Microbiological Quality Control for Master's degree; Code: PHM 703

A-Basic Information

Programme(s) on which the course is given:	Master's degree of pharmaceutical sciences (Microbiology and Immunology)
Department responsible for offering the course:	Department of Microbiology and Immunology
Department responsible for teaching the course:	Department of Microbiology and Immunology
Academic year:	Pre-master courses-2023/2024-second semester
Course title and code:	Microbiological quality control, Code: PHM 703
Contact hours (credit hours):	Lecture: 3 (3)
Course Coordinator:	Dr. Amr Shaker

B- Professional Information

The course aim and intended learning outcomes are based on that mentioned in the programme specifications, with more course-related specific details.

1 - Overall Aims of Course

Upon successful completion of this course, the students should be familiar with fundamental concepts of microbiological quality control of pharmaceuticals. They should also understand the quality assurance and control of sterile and non-sterile products. They should also have a background on evaluation of antimicrobial agents.

2 - Intended Learning Outcomes of Course (ILOs)

a- Knowledge and Understanding:

The students should be able to:

a1. Enumerate the hazards of microbial contamination.

a2. Define and understand quality control, quality assurance, good manufacture practice, good analytical practice, total quality assurance.

a3. Understand the principles of sterilization.

a4. Be familiar with tests for determination of pyrogen and bacterial endotoxins in pharmaceuticals.

a5. Principles of quality assurance and control of sterile and non-sterile products.

a6. Basic concepts of evaluation of antimicrobial agents

B- intellectual skills

The students should be able to:

b1. Estimate and differentiate between the different techniques used in evaluation of antimicrobial agents.

b2. Understand different methods of quality assurance of sterile and non-sterile products.

b3. Analyze and evaluate different methods of sterilization

b4. Solve problems related to microbial hazards.

b5. Take professional decision regarding pharmaceutical industry.

C. General and Transferable Skills

The students should be able to:

d1. work and learn independently

d2. Have adequate presentation skills

d3. Have problem solving skills.

d4. Master the basic techniques of good laboratory practice.

3. Course Contents

Topics	No. of hours	No. of Lectures
Overview on microbiological quality control	3	1
Study of microbial quality control of sterile products (parenterals, opthalmics): - Sterility Tests. - Bacterial endotoxins test. - Rabbit pyrogen test. - Parametric release of Terminally Sterilized Pharmaceutical Products. - Biological indicators for sterilization.	6	2
Study of microbial quality control of nonsterile products (topical, oral preparations): - Microbial enumeration tests. - Tests for specified microorganisms. - Acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use	6	2
Study of microbial quality control of nonsterile products (Dietary supplements): - Microbial enumeration tests. - Microbiological procedures for absence of specified micro-organism. - Microbiological attributes of nonsterile nutritional and dietary supplements.	6	2
Antibiotics—microbial assays Principles of evaluation of antimicrobial agent	6	2
-Evaluation of non-antibiotics antimicrobials -Quality control of water	3	1
Microbiological quality control of biological products	6	2
Terminally sterilized pharmaceutical products	3	1
Microbiological quality control of nutritional and dietary supplements	3	1
Quality control of air	3	1
Total	45	15

4. Teaching and Learning Methods

1- Lectures

2- Discussion sessions

3- Assignments

5- Student Assessment Methods

- **Activities** (presentations)
- **Final written exam** to assess the ability of student to remember and retrieve information as well as understanding of the scientific background.
- **Oral Exam** to assess skills of analysis, scientific thinking as well as scientific discussion

Assessment Schedule

Assessment 1	Activities	Week 10
Assessment 2	Final written exam	Week 16
Assessment 3	Oral exam	Week 16

Weighting of Assessments

Activities	10%
Final-written exam	80%
Oral exam	10%
Total	**100%**

6- List of References

A. Course notes

- Lecture notes of microbiological control.
- US pharmacopeia

B. Recommended textbooks

- Lippincott's in Microbiology
- Topley & Wilson Text Book of Microbiology
- Methods in Biotechnology

C. Websites

- www.ncbi.nlm.nih.gov
- www.sciencedirect.com
- www.springerlink.com

7- Facilities Required for Teaching and Learning

- Study halls
- Overhead projector
- Data show
- Internet

Course Coordinator: **Dr. Amr Shaker**

Amr Shaker

Acting Head of Department: **Assoc. Prof. Dr. Sarra Ebrahim Saleh**

Sarra Saleh

Course name	Microbiological control For Master degree.
Code	PHM703

Course matrix

contents	a1	a2	a3	a4	a5	a 6	b1	b2	b3	b4	b5	d1	d2	d3	d4
Overview on microbiological quality control															
Study of microbial quality control of sterile products (parenterals, opthalmics): - Sterility Tests. - Bacterial endotoxins test. - Rabbit pyrogen test. - Parametric release of Terminally Sterilized Pharmaceutical Products. - Biological indicators for sterilization.															
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تم الاعتماد فى محضر مجلس قسم الميكروبيولوجيا والمناعة
جلسة رقم (٦) بتاريخ ٢٠٢٤/٢/١٤