The University of Jordan

Faculty of PharmacyProgram: PharmacyDepartment of Pharmaceutics and Pharmaceutical Technology2013/2014, 1st semester

Pharmaceutical Technology II (1202333)

Credit	2	Level	3 rd year	Pre-	Pharmaceutical
hours				requisite	Technology I
Coordinator		Office		Office	
/ Lecturer		number		phone	
Course		E-mail		Place	
website					

Office hours					
Day/Time	Sunday	Monday	Tuesday	Wednesday	Thursday

Course Description

1. Aqueous Polymeric Coating of Pharmaceutical Dosage Forms.

Introduction, polymers used in coating (properties and chemistry), equipment used in coating (Pan coaters and Fluid-Bed processors), sequence of a coating process, process and polymer parameters that affect the coating quality (Glass transition temperature, viscosity, pan velocity and air temperature), formulation of coating solutions and dispersions, coating problems and their remedies.

2. Hard Gelatin Capsules.

Introduction, raw materials (Gelatin, colorants, and process aids), manufacture (capsule filling, capsule filling machines). Filling of powder formulations (Bench scale filling and Industrial scale filling).

3. Soft Gelatin Capsules.

Introduction, description of soft gelatin capsule as a dosage form, manufacture of soft gels, formulation of soft gels, product quality considerations (in-process testing and finished product testing).

4. Pharmaceutical Suspensions.

Definition, types of suspensions, pharmaceutical applications, Stability: Thermodynamic stability and physical stability (Sedimentation, polymorphic transformation and crystal growth). Stabilization: prevention of sedimentation, prevention of aggregation and caking. Electrical properties of solid interfaces (attractive and repulsive forces, zeta potential and Nernst potential). Flocculated and deflocculated suspensions ingredients used in pharmaceutical suspension formulation. Incompatibility in suspensions. Typical formulations. Production of suspensions. Evaluation and testing of suspensions. Reconstituted suspensions.

5. Pharmaceutical Emulsions.

Definition, types of emulsions, pharmaceutical applications. Destabilization mechanism (thermodynamic stability: Stokes law and physical stability: creaming, coalescence and phase separation). Stabilization mechanisms. Ingredients used in emulsion. Typical formulations for topical, oral and intravenous emulsions. Equipment used for production of pharmaceutical emulsions.

6. Formulation of Parenterals.

Definition and categories. Solubility and solubilization: effect of chemical structure, dielectric constant, effect of pH, salt formation, cosolvent approach. Formulation and ingredients. Stability: Oxidation, change in pH, precipitation, chemical degradation. Packaging materials: glass types and closures.

Learning Objectives

1. To gain knowledge concerning the manufacturing process and formulation of coatings of solid dosage forms.

2. To gain knowledge concerning the applications, formulation and the manufacturing of hard and soft gelatin capsules.

3. To gain knowledge concerning the applications, manufacturing process and formulation of suspensions and emulsions.

4. To gain knowledge concerning the formulation of small volume parenterals.

Intended Learning Outcomes (ILOs):

Successful completion of the course should lead to the following outcomes:

A. Knowledge and Understanding: Student is expected to

- 1. To acquire the knowledge of the physicochemical properties of polymers used in coating and to have the ability to select polymers for certain coating purposes, such as enteric coating and sustained release coating.
- 2. To have the ability to deal with coating equipment, such as pan coater and fluid bed drier. To have the ability to select ingredients for coating formulation.
- 3. To have the ability to recognize coating problems and suggest solutions.
- 4. To know the material a hard gelatin capsule is made from.
- 5. To know the manufacturing process of hard gelatin capsule shell.
- 6. To recognize the different classes of capsule sizes.
- 7. To recognize the filling process of hard gelatin capsule using bench scale equipment and industrial scale equipment.
- 8. To be able to select inactive ingredients for the formulation of hard gelatin capsule fills.
- 9. To be able to describe a soft gelatin capsule and how it differs from hard gelatin capsule.
- 10. To recognize the properties of softgels.
- 11. To know the rational for the selection of softgels as a dosage form.
- 12. To recognize the manufacturing process of softgels.
- 13. To recognize the formulation components of softgel fills.
- 14. To recognize the reason (s) why some drugs are formulated as emulsion.
- 15. To be able to differentiate between emulsion types.
- 16. To be able to describe the destabilization mechanisms of emulsions.
- 17. To know various approaches to stabilize emulsions.
- 18. To be able to select ingredients for emulsion formulation.
- 19. To recognize the process including equipment for the manufacturing of emulsions.
- 20. To be able to evaluate emulsion stability via various accelerated stability tests.
- 21. To recognize the reasons why some drugs are formulated as suspensions.
- 22. To be able to describe the destabilization mechanisms of suspensions. To differentiate between flocculated and deflocculated suspensions in terms of electrical properties of solid-liquid interfaces.
- 23. To be able to compare between flocculated and deflocculated suspensions in terms of the physical behavior of the suspended particles.
- 24. To know various approaches to stabilize suspensions.
- 25. To be able to select ingredients for suspensions formulation.
- 26. To recognize the process including equipments for the manufacturing of emulsions.
- 27. To be able to evaluate suspensions stability via various accelerated stability tests.
- 28. To know the ingredients used in parenteral product formulation.
- 29. To know the various packaging materials used for parenteral product.

B. Intellectual Analytical and Cognitive Skills: Student is expected to

- 1. To be able to suggest coating formulations with the necessary calculations.
- 2. To be able to suggest remedies for coating problems.
- 3. To be able to suggest formulations for soft and hard gelatin capsule fills, and to solve problems encountered during their manufacturing.
- 4. To be able to suggest formulations for pharmaceutical suspensions and to solve problems encountered during their manufacturing and during their stability.
- 5. To be able to suggest formulations for pharmaceutical emulsions and to solve problems encountered during their manufacturing and during their stability.

C. Subject-Specific Skills: Student is expected to

1. Have adequate correlation between theoretical principles and practically applied manufacturing techniques concerning the large scale production of the above mentioned dosage forms.

D. Transferable Key Skills: Students is expected to

- 1. To have the ability for quick adaptation to the working environment in pharmaceutical firms.
- 2. To have the ability to deal with and suggest solutions to the problems encountered during the manufacturing process of pharmaceutical dosage forms in pharmaceutical firms.

ILO/s	Learning Methods	Evaluation Methods		
	Lectures and Discussions, Homeworks.	Exam, Quizes.		

ILOs: Learning and Evaluation Methods

Evaluation

Evaluation	Point %	Date
Midterm Exam	30%	To be announced.
Quiz 1	10%	Week 7 (to be confirmed).
Quiz 2	10%	Week 12 (to be confirmed).
Final Exam	50%	To be announced.

Main References

- 1. The Theory and Practice of Industrial Pharmacy, Lachman, L., Libberman, H.A., and Kanig, J.L. Published by Lea and Febiger, third edition, 1986. Philadelphia, USA.
- 2. Pharmaceutics: The Science of Dosage Form Design, Aulton, M. E., second edition, 2002. Published by Churchill Livingstone. Philadelphia, USA.
- 3. Pharmaceutical Dosage Forms (Dispersed systems), Libberman, H.A. and Lachman, L., 1981. Published by Marcel Dekker. Inc., N.Y., USA.
- 4. Martin's Physical Pharmacy and Pharmaceutical Sciences. Fifth edition, 2006. Published by Lippincott Williams and Wilkins. USA.
- 5. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Allen L.V., Popovich N.G., Ansel H.C. Eighth edition, 2005. Published by Lippincott Williams and Wilkins. USA.