

PHA5177C Advanced Non-Sterile Compounding

Fall, 2020

2 Credit Hours – [A-E Grading]

In this course, students will discover the scope of non-sterile compounding practice and what this practice offers to help fulfill unmet needs in pharmaceutical care. Students will also learn and practice the techniques for producing a variety of compounded non-sterile pharmaceutical preparations according to high standards of quality and accuracy, towards the goal of optimizing patient care through the preparation of high quality and accurate patient-specific dosage forms.

Teaching Partnership Leader

W. Cary Mobley, Ph.D.

- Email: wmobley@cop.ufl.edu
- Office: HPNP 1315
- Phone: 352-273-6282
- Office Hours: By appointment and from 4-5 PM on 9/21 and 10/5 by Zoom
<https://ufl.zoom.us/j/93101556201?pwd=RnV0ZWVlOWJlZ0t5NndXQzIjZUw5dz09>

See Appendix A. for Course Directory of Faculty and Staff Contact Information

Entrustable Professional Activities

This course will prepare you to perform the following activities which the public entrusts a Pharmacist to perform:

Patient Care Provider Domain

4. Implement a care plan in collaboration with the patient, caregivers, and other health professionals.

ST4.2. Educate a patient regarding the appropriate use of a new medication, device to administer a medication, or self-monitoring test.

Practice Manager Domain

14. Fulfill a medication order.

ST14.2. Prepare commonly prescribed medications that require basic sterile compounding or basic non-sterile compounding prior to patient use.

Course-Level Objectives

Upon completion of this course, the student will be able to:

1. Describe the scope of non-sterile compounding practice, including types of practices and the regulatory landscape.
2. Describe USP standards applicable to non-sterile compounding.
3. Describe methods to assure the quality of non-sterile compounded preparations.
4. Describe the underlying therapeutic rationale and dosage forms currently used to help meet patient needs in the following areas of pharmaceutical compounding:
 - a. Pediatrics and Geriatrics

- b. Men's and Women's Health
 - c. Veterinary Health
 - d. Dermatological Conditions
 - e. Cosmeceuticals and Antiaging
 - f. Dentistry
 - g. Pain Management
 - h. Sports Medicine
 - i. Palliative Care
 - j. Hospice
5. Prepare detailed compounding records that follow the standards of USP Chapter 795.
 6. Interpret symbols, abbreviations, and terminology used in prescription writing.
 7. Select appropriate reference sources for location of specific information on drugs and excipients.
 8. Determine, research, and record important physicochemical properties of the ingredients, as they relate to compounded preparations that are stable, safe, and efficacious.
 9. Perform necessary calculations accurately and precisely.
 10. Weigh and measure ingredients accurately, including selecting the most appropriate apparatus for weighing or measuring.
 11. Assure that preparations are prepared so that all ingredients are present in the correct quantities, in known and stable physical and chemical states, and mixed appropriately to assure accurate dosing and predictable and optimal biopharmaceutical behavior when administered to a patient.
 12. Select the most appropriate container to ensure stability of the preparation and to accommodate patient compliance.
 13. Select appropriate auxiliary and cautionary labels to assure proper use and storage of preparations.
 14. Determine the appropriate information with which to counsel patients.
 15. Apply methods of quality assurance to compounded preparations.

Course Pre-requisites.

1. Successful completion of first year of PharmD curriculum, including milestones.
2. Successful completion of Patient Care 5 (Endocrine and Reproductive) – PHA5787C.

Course Co-requisites

None.

Course Outline

See Appendix. Please routinely check your 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

This course does not have a required text. Presenters may require additional materials or readings to supplement the lecture material.

- 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

- None. *A Practical Guide to Contemporary Pharmacy Practice, 2nd or 3rd Ed* JE Thompson
- Applied Pharmaceutics in Contemporary Compounding, 2nd Ed*, R Shrewsbury

Other Required Learning Resources

N/A

Materials & Supplies Fees

None

Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.

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

Assessment Item	Grade Percentage
Online Quizzes, Modules 1-2 (n=2)	8%
Online Quizzes, Modules 3-6 (n=4)	16%
Prescription Compound Record ¹ (n=12) [see Appendix C]	36%
Preparation Quality ² (n=12) [see Appendix D]	36%
Laboratory Professionalism ³ (n=2) [see Appendix E]	4%
Total	100%

Table 1.1 Evaluation and Grading Above

Table 1.2 grading scale

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

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/>

Pharm.D. 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/>

Course Evaluation Process

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at <https://gatorevals.aa.ufl.edu/students/>. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via <https://ufl.bluera.com/ufl/>. Summaries of course evaluation results are available to students at <https://gatorevals.aa.ufl.edu/public-results/>.

Appendix A. Course Directory

Teaching Partnership Leader/Course Director:

W. Cary Mobley, Ph.D.

- Email: wmobley@cop.ufl.edu
- Office: HPNP 1315
- Phone: 352-273-6282

Office Hours: Mondays from 4-5 and by appointment.

Questions to Ask:

- Concerns about performance
- Guidance when there are performance problems (failing grades)
- General questions about content

Instructional Designer:

Name: Holly Fremen

- Email: holly.fremen@cop.ufl.edu
- Office: HPNP 4309
- Phone: 352-273-5558

Academic Coordinator Gainesville Campus:

Name: Misti Merrill

- Email: mmerrill@cop.ufl.edu
- Office: HPNP 4312
- Phone: 352-273-5617

Absence/Tardy Email: (Visit the course policy site for further instructions)

Educational Coordinator Jacksonville Campus:

Name: McKenzie Wallen

- Email: mwallen@cop.ufl.edu
- Office: Jacksonville Campus

Educational Coordinator Orlando Campus:

Name: Iverta Allen

- Email: iallen1@cop.ufl.edu
- Office: Orlando Campus

Questions to Ask:

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence/tardy requests (Only the Academic Coordinator handles absence requests)
- Questions about dates, deadlines, meeting place
- Availability of handouts and other course materials

- Assignment directions
- Questions about grade entries in gradebook (missing grades, incorrect grade)

Appendix C. Prescription Compound Record

Prescription Compound Record - For each prescription, a handwritten compound record must be submitted at the end of the lab session. Typed or photocopied compound records will not be accepted (see separate document entitled "Guidelines for Labels and Compound Records"). To avoid professionalism deductions, as much of this record as possible must be completed before entering the lab session. It is very important to come to the session fully prepared (e.g., entering the lab with blank compound records will not be tolerated and will result in significant professionalism deductions and possible dismissal from the session).

Appendix D. Preparation Quality

Prescription Preparation – Each preparation will be graded for accuracy, quality, and labeling (see Grading Criteria below). Point deductions will be indicated on the relevant compound record.

Note on Minimum Acceptable Grade: Students must achieve at least 6 out of 10 points for the combined *accuracy* and *quality* grades of each prescription (see Grading Criteria below). If less than 6 points are earned, the prescription must be repeated at a time arranged between the student, the course instructor, and the site facilitators. The maximum combined accuracy and quality grade for a repeated Rx will be 7 points.

LABORATORY PERFORMANCE

Compounding techniques will be described in lecture, lab, and reading assignments. Therefore, the student *must come to each lab intellectually prepared* to fill the prescriptions and the student *must come to each lab with a goal of compounding the preparations accurately and efficiently*.

Grading Guidelines

The following is a possible point deduction list, which will be used as a guide to evaluate your performance. Other, preparation-specific criteria may be added during the semester.

Point Deductions for Lab Performance

Compounding Professionalism Deductions		
	5 - 10	Incomplete compound record before the lab session begins (i.e. portions missing that should have been completed ahead of time); possible dismissal from lab
	7	Late compound record (record not turned in by the end of the session). Maximum compound record score of 3 / professionalism score of 3.
	1 – 10	Poor behavior (e.g., excessive talking about extraneous matters, which leads to error or disturbs other students).
	1 – 5	Rough handling of compounding equipment
	2	Dirty lab station or dirty equipment left behind: The student must leave the work area and compounding equipment in pristine condition.
	1 – 10	Insufficient knowledge or insufficient preparation for lab

	1 – 5	Failure to label ingredients during compounding. Labeling the weigh paper is appropriate.
	1 – 10	Tardiness (1 point per minute)
	1 – 10	Failure to work independently on preparation or compound record
	1 – 10	Inability to finish the preparations by the end of lab
	1 – 10	Failure to follow the proper dress code
	2	Ingredient containers haphazardly left open, or leaving spatulas in containers.
	1 – 10	Failure to follow “Laboratory Safety Procedures and Rules” and “General Lab Instructions and Information” as described later in this document.
Prescription Grade Deductions		
Preparation accuracy	Repeat Rx	Incorrect ingredients
	Repeat Rx	Incorrect amount of ingredients
	Repeat Rx	Wrong quantity dispensed
	Repeat Rx	Preparation not uniformly mixed
Preparation quality	Varies	Capsules: Fingerprints, sticky, or not completely snapped shut (2), wrong cap size (7)
	3	Liquids: Solutions not clear. Dispersions separate rapidly.
	3	Semisolids: Preparation is lumpy or gritty
	1	Preparation is on lid, grooves, or outside of container.
	1.5	Wrong <i>type</i> of container (1 point if right type, but wrong size)
Preparation labeling	1	Smudging on label, crooked or wrinkled label
	3	Wrong directions that could affect patient therapy: May include wrong route, wrong dosing interval, wrong number of doses, wrong dosage form, wrong preparation name, wrong beyond-use date
	1.5	Incomplete directions, (e.g., “Mix” instead of “mix and take”)
	2	Wrong quantity dispensed on label
	1.5	Wrong label format (See separate document entitled “Guidelines for Labels and Compound Records”)
	1	Wrong Rx #
	1	Misspelled word
	1	Handwriting on the label
	1.5	Auxiliary label missing from container
	1	Missing units (% , ml , mg , etc.)
Compound Record Deductions		
7	Typed or photocopied compound record	
1 (each)	Ingredient purpose or solubility missing or inaccurate	
2 each	Missing or erroneous calculations (<u>Repeat</u> Rx if directions don’t indicate accurate quantities)	
1 each	Missing ingredients in list	
0.5 each	Missing labels or units in calculations (0.5 pt each instance, 2 points max deduction per Rx)	
1	Compounding directions not concise	
1	Compounding directions not written legibly in a numbered, step-wise manner	
2 each	Missing ingredients or ingredient amounts in compounding directions (<i>Repeat Rx if uncertainty in ingredients or amounts used.</i>)	

Appendix E. Professionalism

Professionalism – The professionalism of the students will be evaluated during each lab. The score for each lab will range from zero to ten. Repeated professionalism infractions will be met with further grade deductions. Categories that will be evaluated include the following:

1. Punctuality
2. Preparedness
3. Behavior
4. Handling of materials and equipment
5. Independence of work
6. Cleanliness
7. Following dress code

Appendix F. Laboratory Safety Procedures and Rules

(Failure to follow lab safety rules and procedures may result in dismissal from the lab)

- 1) **DRUGS AND COMPOUNDED PREPARATIONS MUST NOT BE USED FOR SELF-MEDICATION.**
- 2) **DRUGS AND COMPOUNDED PREPARATIONS MUST NOT BE TASTED UNDER ANY CIRCUMSTANCES.**
- 3) **NO DRINKS OR FOOD IN THE LABORATORY.**
- 4) Students must NOT be in the laboratory in the absence of laboratory personnel. Please wait until you are invited into the lab by laboratory personnel.
- 5) Students will not be allowed in the lab without lab coat and the lab coat must remain closed during the lab session. Students must wear closed-toed shoes in the lab. Gloves will be worn at all times when preparing compounds. Safety glasses and masks must be worn when instructed.
- 6) **Hazardous Waste Collection:** All compounding chemicals and materials contaminated with these chemicals must be disposed of in designated Hazardous Waste containers. Non-contaminated refuse must be disposed of in regular trash bins. Follow the rules to protect our environment and yourself. If you are not sure how to dispose any drug/chemical, ask the instructors. Failure to properly dispose of waste may result in dismissal from the lab.

The following containers will be used for hazardous waste collection in our labs:

- Thirty Gallon Poly Bag Lined Fiber Drums** – All solid and semisolid compounded preparations and contaminated materials, including empty containers, gloves, weighing paper, paper towels, etc.. In some cases, tightly closed liquid preps will be placed in these drums.
- Five Gallon Plastic Buckets** – Buckets containing liquid compounded preparations (must first be tightly closed).
- Broken Glassware Container** - Broken glassware must be reported to the instructors and placed into the designated containers. Mercurial spill from

broken thermometers must be immediately reported.

Biohazard (Red) Bag Lined Box - Any pathological waste (e.g., sterile preps and associated materials, glucose and cholesterol testing materials, etc.) must be disposed of in this bag. Sharps (e.g., needles and amps) must first be placed in SHARPS CONTAINERS

Normal Trash Containers - All papers or stationary not containing chemical or pathological waste are disposable in normal trash.

Information about the University of Florida's Hazardous Waste Management policies can be found at <http://www.ehs.ufl.edu/HMM/>

- 7) Do not place anything in the sinks unless allowed by the lab instructors. Keep all sinks clean.
- 8) Return all drugs, tightly sealed, to their proper place immediately after use. Make sure to return the chemicals in their correct containers. Have the instructors/assistants check this if you are uncertain.
- 9) Use a pen/pencil to write the identification of chemicals/drugs on weigh papers while compounding the prescription.
- 10) Bags, books etc. should be left in the allocated places in the laboratories, away from the workspaces.
- 11) Know the location and use of fire-fighting appliances and eye-wash station in and near the laboratory.
- 12) If you have any known allergy to any chemicals or if you feel sick during the lab, immediately report to the instructors.

Lab Schedules

Sept 25, Lab 1 – Orlando - Group A 8:30-12:30, Group B 1:55-5:55 pm
Sept 25, Lab 1 – Jacksonville (all) 3:00 - 7:00 pm
Oct 14, Lab 2 – Orlando - Group A 8:30-12:30, Group B 1:55-5:55 pm
Oct 14, Lab 2 – Jacksonville (all) 3:00 – 7:00 pm
Sept 30, Lab 1 – Gainesville - Group A 1:55-5:55 pm
Oct 9, Lab 1 – Gainesville - Group B 1:55-5:55 pm
Oct 16, Lab 2 – Gainesville - Group A 1:55-5:55 pm
Oct 30, Lab 2 – Gainesville - Group B 1:55-5:55 pm

Course Outline

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

[Recommended dates for independent study]	Mod #	Activity	Unit Topic	Contact Time [hr.]a	Syllabus Learning Objectives	Responsible
	1	Module	Module 1: Lab 1 Preparations		5-15	Cary Mobley
9/18/2020	1.1	Online Notes	Review: Preparing for Compounding Lab 1 Preparations – Part 1 – Topical Semisolids	60		Cary Mobley
9/21/2020	1.2	Video Lecture	Watch: Preparing for Compounding Lab 1 Preparations – Part 2 – Lab 1 Prescriptions	60		Cary Mobley
DUE 9/24/2020 at 11:59PM	1.1 and 1.2	Assignment Graded	Assignment: Module 1 Online Quiz			Cary Mobley
Upon completion of the lab		Assignment Graded	Assignment: Written Compound Records Completed Before and During Lab Session 1			Cary Mobley
Assigned Dates and Times	1	Lab	Laboratory Session 1: Preparation of Lab 1 Preparations	240		Cary Mobley
	2	Module	Module 2: Lab 2 Preparations		5-15	Cary Mobley
10/7/2020	2.1	Online Notes	Watch: Preparing for Compounding Lab 2 Preparations – Part 1 – Oral Preparations, Sticks, and Suppositories	60		Cary Mobley
10/8/2020	2.2	Video Lecture	Watch: Preparing for Compounding Lab 2 Preparations – Part 2 – Lab 2 Prescriptions	60		Cary Mobley
DUE 10/13/2020 at 11:59pm	2.1 and 2.2	Assignment Graded	Assignment: Module 2 Online Quiz			Cary Mobley
Upon completion of the lab		Assignment Graded	Assignment: Written Compound Records Completed Before and During Lab Session 2			Cary Mobley
Assigned Dates and Times	2	Lab	Laboratory Session 2: Preparation of Lab 2 Preparations	240		Cary Mobley

	3	Module	Module 3: The Scope and Standard of Pharmacy Compounding		1-3	Cary Mobley
11/30/2020	3.1	Video Lecture	Watch: The Scope of Compounding Practice	60		Cary Mobley
11/30/2020	3.2	Video Lecture	Watch: Standards and Quality Assurance in Compounding	60		Cary Mobley
11/30/2020	3.3	Reading	Read: Safety in Compounding	60		Cary Mobley
DUE 12/01/2020 at 11:59pm	3	Assignment Graded	Assignment: Module 3 Online Quiz			Cary Mobley
	4	Module	Module 4: Compounding for Different Types of Patients		4a-4c	Cary Mobley
12/01/2020	4.1	Reading	Read: Pediatric and Geriatric Patients	60		Cary Mobley
12/01/2020	4.2	Reading	Read: Men's and Women's Health	60		Cary Mobley
12/01/2020	4.3	Video Lecture	Watch: Animals – Small, Medium, and Large	60		Cary Mobley
DUE 12/02/2020 at 11:59pm	4	Assignment Graded	Assignment: Module 4 Online Quiz			Cary Mobley
	5	Module	Module 5: Compounding for the Skin		4d-4e	Cary Mobley
12/02/2020	5.1	Reading	Read: Dermatological Conditions – I	60		Cary Mobley
12/02/2020	5.2	Reading	Read: Dermatological Conditions – II	60		Cary Mobley
12/02/2020	5.3	Reading	Read: Dermatological Conditions – III	60		Cary Mobley
DUE 12/03/2020 at 11:59pm	5	Assignment Graded	Assignment: Module 5 Online Quiz			Cary Mobley
	6	Module	Module 6: Compounding for Special Patient Needs		4f-4j	Cary Mobley
12/03/2020	6.1	Reading	Read: Dental Patients and Sports Medicine	60		Cary Mobley
12/03/2020	6.2	Reading	Read: Pain Management	60		Cary Mobley
12/03/2020	6.3	Reading	Read: Hospice and Palliative Care	60		Cary Mobley
DUE 12/04/2020 at 11:59pm	6	Assignment Graded	Assignment: Module 6 Online Quiz			Cary Mobley
			Total Minutes in Course	1440		
			Total Hours in Course	24		