Drugs Delivery 1

Phar 6708 Drug Delivery I
Course Syllabus

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Meeting Time, Place, Credits

2.5 credits
Course Web Site:  https://canvas.umn.edu/courses/78731
Term:  Fall 2018
Dates:  Wednesday (10:10 am – 12:05pm) and Friday (9:05 – 11:00 am) of each week.
Location:  MoosT 1-451 (TC)/163 L. Sci (Duluth)
Target audience:  PDI

Course Instructional Team

Course Directors
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**Course instructor**
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**Teaching Assistants:**
**UMTC**
Name: Gerrit Vreeman
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Name: Rahul Lalge
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Name: Yuexuan Li
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**UMD**
Name: Shirisha Jonnalagadda:
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**Overview of the course**

**Course content:**
In this course, a systematic approach establishes the fundamental physicochemical principles applicable to dosage forms. The foundational scientific principles (continued in DDII) are illuminated with key examples of solution drug dosage forms. These concepts are relevant to current as well as future dosage forms as drugs must be dissolved in a solution before they can be absorbed into the systemic circulation and eventually the site of action.

The fundamental physicochemical principles applicable to dosage forms discussed in this course will also be used in Drug Delivery II, Pharmacokinetics, Biopharmaceutics, and Pharmaceutical Compounding Lab. These principles include: intermolecular forces determining the state of matter, phase equilibria, ionic equilibria, colligative properties, solubility, partitioning, and pH-partition hypothesis, which are applied to solution dosage forms. These fundamentals will enable our students (as active learners) to readily adapt to new pharmaceutical knowledge and challenges during patient care.

**Course format:**
The course is made up of lectures and in-class workshops. Before each lecture, students will be provided with handout, reading assignment, and cases, which will introduce them to upcoming concepts, through Canvas course site. During the lectures, an instructor will explain concepts demonstrated with examples where possible. An in-class workshop on solving problems using the fundamental concepts taught during the lecture will be a part of each lecture. There will be online quizzes each week (See course schedule for details.)
At the beginning of the semester, students will be assigned a drug delivery case study involving the use of principles presented in this course. Students will be assigned to a small group (typically groups of 4 students) to work on this case study project, where two written reports are required. Each group member will receive the same score, and the students will evaluate their peers’ contribution/performance on this team project.

Students are required to attend all class meetings; view all online presentations; complete reading and homework assignments; successfully complete Prerequisite Proficiency Exam, quizzes, mid-term and final examinations, and contribute to case study reports.

Prerequisites

An online Prerequisite Proficiency Exam is required. Calculus (both differential and integral calculus), knowledge of the metric system, proficiency with logarithmic and exponential functions, understanding the use of equations and graphs, and comprehension of the fundamentals of organic chemistry are required for the successful completion of the Proficiency Exam. A passing score will be 70% and students may take the exam twice. Review/remediation material will be available online. **Students must successfully pass the Prerequisite Proficiency Exam with a grade of 70% or higher. Failure to pass the Prerequisite Proficiency Exam will result in the lowering of the final grade (for example receiving a C- rather than a C).**

- Other prerequisites: College of Pharmacy Student or permission of the Course Director.

Computer/Technology Requirements

The University of Minnesota computer and technology requirements are listed here:

- https://docs.google.com/document/d/1artQ5e1rbzxe8lEtWo7BE8k8snZAEgMMz_QcW8yJ-I/edit#
- https://www.pharmacy.umn.edu/degrees-and-programs/doctor-pharmacy/current-students/technology-resources

Calculator: Graphing calculators or smart phones are not allowed during exams.

Course Goals & Objectives

Main course concepts:
1. Solubility affects drug absorption and it can be modified by controlling solid state properties of drugs and solvent;
2. pH – solubility is a result of ionic equilibria of ionizable drugs. pH affects drug oral bioavailability (pH-partition hypothesis);
3. Isotonicity of solution dosage forms (colligative properties and protein binding and partitioning, which are core principles for drug transport and drug distribution in the body).

<table>
<thead>
<tr>
<th>LEARNING GOALS</th>
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<tr>
<td>After successfully completing this course, the student will be able to:</td>
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1. **Explain** the physicochemical principles underlying the preparation, properties, function and performance of various common types of solution dosage forms. For example,
   - **explain** the colligative properties of aqueous solution and their application to (impact on) the isotonicity of solution dosage forms of a drug;
● explain the importance of solubility and partitioning in the formulation design and absorption and distribution of drugs;
● recognize the linkage between the physicochemical characteristics of a dosage form and the plasma concentration-time profile.

2 Choose the most appropriate type of solution dosage form for optimal drug delivery and optimal drug therapy according to patient-specific characteristics and select suitable inactive/inert ingredients based on their role and functions in solution.
   ● Identify and articulate the physicochemical and formulation properties of drug solutions that influence their delivery to the site of pharmacological action, such as viscosity, taste, and color.

3 Perform the various types of calculations related to the preparation of the common types of solution dosage forms. For example,
   ● calculate the amount of an ionizable drug in solution at biologically relevant pH using the Henderson–Hasselbalch equation.

4 Design a protocol for the extemporaneous compounding of a solution dosage form.
   ● Apply knowledge of properties of drug solutions that influence dosage form design (e.g., stability) and the characteristics of an ideal drug delivery of liquid dosage forms.

5 Engage others in teamwork (other practitioners, patients, or caregivers) to research and determine the best patient care possible under different circumstances.

Attendance Policy

Students are expected to attend every class for which they are registered. Students are expected to attend classes on the campus where they are enrolled. Instructors may choose to take attendance periodically. When a student is unable to attend a class for health or family reasons, the instructor must be informed in advance.

Course Materials
1 Course notes, written by each instructor, available to the students on the course website.

*Assigned readings are indicated in the course schedule.

Assessments and Grading

Assignments and learning activities
● The case-study project described below is a good platform for students to practice different course concepts and ideas within the broader context of patient care. Students usually start working on these team-based case study assignments from the very beginning of the course. This engages students with learning materials and fundamentals covered in the lectures within the context of pharmacy practice. Working in small groups to apply the basic knowledge learned in this course to patient care is critical for team-work, as well as communication skills in solving the problems.
• **Workshop** for hands-on problem-solving will engage students with the content, the instructor, and each other. Students are encouraged to consult instructor, TA, and classmate to solve problems as a means of active learning. The **problem sets** are developed in accordance with the content taught in the preceding lecture(s). For example, students may be asked to calculate solubility of a weak acid in water at different pH values and explain why it is important to patient care. Students will work on the problems first. They are encouraged to discuss the problems with each other while instructors and TAs will walk around the classroom offering help. Finally, the instructor will go over the problem with students. Workshops are required, but not graded.

• Students also have opportunities to practice course concepts through working on **assigned homework problems**. Homework problems are required, but not graded.

**Graded Assessments**

1. **QUIZZES**: There will be 11 quizzes (worth 10 points each) scheduled throughout the semester. Quizzes consist of typically 9–10 multiple choices questions. Quizzes will be available online via the Canvas course site. A total of 30 min is allowed for taking each quiz. A student will be allowed to drop the lowest quiz grade, so he/she would have a maximum of 100 possible points from quizzes.

2. **EXAMS**: Two in-person midterm exams will each be worth 100 points (for a total of 200 points). A comprehensive, in-person two-hour final exam will be given during the Final Exams Week. This is a required exam worth 100 points.

3. **SMALL GROUP CASE STUDY PROJECT**: Small groups of students are assigned case studies which are usually on compounding a solution dosage form to meet specific patients’ needs. Case studies are drawn from pharmacy practice, hence, providing authentic and contextual scenarios for assessing students’ learning. For example, students may be asked to compound 10 mL of 15% tobramycin sterile solution (used as eye drops post-surgery) that is not commercially available at this high strength. They may also be asked to compound a 3 mg/mL lansoprazole solution to fill a prescription for treating acid reflux in infants. To solve the problem, students need to correctly apply the concept of solubility, calculate the amount of drug, tonicity adjusting agent, and water needed. They also need to develop a compounding procedure, address the problem of stability, storage, and provide handling instructions to the patient. In some cases, sterility is also emphasized during the compounding procedure. Completion of two written reports (part I and II) on drug delivery case-study assignment is worth a maximum of 25 points (part I – 10 pts, part II – 15 pts). Each group member will receive the same score, and the students will evaluate their peers’ contribution/performance on this team project. Each student will receive 1 point for the peer evaluation except for students who do not turn in the evaluation form or who receive overwhelmingly negative peer evaluations.

4. **COURSE EVALUATION**: One point will be given for submitting an online course evaluation (a total of two course evaluations are available, the first one in the middle of the semester and the second one during the last week of the semester).

Unless approved by the course instructor ahead of time, NO late work will be accepted.

Each student is bound by the following specific provisions of the Honor Code: Academic misconduct is any unauthorized act which may give a student an unfair advantage over other students, including but not limited to: falsification, plagiarism, misuse of test materials, receiving unauthorized assistance and giving unauthorized assistance. **Students are required to do their own work on all online and in-person exams and quizzes.**

**General Policies**

All required UMN and CoP policies, e.g., Academic Freedom; Attendance; Copyright; Course Evaluations; Disability Accommodations; Exams; FERPA; Grading; etc. apply in this course. They can be accessed at [https://docs.google.com/a/umn.edu/document/d/1arTQ5e1rbzxe8IFtVo7BE8k8snZAEgMMz_QcW8yJ-II/edit](https://docs.google.com/a/umn.edu/document/d/1arTQ5e1rbzxe8IFtVo7BE8k8snZAEgMMz_QcW8yJ-II/edit)

**Recording policy**: This course will be recorded and posted on a secure site to aid the students in learning the material. Lecture archives are not considered a replacement for attending lecture. **Students are expected to attend class.** Recorded lectures are supplemental to the live lectures and are available to help students in learning the material. Students are responsible for all material delivered in the live lecture regardless of successful recording and posting.
Additional Exam Policy

There will be no make-up quizzes given under any circumstances because students are allowed to drop a quiz.

Grading Information
A total of 428 points can be obtained on exams, quizzes and case study report as indicated above. A percentage will be calculated and grades will be assigned as follows:

Course Letter Grades

<table>
<thead>
<tr>
<th>Grade</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>A</td>
<td>93.0 - 100</td>
</tr>
<tr>
<td>A-</td>
<td>90.0 – 93.0</td>
</tr>
<tr>
<td>B+</td>
<td>87.0 – 90.0</td>
</tr>
<tr>
<td>B</td>
<td>83.0 – 87.0</td>
</tr>
<tr>
<td>B-</td>
<td>80.0 – 83.0</td>
</tr>
<tr>
<td>C+</td>
<td>77.0 – 80.0</td>
</tr>
<tr>
<td>C</td>
<td>73.0 – 77.0</td>
</tr>
<tr>
<td>C-</td>
<td>70.0 – 73.0</td>
</tr>
<tr>
<td>D</td>
<td>60.0 – 70.0</td>
</tr>
<tr>
<td>F</td>
<td>0 – 60.0</td>
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</tbody>
</table>

Re-grade Policy
- Exam done with a pencil is not eligible for re-grading.
- Typed request for exam re-grading must be submitted to the course director within one week after receiving the exam back.

Minimum Passing Level
Please refer to the College of Pharmacy Academic Standing and Student Progression Policy and Procedures at [https://www.pharmacy.umn.edu/sites/pharmacy.umn.edu/files/academic_standing_progression_policy_3-19-18.pdf](https://www.pharmacy.umn.edu/sites/pharmacy.umn.edu/files/academic_standing_progression_policy_3-19-18.pdf)

Classroom Etiquette

1. Students are expected to be respectful to the professors, teaching assistants, and your fellow students.
2. Students are expected not be disruptive during class time, which reveals a lack of respect for your fellow students and instructors. Disruptive behavior includes the following:
   a. Arriving late for class
   b. Reading newspaper, doing crossword puzzles (or Sudoku!), studying for exams, texting, sending and receiving IM’s, shopping online, etc.
c Habitually leaving class early.
d Conducting side conversations while the instructor is lecturing.
e Having your cell phone ring
f Snoring

3 Student announcements may be made before class officially starts, after it officially ends, or during class breaks.