

## COURSE DESCRIPTION TEMPLATE FOR GRADUATE STUDIES

**Faculty:** Faculty of Graduate Studies

**Department:** Program of Pharmaceutical Sciences.

<b>COURSE TITLE</b>	Drug Formulation and Drug Delivery II	<b>COURSE CODE</b>	1202726
<b>LECTURERS</b>	Hatim S. AlKhatib	<b>Email:</b> h.khatib@ju.edu.jo	
<b>CREDITS</b>	3	<b>PRE-REQUISITES</b>	1202721
<b>DURATION OF COURSE</b>	16 weeks, 3 h per week		
<b>OBJECTIVES:</b>			
<p>Upon completion of this course, the student should be able to</p> <ol style="list-style-type: none"> <li>1. Develop a critical awareness of the product development regulatory environment.</li> <li>2. Understand the application of advanced formulation sciences to finished dosage form.</li> </ol>			
<b>SYLLABUS PLAN:</b>			
<ul style="list-style-type: none"> <li>• <b>Pre-development activities.</b></li> <li>• <b>Product development</b> <ul style="list-style-type: none"> <li>○ <b>Product-specific analytical methods</b></li> <li>○ <b>Characterization of comparator finished pharmaceutical product(s)</b></li> <li>○ <b>Formulation selection experiments</b></li> <li>○ <b>Microbiological attributes</b></li> <li>○ <b>Compatibility studies</b></li> </ul> </li> <li>• <b>Components of finished pharmaceutical product</b> <ul style="list-style-type: none"> <li>○ <b>Active pharmaceutical ingredient</b></li> <li>○ <b>Excipients</b></li> <li>○ <b>Container Closure systems</b></li> <li>○ <b>Devices</b></li> </ul> </li> <li>• <b>Manufacturing process development</b> <ul style="list-style-type: none"> <li>○ <b>Selection of process</b></li> <li>○ <b>Finished pharmaceutical product specifications</b></li> <li>○ <b>Scale-up and validation</b></li> </ul> </li> <li>• <b>Drug product performance</b> <ul style="list-style-type: none"> <li>○ <b>Dissolution</b></li> <li>○ <b>Stability</b></li> <li>○ <b>Bioequivalence</b></li> <li>○ <b>In vitro – in vivo correlation</b></li> </ul> </li> <li>• <b>ANDA regulatory approval process</b></li> <li>• <b>Post approval changes</b></li> <li>• <b>Post marketing surveillance</b></li> </ul>			
<b>ASSIGNMENTS:</b>			
<ol style="list-style-type: none"> <li>1. Presentation: each student is assigned for a topic on which he explores the literature and the internet, and then writes a report which he will talk about it and discuss it with his colleagues in the form of a seminar.</li> </ol>			
<b>ASSESSMENT:</b> Midterm exam (30%), Assignments (30%), and Final exam (40%).			

