

The primary purpose of this course is for the learner to achieve a clear and comprehensive understanding of the rational formulation and usage of drug products and preparations as they relate to development of logically sound explanations of and arguments for a particular patient’s drug therapy.

Course Prerequisites: -- Satisfactory completion of Block 1

Course Corequisites: -- PHA5021C Personal and Professional Development I

Course Faculty and Staff	
Course Director	Instructional Designer
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Academic Coordinators	
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Teaching Faculty	
Robin Moorman-Li, Pharm.D., BCACP, CPE <ul style="list-style-type: none"> Email: moorman@cop.ufl.edu Office: Jacksonville Campus Phone: 904-244-9590 	Mei He, Ph.D. <ul style="list-style-type: none"> Email: MHe@cop.ufl.edu Office: Gainesville Campus Phone: 352-273-9847

[Faculty and Staff: Who to Contact and Questions to Ask](#)

Office Hours: Please see the Canvas course site for posted office hours.

Faculty Locations:

Gainesville	PC: P-320 PEP: HPNP 2336	Jacksonville	Tower 2, First Floor
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Course Objectives and Educational Outcomes	
Course Objectives: Upon completion of this course, the student will be able to:	Linked Educational Outcome
1. Drug Development, Approval, and Manufacture	
a. Explain the drug development and approval processes for new chemical entities, generic and orphan drugs, drugs for compassionate use, and for changes in the drug product.	Learner
b. Describe the most critical concepts in the manufacture of sterile and non-sterile dosage forms, the standards for good manufacturing practices, and nature of compendial standards for chemicals, devices, and drug products.	Learner

2. Biopharmaceutics	
a. Describe the concepts important for understanding and predicting the relationships between the physicochemical properties of the drug, the drug's fate in the body after its administration as a dosage form, and the resulting onset, duration, and intensity of drug action.	Learner
b. In the therapeutic reasoning process, assess the relevance of formulation and biopharmaceutical properties of drugs.	Learner Problem-solver
3. Fundamental Physicochemical Properties	
a. Describe the fundamental physicochemical properties that are important for the rational design and formulation of stable dosage forms.	Learner
b. Develop causal explanations for the effects of fundamental physicochemical properties on the biopharmaceutical behavior of drugs and dosage forms in the body.	Learner Problem-solver
c. In the diagnostic reasoning process, determine and explain any implicated relationships between the drug's physicochemical properties or formulation and drug therapy problems.	Learner Problem-solver
4. Chemical and Physical Drug Stability	
a. Explain the major mechanisms of drug and dosage form chemical and physical instability, including formulation ingredient incompatibilities.	Learner
b. Describe formulation, packaging, and storage approaches for optimizing drug and drug product stability.	Learner
5. Drug Dosage Forms	
a. Explain the nature of all pharmaceutical dosage forms, including how they are designed, formulated, manufactured, compounded, and quality tested.	Learner
b. Assess and recommend, in the therapeutic reasoning process, the dosage form(s) and route(s) of administration that will best enable the patients to reach his or her therapeutic goal(s).	Learner Problem-solver
6. Drug Dosage Form Administration	
a. Explain the anatomical and physiological properties important for drug delivery for all parenteral and non-parenteral routes of drug administration.	Learner Problem-solver
b. In the diagnostic reasoning process, determine and explain any implicated relationships between the dosage form or its administration and drug therapy problems.	Learner Problem-solver
c. In the therapeutic reasoning process, assess and recommend the route(s) and techniques of dosage form administration that will best enable the patient to reach his or her therapeutic goal(s) and minimize untoward effects.	Learner Problem-solver
7. Pharmaceutical Calculations	
a. Demonstrate competence in performing pharmaceutical calculations according to standards that maximize accuracy and precision and to minimize the risk for error.	Learner Problem-solver
b. Assess the reasonableness of answers based on the understanding of the goals and purpose of the calculation.	Learner Problem-solver
8. Drug Preparation Compounding	
a. Explain compounding skills that are used for the most common types of non-sterile preparations, employing standards of good compounding practices and compounding regulations.	Learner
b. Provide rational counseling advice for the proper usage of compounded preparations.	Learner

9. Control of Drug Delivery	
a. Describe the rationale and approaches for the spatial and temporal control of drug delivery, describing examples, advantages and disadvantages for each route of drug administration.	Learner
10. Pharmaceutics of Recombinant Therapeutic Proteins and Related Biologics	
a. Explain the production, physicochemical properties, stability, formulation, and delivery of therapeutic proteins that distinguish biologics from small molecule compounds.	Learner Problem-solver
b. Understand the development and approval process for biosimilar biological products.	Learner Problem-solver
c. Recommend proper storage, handling, and administration techniques of therapeutic proteins.	Learner Problem-solver

Course Resources and Fees

Course Outline

See Appendix A. Please routinely check your Google campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/times, deadlines, and room changes.

Required Textbooks/Readings

There are no required textbooks for this course. Required readings will be posted on Canvas.

Use [UF VPN to access UF Libraries Resources](#) when off-campus. The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the [HSC Library Website](#) at this URL: <http://www.library.health.ufl.edu/>

Suggested Textbooks/Readings

1. Mobley WC, Amiji MM, Cook TJ, eds. (2019). Applied Physical Pharmacy, 3e. New York, NY: McGraw-Hill.
 - Available in Access Pharmacy. [Applied Physical Pharmacy, 3e | AccessPharmacy | McGraw-Hill Medical \(mhmedical.com\)](#)
2. Allen LV, Ansel HC. Pharmaceutical Dosage Forms and Delivery Systems, 10th Ed., Lippincott Williams and Wilkins. ISBN: 978-1-45-118876-9
3. Washington N, Washington C, Wilson C. (2001). Physiological Pharmaceutics: Barriers to Drug Absorption, 2nd Ed, Taylor & Francis.
 - a. E-book available free on-line at UF library.
4. Thompson, JE. A Practical Guide to Contemporary Pharmacy Practice, 3rd Edition. Lippincott Williams and Wilkins. ISBN: 0781783968

Other Required Learning Resources

N/A

Materials & Supplies Fees

N/A

Evaluation and Grading

Student Evaluation & Grading

The Canvas© gradebook will be set-up using the percentages below to compute the grade.

Assessment Item	Grade Percentage
Exams 1-3: 20% each	60%
Exam 4: 17%	17%
Online Formative Assessments (6 @ 0.5% ea.)	3%
In-Class Formative Assessments (5 @ 1% ea.)	5%
In-Class Collaborative Problem-Solving Exercise (5 @ 3% ea.)	15%
Total	100%

Grading Scale

Percentage	Letter Grade	Percentage	Letter Grade	Percentage	Letter Grade
92.50-100%	A	79.50-82.49%	B-	66.50-69.49%	D+
89.50-92.49%	A-	76.50-79.49%	C+	62.50-66.49%	D
86.50-89.49%	B+	72.50-76.49%	C	59.50-62.49%	D-
82.50-86.49%	B	69.50-72.49%	C-	< 59.50%	E

Rounding of grades:

Final grades in Canvas will be rounded to the 2nd decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and NO EXCEPTIONS will be made in situations where a student's grade is "close."

University of Florida Honor Pledge and Academic Dishonesty

UF students are bound by The Honor Pledge which states "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: "On my honor, I have neither given nor received unauthorized aid in doing this assignment."

The Conduct Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Expectations for Artificial Intelligence and when use constitutes academic dishonesty is outlined below.

Tendering information (giving your work to another to be copied, giving someone answers to assessment questions, informing another person in a later section about the questions that appear on an assessment that you have taken, or giving or selling a paper to another student), is considered academic dishonesty.

Students are required to report any condition that facilitates academic misconduct to appropriate personnel. Failure to report is also considered academic dishonesty. If you have any questions or concerns, please consult the course's Teaching Partnership Leader/Course Director or Assistant Dean for Curricular Affairs.

See the [UF Conduct Code website](#) for more information. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Assignment Descriptions

See Canvas course site for assignment descriptions and instructions.

Course-Related Policies

UF Resources and Policies

University of Florida resources and policies can be found at this URL: <https://go.ufl.edu/syllabuspolicies>

PharmD Course Policies

The Policies in the following link apply to this course. Review the General [Pharm.D. Course Policies](#) carefully, at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/course-policies/>

Attendance Policy

Attendance is mandatory for active learning sessions such as team-based learning sessions, case discussions, laboratory sessions, and other activities that the instructor designates as required. This course has 5 required sessions. A student who misses greater than 1 session(s) for this course will receive an incomplete in the course and will retake the course during the next offering, resulting in delayed graduation.

Makeup Assignments

Makeup assignments will be required for excused absences from all Active Learning Sessions. Students will be required to complete the makeup assignment within one week of the missed session.

Late Assignments

Late assignments and assessments will not be accepted and will result in a grade of zero.

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software.

1. ExamSoft™ Testing Platform
2. Canvas™ Learning Management System

For technical support, navigate to [Educational Technology and IT Support Contact Information](#) at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/technical-help/>

Artificial Intelligence (AI) Use for Assessments

The use of generative AI in assessments is prohibited, unless explicitly allowed by the course instructor. Assessments include any submitted work, graded or ungraded, that will be evaluated. These include, but are not limited to, quizzes, exams, assignments, writing projects, etc. If a student is uncertain about the use of AI technology, it is the student's responsibility to ask the instructor prior to beginning the assignment or assessment.

When authorized by the course director/course instructors, students may use AI technologies in the completion of an assessment if they acknowledge all use by naming the technology, describing how it was employed, and adhering to any other requirement stipulated in the assessment's instructions. Failure to acknowledge the use of AI technology or disregarding instructions related to the use of AI for assessments is considered academic misconduct. Students must disclose the use of AI and AI-assisted technologies by following the instructions below.

Application of AI technology must be done with human oversight and control, and students should carefully review and edit the result, as AI can generate outputs that can be incorrect, incomplete, or biased. **Students assume full responsibility for all content, including errors and omissions, if AI is employed.** Additionally, privacy is a concern with AI-generated content. Most commercially available AI systems are not compliant with [HIPAA](#) or FERPA protections, inputting patient or student information is prohibited by federal law.

<p>Instructions to acknowledge the use of AI:</p> <p>Statement: During the preparation of this assignment I/we, [INSERT NAME/S], used [INSERT TOOL / SERVICE] in order to [INSERT REASON OR PURPOSE]. After using this tool/service, I/we reviewed and edited the content as needed and take full responsibility for the content of the submission.</p>
<p>Penalties for unauthorized use: Unauthorized use of AI text generators for assessments is considered evidence of academic dishonesty (see policy on academic dishonesty).</p>
<p>Disability Resource Center</p> <p>Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the Disability Resource Center. See the Get Started with the DRC webpage on the Disability Resource Center site. It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.</p>
<p>Course Evaluation Process</p> <p>Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online. Students can complete evaluations in three ways:</p> <ol style="list-style-type: none"> 1. The email they receive from GatorEvals, 2. Their Canvas course menu under GatorEvals, or 3. The central portal at https://my-ufl.bluera.com <p>Guidance on how to provide constructive feedback is available at https://gatorevals.aa.ufl.edu/students/. Students will be notified when the evaluation period opens. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/</p>

Appendix A: Course Outline

Date / Time [Recommended for Independent Study]	Mod#	Activity	Activity Title	Contact Time (min)	Faculty
09/22/25	1	Module	Module 1: Course Overview, New Drug Development, Introduction to Biopharmaceutics, Pharmaceutical Pre-formulation, Drug Stability, Parenteral Drug Delivery (Objectives 1-7)		Cary Mobley
09/22/25	1.1	Lecture Video	Watch: Course Overview	30	Cary Mobley
		Quiz (Self-Assessment)	Course Introduction Quiz		Cary Mobley
09/22/25	1.2	Lecture Video	Watch: New Drug Development	60	Cary Mobley
09/23/25	1.3	Lecture Video	Watch: Intro to Biopharmaceutics I	32	Cary Mobley
09/24/25	1.4	Lecture Video	Watch: Intro to Biopharmaceutics II	50	Cary Mobley
09/24/25	1.5	Lecture Video	Watch: Pharmaceutical Preformulation I	38	Cary Mobley
09/24/25	1.6	Lecture Video	Watch: Pharmaceutical Preformulation II	39	Cary Mobley
09/24/2025 DUE 11:59 PM	1.2-1.6	Quiz (Online)	Assignment: Online Formative Assessment 1: New Drug Development through Preformulation II		Cary Mobley

09/25/25	1.7	Lecture Video	Watch: Pharmaceutical Preformulation III	34	Cary Mobley
09/25/25	1.8	Lecture Video	Watch: Pharmaceutical Preformulation IV	53	Cary Mobley
09/26/25	1.9	Lecture Video	Watch: Drug Stability I	56	Cary Mobley
09/26/25	1.10	Lecture Video	Watch: Drug Stability II	40	Cary Mobley
09/26/25	1	Reading	ALS Prep: Reading (See Canvas)	50	Cary Mobley
09/29/2025 DUE:11:59 PM	1.7-1.10	Quiz (Online)	Assignment: Online Formative Assessment 2: Preformulation III - Drug Stability II)		Cary Mobley
09/30/2025 at 8:00am - 9:50am	1.2-1.10 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 1: Problem-Solving Exercise	110	Cary Mobley
09/30/25		Quiz (In Class)	In-Class Formative Assessment #01		Cary Mobley
09/30/25		Assignment (Graded)	In-Class Collaborative Problem Solving Exercise #01		Cary Mobley
09/30/25	1.11	Lecture Video	Watch: Parenteral Drug Delivery I	54	Cary Mobley
10/01/25	1.12	Lecture Video	Watch: Parenteral Drug Delivery II	50	Cary Mobley
10/01/25	1.13	Lecture Video	Watch: Parenteral Drug Delivery III	45	Cary Mobley
10/02/25	1.14	Lecture Video	Watch: Parenteral Drug Delivery IV	47	Cary Mobley
10/03/2025 at 1:00pm - 3:00pm	1	Exam	Exam 1: Module 1	120	Cary Mobley
	2	Module	Module 2:Oral Drug Delivery, Powders, Granules, Capsules, Tablets, Liquids, Buccal/SL, Rectal (Objectives 5-6)		Cary Mobley
10/03/25	2.1	Lecture Video	Watch: Oral Drug Delivery Overview	24	Cary Mobley
10/06/25	2.2	Lecture Video	Watch: Powders/Granules I	28	Cary Mobley
10/07/25	2.3	Lecture Video	Watch: Powders/Granules II	32	Cary Mobley
10/08/25	2.4	Lecture Video	Watch: Capsules I	42	Cary Mobley
10/08/25	2.5	Lecture Video	Watch: Capsules II	44	Cary Mobley
10/09/25	2.6	Lecture Video	Watch: Tablets I	52	Cary Mobley
10/09/25	2.7	Lecture Video	Watch: Tablets II	55	Cary Mobley
10/09/2025 DUE: 11:59pm	2.1-2.7	Quiz (Online)	Assignment: Online Formative Assessment 3: Oral Overview to Tablets II		Cary Mobley
10/10/25	2.8	Video Lecture	Watch: Oral Liquids I	42	Cary Mobley
10/10/25	2.9	Video Lecture	Watch: Oral Liquids II	43	Cary Mobley
10/10/25	2.10	Video Lecture	Watch: Oral Liquids III	45	Cary Mobley
10/10/25	2.11	Video Lecture	Watch: Oral Liquids IV	60	Cary Mobley
10/14/25	2.12	Lecture Video	Watch: Sublingual/Buccal Drug Delivery	46	Cary Mobley
10/14/25	2.13	Lecture Video	Watch: Rectal Drug Delivery	45	Cary Mobley
10/14/25	2	Reading	ALS Prep: Reading with Assignment (See Canvas)	50	Cary Mobley
10/14/2025 DUE: 11:59PM	2.7-2.13	Quiz (Online)	Assignment: Online Formative Assessment 4: Oral Liquids to Rectal		Cary Mobley
10/15/2025 at 8:00am - 9:50am	2.1-2.13 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 2: Problem-Solving Exercise	110	Cary Mobley, Robin Moorman Li
10/15/25		Quiz (In Class)	In-Class Formative Assessment #02		Cary Mobley
10/15/25		Assignment (Graded)	In-Class Collaborative Problem Solving Exercise #02		Cary Mobley
10/22/2025 at 2:00pm - 4:00pm	2	Exam	Exam 2: Module 2	120	Cary Mobley

	3	Module	Module 3: Topical, Vaginal, Ophthalmic, Intranasal, Pulmonary, Advanced, Pharmaceutical Biotechnology (Objectives 5, 6, 9, 10)		Cary Mobley
10/22/25	3.1	Lecture Video	Watch: Topical Drug Delivery I	53	Cary Mobley
10/23/25	3.2	Lecture Video	Watch: Topical Drug Delivery II	68	Cary Mobley
10/24/25	3.3	Lecture Video	Watch: Vaginal Drug Delivery	19	Cary Mobley
10/24/25	3.4	Lecture Video	Watch: Ophthalmic Drug Delivery I	30	Cary Mobley
10/28/25	3.5	Lecture Video	Watch: Ophthalmic Drug Delivery II	46	Cary Mobley
10/29/25	3.6	Lecture Video	Watch: Intranasal Drug Delivery	34	Cary Mobley
10/29/25	3.7	Lecture Video	Watch: Pulmonary Drug Delivery I	50	Cary Mobley
10/30/25	3.8	Lecture Video	Watch: Pulmonary Drug Delivery II	58	Cary Mobley
10/30/25	1.5	Reading	ALS Prep: Reading with Assignment (See Canvas)	50	Cary Mobley
10/30/2025 DUE: 11:59 PM	3.1-3.8	Quiz (Online)	Assignment: Online Formative Assessment 5: Topical to Pulmonary		Cary Mobley
10/31/2025 at 10:00am - 11:50am	3.1-3.8 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 3: Problem-Solving Exercise	110	Cary Mobley
10/31/25		Quiz (In Class)	In-Class Formative Assessment #03		Cary Mobley
10/31/25		Assignment (Graded)	In-Class Collaborative Problem Solving Exercise #03		Cary Mobley
10/31/25	3.9	Lecture Video	Watch: Advanced Drug Delivery I	26	Cary Mobley
11/03/25	3.10	Lecture Video	Watch: Advanced Drug Delivery II	61	Cary Mobley
11/04/25	3.11	Lecture Video	Watch: Advanced Drug Delivery III	46	Cary Mobley
11/05/25	3.12	Lecture Video	Watch: Advanced Drug Delivery IV	42	Cary Mobley
11/05/25	3.13	Lecture Video	Watch: Pharmaceutical Biotechnology I	38	Mei He
11/06/25	3.14	Lecture Video	Watch: Pharmaceutical Biotechnology II	44	Mei He
11/06/25	1.5	Reading	ALS Prep: Reading (See Canvas)	50	Cary Mobley
11/06/25 DUE: 11:59pm	3.9-3.14	Quiz (Online)	Assignment: Online Formative Assessment 6: Advanced to Pharm. Biotechnology		Cary Mobley
11/07/2025 at 8:00am - 9:50am	3.9-3.14 & ALS Prep Reading	Active Learning Session--VC	Active Learning Session 4: Problem-Solving Exercise	110	Cary Mobley, Mei He, Robin Moorman Li
11/07/25		Quiz (In Class)	In-Class Formative Assessment #04		Cary Mobley
11/07/25		Assignment (Graded)	In-Class Collaborative Problem Solving Exercise #04		Cary Mobley
11/12/2025 at 2:00pm - 4:00pm	3	Exam	Exam 3: Module 3	120	Cary Mobley
	4	Module	Module 4: Pharmaceutical Calculations and Compounding (Objectives 5, 7, 8)		Cary Mobley
11/13/25	4.1	Lecture Video	Watch: Introduction to Calculations I	56	Cary Mobley
11/13/25	4.2	Lecture Video	Watch: Introduction to Calculations II	58	Cary Mobley
11/14/25	4.3	Lecture Video	Watch: Introduction to Calculations III	61	Cary Mobley
11/14/2025 at 11:50am - 12:15pm		Course Evaluation	Course Evaluation		
12/02/2025 at 1:00pm - 2:50pm	4.1-4.3	Active Learning Session--VC	Active Learning Session 5: Problem-Solving Exercise	110	Cary Mobley, Robin Moorman Li

12/02/25		Quiz (In Class)	In-Class Formative Assessment #05		Cary Mobley
12/02/25		Assignment (Graded)	In-Class Collaborative Problem Solving Exercise #05		Cary Mobley
12/03/25	4.4	Lecture Video	Watch: Overview of Compounding I	58	Cary Mobley
12/03/25	4.5	Lecture Video	Watch: Overview of Compounding II	43	Cary Mobley
12/05/25	4.6	Lecture Video	Watch: Compounding Selected Dosage Forms I	38	Cary Mobley
12/05/25	4.7	Lecture Video	Watch: Compounding Selected Dosage Forms II	39	Cary Mobley
12/09/2025 at 2:00pm - 4:00pm		Exam	Exam 4: Module 4		Cary Mobley
			Total Min	3264	
			Total Hours	65.28	