COURSE DESCRIPTION TEMPLATE FOR GRADUATE STUDIES

Faculty: Faculty of Graduate Studies

Department: Program of Pharmaceutical Sciences.

<table>
<thead>
<tr>
<th>COURSE TITLE</th>
<th>Drug Formulation and Drug Delivery II</th>
<th>COURSE CODE</th>
<th>1202726</th>
</tr>
</thead>
<tbody>
<tr>
<td>LECTURERS</td>
<td>Hatim S. AlKhatib</td>
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<tr>
<td>CREDITS</td>
<td>3</td>
<td>PRE-REQUISITES</td>
<td>1202721</td>
</tr>
<tr>
<td>DURATION OF COURSE</td>
<td>16 weeks, 3 h per week</td>
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OBJECTIVES:
Upon completion of this course, the student should be able to
1. Develop a critical awareness of the product development regulatory environment.
2. Understand the application of advanced formulation sciences to finished dosage form.

SYLLABUS PLAN:
• Pre-development activities.
• Product development
  o Product-specific analytical methods
  o Characterization of comparator finished pharmaceutical product(s)
  o Formulation selection experiments
  o Microbiological attributes
  o Compatibility studies
• Components of finished pharmaceutical product
  o Active pharmaceutical ingredient
  o Excipients
  o Container Closure systems
  o Devices
• Manufacturing process development
  o Selection of process
  o Finished pharmaceutical product specifications
  o Scale-up and validation
• Drug product performance
  o Dissolution
  o Stability
  o Bioequivalence
  o In vitro – in vivo correlation
• ANDA regulatory approval process
• Post approval changes
• Post marketing surveillance

ASSIGNMENTS:
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.

ASSESSMENT: Midterm exam (30%), Assignments (30%), and Final exam (40%).