

Course outline

Course Description

In this course the students will apply some of the knowledge they gained in pharmaceutical microbiology & Sterilization and sterile manufacturing. The students will prepare growth media, perform tests used to monitor the environment (air, personnel, water, etc). Also the students will perform microbial identification through gram staining. The students will perform and evaluate different Sterilization techniques. The students will perform various in vitro tests for evaluating antimicrobial agents & will perform some microbial quality tests for sterile and non-sterile products.

Course Objectives

By the end of this practical the student will develop the following skills

1. Explain and correctly demonstrate use of the scientific method
2. Transfer living microbes using aseptic technique.
3. Demonstrate proficiency and use of the following in the laboratory: streak plate isolation technique; bacterial staining techniques; wet mounts; and proper culture handling.
4. Visually recognize and explain the macroscopic and microscopic characteristics of fungi, protozoa, and bacteria.
5. Understand and explain environmental factors that influence microbes.
6. Properly obtain, culture, identify, and explain microorganisms in environmental cultures.
7. Measure the efficacy and potency of different antimicrobial agents
8. use different sterilization methods and designing optimum sterilization cycles
9. Monitor microbiological quality for both sterile and non-sterile dosage forms

Intended Learning Outcomes (ILOs)

A. Knowledge and Understanding: When students have completed the program, they will be able to:

A-1 Know the general laboratory safety awareness practical skills.

A-2 Know the different qualitative and quantitative tests that are used to differentiate bacterial growth.

A-3 Understand the basic structure and classification of bacteria

A-4 Analyze the mechanism of infection, Susceptibility and resistance of bacteria.

A-5 Evaluate microbial susceptibility towards different antimicrobial agents.

A-6 Evaluate and apply various sterilization techniques

A-7 Know the different techniques that are used to monitor microbial quality of the environment and pharmaceutical preparations.

A-8 Know the different methods that are used to control microbial contamination. A-9 Know the different methods used to identify microorganisms.

A-10 Know the different methods used to culture microorganisms and the different media used.

B. Essential for Practice and Care (Intellectual Skills): When students have completed the program, they will be able to:

B-1 Calculate and interpret the MIC of different antimicrobial agents.

B-2 Judge the microbial quality of different pharmaceutical preparation and environmental conditions.

B-4 Identify microorganisms macroscopically and microscopically. B-5 Quantifying microbial contamination.

C. Approach to Practice Pharmacy: When students have completed the programme they will be able to:

C-1 Practical skills of aseptic techniques.

C-2 Practical skills of handling microbial culture.

C-3 Practical skills of identifying and quantifying bacterial culture.

C-4 Practical skills of performing different susceptibility tests.

D. Personal and Professional Development: When students have completed the programme they gain the skills of:

D-1 Team work.

D-2 Time management.

D-3 Data collection, presentation and interpretation.

D-4 Written and oral communication.

D-5 Analysis.

**Reading List / References:
Supplementary Textbook(s)**

1. Textbook:

Pharmaceutical Microbiology Laboratory Manual

Course Contents					
Week	Credit Hours	ILOs	Topics	Teaching Procedure	Assessment methods
1	3	A B C D	Orientation, course outline, lab safety, lab tools, microscopy. -Aseptic technique -Appropriate hygienic practices -Hand wash	Lecturing	Class participation
2	3	A B C D	- Preparation of culture media under aseptic conditions. - Sources of microbial contamination -Quality assurance –microbial monitoring of environment	Lecturing discussion Practical work	Class participation Laboratory Report Lab work evaluation Assignment
3	3	A B C D	Culturing Methods and Plating Techniques	Lecturing discussion Practical work	Class participation Laboratory Report Lab work evaluation Assignment
4	3	A B C D	Bacterial Identification Simple staining, Gram staining and differential medium	Lecturing discussion Practical work	Class participation Laboratory Report Lab work evaluation Assignment
5	3	A B C D	Sterilization Methods and Principles	Lecturing discussion Practical work	Class participation Laboratory Report Lab work evaluation Assignment
7	3	A B C D	Testing of disinfectants	Lecturing discussion Practical work	Class participation Laboratory Report Lab work evaluation Assignment
8	3	A B C D	Qualitative methods used for the evaluation of bacteriostatic activity of different antimicrobial agents	Lecturing discussion Practical work	Class participation Laboratory Report Lab work evaluation Assignment
9	3	A B C D	Determination of the minimal inhibitor concentration (MIC) of a bacteriostatic substance by agar diffusion and broth dilution method	Lecturing discussion Practical work	Class participation Laboratory Report Lab work evaluation Assignment
10	3	A B C D	Sterility testing of a pharmaceutical product	Lecturing discussion Practical work	Class participation Laboratory Report Lab work evaluation Assignment

11	3	A B C D	Data handling and interpretation associated with heat sterilization processes	Lecturing discussion Practical work	Class participation Laboratory Report Lab work evaluation Assignment
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Grade Distribution		
Assessment	Grade	Date
1. Quizzes	15%	Not announced/ (4 quizzes)
2. Reports	10%	Weekly
3. Lab Evaluation (lab performance, readiness, etc)	10%	Weekly
4. Mid Exam (Practical)	25%	To be announced
5. Final Exam (Theoretical)	40%	To be announced
<p><u>Student Evaluation (out of 10):</u></p> <p>Each student is evaluated weekly based on the following points:</p> <ul style="list-style-type: none"> A. Attendance on time (2 mark) B. Behavior and adherence to basic lab requirements (e.g. Appearance: Lab-Coat, hair) (1.5 mark) C. Availability of Foil, Gloves, Markers, & Cleaning tools (2 mark) D. Balance & Machines Use & Tools Use & their Cleaning (1 mark) E. Team work (1 mark) F. Procedure: Preparation & Adherence & Time frame (2.5 mark) 		

Important regulations

- ◆ On average, students need to spend 3 hrs. of study and preparation weekly.
- ◆ Excellent attendance is expected. According to the university policy, students who miss more than 15% of the lecture hours with or without excuse will be dismissed from the course
- ◆ **Student Responsibilities:** You are responsible for all course material/assignments on the day they are presented or due. Carefully read through the following course guidelines:
- ◆ At the beginning of the lectures, be on time and don't leave before the end of the lecture without an accepted excuse.
- ◆ **Assignments** are due at the beginning of the class period on the date/time designated by the instructor.
- ◆ **Late course work is not accepted (e.g. projects, reports, papers...)**, unless otherwise indicated by the instructor. Work will only be accepted in an emergency situation.
- ◆ **Missed class notes** are not provided by the instructor and must be obtained from other students. See missed lab session below for more information.
- ◆ **Missed handouts** – may be picked up from the instructor or online if posted.
- ◆ **Missed exams and quizzes. Lab exams** are only offered at specified times and must be taken at that time. Exceptions to this will only be made for an extreme emergency (to be determined by the instructor). **Missed pre-lab quizzes** may not be made up and will result in a grade of zero for the missed quiz.
- ◆ **Missed lab session (excludes lab exam day).** In case of expected and valid excuse and if space is available you will be expected to attend another lab session to complete assigned work (you must contact your instructor to arrange this within 24 hours of the missed session). If this is not possible, and you are given an excused absence, **you will be expected to make up the work at an assigned time** for any clarification, please communicate with your instructor during his office hours or by appointment.

- ◆ ***If your excuse is not valid you will take zero evaluation in your missed lab (all lab related session work).***
 - ◆ ***Course Work - Incorrect content, formatting, general appearance, spelling, and grammar*** will result in point deductions from a student's work.
 - ◆ ***mobile*** and other electronic devices must be turned off while you are in class. During assessments, electronic devices that are on may result in a forfeiture of the assessment.
 - ◆ Listen well to the lecture and avoid side discussions, if you have a question, ask your instructor and not your colleague.
 - ◆ If you have any information, document your reference, i
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 - ◆ If you didn't, then you broke the intellectual property rights law and the law will be applied
 - For more information, visit the website:
 - o <http://www.plagiarism.org/>
- Exams are scheduled and offered at specified times throughout the semester, you are expected to attend all. If not, make-up exams will be offered for valid reasons. It may be different from regular exams in content and format.
- ◆ Cheating, academic misconduct, fabrication and plagiarism will not be tolerated, and the university policy will be applied.