding microorganisms and microbial byproducts like exotoxin and endotoxin from water and other starting materials, and this subject in pharmaceutical industry are integral to drug development, ensuring the safety and effectiveness of pharmaceutical products, and contributing to advancements in medical science.

**Teaching and Examination Scheme:**

Teaching Scheme			Credits	Examination Marks					Total Marks
CI	T	P	C	Theory Marks		Practical Marks		CA	
				ESE	MSE	V	P	ALA	
3	1	4	6	75	25	10	25	15	150

*Legends: CI-Class Room Instructions; T – Tutorial; P - Practical; C – Credit; ESE - End Semester Examination; MSE- Mid Semester Examination; V – Viva; CA - Continuous Assessment; ALA- Active Learning Activities.*

**Course Content:**

Chapter No.	Course content	Hrs	% Weightage
1.	<ul style="list-style-type: none"> <li>• Introduction, history of microbiology, its branches, scope and its Importance.</li> <li>• Introduction to Prokaryotes and Eukaryotes</li> <li>• Study of ultra-structure and morphological classification of bacteria, nutritional requirements, raw materials used for culture media and physical parameters for growth, growth curve, isolation and preservation methods for pure cultures, cultivation of anaerobes.</li> <li>• Quantitative measurement of bacterial growth (total &amp; viable count).</li> </ul>	10	22





	<ul style="list-style-type: none"> <li>• Study of different types of phase contrast microscopy, dark field microscopy and electron microscopy.</li> </ul>		
2.	<ul style="list-style-type: none"> <li>• Identification of bacteria using staining techniques (simple, Gram's &amp; acid fast staining) and biochemical tests (IMViC).</li> <li>• Study of principle, procedure, merits, demerits and applications of physical, chemical gaseous, radiation and mechanical method of sterilization.</li> <li>• Evaluation of the efficiency of sterilization methods.</li> <li>• Equipments employed in large scale sterilization.</li> <li>• Sterility indicators.</li> </ul>	10	22
3.	<ul style="list-style-type: none"> <li>• Study of morphology, classification, reproduction/replication and cultivation of Fungi and Viruses.</li> <li>• Classification and mode of action of disinfectants</li> <li>• Factors influencing disinfection, antiseptics and their evaluation. For bacteriostatic and bactericidal actions Evaluation of bactericidal &amp; Bacteriostatic.</li> <li>• Sterility testing of products (solids, liquids, ophthalmic and other sterile products) according to IP, BP and USP.</li> </ul>	10	22
4.	<ul style="list-style-type: none"> <li>• Designing of aseptic area, laminar flow equipments; study of different sources of contamination in an aseptic area and methods of prevention, clean area classification.</li> <li>• Principles and methods of different microbiological assay. Methods for standardization of antibiotics, vitamins and amino acids.</li> <li>• Assessment of a new antibiotic.</li> </ul>	8	18
5.	<ul style="list-style-type: none"> <li>• Types of spoilage, factors affecting the microbial spoilage of pharmaceutical products, sources and types of microbial contaminants, assessment of microbial contamination and spoilage.</li> <li>• Preservation of pharmaceutical products using antimicrobial agents, evaluation of microbial stability of formulations.</li> </ul>	7	16





**Continuous Assessment:**

(For each activity maximum-minimum range is 5 to 10 marks)

Sr. No	Active Learning Activities	Marks
1.	<b>Urine Samples Module</b> (microbiological analysis of clinical urine samples): Faculty will provide cases or urine abnormal report and students group or individual has to analyze and summarize and upload on GMIU web portal.	5
2.	<b>Problem Based Learning:</b> Divide the class into groups and assign each group a specific aspect of the investigation (e.g., manufacturing equipment, personnel, and raw materials). Have each group present their findings and recommendations to the class and explanation in details upload on GMIU web portal.	10
Total		15

**Suggested Specification table with Marks (Theory):75**

Distribution of Theory Marks (Revised Bloom's Taxonomy)						
Level	Remembrance (R)	Understanding (U)	Application (A)	Analyze (N)	Evaluate (E)	Create (C)
Weightage	25%	40 %	20%	05%	10%	-

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

**Course Outcome:**

After learning the course the students should be able to:	
CO1	Explain the importance of microbial quality control.
CO2	Apply microbiological principles to solve practical problems related to pharmaceutical microbiology, such as contamination issues in manufacturing.
CO3	Develop basic laboratory skills in microbiological techniques, including aseptic techniques, isolation, and identification of microorganisms.
CO4	Identify common microbial pathogens and understand their role in infectious diseases, as well as the principles of antimicrobial therapy.
CO5	Familiar with regulatory guidelines and requirements related to microbial quality control in pharmaceutical manufacturing, including Good Manufacturing Practices (GMP).



**List of Practical**

Sr. No	Descriptions	Unit No	Hrs
1.	Introduction and study of different equipments and processing B.O.D. incubator, laminar flow, aseptic hood and microscopes used in experimental microbiology.	1	4
2.	Introduction and study of different equipments and processing autoclave, hot air sterilizer, deep freezer and refrigerator used in experimental microbiology.	1	4
3.	Sterilization of glassware, preparation and sterilization of media	1	4
4.	Sub culturing of bacteria and fungus. Nutrient stabs and slants preparations.	2	4
5.	To identify the given bacterial culture by Simple staining and Grams staining method. (Demonstration with practical).	2	4
6.	Acid Fast Staining of Bacteria (Mycobacterium species).	1	4
7.	Isolation of pure culture by the use of plate, streak plate and spread plate techniques.	3	4
8.	To determine the potency of given sample of penicillin and to construct a standard graph.	3	4
9.	To determine microbial assay of penicillin by disc plate method		
10.	To observe the motility of bacteria in a given bacterial culture by hanging drop method	3	4
11.	To determine the microbiological water Quality.	3	4
12.	To demonstrate bactericidal effect of UV light and View of chemical antimicrobial on bacteria	4	4
13.	To study the characterization of microbes through biochemical reactions.( Indole Test))	3	4
14.	To study the characterization of microbes through biochemical reactions.( MR-VP TEST)	4	4
15.	To study the characterization of microbes through biochemical reactions.( IMVIC test)	4	4
		Total	60

**Instructional Method:**

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, MOOCs etc.



From the content 10% topics are suggested for flipped mode instruction.

Students will use supplementary resources such as online videos, NPTEL/SWAYAM videos, e-courses, Virtual Laboratory

The internal evaluation will be done on the basis of Active Learning Assignment

Practical/Viva examination will be conducted at the end of semester for evaluation of performance of students in laboratory.

### Reference Books:

- [1] W.B. Hugo and A.D. Russel: Pharmaceutical Microbiology, Blackwell Scientific Publications, Oxford London.
- [2] Prescott and Dunn. Industrial Microbiology, 4<sup>th</sup> edition, CBS Publishers & Distributors, Delhi.
- [3] Pelczar, Chan Kreig, Microbiology, Tata McGraw Hill edn.
- [4] Malcolm Harris, Balliere Tindal and Cox: Pharmaceutical Microbiology.
- [5] Rose: Industrial Microbiology.
- [6] Probisher, Hinsdill et al: Fundamentals of Microbiology, 9<sup>th</sup> ed. Japan
- [7] Cooper and Gunn's: Tutorial Pharmacy, CBS Publisher and Distribution.
- [8] Pepler: Microbial Technology.
- [9] I.P., B.P., U.S.P.- latest editions.
- [10] Ananthnarayan : Text Book of Microbiology, Orient-Longman, Chennai
- [11] Edward: Fundamentals of Microbiology.
- [12] N.K.Jain: Pharmaceutical Microbiology, Vallabh Prakashan, Delhi
- [13] Bergeys manual of systematic bacteriology, Williams and Wilkins- A Waverly Company

