



Course Specification

— (Bachelor)

Course Title: Pharmaceutical Quality Control and Good Manufacturing Practice

Course Code: PHCU-537

Program: Pharmaceutical Sciences

Department: Pharmaceutics

College: College of Pharmacy

Institution: Najran University

Version: 3

Last Revision Date: 18/8/2024



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A. General information about the course:

1. Course Identification

1. Credit hours: 2 credits (2+0)

2. Course type

A. ☐ University ☐ College ☐ Department ☐ Track ☒ Program
B. ☒ Required ☐ Elective

3. Level/year at which this course is offered: (10th Level / 5th Year)

4. Course general Description:

This course is designed to familiarize the students with the quality assurance and regulatory affairs that include good manufacturing practice (GMP) and quality control aspects of raw materials and finished products. The quality control includes the final testing of the product besides the in – process quality control of different dosage forms. This course also outlines the principles of self-inspection, validation, and handling of product recalls and complaints.

5. Pre-requirements for this course (if any):

PHCU-534

6. Co-requisites for this course (if any):

NA

7. Course Main Objective(s):

The course provides the students with the basic concepts and guidance for manufacturing, testing, and quality assurance.

2. Teaching mode (mark all that apply)

No	Mode of Instruction	Contact Hours	Percentage
1	Traditional classroom	30	100
2	E-learning		
3	Hybrid <ul style="list-style-type: none"> Traditional classroom E-learning 		
4	Distance learning		



3. Contact Hours (based on the academic semester)

No	Activity	Contact Hours
1.	Lectures	30
2.	Laboratory/Studio	
3.	Field	
4.	Tutorial	
5.	Others (specify)	
Total		30

B. Course Learning Outcomes (CLOs), Teaching Strategies and Assessment Methods

Code	Course Learning Outcomes	Code of PLOs aligned with program	Teaching Strategies	Assessment Methods
1.0	Knowledge and understanding			
1.1	Demonstrate knowledge and understanding of good manufacturing practice (GMP) and quality assurance	K3	Lectures	-Written exams with MCQs -Assignments
...				
2.0	Skills			
2.1	Demonstrate ability to develop and apply good manufacturing practice (GMP) for pharmaceutical formulations development	S3	-Lectures -Problem based learning -Group discussion	-Written exams with MCQs -Assignments
2.2				
...				
3.0	Values, autonomy, and responsibility			
3.1	Demonstrate ability to confidence and independent thinking	V4	-Small group discussion -Problem based learning	-Observation Card -Presentations

C. Course Content

No	List of Topics	Contact Hours
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1.	Introduction to pharmaceutical industry and GMP	2
2.	Therapeutic goods regulator	2
3.	Production: premises and equipment	2
4.	Air cleanliness levels	1
5.	Prevention of cross contamination	1
6.	Processing operation and packaging operation	2
7.	Quality control: documentation, specifications, sampling, testing, and ongoing stability program	6
8.	Sampling Training and personnel hygiene	4
9.	Quality assurance: self-inspection	4
10.	Validation	4
11.	Product complaints and recall	2
Total		30

D. Students Assessment Activities

No	Assessment Activities *	Assessment timing (in week no)	Percentage of Total Assessment Score
1.	Quiz-I	4	5%
2.	Midterm Theoretical Exam	7-9	25%
3.	Quiz-II	12	5%
4.	Assignments	15	10%
5.	Observation Card and Oral presentations	16	5%
6.	Final Exam	17-19	50%
	Total		100%

*Assessment Activities (i.e., Written test, oral test, oral presentation, group project, essay, etc.).

E. Learning Resources and Facilities

1. References and Learning Resources

Essential References	Electronic FDF book: The encyclopedia of pharmaceutical technology, third edition, James Swarbrick. Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Vol. 2, Good manufacturing practices and inspection. — 2 nd ed. 2007. WHO Guide to Good Manufacturing Practice for Medicinal Products, Version 3. Drug Sector Saudi Food & Drug Authority
Supportive References	Good Manufacturing Practices for Pharmaceuticals, Sixth Edition edited by Joseph D. Nally, Informa Healthcare.
Electronic Materials	https://sdl.edu.sa/SDLPorta1/en/Publishers.aspx http://dlaf.nu.edu.sa/en/e-libraries





	http://www.nu.edu.sa/en/web/deanship-of-libraries-affairs/85 http://lib.nu.edu.sa/DigitalLibrary.aspx
Other Learning Materials	

2. Required Facilities and equipment

Items	Resources
facilities (Classrooms, laboratories, exhibition rooms, simulation rooms, etc.)	Classrooms containing at least 25 seats for student
Technology equipment (projector, smart board, software)	Projector for power point presentations with internet
Other equipment (depending on the nature of the specialty)	

F. Assessment of Course Quality

Assessment Areas/Issues	Assessor	Assessment Methods
Effectiveness of teaching	Students	Indirect
Effectiveness of Students assessment	Examination Committee	Direct
Quality of learning resources	Course Coordinator and Students	Indirect
The extent to which CLOs have been achieved	Course Coordinator	Direct
Other		

Assessors (Students, Faculty, Program Leaders, Peer Reviewer, Others (specify))

Assessment Methods (Direct, Indirect)

G. Specification Approval

COUNCIL /COMMITTEE	Pharmaceutics Department Committee
REFERENCE NO.	14460216-1060-00001
DATE	21/8/2024

