

# **Pharmacy Lab 3: Sterile Products and Intravenous Admixtures**

## **PHAR 7193**

### **Fall Semester 2021**

#### **Course Description**

This laboratory course will provide students with hands on experience in preparing and dispensing parenteral and sterile products and admixtures using aseptic techniques.

#### **Additional Course Information**

This course will provide students with the knowledge and skills to compound sterile preparations according to established standards and best practices. Emphasis will be given on proper garbing, use of laminar flow hood, handling, and labeling of sterile preparations.

**Course Credit:** 1 credit hour

**Pre-Requisites:** PHAR 7201 Pharmacy Calculations

**Co-Requisites:** None

#### **Class Meeting Days, Time & Location**

Pre-lab sessions: W.T. Brookshire Hall Room 136; Monday; 11:00 am – 12:00 pm

Lab sessions: W.T. Brookshire Hall Room 211; 235

Tuesday: Session: 9:00 am – 11:00 am

Wednesday: Session: 9:00 am – 11:00 am

**\*\*Please see course schedule for exam times\*\***

**\*\*Students Must Attend Their Assigned Lab Day\*\***

#### **Course Coordinator**

Jose Vega, Pharm.D.

Office WTB 239

Phone: 903-565-6581

Cell: 325-829-8982

Email: [jvega@uttyler.edu](mailto:jvega@uttyler.edu)

Office hours: 12 pm – 1 pm Monday, 11 am – 12 pm Tuesday and Wednesday, open door, and by appointment

Preferred method of contact: email

#### **Fisch College of Pharmacy (FCOP) and UT Tyler Policies**

This is part 1 of the syllabus. Part 2 contains UT Tyler and the FCOP course policies and procedures. These are available as a PDF at <https://www.uttyler.edu/pharmacy/academic-affairs/>. For experiential courses (i.e., IPPE and/or APPE), the Experiential Manual contains additional policies and instructions that supplement the Syllabus Part 1 and 2. Please note, the experiential manual may contain policies with different deadlines and/or instructions. The manual should be followed in these cases.

### Required Materials

Most course-required materials are available through the Robert R. Muntz Library. These materials are available either online\* (<http://library.utt Tyler.edu/>) or on reserve.

1. Ochoa, Pamela, and Vega, Jose. *Concepts in Sterile Preparations and Aseptic Technique*. Jones & Bartlett Learning, Burlington, MA, 2015. ISBN:978-1-284-03572-8
2. Other required materials will be posted on the classes' Canvas site. The site address is: [utt Tyler.edu/canvas](http://utt Tyler.edu/canvas).

### Recommended Materials

None

### Course Format

The course may include, but are not limited to, the following activities:

- Independent study of selected readings/ Lecture notes
- Live/video presentation
- Laboratory instruction/ practice

### Course Learning Outcomes (CLOs)

CLOs	PLO(s) Assessed for this CLO	EPAs	Assessment Methods	Grading Method	PPCP Skill(s) Assessed	ACPE Std. 11 & 12
1. Describe the advantages and disadvantages of parenteral administration	1	NA	2,5	ES	NA	NA
2. Recognize various types of supplies and equipment for compounding sterile preparations	1	NA	1,2,5	ES	NA	NA
3. Perform calculations as required for sterile compounding	1	3.2	1,2,5	ES	NA	NA
4. Demonstrate proper aseptic garbing, hand washing, hood cleaning, sharp handling techniques	1	NA	1,3,4	RUB	NA	NA
5. Summarize USP Chapter 797 regulations and guidelines for compounded sterile preparations	1	NA	2,5	ES	NA	NA
6. Recognize principles of compatibility and stability when compounding sterile preparations	1	3.2	1,2,5	ES	NA	NA
7. Summarize USP Chapter 800 regulations and guidelines for compounded sterile hazardous preparations	1	NA	2,5	ES	NA	NA
8. Compare the differences between compounding parenteral nutrition preparations and other sterile compounded preparations	1	NA	1,2,5	ES	NA	NA
9. Describe patient safety considerations when compounding pediatric parenteral preparations	1	3.2	2,5	ES	NA	NA

10. Explain the elements, regulations, and guidelines for quality assurance and quality control when compounding sterile preparations	1	3.2	2,5	ES	NA	NA
11. Prepare a compounded preparation using proper aseptic techniques that is free of microbial contamination	1	5.2	4	RUB	NA	NA

### Course Assessment Methods

	Assessment Method	Description
1	Weekly lab participation	Weekly participation grades based on preparedness for lab, professionalism, participation during lab, correct technique, complete products and correct labels
2	Weekly written quizzes	7-11 unannounced quizzes, 4-5 questions covering material from prior week(s), standard MCQ, select all that apply, fill in the blank, true/false, short answer questions
3	Midterm lab exam	Compounding a medium risk parental preparation in the hood using aseptic techniques, manipulation accuracy will be observed and graded, this exam will be recorded, and you will perform a self-evaluation of your video
4	Final lab exam	Compounding a medium risk parental preparation in the hood using aseptic techniques, manipulation accuracy and microbial growth will be observed and graded, preparation will be evaluated for evidence of microbial growth after two weeks of incubation
5	Midterm written exam	In-person exam, 40-60 questions, standard MCQ, select all that apply, fill in the blank, true/false, short answer questions
6	Final written exam	In-person exam, cumulative exam, 40-60 questions, standard MCQ, select all that apply, fill in the blank, true/false, short answer questions

### Grading Policy & Grade Calculation

Grades will be determined based on evaluation of individual cumulative lab participation assessments, midterm examinations, final examinations, and quizzes. Examinations may consist of multiple-choice, true/false, short-answer, essay, and problem-based questions, skills assessment, sterile techniques and media fill test.

As a laboratory course requiring minimal individual competency in both practical skills demonstrations and core knowledge, students must achieve an average score of  $\geq 70\%$  on the experiential training components of the course and an average score of  $\geq 70\%$  on the didactic components of the course in order to pass the course.

During the time the course is in progress, students whose cumulative course percentage falls below 70.0% may receive an academic alert and be subject to periodic course content review in special sessions with the course instructor(s). The student's faculty advisor may receive an academic alert to act upon on the student's behalf. All examinations, tests, and assignments, including the final examination, may be **cumulative**. Students are responsible for material presented during the prior courses. The grading scale for all graded material is below. The final course grade will be assigned according to the calculated percentage and the percentages will not be rounded upward or downward. For additional information, see examination/assessment policy below.

## Grade Calculation

### Experiential Training Components

Weekly lab participation	10%
Midterm lab examination	20%
Final lab examination	20%

### Didactic Components

Weekly written quizzes	10%
Midterm written examination	20%
<u>Final written examination</u>	<u>20%</u>

Total 100%

A	90 - 100 %
B	80 - 89.999 %
C	70 - 79.999 %
D	65.0 - 69.999 %
F	< 65.0 %

### NOTES

- The final lab exam will be based on the performance of the practical exam according to proper techniques and manipulations. Microbial growth of the media fill test will be on a **pass/fail basis (all or none for the course)**. Presence of microbial growth will result in a failure and require remediation. Following remediation, the student will be required to re-test. If the media from the re-test has no growth, the student will receive a final lab exam score of 70%. If the media from the re-test is positive for microbial growth, the student will be required to repeat the course.
- Any student showing to lab midterm exam and lab final exam with makeup, fingernail polish/ false nails, false eyelashes, jewelry, etc. (please see proper attire section of syllabus) or late will not be allowed to test and will have to come back with a maximum exam grade of a 70% upon taking exam.

### **Course Remediation and Reassessment Policy**

Please see the Student Handbook (<https://www.utt Tyler.edu/pharmacy/student-handbook/index.php>)

### **Proper Lab Attire**

- Students are expected to respect the learning environment and exhibit professional appearance at all times. Professional attire in the clinical laboratory shows consideration for one-self, peers, faculty, patients, visitors, and co-workers.
- Surgical scrubs shed few particles and must be worn during lab. Lab coats, hair covers, masks, gloves, and shoe covers will be provided and must be worn during all sterile product preparations. Shorts, t-shirts, and jeans are not considered appropriate attire. For safety reasons, skirts or other garments that leave portions of the legs uncovered and open-toed shoes will not be allowed.

- For comfort, students are encouraged to wear shoes that are comfortable during prolonged standing in the lab.
- Jewelry should not be worn in the lab. This includes facial ornamentation. Rings, earrings, etc. should be removed and placed in a safe location during the lab. Students are responsible for the security of their jewelry. It is recommended that valuable jewelry be left at home.
- During the laboratory midterm and final exams students will be required to wear surgical scrubs and will not be allowed to wear makeup, fingernail polish/ false nails, false eyelashes, or jewelry or anything that would compromise air quality. Hair and skin must be clean and well groomed.
- Students donning inappropriate attire in the laboratory may be asked to leave and return in appropriate attire, incurring an unexcused absence for each occurrence.

### **Information for Classrooms and Laboratories**

Students are expected to wear face masks covering their nose and mouth in public settings (including classrooms and laboratories). The UT Tyler community of Patriots views adoption of these practices consistent with its Honor Code and a sign of good citizenship and respectful care of fellow classmates, faculty, and staff.

## **Case Study Syllabus Section – P2 Fall Fall 2021**

### **Case Studies**

Case Studies is a longitudinal supplement intended to reinforce and integrate concepts and skills from the P2 fall curriculum. **Content and concepts from Case Studies will be integrated into summative exams for the P2 fall courses.**

### **Case Studies Format**

Case days may include, but are not limited to, the following activities:

1. Guided discussions
2. Individual and team active learning strategies
  - a. Individual and team case application of content and concepts
  - b. Individual and team case presentation of content and concepts
  - c. Individual and team SOAP note(s)

### **Case Studies Expectations**

Attendance and full participation are a student obligation and expectation. Failure to attend each Case Studies session will result in a 2% deduction from the final course grade to which the session is assigned. To ensure equitable distribution among P2 fall courses, each session will have an “Assigned Course” that will house the 2% deduction in the final course grade in the event of an unapproved absence. Failure to attend all Case Studies sessions would result in a 2% deduction from the final grade of each of the following courses: PHAR 7193, 7302, 7481, 7582, and 7219.

At the discretion of the session’s assigned course coordinator, absences from a case session may be either approved or unapproved. Students are expected to notify the session’s assigned course coordinator *as soon as possible, and no later than 9 AM the morning of the requested absence, with supporting documentation of the absence provided within 3 days of the absence per the College of Pharmacy Policies available in Part 2 of the Syllabus.*

*Example.* Unapproved absences for sessions 2 and 4, would result in 2% final course grade deduction for both PHAR 7302 and PHAR 7582. At the end of the semester if the student’s course grades for PHAR 7302 were 91%

and 71% respectively, their final grade would be reduced to 89% and 69% respectively because of their Case Studies' absences.

### Case Study Schedule

Case Studies will be held over five sessions on Fridays from 2-5 PM. Although each session's attendance deduction is assigned to a specific course, case content is not limited to that course and will be integrated into summative exams for the P2 fall courses.

<b>P2 Fall 2021 Case Study Schedule</b>					
<b>Session</b>	<b>Date</b>	<b>Assigned Course</b>	<b>Assigned Course Coordinator</b>	<b>Topic</b>	<b>Instructors</b>
<b>1</b>	<b>9/17</b>	PHAR 7193	Dr. Vega	Case Studies Introduction Case Modeling	Drs. Brazill and Rice
<b>2</b>	<b>10/1</b>	PHAR 7302	Dr. Brunner	Case 1	TBD
<b>3</b>	<b>10/8</b>	PHAR 7481	Dr. Dunn	Case 1	TBD
<b>4</b>	<b>11/5</b>	PHAR 7582	Dr. Wilder	Case 2	TBD
<b>5</b>	<b>11/19</b>	PHAR 7219	Dr. Smith	Case 2 Individual Presentation	TBD

## IL3 Course Schedule (PHAR 7193), Fall 2021

Week/ Date	Monday Pre-Lab WTB 136 Topic (11 am - 12 pm)	Instructor	Tuesday – Wednesday Lab Topic WTB 211; 235 (9 am -11 am)	CLO	Disease States
Week 1 8/23/21	<b>Compounding:</b> Introduction to Parenteral Preparations Supplies and Equipment for Compounding Sterile Preparations, <b>Room WTB 137</b>	Vega	<b>Compounding:</b> Calculations Lab <b>Room WTB 137</b>	3	S20.99
Week 2 8/30/21	<b>Compounding:</b> Microbiological Considerations, <b>Room WTB 137</b>	Ochoa	<b>Calculations/ Compounding:</b> Calculations Lab <b>Room WTB 137</b>	1,3,4,5	S20.99
Week 3 9/6/21	Labor Day Holiday (NO Pre-Lab)		<b>Compounding:</b> Station Clean-Up Garbing/ Hand Washing Calculations	1,4,5	S20.99
Week 4 9/13/21	<b>Compounding/ Patient Safety:</b> Primary and Secondary Engineering Controls	Ochoa	<b>Compounding/ Calculations:</b> Hood Cleaning Sterile Gloves/Fingertip Testing Adaptable Vial Systems Calculations	3,4,5	S20.99
Week 5 9/20/21	<b>Compounding:</b> Aseptic Techniques and Compounding Manipulations	Vega	<b>Compounding:</b> Positive and Negative Pressure Vial Preparation Reconstitute Vial Preparation Ampule Preparation	3,4,5	S20.99
Week 6 9/27/21	<b>Compounding:</b> Aseptic Techniques and Compounding Manipulations	Vega	<b>Compounding:</b> Positive and Negative Pressure Vial Preparation Reconstitute Vial Preparation Ampule Preparation	3,4,5	S20.99
Week 7 10/4/21	<b>Compounding/ Patient Safety:</b> Principles of Compatibility and Stability	Ochoa	<b>Compounding:</b> Practice Midterm Exam: Reconstitute Vial Incompatibility	3,4,6	S20.99
Week 8 10/11/21	<b>Pre-Lab Midterm Exam</b> Monday 10/11/21 11 am-1 pm <b>Room 136</b>		<b>Compounding:</b> Lab Midterm Exam Time Slots Between 7:45 am-1 pm	4,5	S20.99
Week 9 10/18/21	<b>Compounding:</b> Considerations for IV Medications in Infants and Children	Vega	<b>Compounding/ Patient Safety/ Calculations:</b> Pediatric Preparations	3,4,5,9	\$18.02
Week 10 10/25/21	<b>Compounding:</b> Multiple Product Preparations for Parenteral Nutrition	Vega	<b>Compounding/ Calculations:</b> Total Parenteral Nutrition Preparation	3,4,5,6,8	\$17.01
Week 11 11/1/21	<b>Compounding:</b> Preparation of Hazardous Drugs	Hightower	<b>Compounding:</b> Hazardous Drug Preparation Chemo Spill Kit	3,4,5,7	\$16.01
Week 12 11/8/21	<b>Compounding/ Patient Safety/ Law:</b> Quality Assurance and Quality Control	Ochoa	<b>Compounding:</b> Practice Final Exam: Growth Media Surface Sampling	4,5,10	S20.99
Week 13 11/15/21	<b>Pre-Lab and Lab Final Exams Review</b>	Vega	<b>Compounding:</b> Lab Final Exam Time Slots Between 7:45 am-1 pm	1,2,3,4,5, 6,7,8,9, 10,11	S20.99
Holiday 11/22/21	Thanksgiving Holiday (NO Pre-Lab)		Thanksgiving Holiday (NO Labs)		
Week 14 11/29/21	<b>Compounding/Patient Safety:</b> Patient Safety Pre-Lab	Vega	<b>Compounding/ Patient Safety:</b> Patient Safety Lab	1,2,3,4,5, 6,7,8,9, 10,11	S20.99
Week 15 12/6/21	<b>Finals Week</b> <b>Pre-Lab Final Exam</b> Thursday 12/9/21 9 am-11 am <b>Room 136</b>		Finals Week (NO Labs) <b>(Lab Final Exam Re-Tests)</b>	1,2,3,4,5, 6,7,8,9, 10,11	S20.99