Sterile Laboratory 3 (IL-3)
PHAR 7193
Fall Semester 2020

Course Description
This laboratory course will provide students with hands on experience in preparing and dispensing parenteral and sterile preparations 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 practice. 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 133 and 136; Monday; 10:00 am – 11:00 am

Zoom Meeting
https://uttyler.zoom.us/j/94690908874?pwd=eElFcXNmRkZCS1VRNXpCdEVZQVozQT09

Meeting ID: 946 9090 8874
Passcode: 256184
One tap mobile
+13462487799,,94690908874# US (Houston)
+12532158782,,94690908874# US (Tacoma)

Lab sessions: W.T. Brookshire Hall Room 211; 235
Tuesday: Session 1: 8:00 am – 10:00 am and Session 2: 10:00 am – 12:00 pm
Wednesday: Session 1: 8:00 am – 10:00 am and Session 2: 10:00 am – 12:00 pm
Thursday: Session1: 8:00 am – 10:00 am and Session 2: 10:00 am – 12:00 pm

****Please see course schedule for exam times****
****Students Must Attend Their Assigned Lab Day****

Course Coordinator
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Office hours: 11 – 1 pm Monday, 12 – 1 pm 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 and Part 3 contains policies specific to Fall 2020. 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)

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 type 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	1,2
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 quizzes	7-11 unannounced quizzes, 5 question(s) 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	Final written exam	Cumulative exam, 40-50 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.

All students must demonstrate minimal individual competency. Therefore, students must earn an overall score of ≥ 70.0% to earn a letter grade of 'C' or higher.

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

Weekly lab participation	10%
Weekly quizzes	15%
Midterm lab examination	25%
Final lab examination	25%
Final written examination	25%
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 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, nail polish/ fake nails, 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 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.
- Hair and skin must be clean and well groomed. Fingernail polish, false nails, makeup, false eyelashes, etc. will not be allowed during midterm and final lab exams.
- During the laboratory midterm and final exams students will be required to wear surgical scrubs and will NOT be allowed to wear makeup, nail polish/ fake nails, or jewelry or anything that would compromise air quality.
- 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 2020

Week/ Date	Monday Pre-Lab WTB 133, 136 Topic (10-11 am)	Instructor	Tuesday – Thursday Lab Topic WTB 211; 235 (Tu-Th: 8-10 am and 10-12 pm)	CLO	Disease States
Week 1 8/24/20	**Compounding:** Introduction to Parenteral Preparations Supplies and Equipment for Compounding Sterile Preparations	Vega	**Compounding:** Station Clean-Up Garbing/ Hand Washing Calculations	1,4,5	S20.01
Week 2 8/31/20	**Compounding:** Microbiological Considerations	Ochoa	**Compounding:** Calculations Lab **Room WTB 235**	3	S20.01
Week 3 9/7/20	Labor Day Holiday (NO Pre-Lab)		**Calculations Compounding:** Calculations Lab **Room WTB 235**	1,3,4,5	S20.01
Week 4 9/14/20	**Compounding/ Patient Safety:** Primary and Secondary Engineering Controls	Ochoa	**Compounding/ Calculations:** Hood Cleaning Sterile Gloves/Fingertip Testing Adaptable Vial Systems Calculations	3,4,5	S20.01
Week 5 9/21/20	**Compounding:** Aseptic Techniques and Compounding Manipulations	Vega	**Compounding:** Positive and Negative Pressure Vial Preparation Reconstitute Vial Preparation Ampule Preparation	3,4,5	S20.01
Week 6 9/28/20	**Compounding:** Aseptic Techniques and Compounding Manipulations	Vega	**Compounding:** Positive and Negative Pressure Vial Preparation Reconstitute Vial Preparation Ampule Preparation	3,4,5	S20.01
Week 7 10/5/20	**Compounding/ Patient Safety:** Principles of Compatibility and Stability	Ochoa	**Compounding/ Communication:** Practice Midterm Exam: Reconstitute Vial Incompatibility	3,4,6	S20.01
Week 8 10/12/20	Lab Midterm Exam Week (NO Pre-Lab)		**Compounding:** Lab Midterm Exam Time Slots Between 7:30 am-1 pm	4,5	S20.01
Week 9 10/19/20	**Compounding:** Preparation of Hazardous Drugs	Carter (PGY1)	**Compounding:** Hazardous Drug Preparation Chemo Spill Kit	3,4,5,7	S16.01
Week 10 10/26/20	**Compounding:** Multiple Product Preparations for Parenteral Nutrition	White (PGY1)	**Compounding/ Calculations:** Total Parenteral Nutrition Preparation	3,4,5,6,8	S17.01
Week 11 11/2/20	**Compounding:** Considerations for IV Medications in Infants and Children	Vega	**Compounding/ Patient Safety/ Calculations:** Pediatric Preparations	3,4,5,9	S18.02
Week 12 11/9/20	**Compounding/ Patient Safety/ Law:** Quality Assurance and Quality Control	Ochoa	**Compounding:** Practice Final Exam: Growth Media Surface Sampling	4,5,10	S20.01
Week 13 11/16/20	**Finals Week** **Pre-Lab Final Exam** **Monday 11/16/20 8 am-10:50 am** **Room 136 and 137**	Vega	**Compounding:** Lab Final Exam Time Slots Between 7:30 am-1 pm	1,2,3,4,5, 6,7,8,9, 10,11	S20.01
Holiday 11/23/20	Thanksgiving Holiday (NO Pre-Lab)		Thanksgiving Holiday (NO Labs)		
Week 14 11/30/20	**Compounding:** Patient Safety Pre-Lab **Online: Zoom**	Vega	**Patient Safety:** Patient Safety Lab **Online**	1,2,3,4,5, 6,7,8,9, 10,11	S20.01
Week 15 12/7/20			Finals Week (NO Labs) **(Lab Final Exam Re-Tests)**	1,2,3,4,5, 6,7,8,9, 10,11	S20.01