Course Description Form

1. Course Name:

Dosage form Design (DFD)

2. Course Code:

Phind24_5210--

3. Semester / Year:

Second semester/2024-2025/ Fifth Year

4. Description Preparation Date:

01/09/2024

5. Available Attendance Forms:

Students' signature on attendance sheet

6. Number of Credit Hours (Total) / Number of Units (Total)

2 hours Theoretical /2 units

7. Course administrator's name

Theoretical

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Practical

Not applicable

8. Course Objectives

1. New drug development and approval process
2. General considerations in dosage form design.
3. Preformulation and Pharmaceutical consideration in dosage form design.
4. Current good manufacturing practice (cGMP)
5. Biopharmaceutics and Pharmacokinetic of drugs in dosage form design

9. Teaching and Learning Strategies

Strategy	Lecturing Homework Quiz

10. Course Structure

Week	**Hours**	**Required Learning Outcomes**	**Unit or subject name**	**Learning method**	**Evaluation method**
1	2	Drug discovery and drug design	New drug development and approval process	Theoretical lectures.	Paper-based exams
2	2	Biological characterization And Early formulation	New drug developm and approval proces	Theoretical lectures.	Paper-based exams
3		Clinical studies	New drug developm and approval proces	Theoretical lectures.	Paper-based exams

4	2	1. List common terms used in the Current Good Manufacturing Practice 2. (cGMP) for finished pharmaceuticals 3. 2. Describe the organization and personnel required by cGMP	cGMP	Theoretical lectures.	Paper-based exams
5	2	1. Describe the intent and importance of written procedures within the various components of cGMP 2. Describe the various types of tamper-evident packaging, and provide a product example of each type	cGMP	Theoretical lectures.	Paper-based exams
6	2	1. Differentiate between pharmaceutical manufacturing and extemporaneous compounding 2. Describe Chapter 795 of the current United States Pharmacopeia (USP)	cGMP	Theoretical lectures.	Paper-based exams
7	2	1. List reasons for the incorporation of drugs into various dosage forms 2. Compare and contrast the advantages/disadvantages of various drug dosageforms 3. Describe the information needed in preformulation studies to characterize a drug substance for possible inclusion into a dosage form	Pharmaceutical and formulation considerations	Theoretical lectures.	Paper-based exams
8	**Mid-term exam**				
9	2	1. Describe the five types of drug instability of concern to the practicing pharmacist 2. Describe the purpose and general protocol for accelerated stability studies	Pharmaceutical and formulation considerations	Theoretical lectures. .	Paper-based exams
11	2	1. Summarize approaches employed to stabilize drugs in pharmaceutical dosage forms	Pharmaceutical and formulation considerations	Theoretical lectures. Laboratory demonstration.	Paper-based exams

		2. Calculate rate reactions for various liquid dosage forms 3. Categorize various pharmaceutical ingredients and excipients			
12	2	Principles of drug absorption	Biopharmaceutical a Pharmacokinetics consideration	Theoretical lectures. Laboratory demonstration.	Paper-based exams
13	2	Dissolution and drug absorption	Biopharmaceutical a Pharmacokinetics consideration	Theoretical lectures. Laboratory demonstration.	Paper-based exams
14	2	Bioavailability and bioequivalence	Biopharmaceutical a Pharmacokinetics consideration	Theoretical lectures. Laboratory demonstration.	Paper-based exams
15	Seminars				

11. Course Evaluation

- 30 M Theoretical assessment;
  (paper-based mid-term exam + quiz + attendance + seminar)
- 70 M paper-based theoretical final exam

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  Total 100 M

12. Learning and Teaching Resources

Required textbooks	Ansel's Pharmaceutical Dosage Forms and Drug Delivery
Main references (sources)	Ansel's Pharmaceutical Dosage Forms and Drug Delivery
Electronic References, Websites	