Jerash University
Faculty of Pharmacy

Course Syllabus

Course Title: Pharmaceutical quality and assurance	**Course code: 1101552**
Course Level: 5th year	**Course prerequisite** : **Pharmaceutics 2**
Lecture Time: TBA	**Credit hours: 3 hours**

Academic Staff Specifics

Name	Rank	Office Number and Location	Office Hours	E-mail Address
Dr. Shadi Gharaibeh	**Associate Prof.**	**405**	**TBA**	**TBA**

Module description:

In this course the student learns about aspects important in the quality of pharmaceutical products and how it is assured in the pharmaceutical industry. In addition the student learns the importance of implementation of Good Manufacturing Guidelines to ensure the highest possible quality of the pharmaceutical product.

Module objectives:

The aim of this course is to provide the student with knowledge and understanding of quality control and assurance of pharmaceutical products, Good Manufacturing guidelines, pharmaceutical plant design to ensure product quality, and equipment used in quality control units for product analysis.

Teaching methods:

Lectures (interactive; group discussion)

Learning outcomes:

At the end of this module, students will be able to:

1. Understands what is meant by quality of a pharmaceutical product.
2. Understand the importance of implementing Good Manufacturing Practice guidelines on pharmaceutical product quality.
3. Understand the guidelines of Good Manufacturing Practice.
4. Understand the proper designs of pharmaceutical plants in order to ensure high quality of pharmaceutical products.
5. Understand scale up techniques in pharmaceutical industry.
6. Understand the usage, components, and methods of operation of key analytical equipment used in quality control units of pharmaceutical plants.

Assessment instruments

- Short reports and/ or presentations, and/ or Short research projects
- Quizzes.
- Home works
- Final examination: 40 marks

Allocation of Marks	
Assessment Instruments	**Mark**
First examination	**20%**
Second examination	**20%**
Final examination: 40 marks	**40%**
Reports, research projects, Quizzes, Home works, Projects	**20%**
Total	**100%**

Course/module academic calendar

week	Basic and support material to be covered
(1-3)	❖ Good Manufacturing Practice guidelines in pharmaceutical manufacturing ▪ General information: ▪ Status. ▪ Applicability. ▪ Definitions.
(4-6)	❖ Current Good Manufacturing Practice guidelines in pharmaceutical manufacturing • Organization and Personnel • Buildings and Facilities • Equipment • Control of Components and Drug Product Containers and Closures • Production and Process Controls
(6-8)	❖ Current Good Manufacturing Practice guidelines in pharmaceutical manufacturing • Packaging and Labeling Control • Holding and Distribution • Laboratory Controls • Records and Reports • Returned and Salvaged Drug Products
(8-11)	❖ Pharmaceutical plant design ▪ manufacturing site selection ▪ Design of the manufacturing facility ▪ Control of the facilities environmental conditions ▪ Architectural considerations ▪ Validation of manufacturing facilities

(11-13)	❖ Scale up techniques ▪ Requirements for successful scale up ▪ Pilot plant studies ▪ General considerations ▪ Product considerations
(13-15)	❖ Equipment used in Quality Control unit for product analysis ▪ HPLC ▪ UV spectrometer ▪ IR spectrometer ▪ Viscometer ▪ Dissolution, disintegration, and friability testers ▪ Others

Expected workload:

On average students need to spend 3 hours of study and preparation for each 50-minute lecture/tutorial.

Attendance policy:

Absence from lectures and/or tutorials shall not exceed 15%. Students who exceed the 15% limit without a medical or emergency excuse acceptable to and approved by the Dean of the relevant college/faculty shall not be allowed to take the final examination and shall receive a mark of zero for the course. If the excuse is approved by the Dean, the student shall be considered to have withdrawn from the course.

Module references:

Text book:

1. Good Manufacturing Practices for Pharmaceuticals, Seventh Edition (Drugs and the Pharmaceutical Sciences), 7th Edition by Graham P. Bunn (Editor).

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