Course Description Form

1. Course Name:

Dosage Form Design (DFD)

2. Course Code:

Phind23_5210--

3. Semester / Year:

2nd Semester/5th year

4. Description Preparation Date:

01/02/2024

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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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 d development approval process	Theoretical lectures	Paper-based exams
3		Clinical studies	New d development approval process	Theoretical lectures	Paper-based exams
4	2	1. List common terms used in the Current	cGMP	Theoretical lectures	Paper-based exams

		Good Manufacturing Practice 2. (cGMP) for finished pharmaceuticals 3. 2. Describe the organization and personnel required by cGMP			
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	Pharmaceutical and formulation considerations	Theoretical lectures	Paper-based exams

		concern to the practicing pharmacist 2. Describe the purpose and general protocol for accelerated stability studies			
11	2	1. Summarize approaches employed to stabilize drugs in pharmaceutical dosage forms 2. Calculate rate reactions for various liquid dosage forms 3. Categorize various pharmaceutical ingredients and excipients	Pharmaceutical and formulation considerations	Theoretical lectures Laboratory demonstration	Paper-based exams
12	2	Principles of drug absorption	Biopharmaceutical and Pharmacokinet consideration	Theoretical lectures	Paper-based exams
13	2	Dissolution and drug absorption	Biopharmaceutical and Pharmacokinet consideration	Theoretical lectures	Paper-based exams
14	2	Bioavailability and bioequivalence	Biopharmaceutical and Pharmacokinet consideration	Theoretical lectures	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

100 M total

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	