



# Course Specification

## (Bachelor)

**Course Title:** Sterile Dosage Forms

**Course Code:** : PHCU-536

**Program:** Pharmaceutical Sciences

**Department:** Pharmaceutics

**College:** Pharmacy

**Institution:** Najran University

**Version:** 3

**Last Revision Date:** 21 August 2024



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## A. General information about the course:

### 1. Course Identification

1. Credit hours: ( ..... )

3 hours (2+1)

2. Course type

A. ☐ University ☐ College ☐ Department ☐ Track ☒ Program

B. ☒ Required ☐ Elective

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

4. Course general Description:

The course is designed to familiarize the student with physiochemical characteristics as well as formulation design of parenteral and ophthalmic dosage form. The topic cover in this subject includes introduction to sterile product; *Parenteral dosage forms* – preparation, advantages and disadvantages, route of administration for parenteral, official types of injections, formulation components, production facility and evaluation of parenteral preparations; *Ophthalmic dosage forms* - definition, physiology and anatomy of eye, type of ophthalmic preparations, formulation components and packaging of ophthalmic preparations.

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

PHCU 535

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

NA

7. Course Main Objective(s):

- I. To study the physiochemical characteristics of sterile dosage forms - parenteral and ophthalmic drug delivery.
- II. To study the formulation design perspectives of sterile dosage forms - parenteral and ophthalmic drug delivery.

### 2. Teaching mode (mark all that apply)

No	Mode of Instruction	Contact Hours	Percentage
1	Traditional classroom	60	100
2	E-learning		
3	Hybrid <ul style="list-style-type: none"> <li>Traditional classroom</li> <li>E-learning</li> </ul>		





No	Mode of Instruction	Contact Hours	Percentage
4	Distance learning		

### 3. Contact Hours (based on the academic semester)

No	Activity	Contact Hours
1.	Lectures	30
2.	Laboratory/Studio	30
3.	Field	
4.	Tutorial	
5.	Others (specify)	
Total		60

## 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 concept and knowledge of sterile dosage forms with detail of parenteral and ophthalmic products	K1	Lectures	1. Written exam 2. Assignments
1.2	Demonstrate the understanding related to principles involved in sterile products development	K3	Lectures	1. Written exam 2. Assignments
...				
2.0	Skills			
2.1	Demonstrate the quality evaluation of sterile dosage forms for parenteral and	S3	Lectures, Lab work	Written exam Practical exams Lab. reports





Code	Course Learning Outcomes	Code of PLOs aligned with program	Teaching Strategies	Assessment Methods
	ophthalmic drug delivery			
2.2				
...				
<b>3.0</b>	<b>Values, autonomy, and responsibility</b>			
3.1	Demonstrate ability to work independently and professionally on related topics	V1	Problem-based learning	Practical Exam, Observation Card
3.2				
...				

### C. Course Content

No	List of Topics	Contact Hours
1.	Introduction to sterile preparations, <i>Parenteral dosage forms</i> : preparation, advantages, and disadvantages	1
2.	<i>Parenteral dosage forms</i> : preparation, advantages and disadvantages	1
3.	Routes of administration of parenteral and Different types of parenteral preparation	2
4.	Formulation components of parenteral product	2
5.	Production facilities for parenteral product	4
6.	Evaluation of parenteral preparations	2
7.	<i>Ophthalmic preparations</i> : definition, physiology and anatomy of the eye	2
8.	Classification of ocular preparation: solutions, suspensions, semisolids dosage forms, solids dosage forms, intraocular dosage forms	2
9.	Inactive ingredients in topical ophthalmic drops: vehicles, tonicity adjusting agents, pH adjusting agents and buffers, stabilizers and antioxidants, surfactants and viscosity modifiers.	2
10.	<i>Semisolid ophthalmic dosage forms</i> : ointments, gels; <i>Solid dosage forms</i> : ocular inserts; Packaging of ophthalmic preparations.	3
11.	ocular inserts; Packaging of ophthalmic preparations.	1
12.	Intraocular dosage forms	2
13.	Miscellaneous: ocular iontophoresis, vesicular dosage forms, contact lenses and care solutions	3
14.	contact lenses and care solutions	1
15.	Revision	2
	Total	<b>30</b>
16.	Introduction	2
17.	Preparation and characterization of large volume parenterals	2





18.	Preparation and characterization of small volume parenterals	4
19.	Ophthalmic preparations: eye drops, eye lotions and eye ointments	4
20.	Sterilization techniques	2
21.	Introduction to Isotonicity	2
22.	Isotonicity adjustment by sodium chloride equivalent method	2
23.	Isotonicity adjustment by freezing point depression method	2
24.	Isotonicity adjustment by white-Vincent method and U.S.P method	4
25.	Math's and dosage calculation for parenteral products	4
26.	Calculation of i.v. admixtures and i.v. infusion flow rate	2
<b>Total</b>		<b>30</b>

## D. Students Assessment Activities

No	Assessment Activities *	Assessment timing (in week no)	Percentage of Total Assessment Score
1.	Midterm exam	7	20%
2.	Assignments	15	05%
3.	Quiz 1	4	05%
4.	Quiz 2	9	05%
5.	Lab. Practical Quiz and notebook	15	10%
6.	Observation card	2-15	05%
7.	Final Practical exam	16	10%
8.	Final Theory exam	17-19	40%
9.	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

<b>Essential References</b>	1. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 10th Edition, 2014, edited by Loyd V. Allen, Howard C. Ansel. 2. Pharmaceutics - The Science of Dosage Form Design, 2nd edition, 2002, edited by M.E. Aulton.
<b>Supportive References</b>	Remington: The Science and Practice of Pharmacy, 22nd Edition, 2013, edited by Loyd V. Allen Jr. Power point slides/word file
<b>Electronic Materials</b>	<a href="https://sdl.edu.sa/SDLPortal/en/Publishers.aspx">https://sdl.edu.sa/SDLPortal/en/Publishers.aspx</a> <a href="http://dlaf.nu.edu.sa/en/e-libraries">http://dlaf.nu.edu.sa/en/e-libraries</a>
<b>Other Learning Materials</b>	Excel software for calculations





## 2. Required Facilities and equipment

Items	Resources
<b>facilities</b> (Classrooms, laboratories, exhibition rooms, simulation rooms, etc.)	1. Suitable lecture room equipped with data show and internet and sufficient number of seats. 2. Suitable laboratories equipped with health and safety tools, internet and sufficient number of seats.
<b>Technology equipment</b> (projector, smart board, software)	Computers, data show, sound systems and internet
<b>Other equipment</b> (depending on the nature of the specialty)	1. Autoclave 2. Hot air oven 3. Water bath 4. Membrane filtration 5. Vortex mixer 6. Hot plate with magnetic stirrer

## 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

<b>COUNCIL /COMMITTEE</b>	Pharmaceutics Department Council
<b>REFERENCE NO.</b>	14460216-1060-00001
<b>DATE</b>	21/8/2024

