Pharmaceutics/Biopharmaceutics

PHRM 2270
2016-2017 (Full Course)

Credit Hours: 6

Class Contact Hours: 78 hours

Sept. 09 – Dec. 9, 2016: Tuesday/Friday, 10:30-11:45, Basement 071, Apotex Center
Jan. 6 – Apr. 7, 2017: Tuesday/Friday, 10:30-11:45, TBA, Apotex Center

Course Instructors:

Dr. D. Cote (Fall-Term Instructor)
Room 225, Apotex Center
Tel: 474-6901
Email: cote2@cc.umanitoba.ca

Dr. X. Gu (Winter-Term Instructor)
Room 317, Apotex Center
Tel: 474-6903
Email: xgu@cc.umanitoba.ca

Dr. E. Ho (Winter-Term Instructor/Coordinator)
Room 329, Apotex Center
Tel: 272-3180
Email: emmanuel_ho@umanitoba.ca
Learning Goals of the Course:

Upon successful completion of the course, the student will understand the concepts of dosage forms, dosage preparation and drug stability, and the relevance between drug delivery optimization and therapeutic outcome. The knowledge obtained from this course will prepare students for future careers as pharmacists in the community, hospital, industry, government, and other related capacities.

Course Objectives:

Upon completion of this course, the students should be able to:

1. Explain the relationship among physicochemical and biological factors, dosage forms, routes of administration and therapeutic outcomes;

2. Illustrate the principles of pharmaceutics and biopharmaceutics in dosage form design and development;

3. Describe production procedures, quality control measurements and stability improvements for tablets and sterile products:
   - Granulation
   - Tableting
   - Coating
   - Stability
   - Dissolution
   - Sterility

4. Summarize different routes of drug administration in principles and applications:
   - Oral drug administration
   - Parenteral drug administration
   - Buccal/sublingual drug administration
   - Nasal drug administration
   - Ocular drug administration
   - Pulmonary drug administration
   - Transdermal drug administration
   - Rectal/vaginal drug administration
   - Radiopharmacy

5. Identify the needs and differences in drug use for various patient groups, and devise appropriate strategies from perspectives of dosage forms
   - Pediatric dosage forms
   - Geriatric dosage forms
Level and Sequence of the Course:

This course builds on the knowledge obtained from *Fundamentals of Pharmaceutics* (PHRM1300). Knowledge and background of physical chemistry, medicinal chemistry and analytical chemistry are essential.

Teaching and Learning Methods:

The course is defined in terms of course goals and objectives. Information is provided to the students in a lecture format. The students are encouraged to actively participate in class discussions throughout the course. Pharmaceutics/biopharmaceutics is one of the fundamental cornerstones of pharmacy curriculum. The importance and relevance of pharmaceutics/biopharmaceutics will be illustrated by examples closely related to pharmacy practice. Current research directions and applications will also be included to reflect the latest development in pharmaceutics areas.

Assessment Process:

Four examinations will be set up throughout the academic year to evaluate the students’ knowledge and understanding of the course objectives and goals.

- *Fall Midterm Exam (October 13, 2016)*: 2 hours *(15 % of Course Grade)*
- *Christmas Exam (December 12-22, 2016)*: 2 hours *(15 % of Course Grade)*
- First Term Assignments: 5 *(10 % of Course Grade)*
- *Winter Midterm Exam (February 17, 2017)*: 1 hour *(20 % of Course Grade)*
- *Final Exam (April 10-25, 2017)*: 2 hours *(40 % of Course Grade)*

The final mark (out of 100) will be translated to a course letter grade according to the following range,

- A+ >90 %
- A  80-89 %
- B+  75-79 %
- B   70-74 %
- C+  65-69 %
- C   60-64 %
- D   50-59 %
- F   <50 %

Assessment Criteria and Grading:

Information, as well as its presentation, will be taken into consideration when exams are evaluated. All of the assessments are carried out by evaluating each student’s response to a given question relative to a marking key prepared by the instructor. The performance of the
class in the midterm exams will be discussed in a subsequent lecture, to provide feedback on the overall class performance. The procedure for the review of the final exam is governed by formal regulations published annually by Student Records.

**Assessment Policies:**

The assessment and academic policies of the College of Pharmacy listed in the University Calendar will be respected. Particularly important are the regulations concerning attendance at class, eligibility for medals, scholarships, awards and prizes, and deferment of examinations due to illness.

**Recommended Texts and References:**

*Modern Pharmaceutics*

*Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems*
Allen LV, Popovich NG, Ansel HC (Editors), 9th Edition, Williams & Wilkins, Philadelphia, 2010

*Remington. The Science and Practice of Pharmacy*

Course handouts will be provided prior to each subject. Check University of Manitoba Jump Portal for regular course updates and relevant materials/messages.

**List of Topics:**

September – December, 2016

1. Orientation (09/09/2016)
2. Drug Stability (09/13,16/2016)
3. Expiration Dating (09/20/2016)
5. Solubility (09/30, 10/04/2016)
6. Preformulation (10/11/2016)
7. **FALL BREAK (10/06 – 10/10; No Class)**
8. **MIDTERM EXAM (10/13/2016)**
9. Tablets I (10/14/2016)
10. Tablets II (10/18,21/2016)
11. Medication/Tube Feeding (10/25/2016)
15. Laminar Air Flow Cabinets and Clean Rooms (11/25/2016)
16. USP <797> (11/29/2016)
17. Microbial Control (12/02/2016)
18. Drug Incompatibilities (12/06/2016)

January – April, 2017

**PDW (01/04 – 01/06; No Class)**
20. Introduction to Dosage Form Design (01/10/2017)
22. Buccal and Sublingual Drug Delivery (01/24/2017)
23. Transdermal Drug Delivery (01/27,31/2017)
24. Nasal Drug Delivery (02/3,7/2017)
25. Ocular Drug Delivery (02/10/2017)
26. Pulmonary Drug Delivery I (02/14/2017)

**MIDTERM EXAM (02/17)**

**READING WEEK (02/20 – 02/24; No Class)**
27. Pulmonary Drug Delivery II (02/28/2017)
28. Parenteral Drug Delivery (03/03,07,10,14/2017)
29. Rectal and Vaginal Drug Delivery (03/17,21/2017)
30. Pediatric and Geriatric Pharmaceuticals (03/24,28/2017)
31. Dietary Supplements and Nutraceuticals (03/31/2017)
32. Pharmaceutical Packaging (04/04/2017)
33. Delivery of Peptides and Proteins (04/07/2017)

**Notes:**

Any course-related materials and announcements will be posted in the University of Manitoba UM Learn under Course PHRM2270. Students are encouraged to check for updates on a regular basis, as well as to send feedback and opinions regarding course content and teaching evaluation to the Course Coordinators/Instructors.
### PHRM 2270 – Course Objectives
At the completion of this course, the student should be able to:

| 1. Explain the relationship among physicochemical and biological factors, dosage forms, routes of administration and therapeutic outcomes | Connections | 1.2 | Functional |
|  |  | 1.3 | Functional |
|  |  | 1.4 | Functional |
|  |  | 1.6 | Functional |
|  |  | 3.3 | Functional |
|  |  | 4.3 | Functional |
|  |  | 6.1 | Functional |
|  |  | 6.2 | Functional |

| 2. Illustrate the principles of pharmaceutics and biopharmaceutics in dosage form design and development | Connections | 1.2 | Functional |
|  |  | 1.3 | Functional |
|  |  | 1.6 | Functional |
|  |  | 6.1 | Functional |
|  |  | 6.2 | Functional |

| 3. Describe production procedures, quality control measurements and stability improvements for tablets and sterile products e.g. granulation, coating, dissolution, etc. | Extensions | 4.2 | Functional |
|  |  | 4.3 | Functional |
|  |  | 6.1 | Functional |
|  |  | 6.2 | Functional |

| 4. Summarize different routes of drug administration in principles and applications: e.g. parenteral, nasal, ocular, etc. | Extensions | 1.2 | Functional |
|  |  | 1.3 | Functional |
|  |  | 1.6 | Functional |
|  |  | 6.1 | Functional |
|  |  | 6.2 | Functional |

| 5. Identify the needs and differences in drug use for various patient groups, and devise appropriate strategies from perspectives of dosage forms e.g. pediatric, geriatric, etc. | Extensions | 1.2 | Functional |
|  |  | 1.3 | Functional |
|  |  | 1.4 | Functional |
|  |  | 1.6 | Functional |
|  |  | 2.1 | Functional |
|  |  | 2.3 | Functional |
|  |  | 6.1 | Functional |
|  |  | 6.2 | Functional |
|  |  | 6.3 | Functional |
## Number of Hours in the Curriculum

### SCHEDULE

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Topic</th>
<th>Instructor</th>
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<tr>
<td>Sept 09</td>
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<td>Orientation</td>
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<td>Sterile Products: Ophthalmics</td>
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**Course Technology:**

It is the general University of Manitoba policy that all technology resources are to be used in a responsible, efficient, ethical and legal manner. Students can use all technology in classroom settings only for educational purposes approved by the instructor and/or the University of Manitoba Disability Services. Students should not participate in personal direct electronic messaging / posting activities (e-mail, texting, video or voice chat, wikis, blogs, social networking (e.g. Facebook) online and offline “gaming” during scheduled class time. Course materials are provided on UM Learn and can be accessed electronically at [https://universityofmanitoba.desire2learn.com/d2l/login](https://universityofmanitoba.desire2learn.com/d2l/login)

**Voluntary Withdrawal:**

Course feedback and assessment will be provided before the voluntary withdrawal (VW) date. For the 2016-2017 academic year in Years 1, 2 and 3 of the Pharmacy program, the VW date for fall courses is November 18, 2016 and for winter courses and span courses (courses that continue for both terms) the VW date is March 17, 2017. PLEASE NOTE HOWEVER, THAT STUDENTS CONTEMPLATING VOLUNTARILY WITHDRAWING FROM A COURSE SHOULD SPEAK TO THE DEAN’S OFFICE BEFORE DOING SO. THERE ARE SIGNIFICANT CONSEQUENCES OF WITHDRAWING FROM A COURSE DURING THE PROFESSIONAL PROGRAM.

**Academic Integrity:**

The coordinator and instructors of this course and the University of Manitoba hold copyright over the course materials, presentations and lectures which form part of this course. No audio or video recording of lectures or presentations is allowed in any format, openly or
surreptitiously, in whole or in part without permission of the course coordinator. Course materials (both paper and digital) are for the participant’s private study and research.

**Student Accessibility Services (SAS):**

If you are a student with a disability, please contact SAS for academic accommodation supports and services. Students who have, or think they may have, a disability (e.g. mental illness, learning, medical, hearing, injury-related, visual) are invited to contact SAS to arrange a confidential consultation. The coordinator of this course is willing to meet with students to discuss accommodations recommended by SAS.

*Student Accessibility Services* [http://umanitoba.ca/student/saa/accessibility/](http://umanitoba.ca/student/saa/accessibility/)

520 University Centre
204-474-7423  [Student_accessibility@umanitoba.ca](mailto:Student_accessibility@umanitoba.ca)

**Student Support:**

Please refer to the attached Schedule “A” for a list of student supports provided by the University of Manitoba.
Schedule “A”

Section A: Academic Supports

Writing and Learning Support:

The Academic Learning Centre (ALC) offers services that may be helpful to you throughout your academic program. Through the ALC, you can meet with a learning specialist to discuss concerns such as time management, learning strategies, and test-taking strategies. The ALC also offers peer supported study groups called Supplemental Instruction (SI) for certain courses that students have typically found difficult. In these study groups, students have opportunities to ask questions, compare notes, discuss content, solve practice problems, and develop new study strategies in a group-learning format.

You can also meet one-to-one with a writing tutor who can give you feedback at any stage of the writing process, whether you are just beginning to work on a written assignment or already have a draft. If you are interested in meeting with a writing tutor, reserve your appointment two to three days in advance of the time you would like to meet. Also, plan to meet with a writing tutor a few days before your paper is due so that you have time to work with the tutor’s feedback.

These Academic Learning Centre services are free for U of M students. For more information, please visit the Academic Learning Centre website at: http://umanitoba.ca/student/academiclearning/

You can also contact the Academic Learning Centre by calling 204-480-1481 or by visiting 201 Tier Building.

University of Manitoba Libraries (UML):

As the primary contact for all research needs, your liaison librarian can play a vital role when completing academic papers and assignments. Liaisons can answer questions about managing citations, or locating appropriate resources, and will address any other concerns you may have, regarding the research process. Liaisons can be contacted by email or phone, and are also available to meet with you in-person. A complete list of liaison librarians can be found by subject: http://bit.ly/WcEbA1 or name: http://bit.ly/1tJ0bB4. In addition, general library assistance is provided in person at 19 University Libraries, located on both the Fort Garry and Bannatyne campuses, as well as in many Winnipeg hospitals. For a listing of all libraries, please consult the following: http://bit.ly/1sXe6RA. When working remotely, students can also receive help online, via the Ask-a-Librarian chat found on the Libraries’ homepage: www.umanitoba.ca/libraries.
Section B: Medical and Mental Health

For 24/7 mental health support, contact the Mobile Crisis Service at 204-940-1781.

Student Counselling Centre:

Contact SCC if you are concerned about any aspect of your mental health, including anxiety, stress, or depression, or for help with relationships or other life concerns. SCC offers crisis services as well as individual, couple, and group counselling. Student Counselling Centre: [http://umanitoba.ca/student/counselling/index.html](http://umanitoba.ca/student/counselling/index.html)
474 University Centre or S207 Medical Services
(204) 474-8592

Student Support Case Management:

Contact the Student Support Case Management team if you are concerned about yourself or another student and don’t know where to turn. SSCM helps connect students with on and off campus resources, provides safety planning, and offers other supports, including consultation, educational workshops, and referral to the STATIS threat assessment team.
520 University Centre
(204) 474-7423

University Health Service:

College of Pharmacy Students may access medical services by calling 204-940-8777 and identifying yourself as a Bannatyne student at the University of Manitoba. The address of the clinic is 425 Elgin Ave.

Alternatively, contact UHS for any medical concerns, including mental health problems. UHS offers a full range of medical services to students, including psychiatric consultation.
University Health Service [http://umanitoba.ca/student/health/](http://umanitoba.ca/student/health/)
104 University Centre, Fort Garry Campus
(204) 474-8411 (Business hours or after hours/urgent calls)
Health and Wellness:

Contact our Health and Wellness Educator if you are interested in information on a broad range of health topics, including physical and mental health concerns, alcohol and substance use harms, and sexual assault.

Health and Wellness Educator  http://umanitoba.ca/student/health-wellness/welcome.html
Katie.Kutryk@umanitoba.ca
469 University Centre  (204) 295-9032

Live Well @ UofM:

For comprehensive information about the full range of health and wellness resources available on campus, visit the Live Well @ UofM site:

http://umanitoba.ca/student/livewell/index.html

Section C: Copyright

All students are required to respect copyright as per Canada’s Copyright Act. Staff and students play a key role in the University’s copyright compliance as we balance user rights for educational purposes with the rights of content creators from around the world. The Copyright Office provides copyright resources and support for all members of the University of Manitoba community. Visit http://umanitoba.ca/copyright for more information.

Section D: Policies and Procedures

Your rights and responsibilities:

As a student of the University of Manitoba you have rights and responsibilities. It is important for you to know what you can expect from the University as a student and to understand what the University expects from you. Become familiar with the policies and procedures of the University and the regulations that are specific to your faculty, college or school.

The Academic Calendar http://umanitoba.ca/student/records/academiccalendar.html is one important source of information. View the sections University Policies and Procedures and General Academic Regulations.

While all of the information contained in these two sections is important, the following information is highlighted.

- If you have questions about your grades, talk to your instructor. There is a process for term work and final grade appeals. Note that you have the right to access your
final examination scripts. See the Registrar’s Office website for more information including appeal deadline dates and the appeal form http://umanitoba.ca/registrar/

- You are expected to view the General Academic Regulation section within the Academic Calendar and specifically read the Academic Integrity regulation. Consult the course syllabus or ask your instructor for additional information about demonstrating academic integrity in your academic work. Visit the Academic Integrity Site for tools and support http://umanitoba.ca/academicintegrity/ View the Student Academic Misconduct procedure for more information.

- The University is committed to a respectful work and learning environment. You have the right to be treated with respect and you are expected conduct yourself in an appropriate respectful manner. Policies governing behavior include the:

  Respectful Work and Learning Environment
  http://umanitoba.ca/admin/governance/governing_documents/community/230.html

  Student Discipline
  http://umanitoba.ca/admin/governance/governing_documents/students/student_discipline.html and,

  Violent or Threatening Behaviour
  http://umanitoba.ca/admin/governance/governing_documents/community/669.html

- If you experience Sexual Assault or know a member of the University community who has, it is important to know there is a policy that provides information about the supports available to those who disclose and outlines a process for reporting. The Sexual Assault policy may be found at: http://umanitoba.ca/admin/governance/governing_documents/community/230.html More information and resources can be found by reviewing the Sexual Assault site http://umanitoba.ca/student/sexual-assault/

- For information about rights and responsibilities regarding Intellectual Property view the policy http://umanitoba.ca/admin/governance/media/Intellectual_Property_Policy_-_2013_10_01.pdf
For information on regulations that are specific to your academic program, read the section in the Academic Calendar and on the respective faculty/college/school web site http://umanitoba.ca/faculties/.

Contact an Academic Advisor within our faculty/college or school for questions about your academic program and regulations http://umanitoba.ca/academic-advisors/

Student Advocacy:

Contact Student Advocacy if you want to know more about your rights and responsibilities as a student, have questions about policies and procedures, and/or want support in dealing with academic or discipline concerns. http://umanitoba.ca/student/advocacy/
520 University Centre
204 474 7423
student_advocacy@umanitoba.ca