



**The University of Jordan**

**Accreditation & Quality Assurance Center**

**COURSE Syllabus**

1	Course title	Pharmaceutical Microbiology II 1202441
2	Course number	1202441
3	Credit hours (theory, practical)	2 (theory)
	Contact hours (theory, practical)	2 (theory)
4	Prerequisites/corequisites	Prerequisite: 1202341 (Pharmaceutical Microbiology I)
5	Program title	BSc in Pharmacy and PharmD
6	Program code	
7	Awarding institution	The University of Jordan
8	Faculty	Pharmacy
9	Department	Pharmaceutics and Pharmaceutical Technology
10	Level of course	Undergraduate
11	Year of study and semester (s)	First semester of the 4 <sup>th</sup> year
12	Final Qualification	BSc in Pharmacy or PharmD
13	Other department (s) involved in teaching the course	N/A
14	Language of Instruction	English
15	Date of production/revision	31 January 2016

#### 16. Course Coordinator:

To be determined for each semester

#### 17. Course instructors:

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**18. Course Description:**

- Introduce the students for the concept of sterilization, disinfection, antisepsis and preservation.
- Introduce the students for the different chemical and physical methods used to control microbial contamination.
- Introduce the students for the methods used for the evaluation of antimicrobial efficacy and factors affecting it.
- Introduce the students for the principle of controlled environment, quality control and quality assurance.

**19. Course aims and outcomes:****A- Aims:**

1. Know the meaning of bactericidal, bacteriostatic and chemical sterilants.
2. Know the different biocides, their chemical nature, & their use
3. Know the methods used to evaluate biocidal agent activity
4. Know the factors that affect microbial spoilage, its outcome & how to protect the pharmaceutical products from it.
5. Know the principles of sterilization, methods & applications
6. How to select a suitable sterilization method
7. Know the principles of the controlled environment (aseptic and clean room facilities)

**B- Intended Learning Outcomes (ILOs): Upon successful completion of this course students will be able to ...****A. Knowledge and Understanding:** Student is expected to

- A1- Know the meaning of biocide and the difference between biocide and antibiotic
- A2- Know the meaning of disinfection, antisepsis, and preservation process
- A3- Know the meaning of bacteriocidal, bacteriostatic and chemical sterilants.
- A4- Know the different biocides in use, their chemical nature, their spectrum of activity and their mode of actions.
- A5- Know the different chemical and physical factors that affect the antimicrobial activity
- A6- Know the different in vitro tests used to evaluate the efficacy, the potency and the capacity of different biocides
- A7- Know the effect of microorganisms on the spoilage of pharmaceutical preparations
- A8- Know the principle of preservation
- A9- Know the different quality control and quality assurance measures for the control of microbial contamination
- A10- Know the principle of sterilization
- A11- Know the different methods used for sterilization
- A12- Know the different sterile products available in the markets
- A13- Know the principle of the controlled environment (aseptic and clean room facilities)

**B. Intellectual, Analytical and Cognitive Skills:** Student is expected to

- B1- Decide the best biocide to be used in different practical situations
- B2- Calculate the temperature and dilution coefficients of different antimicrobial agents and interpret the results towards their effect on the antimicrobial efficacy
- B3- Interpret the results of the different tests used to evaluate the antimicrobial efficacy
- B4- Decide the appropriate test to be performed on different pharmaceutical preparation so as to measure their microbial quality
- B5- Calculate the appropriate time/temp schedule for an autoclaving process to produce specific quality assurance
- B6- Decide the appropriate sterilization procedure for a certain object
- B7- Allocate the different measures to be taken to obtain an aseptic and clean environment and monitor those measures

**C. Subject-Specific Skills:** Student is expected to

- C1- Decide the suitable biocide to be used for certain situation or product  
 C2- Design a suitable testing method to evaluate a biocidal agent  
 C3- Design a suitable drug formulation & or packaging material for drug products  
 C4- Select suitable sterilization process for specific object  
 C5- Design an aseptic or clean area in manufacturing plant

**D. Transferable Key Skills:** Students is expected to

- D1- Communicate effectively with the drug manufacturing bodies concerning GMP for microbial quality monitoring & aseptic manufacturing  
 D2- Gain basis for the design of different disinfection policies in hospitals or pharmaceutical industry  
 D3- Develop the skills of self-learning

**C- Program Competencies Achieved in This Course:**

- Recognize and follow proper storage conditions of medicines
- Package medicines properly to ensure their stability, safety and patient accessibility
- Identify drug-drug and drug-food interactions of medicines
- Recognize the significance and identify the principles of infection control
- Recognize the principles of drug safety and efficacy evaluation
- Recognize the role of pharmaceutical excipients and their uses in drug formulations
- Characterize various pharmaceutical dosage forms
- Identify formulation principles and product development stages
- Recognize various pharmaceutical manufacturing processes
- Comply with principles of good manufacturing practice (GMP) and good laboratory practice (GLP)
- Recognize quality assurance principles
- Recognize quality control principles
- Demonstrate the ability to perform proper documentation
- Identify the general principles of environmental control within pharmaceutical manufacturing sites
- Store pharmaceutical products in proper facilities under suitable storage conditions

**20. Topic Outline and Schedule:**

Topic	Week	Instructor	Achieved ILOs	Evaluation Methods	Reference
Chemical Disinfectants, Antiseptics and Preservatives	1-3		A1-A4, B1, C1, D2	Exams	Hugo and Russell's Pharmaceutical Microbiology
Non-antibiotic Antimicrobial Agents: Mode of Action and Resistance	4		A4	Exams	Same as above
Laboratory Evaluation of Antimicrobial Agents	5-7		A5-A6, B2-B3, C2	Exams	Same as above
Microbial Spoilage, Infection Risk and Contamination Control	8-10		A7-A9, B4, C3	Quiz/ Exams	Same as above
Sterilization Procedures and Sterility Assurance	11-13		A10-A11, B5	Exams	Same as above
Sterile Pharmaceutical Products	14		A12, B6, C4	Exams	Same as above
Principles of Good Manufacturing Practice	15		A13, B7, C5, D1	Exams	Same as above

## 21. Teaching Methods and Assignments:

Development of ILOs is promoted through the following teaching and learning methods:

### A. Teaching Methods:

- Lectures
- Self-Reading
- Multimedia demonstrations

### B. Learning Skills:

- Critical thinking
- Scientific reasoning
- Digital literacy
- Communication skills
- Problem-solving skills
- Self-directed learning

## 22. Evaluation Methods and Course Requirements:

Opportunities to demonstrate achievement of the ILOs are provided through the following assessment methods and requirements:

- Exams
- Quizzes

## 23. Course Policies:

A- Attendance policies:

- As per the applicable university regulations

B- Absences from exams and handing in assignments on time:

- As per the applicable university regulations

C- Health and safety procedures:

- N/A

D- Honesty policy regarding cheating, plagiarism, misbehavior:

- As per the applicable university regulations

E- Grading policy:

- Midterm exam (40%)
- Quiz (10%)
- Final (50%)

F- Available university services that support achievement in the course:

- University libraries
- Student computer labs
- University website (including E-Learning and faculty member websites)

**24. Required equipment:**

- Computer connected to the internet and data show projector
- Whiteboard and associated equipment

**25. References:**

A- Required book (s), assigned reading and audio-visuals:

- Denyer, S. P., N. A. Hodges, S. P. Gorman, and B. F. Gilmore. *Hugo and Russell's Pharmaceutical Microbiology*. Wiley-Blackwell, UK; 8<sup>th</sup> Edition. (2011).

B- Recommended books, materials, and media:

- Adam Fraise, Jean-Yves Maillard & Syed Sattar. *Principles and Practice of Disinfection, Preservation & Sterilization*. Wiley-Blackwell, UK; 5<sup>th</sup> Edition (2013)
- Michael J. Akers. *Sterile Drug Products: Formulation, Packaging, Manufacturing and Quality*. CRC Press; 1<sup>st</sup> Edition (2010)
- Richard Schwalbe, Lynn Steele-Moore & Avery C. Goodwin. *Antimicrobial Susceptibility Testing Protocols*. CRC Press; 1<sup>st</sup> edition (2007)

**26. Additional information:**

Name of Course Coordinator: -----Signature: ----- Date: -----

Head of curriculum committee/Department: ----- Signature: -----

Head of Department: ----- Signature: -----

Head of curriculum committee/Faculty: ----- Signature: -----

Dean: ----- -Signature: -----

Copy to:

Head of Department  
Assistant Dean for Quality Assurance  
Course File