# Hashemite University
# Faculty of Pharmaceutical Sciences
# Department of Pharmaceutics and Pharmaceutical Technology

**Semester: Second** **Year: 2019/2020**

| Course Information | |
|---|---|
| **Course Title** | Industrial Pharmacy 2 |
| **Course Number** | 131701471 |
| **Credit Hours** | 2 |
| **Prerequisites** | 131701436 |

| Instructor | |
|---|---|
| **Name** | Dr. Nizar M. Al-Zoubi |
| **Office** | 1036 |
| **Office Phone** | 5466 |
| **Office Hours** | To be announced |
| **E-mail** | nzoubi@hu.edu.jo |

## Course Description

This course covers: 1. pharmaceutical manufacturing processes (Coating, clarification and packaging) 2. formulation, manufacturing and quality requirements for capsules, modified release oral dosage forms and aerosols and nanomedicines 3. Pharmaceutical preformulation.

## Course Objectives

This course aims to develop qualified pharmacists in the field of pharmaceutical industry by providing students with theoretical knowledge (including processes, machinery, materials, formulation, standards and quality requirements) in relation to the covered topics.

## Intended Learning Outcomes

**After successful completion of this course student is expected to :**

**A- Knowledge and understanding**

**A1:** To be able to describe and distinguish the commonly used equipment for coating, encapsulation, clarification and packaging.

**A2:** To understand the mechanisms related to clarification

**A3:** To know the categories of additives used in the manufacturing of capsules and in preparing coating dispersion, the function of each category and examples of each category.

**A4:** To know various problems encountered in the coated tablets and the possible solution for each problem.

**A5:** To know the different approaches for modifying release from oral dosage forms and the principle of their formulation**.**

**A6:** To know the quality control tests for the intermediate (powder mixes and granules) and

final solid dosage forms (capsules). These include tests to assess content uniformity, weight variation, disintegration and dissolution.

**A7:** To know the formulation, manufacturing and quality control testing of aerosols and other systems used for pulmonary delivery.

**A8:** To know the different types of nanoparticles and their methods of preparation.

**A9:** To recognize the different issues tested in preformulation step and their importance to the forthcoming formulation step.

**B- Intellectual skills**

**B1:** To be able to analyze, present and compare the data obtained from some tests, such as particle size analysis , flowability and dissolutions tests.

**B2:** become able to suggest and discuss a manufacturing procedure for tablet dosage forms

**B3:** become able to analyze the effect of each manufacturing step on the final result

**B4:** become able to analyze and compare different solutions for a manufacturing problem.

**C- Approach to practice pharmacy**

**D- Personal and professional development**

**D1:** To understand the general duties of pharmacist in different department of a pharmaceutical manufacturing company: research and development department, quality control department, quality assurance department and quality control department.

**D2:** To develop of problem solving and critical thinking skills

**D3:** To develop the ability to utilize IT skills in gaining and presenting information

**D4:** To develop skills of team work and time management

| Reading List | |
|---|---|
| **1 (textbook)** | Aulton M., Taylor Kevin (ed.), Aulton's Pharmaceutics The design and Manufacture of Medicine, Elsevier, 5th edition, 2017. |
| **2** | Khar RK, Vyas SP, Ahmad FJ, Jain GK (2013). Lachman/liebermans: The Theory and Practice of Industrial Pharmacy. 4th editionCbs Publishers & Distributors. |
| **3** | Remington: The Science and Practice of Pharmacy, LIPPINCOTT WILLIAMS & WILKINS, 21th ed, 2006. |
| **4** | Augsburger, L., Hoag, S., (eds), *Pharmaceutical dosage forms: Tablets*, Informa healthcare, New York, 3rd edition, 2008. |

**Course Contents**

| Topics | Topic Details | Reference No. | Chapter | Estimated no. of hours | Assessment |
|---|---|---|---|---|---|
| **Coating of tablets and multiparticulates** | Reasons of tablet coating<br>Types of coating processes<br>Film coating<br>Sugar coating<br>Compression coating<br>Other coating methods and technologies<br>Coating of tablets<br>Standards for coated tablets<br>Coating of multiparticulates<br>Types of multiparticulate | 1 | 32 | 4 | |

| | | | | | |
|---|---|---|---|---|---|
| **Hard gelatin capsules** | Introduction<br>Raw materials<br>Manufacture<br>Formulation | 1 | 33 | 3 | |
| **Soft gelatin capsules** | Introduction<br>Manufacture of softgels<br>Formulation of softgels<br>Product quality considerations | 1 | 34 | 3 | |
| **Modified release oral drug delivery** | Drug concentrations by modified-release dosage forms<br>Design of oral modified-release drug delivery systems<br>Formulation of modified-release dosage forms<br>Monolithic matrix delivery systems<br>Membrane-controlled drug delivery systems:<br>Osmotic pump systems<br>Delivery systems for targeting to specific sites in the GIT: Gastric retentive systems, Colonic delivery systems | 1 | 31 | 5 | |
| | | | | | Midterm exam |
| **Aerosols and Pulmonary drug delivery systems** | Aerosols<br>Advantages of the aerosol dosage form<br>Propellant<br>Aerosols systems and formulation<br>Aerosol container and valve assembly<br>Filling operations<br>Dry powder inhalers<br>Advantages of dry powder inhalers<br>Formulation of dry powder inhalers<br>Nebulizers | 1 | 37 | 5 | |
| **Pharmaceutical nanotechnology and nanomedicines** | Introduction<br>Applications of pharmaceutical Nanotechnology<br>Nanoparticles engineering | 1 | 44 | 3 | |

| | | | | | |
|---|---|---|---|---|---|
| **Pharmaceutical Preformulation** | The concept of preformulation<br>Spectroscopy<br>Solubility<br>Dissolution<br>Melting point: Techniques,<br>Polymorphism, Crystal purity<br>Assay development<br>Drug and product stability:<br>Temperature, Order of reaction,<br>degredation reactions, Solid-state<br>stability, Hygoscopicity, Stability<br>assessment<br>Microscopy: Crystal morphology,<br>Particle size analysis<br>Powder flow properties<br>Compression properties<br>Excipient compatibility: Method**s,**<br>Interpretation | 1 | 23 | 3 | |
| **Clarification** | Filtration<br>Types of filtration<br>Mechanisms of filtration<br>Factors affecting the rate of<br>filtration<br>Methods used to increase filtration<br>rate<br>Filtration equipment<br>Centrifugation<br>Principles of centrifugation,<br>Industrial centrifuges | 1 | 25 | 2 | |
| **Packaging** | Introduction<br>Stages in the development of a<br>pack-product combination<br>Pack selection<br>Packaging materials<br>Closures<br>Filling<br>Labeling<br>Quality control of packaging | 1 | 46 | 3 | |
| | | | | | Final exam |

| Grade Distribution | | |
|---|---|---|
| **Assessment** | **Grade** | **Date** |
| - Midterm Exam | 40 | |
| - Quiz | 10 | |
| - Final Exam | 50 | |

## Important regulations

- On average, students need to spend 4 hrs of study and preparation weekly.
- Excellent attendence is expected. According to the university policy, students who miss more than 15% of the lecture hours with or without excuse will be dismissed from the course
- At the beginning of the lectures, be on time and don't leave before the end of the lecture without an accepted excuse
- If you missed a class, it is your responsibility to find out about any announcements or assignments you have missed
- For any clarification, please communicate your instructor at his posted office hours or by appointment
- Switch off your mobile or keep it silent throughout the lecture
- Listen well to the lecture and avoid side discussions, if you have a question, ask your instructor and not your collegue
- If you have any information, document your reference, if you didn't, then you broke the intellectual property rights law and the law will be applied
    - For more informations, visit the website:
        - http://www.plagiarism.org/
- Exams are scheduled to be given three times throughout the semester, your are expected to attend all. If not, make-up exams will be offered for valid reasons. It may be different from regular exams in content and format.
- Cheating, academic diconduct, fabrication and plagiarism will not be tolerated, and the university policy will be applied

**Last updated on 22 /1 / 2021 by : Dr. Nizar Al-Zoubi**