Pharmacy Lab 3: Sterile Products and Intravenous Admixtures PHAR 7193

Fall Semester 2023

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 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 235; Monday; 11:00 am – 12:00 pm

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

Tuesday Session: 9:00 am – 11:00 am

Supplemental instruction: W.T. Brookshire Hall Room 211; 235

Tuesday Session: 11:00 am - 12:00 pm

- **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

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

Preferred method of contact: email

Faculty: Pamella Ochoa, Pharm.D.

Office Location: WTB 329 Phone Number: (903) 565-5596 Email: <u>POchoa@uttyler.edu</u> Best way to contact: Email

Office hours: Mondays 10:00 am - 11:00 am; Wednesdays 1:30-3:00 AND by appointment

Instructor: Joseph Chase, CPhT

Office Location: WTB 217 (Inside WTB 212)

Phone Number: (903) 565-6419 Email: <u>jchase@uttyler.edu</u> Best way to 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.uttyler.edu/) or on reserve.

- 1. Ochoa, Pamella, 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: uttyler.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)

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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	2,5,6	ES	NA	NA
2. Recognize various types of supplies and equipment for compounding sterile preparations	1	NA	1,2,5,6	ES	NA	NA
3. Perform calculations as required for sterile compounding	1	3.2	1,2,5,6	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	2,5,6	ES	NA	NA
6. Recognize principles of compatibility and stability when compounding sterile preparations	1	3.2	1,2,5,6	ES	NA	NA

7. Summarize USP Chapter 800 regulations and guidelines for compounded sterile hazardous preparations	1	NA	2,5,6	ES	NA	NA
8. Compare the differences between compounding parenteral nutrition preparations and other sterile compounded preparations	1	NA	1,2,5,6	ES	NA	NA
9. Describe patient safety considerations when compounding pediatric parenteral preparations	1	3.2	2,5,6	ES	NA	NA
10. Explain the elements, regulations, and guidelines for quality assurance and quality control when compounding sterile preparations	1	3.2	2,5,6	ES	NA	NA
11. Prepare a compounded preparation using proper aseptic techniques that is free of microbial contamination	1	5.2	1,3,4	RUB	NA	NA

Course Assessment Methods

	Assessment Method	Description
1	Weekly lab grade	Weekly participation grades based on preparedness for lab, professionalism, participation during lab, utilization of proper techniques for the preparation and handling of sterile compounds, handwashing, garbing, and attendance
2	Weekly written quizzes	7-11 quizzes, 5-7 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

Students must pass the Experiential Training Components (Lab) and the Didactic Components (Pre-Lab) separately, i.e. the student must receive a score of 70% or higher in the Lab and a 70% or higher in the Pre-Lab to pass this course. If a student receives less than 70% in either the Lab or Pre-Lab, they will receive a D or F in the course. For example, if a student receives 80% in Lab and 64% in the Pre-Lab, they will receive a final grade of F. If the student receives 80% in the Lab and 66% in the Pre-Lab, the student will receive a final grade of D.

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. Course grades will not be rounded upward or downward. For additional information, see examination/assessment policy below.

Grade Calculation

Experiential Training Components (Lab)

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

Didactic Components (Pre-Lab)

Weekly written quizzes	10%
Midterm written examination	20%
Final written examination	20%

A	90 - 100 %
В	80 - 89.999 %
С	70 - 79.99 9 %
D	65.0 - 69.99 9 %
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). The presence of microbial growth will result in a failure and require a retest. 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 up 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.uttyler.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 oneself, 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 comfortable shoes 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, 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.

IL3 Course Schedule (PHAR 7193), Fall 2023

Week/	Monday Pre-Lab Instruc		Tuesday Lab Topic	CLO	Disease
Date	WTB 235		WTB 211; 235 (9 am -11 am)		States
	Topic (11 am - 12 pm)				
Week 1 8/21/23	Compounding: Introduction to Parenteral Preparations Supplies and Equipment for Compounding Sterile Preparations	Vega	Compounding: Calculations Lab Room WTB 235	1,2,3	S20.99
Week 2 8/28/23	Compounding: Microbiological Considerations	Ochoa	Calculations/ Compounding: Calculations Lab Room WTB 235	1,3,4,5	S20.99
Week 3 9/4/23	Labor Day Holiday (NO Pre-Lab)		Compounding: Station Clean-Up Garbing/ Hand Washing Calculations	1,4,5	S20.99
Week 4 9/11/23	Compounding/ Patient Safety: Primary and Secondary Engineering Controls	Ochoa	Compounding/ Calculations: Hood Cleaning Sterile Gloves/Fingertip Testing Adaptable Vial Systems Calculations	3,4,5	S20.99
Week 5 9/18/23	Compounding: Aseptic Techniques and Compounding Manipulations	Vega	Compounding: Positive and Negative Pressure Vial Preparation Reconstitute Vial Preparation Ampule Preparation	3,4,5	S20.99
Week 6 9/25/23	Compounding: Aseptic Techniques and Compounding Manipulations	Vega	Compounding: Positive and Negative Pressure Vial Preparation Reconstitute Vial Preparation Ampule Preparation	3,4,5	S20.99
Week 7 10/2/23	Compounding/ Patient Safety: Principles of Compatibility and Stability	Ochoa	Compounding: Practice Midterm Exam: Reconstitute Vial Incompatibility	3,4,5,6	S20.99
Week 8 10/9/23	Pre-Lab Midterm Exam Monday 10/9/23 11 am-1 pm Room 235		Compounding: Lab Midterm Exam Time Slots Between 9:00 am-1 pm	1,2,3,4,5, 6,11	S20.99
Week 9 10/16/23	Compounding: Considerations for IV Medications in Infants and Children	Vega	Compounding/ Patient Safety/ Calculations: Pediatric Preparations	3,4,5,9	S18.02
Week 10 10/23/23	Compounding: Multiple Product Preparations for Parenteral Nutrition	Vega	Compounding/ Calculations: Total Parenteral Nutrition Preparation	3,4,5,6,8	S17.01
Week 11 10/30/23	Compounding: Preparation of Hazardous Drugs	Ochoa	Compounding: Hazardous Drug Preparation Chemo Spill Kit	3,4,5,7	S16.01
Week 12 11/6/23	Compounding/ Patient Safety/ Law 1: Quality Assurance and Quality Control	Ochoa	Compounding: Practice Final Exam: Growth Media Surface Sampling	3,4,5,10	S20.99
Week 13 11/13/23	Compounding/ Patient Safety/ Law 2: Quality Assurance and Quality Control	Ochoa	Compounding: Lab Final Exam Time Slots Between 9:00 am-1 pm	3,4,5,10	S20.99
Holiday 11/20/23	Thanksgiving Holiday (NO Pre-Lab)		Thanksgiving Holiday (NO Labs)		
Week 14 11/27/23	Compounding/Patient Safety: Patient Safety Pre-Lab	Vega	Compounding/ Patient Safety: Patient Safety Lab	1,2,3,4,5, 6,7,8,9, 10,11	S20.99
Week 15 12/4/23	Finals Week Pre-Lab Final Exam Wednesday 12/6/23 9 am-12 pm Room 235		Finals Week (NO Labs) (Lab Final Exam Re-Tests)	1,2,3,5, 6,7,8,9, 10	S20.99