

## T6. Course Specification (CS)

Institution	Najran University	Date	22/02/2017
College/Department	College of Pharmacy/Pharmaceutics		

### A. Course Identification and General Information:

1. Course title and code : Sterile dosage forms, PHCU 536			
2. Credit hours : <b>3 (2+1)</b>			
3. Program(s) in which the course is offered. (If general elective available in many programs indicate this rather than list programs) <b>Pharmaceutical Sciences</b>			
4. Name of faculty member responsible for the course : <b>Dr. Javed Ahmad</b>			
5. Level/year at which this course is offered : <b>10<sup>th</sup> / Second Semester 1437-1438H</b>			
6. Pre-requisites for this course (if any) PHCU 535			
7. Co-requisites for this course (if any)			
8. Location if not on main campus			
9. Mode of Instruction (mark all that apply)			
a. Traditional classroom	<input checked="" type="checkbox"/>	What percentage	<b>100</b>
b. Blended (traditional and online)	<input type="checkbox"/>	What percentage	<input type="text"/>
c. e-learning	<input type="checkbox"/>	What percentage	<input type="text"/>
d. Correspondence	<input type="checkbox"/>	What percentage	<input type="text"/>
f. Other	<input type="checkbox"/>	What percentage	<input type="text"/>
Comments:			

عليه تعليق [T1]:  
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## B. Objectives

1. What is the main purpose for this course  
The course is designed to familiarize the student with physiochemical characteristics as well as formulation design of sterile preparation- parenteral and ophthalmic dosage form.
2. Briefly describe any plans for developing and improving the course that are being implemented. (e.g. increased use of IT or web based reference material, changes in content as a result of new research in the field)
  - Use the internet based learning for assignments and reviews.
  - Addition of new contents based on the updated research technology in parenteral and ophthalmic drug delivery.

## C. Course Description (Note: General description in the form used in the Bulletin or handbook should be attached)

### Course 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 preparation*- definition, physiology and anatomy of eye, type of ophthalmic preparations, formulation components and packaging of ophthalmic preparations.

### 1. Topics to be Covered (Theoretical)

List of Topics	No. of Weeks	Contact hours
Introduction to sterile preparations, Parenteral dosage forms: preparation, advantages and disadvantages	1	2
Routes of administration of parenteral and Different types of parenteral preparation	1	2
Formulation components of parenteral	1	2
Production facilities for parenteral product	2	4
Evaluation of parenteral preparations	1	2
Ophthalmic preparations: definition, physiology and anatomy of the eye	1	2

Classification of ocular preparation, solutions, suspensions, semisolids, solids, intraocular dosage forms	1	2
Inactive ingredients in topical ophthalmic drops: vehicles, tonicity adjusting agents, pH adjusting agents and buffers, stabilizers and antioxidants, surfactants and viscosity modifiers.	1	2
Semisolid ophthalmic dosage forms: ointments, gels; Solid dosage forms: ocular inserts; Packaging of ophthalmic preparations.	2	4
Intraocular dosage forms	1	2
Miscellaneous : ocular iontophoresis, vesicular dosage forms, contact lenses and care solutions	2	4
<b>Revision</b>	<b>1</b>	<b>2</b>

Topics to be Covered (Practical)		
List of Topics	No. of Weeks	Contact Hours
Preparation of i.v infusions	1	2
Ophthalmic preparations: eye drops, eye lotions and eye ointments	2	4
Sterilization techniques	1	2
Introduction to Isotonicity	1	2
Isotonicity adjustment by sodium chloride equivalent method	2	4
Isotonicity adjustment by freezing point depression method	1	2
Isotonicity adjustment by white-Vincent method and U.S.P method	2	4
Math's and dosage calculation for parenteral products	2	4
Problems related to dosage calculation	1	2
Selection of syringes for parenteral drug administration	1	2
<b>Revision</b>	<b>1</b>	<b>2</b>

2. Course components (total contact hours and credits per semester):						
	Lecture	Tutorial	Laboratory or studio	Practical	Other:	Total
Contact Hours	30	-	-	30	-	60
Credit	2	-	-	1	-	3

3-Additional private study/learning hours expected for students per week	2 hours
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4. Course Learning Outcomes in NQF Domains of Learning and Alignment with Assessment Methods and Teaching Strategy.
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On the table below are the five NQF Learning Domains, numbered in the left column.

**First**, insert the suitable and measurable course learning outcomes required in the appropriate learning domains (see suggestions below the table)

**Second**, insert supporting teaching strategies that fit and align with the assessment methods and intended learning outcomes.

**Third**, insert appropriate assessment methods that accurately measure and evaluate the learning outcome. Each course learning outcomes, assessment method, and teaching strategy ought to reasonably fit and flow together as an integrated learning and teaching process. (Courses are not required to include learning outcomes from each domain).

Code #	NQF Learning Domains And Course Learning Outcomes	Course Teaching Strategies	Course Assessment Methods
1.0	Knowledge		
1.1	Define sterile dosage forms describe formulation design of sterile dosage form	Lectures, Assignments	MCQ exam Written essay exam
1.2	Outline production facilities for sterile dosage forms preparation	Lectures, Assignments	MCQ exam Written essay exam
1.3			
1.4			

[T2]: Final Exam

[T3]: Final Exam

Code #	NQF Learning Domains And Course Learning Outcomes	Course Teaching Strategies	Course Assessment Methods
<b>2.0</b>	<b>Cognitive Skills</b>		
2.1	Develop pre-formulation considerations for sterile dosage forms.	Oral presentations, Practical classes	Problem-based learning MCQ questions, Practical exam ◀
2.2	Evaluate the sterile dosage forms by quality control tests and calculate and adjust the isotonicity of sterile dosage forms.	Oral presentations, Practical classes	Problem-based learning MCQ questions, Practical exam ◀
<b>3.0</b>	<b>Interpersonal Skills &amp; Responsibility</b>		
3.1	Analyze interpersonal skills and evaluate capacity to show responsibility and appraise critical thinking and decision making during preparation of different sterile formulations.	Interactive small group teaching in labs	Laboratory report, Practical exam
3.2	Evaluate critical thinking by collecting information from different sources to improve Interpersonal skills.	Cooperative study	Open discussions, Oral questions
<b>4.0</b>	<b>Communication, Information Technology, Numerical</b>		
4.1	Interpret and explains the results according to his knowledge, skills and obtained reference materials.	Analysis and reporting	Oral discussions, Evaluation in lectures
4.2	Demonstrate the practical skills to evaluate suitable additives used in preparation of sterile dosage form .	Analysis and reporting	Observation cards in labs
<b>5.0</b>	<b>Psychomotor</b>		
5.1	Demonstrate and operate the pharmaceutical equipment used in the preparation sterile dosage forms in the laboratory	Demonstration of experiments	Observation cards in labs, practical exam
5.2			

[T4]: Final Exam  
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[T5]: Final Exam  
تعليق عليه

5. Schedule of Assessment Tasks for Students During the Semester			
	Assessment task (e.g. essay, test, Quizzes, group project, examination, speech, oral presentation, etc.)	Week Due	Proportion of Total Assessment
1.	First Quiz	4	5
2.	Midterm Theoretical Exam	8	20
3.	Second Quiz	12	5
4.	Attendance and observations	15	10
5.	Practical Exam	15	20
6.	Final Written Exam	16	40

عليه تعليق [T6]: المفروض أنه يوجد تدريس في هذا الأسبوع

#### D. Student Academic Counseling and Support

1. Arrangements for availability of faculty and teaching staff for individual student consultations and academic advice. (include amount of time teaching staff are expected to be available each week)
  - Office hour : (2 hours per week + appointment with student)
  - Help session : (Problem solving): As required per week

Course coordinator and lecturers of the course would be happy to answer all students' quires during or after the lectures, and personal meeting, - Office hours for the course coordinator and lecturer(s) of the course are affixed in their respective offices and this will be at least 8 hours per week.

#### E. Learning Resources

1. List Required Textbooks
<ul style="list-style-type: none"> <li>The encyclopedia of pharmaceutical technology, third edition, James Swarbrick; electronic version CRC publication. USA 2015</li> </ul>
2. List Essential References Materials (Journals, Reports, etc.)
<ul style="list-style-type: none"> <li>Pharmaceutics- The Science of Dosage Form Design, M.E. Aulton. , 6<sup>th</sup> edition, 2015, Elsevier Publication, USA</li> <li><b>Allen L.V., Popovich N. G. and Ansel H. C. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 8th Edition, Lippincott Williams &amp; Wilkins.</b></li> </ul>
3. List Electronic Materials Web Sites, Facebook, Twitter, etc.
<ul style="list-style-type: none"> <li><a href="https://sdl.edu.sa/SDLPortal/en/Publishers.aspx">https://sdl.edu.sa/SDLPortal/en/Publishers.aspx</a></li> <li><a href="http://dlaf.nu.edu.sa/en/e-libraries">http://dlaf.nu.edu.sa/en/e-libraries</a></li> <li><a href="http://www.nu.edu.sa/en/web/deanship-of-libraries-affairs/85">http://www.nu.edu.sa/en/web/deanship-of-libraries-affairs/85</a></li> <li><a href="http://lib.nu.edu.sa/DigitalLibrary.aspx">http://lib.nu.edu.sa/DigitalLibrary.aspx</a></li> <li><a href="https://www.journals.elsevier.com/international-journal-of-pharmaceutics/">https://www.journals.elsevier.com/international-journal-of-pharmaceutics/</a></li> <li><a href="https://www.journals.elsevier.com/colloids-and-surfaces-b-biointerfaces">https://www.journals.elsevier.com/colloids-and-surfaces-b-biointerfaces</a></li> </ul>
4. Other learning material such as computer-based programs/CD, professional standards or regulations and software.

عليه تعليق [T7]: تاريخ النشر

#### F. Facilities Required

Indicate requirements for the course including size of classrooms and laboratories (i.e. number of seats in classrooms and laboratories, extent of computer access etc.)
1. Accommodation (Classrooms, laboratories, demonstration rooms/labs, etc.)
<ul style="list-style-type: none"> <li>A lecture hall containing at least 25 seats for student.</li> <li>A well-equipped laboratory containing at least 25 seats for the student.</li> </ul> <p>- Lecture rooms having seating arrangement for 20-30 students, provided with overhead projector, Data show projector and white board /smart board.</p> <p>- Well-equipped pharmaceuticals laboratory with overhead projector, data show projector and white board /smart board.</p>
2. Computing resources (AV, data show, Smart Board, software, etc.)
Computers , Data Show, Projectors
3. Other resources (specify, e.g. if specific laboratory equipment is required, list requirements or attach list)

### G. Course Evaluation and Improvement Processes

1. Strategies for Obtaining Student Feedback on Effectiveness of Teaching	<ul style="list-style-type: none"> <li>➤ Course evaluation by students</li> <li>➤ Faculty student general meeting</li> <li>➤ To get the most realistic responses about the course and teaching procedures from the student, the student questionnaire / feed-back form will be provided to the students at different time points through semester.</li> <li>➤ At the beginning of semester (very first lecture, explain the course detail).</li> <li>➤ During the semester (about course content and teaching procedures)</li> <li>➤ At the End of the course (overall evaluation of the course and instructors)</li> </ul>
2. Other Strategies for Evaluation of Teaching by the Instructor or by the department.	<ul style="list-style-type: none"> <li>• Peer consultation on teaching</li> <li>• Group discussions with the college teaching staff</li> </ul>
3. Processes for Improvement of Teaching :	<ul style="list-style-type: none"> <li>• Continuous updating of course contents.</li> <li>• Regular meetings where problems are discussed and solutions given.</li> <li>• Workshops on teaching methodology.</li> <li>• Review of recommended teaching strategies.</li> </ul>
4. Processes for Verifying Standards of Student Achievement (e.g. check marking by an independent member teaching staff of a sample of student work, periodic exchange and remarking of tests or a sample of assignments with staff at another institution)	<p>Comparing the course material with exam, Random rechecking of exams.</p>
5. Describe the planning arrangements for periodically reviewing course effectiveness and planning for improvement	<ul style="list-style-type: none"> <li>• The course material and learning outcome are periodically reviewed and the changes to be taken are in the departmental and higher councils.</li> <li>• The contents of course will be reviewed and up dated each year by pharmaceutics staff/course coordinators according to the recent researches and discoveries in pharmaceutics field.</li> </ul>

**تعليق [T8]:**  
-Course Report and suggested improvement Plan  
-Evaluation of course Portfolio and Conducting trend analysis

**تعليق [T9]:** Monitoring and Evaluating the strategies of teaching and assessment  
Monitoring and Evaluating the strategies of Measuring the Achievement of the Course Intended Learning Outcomes

**تعليق [T10]:**  
Evaluation of course Portfolio and Conducting trend analysis

Name of instructor: Dr. Javed Ahmad

Signature :

Date Report Completed: 22/02/2017

Name of field experience teaching staff: Dr. Javed Ahmad



Program coordinator:

Signature: \_\_\_\_\_ Date received: \_\_\_\_\_