







**PHC 340Y: Pharmaceutical Chemistry Laboratory****I. CONTACTS****INSTRUCTORS:**

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**STUDENT HOURS:****Fall Term:**

Lectures: Mondays 3-4p EDT in HS106

Labs: Thursdays 9a-1p EDT in PB860

**Winter Term:**

Lectures: Tuesday 11a-12p EDT in HS108

Labs: Thursdays 1-5p EDT in PB860

## II. COURSE OVERVIEW

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### COURSE DESCRIPTION:

**Welcome to PHC 340Y!** This course is a hands-on deep dive into the exciting world of drug research, development, and manufacture. The overarching goal of this course is to introduce students to theoretical and applied concepts in pharmaceutical chemistry, in research, development, and manufacturing contexts. The course is designed with lectures and laboratories covering major areas in pharmaceutical chemistry. The lectures and laboratories have been carefully scheduled together, to allow you to make practical hands-on connections to concepts discussed during lectures. The course covers selected topics pertinent to drug development such as acid/base equilibria, buffer preparation, drug solubility, drug polymorphs and salt selection, pKa, and co-solvency. The course also examines characterizing properties of common liquid, semi-solid and solid drug vehicles, such as viscosity, degradation kinetics/stability, diffusivity, tonicity, particle size distribution, and powder flowability. Emphasis is placed on the **process** of drug manufacture. We will be creating liquid suspensions, emulsions, capsules, tablets, suppositories, gummy bears, isotonic solutions, and some very fun and interesting dosage forms. The equipment you will be using is commonly found in formulation labs, pharmacies, pharmaceutical research labs, and pharmaceutical manufacturing plants. You will use state-of-the-art equipment such as a US Pharmacopeia (USP) dissolution apparatus, a rotary tablet press, a low- and high-shear granulator, a particle sizer, and a tablet coating machine. This equipment is unique in the University of Toronto, and very interesting to operate. A module on ethics and academic integrity will discuss cutting-edge applications of ethics in research, and issues arising when complex scientific solutions are proposed to regulatory bodies and to the public eye.

### STUDENT LEARNING OUTCOMES:

By the end of PHC 340Y, students will ...

- 1) Be equipped with both the lingo and scientific concepts ubiquitous in pharmaceutical industry.
- 2) Become familiarized with Good Documentation Practices and Good Manufacturing Practices.
- 3) Gain a working knowledge of USP tests such as tablet hardness, USP dissolution, friability, content uniformity, and weight uniformity.
- 4) Gain valuable feedback and practice in scientific writing of laboratory reports. This skill will translate well to graduate work in the sciences, and proper documentation in pharmaceutical regulatory and industrial contexts.
- 5) Gain confidence and experience in formulation science, taking into account pharmaceuticals concepts such as stability, viscosity, particle sizing, and organoleptic properties.
- 6) Gain a foundational level of knowledge of pharmaceuticals to apply to higher level courses in Pharmaceutical Chemistry, and undergraduate/graduate research projects in Pharmaceutical Sciences.
- 7) Be able to design and investigate your own pharmaceutical preparations safely and carefully, always being mindful of the dangers of the lab environment.
- 8) Be introduced to the increasingly important category of biologic therapeutics.
- 9) Be instilled with an enthusiasm in pharmaceuticals and pharmaceutical compounding.

### PREREQUISITE COURSE(S):

This course requires a basic understanding of chemistry laboratory practices and methodologies.

The following courses are pre-requisites for PHC 340Y:

CHM247H1/CHM249H1; (CHM220H1/CHM222H1), CHM223H1; BCH210H1

This course is a prerequisite for: PHC435H1, PHC430H1.

This course is *recommended* to be taken before PHC489Y. However, it is not a prerequisite for this course.

## READINGS:

### Required Text

1. Dubins D. Pharmaceutical Chemistry Laboratory Manual. Leslie Dan Faculty of Pharmacy, University of Toronto, 2022-23.

The course laboratory manual was written specifically for this course. It will be provided electronically on the course website.

### Recommended Texts

2. Sinko, Patrick J. Martin's Physical Pharmacy and Pharmaceutical Sciences. Lippincott Williams & Wilkins; 6 edition (Feb 21, 2010)
3. Troy, David B. Remington – The Science and Practice of Pharmacy. Lippincott Williams & Wilkins; 21 edition (May 19, 2005)
4. Aulton, Michael E. Aulton's Pharmaceutics: The Design and Manufacture of Medicines. A Churchill Livingstone Title; 3 edition (Nov 1, 2007)
5. Allen, Loyd V. Jr. et al. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems. Lippincott Williams & Wilkins; 9 edition (Jan 7, 2010)
6. Rowe, Raymond C et al. Handbook of Pharmaceutical Excipients. Pharmaceutical Press; 6th edition (2009). Available online, U of T Library permalink:  
<http://simplelink.library.utoronto.ca/url.cfm/141954> (UTORid login required)

Course notes, objectives, and information will be made available through the University of Toronto [Quercus](#) system. Printable worksheets will be provided for selected laboratories.

## III. COURSE ORGANIZATION

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### COURSE SCHEDULE, LOCATION, AND RELEVANT SESSIONAL DATES:

Lectures will take place in person in the fall term (HS106) and the winter term (HS108). Labs will take place in person in PB860 (fall and winter terms).

<b>Fall Term 2022</b>	<b>Labs (PB860)</b> Thursdays 9am-1pm EDT	<b>Lectures (HS 106)</b> Mondays 3pm-4pm EDT
<b>Lab 1</b> – Safety Lecture, Locker Check-in, Examination of UV Spectroscopy and Preparation of a Standard Curve	8-Sep-22	
<b>Lecture 1</b> – Acid/Base Equilibria (Alexander Baker)		12-Sep-22
<b>Lab 2</b> – Preparation of pH Buffers	15-Sep-22	
<b>Lecture 2</b> – Phase Partitioning (Alexander Baker)		19-Sep-22
<b>Lab 3<sup>†</sup></b> – Effect of pH on the Partition Coefficient of a Slightly Soluble Weak Acid	22-Sep-22	

<b>Lecture 3</b> – Polymorph and Salt (Ping Lee)		26-Sep-22
<b>Lab 4*</b> - Characterization of Drug Candidates (I) – Measuring Solubility and pK <sub>a</sub> <b>Presentation: Formal Lab Reports – Structure and Guidelines (both TAs)</b>	29-Sep-22	
<b>Lecture 4</b> – Mixing (Alexander Baker)		3-Oct-22
<b>Lab 5*</b> – Characterization of Drug Candidates (II) – Co-solvency, Salt Selection and Polymorph Identification	6-Oct-22	
<b>Lab 6*</b> – Thermodynamics of Mixing – Enthalpy and Volume <b>Presentation: Writing Formal Lab Reports for PHC 340 (Nina Munteanu)</b>	13-Oct-22	
<b>Lecture 5</b> – Rheology (Alexander Baker)		17-Oct-22
<b>Lab 7*</b> – Examination of Viscosity and Suspending Agents	20-Oct-22	
<b>Lecture 6</b> – Chemical Kinetics & Stability (Ping Lee)		24-Oct-22
<b>Lab 8<sup>‡</sup></b> – Kinetics of Acetylsalicylic Acid Hydrolysis	27-Oct-22	
<b>Lecture 7</b> – Diffusion and Membrane Transport 1 (Ping Lee)		31-Oct-22
<b>Lab 9</b> – Diffusion and Membrane Transport 1: Permeation Measurement [Exercise 2: Quassignment for Lab 10]	3-Nov-22	
<b>Reading Week Nov 7-11</b>		
<b>Lecture 8</b> – Colligative Properties (Alexander Baker)		14-Nov-22
<b>Lab 10*</b> – Tonicity and Pharmaceutics	17-Nov-22	
<b>Lecture 9</b> – Diffusion and Membrane Transport 2 (Ping Lee)		21-Nov-22
<b>Lab 11<sup>‡</sup></b> – Diffusion and Membrane Transport 2: Drug Release from Ointment Bases	24-Nov-22	
<b>Lecture 10</b> – Molecules at Interfaces (Alexander Baker)		28-Nov-22
<b>Lab 12*</b> – Estimation of Critical Micelle Concentration (CMC) of a Surfactant in Water	1-Dec-22	
<b>Lecture 11</b> – Particle Size and Powder Flow (Ping Lee)		5-Dec-22

<i><b>Winter Term 2023</b></i>	<b>Labs (PB860)</b> Thursdays 1pm-5pm EDT	<b>Lectures (HS108)</b> Tuesdays 11a-12p EDT
<b>Lecture 12</b> – Pharmaceutical Granulation (Ping Lee)		10-Jan-23
<b>Lab 13*</b> – Optimization of Powder Flow and Particle Size Determination	12-Jan-23	
<b>PHC340 Midterm</b>		
		17-Jan-23
<b>Lab 14</b> – Pharmaceutical Granulations, Part 1	19-Jan-23	
<b>Lecture 13</b> – Tableting and Dissolution Testing (Ping Lee)		24-Jan-23
<b>Lab 14<sup>‡</sup></b> – Pharmaceutical Granulations, Part 2	26-Jan-23	
<b>Lecture 14</b> – Measurement, Part 1 (Alexander Baker)		31-Jan-23
<b>Lab 15</b> – Tableting and Dissolution Testing, Part 1	2-Feb-23	
<b>Lecture 15</b> – Measurement, Part 2 (Alexander Baker)		7-Feb-23
<b>Lab 15</b> – Tableting and Dissolution Testing, Part 2	9-Feb-23	
<b>Lecture 16</b> – Synthetic Biology and Human Health, Part 1 (Alexander Baker)		14-Feb-23
<b>Lab 15<sup>‡</sup></b> – Tableting and Dissolution Testing, Part 3	16-Feb-23	
<b>Reading Week Feb 20-24</b>		
<b>Lecture 17</b> – Synthetic Biology and Human Health, Part 2 (Alexander Baker)		28-Feb-23
<b>Lab 16</b> – Mystery Laboratory	2-Mar-23	
<b>Lab 17<sup>‡</sup></b> – Synthesis and Examination of Colloids	9-Mar-23	

<b>Lecture 18</b> – Mold Calculations (David Dubins)		14-Mar-23
<b>Lab 18*</b> – Drug Formulations Using Molds	16-Mar-23	
<b>Lecture 19</b> – Ethics & Academic Integrity (Julian Ferguson)		21-Mar-23
<b>Lab 19</b> – Advanced Formulations Project, Part 1	23-Mar-23	
<b>Lecture 20</b> – Ethics & Academic Integrity (Julian Ferguson)		28-Mar-23
<b>Lab 19<sup>‡</sup></b> – Advanced Formulations Project, Part 2. <b>Lab Check-Out.</b>	30-Mar-23	
<b>Industrial Tour (TBD)</b>	6-Apr-23	
<b>PHC340 Final Exam</b>		During final exam period

<sup>‡</sup> Lab Report to be completed for evaluation

\* Lab Worksheet to be completed for evaluation

For important academic sessional dates, visit:

<https://www.artsci.utoronto.ca/current/dates-deadlines/academic-dates>

<https://sgs.calendar.utoronto.ca/sessional-dates>

## LECTURES

This course is organized into twenty lecture sections, with labs complementing themes in the lectures. In the Fall term, the lectures are scheduled to be in-person on Mondays in PB255, and will be offered online until Monday September 20<sup>th</sup>. In the Winter term, lectures are scheduled to be in-person on Tuesdays in BA B024 (Bahen Centre, at 40 St. George St.).

## HOW TO PREPARE FOR CLASS

- 1) Read the associated section in the PHC340Y laboratory manual;
- 2) Perform any necessary calculations required in the manual;
- 3) Prepare your laboratory notebook with your pre-lab notes and tables;
- 4) Arrive on time, and prepared to write a pre-lab surprise quiz;
- 5) In general, most lectures and practical activities will require:
  - Lab Notebook
  - PHC340Y Laboratory Manual
  - Your Student T-Card
  - Ruler
  - Pen
  - Highlighter
  - Non-programmable calculator

## IV. EVALUATION/GRADING SCHEME

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### OVERVIEW:

The final grade for PHC 340Y will be based on nine laboratory worksheets, seven formal laboratory reports, two to three surprise laboratory quizzes, one midterm test, and one final exam.

Assessment methods are balanced to address different learning styles. Questions on the examinations will be drawn primarily from the lecture material, laboratories, lab manual, and concepts discussed in lectures and activities.

**ASSESSMENT DATES & MARK BREAKDOWN:**

The weighting of the evaluative components of the course are as follows:

**1) Laboratory Worksheets (8) and Formal Laboratory Reports (7)**

Weight: **65%**

Dates: Provided in the course schedule.

Due: One week from completion of the laboratory, at the beginning of the following lab.

Note: The lab assessments are weighted as follows:

<b>Lab</b>	3	4	5	6	7	8	10	9&11	12	13	14	15	17	18	19
<b>Type</b>	RPT	WS	WS	WS	WS	RPT	WS	RPT	WS	WS	RPT	RPT	RPT	WS	RPT
<b>Weight</b>	0.5	0.5	0.5	0.5	0.5	1	0.5	1	0.5	0.5	1	1	1	0.5	1

(RPT=Formal Lab Report, WS=Lab Worksheet)

**The lowest laboratory worksheet mark** and the **lowest laboratory report mark** will be dropped from the assessment scheme for each student.

**2) Quizzes (2-3)**

Weight: **5%**

Dates: Surprise in-class quizzes, administered during the first 10 minutes of the lab. Please arrive on time to each lab.

Assessment Style: Short answer, MCQ, fill-in-the-blank, calculations, and other various assessment styles.

Note: Lab quizzes are weighted equally.

**3) Midterm Test**

Weight: **15%**

Date: 18-Jan-22

Material: Fall term lectures and laboratories.

Assessment style: Calculations, short answer, matching, MCQ, fill-in-the-blank.

**4) Final Exam**

Weight: **15%**

Date: Scheduled during final examination period

Material: Entire Course (cumulative). Emphasis on concepts in Winter term.

Assessment style: Calculations, short answer, matching, MCQ, fill-in-the-blank.

**V. COURSE POLICIES**

- Each member of this course is expected to maintain a:
  - (i) professional and respectful attitude during all course activities, including classes, laboratories, and online activity.
  - (ii) personal calendar/schedule/organizer to ensure that all course activities are completed, and due dates are met.
  - (iii) collection of notes recorded independently based on concepts covered in course activities (students registered with Accessibility Services requiring a class note-taker will have access to this accommodation)
  - (iv) familiarity with the university policy on Academic Integrity (overleaf)



### ***Lateness Policy***

Lab reports and worksheets are due **by electronic submission only, through Quercus**. Labs are generally due one week from performing the lab, **by the beginning of the next lab**. For late submissions, there will be an academic penalty imposed of **10% per calendar day**, in accordance with departmental policies. Submissions will not be accepted beyond 1 week from the original due date.

Students who are more than 30 minutes late for a laboratory will not be admitted to the lab. Please plan on arriving to the lab on time.

### ***E-mail***

- For course concerns or issues with non-academic problems, such as conflicts, illness and academic accommodations, please email [alexander.baker@mail.utoronto.ca](mailto:alexander.baker@mail.utoronto.ca) or [d.dubins@utoronto.ca](mailto:d.dubins@utoronto.ca).
- When you e-mail an individual, the language and tone of your email professional. Email only one member of the teaching team. Most emails will receive a reply within 24 hours of being sent (except on weekends) but keep your expectations reasonable as to the degree of detail that an email reply to your enquiry can realistically provide.

### ***Course Environment***

- The University of Toronto is committed to equity, human rights and respect for diversity. All members of the learning environment in this course should strive to create an atmosphere of mutual respect where all members of our community can express themselves, engage with each other, and respect one another's differences. U of T does not condone discrimination or harassment against any persons or communities. If you have any questions, comments, or concerns, we encourage you to reach out to the staff in our Equity Offices.

### ***Privacy Policy***

- Parts of this course, including your participation, may be recorded on video and will be available to students in the course for viewing remotely and after each session.
- Course videos and materials belong to your instructor, the University, and/or other sources depending on the specific facts of each situation and are protected by copyright. Do not download, copy, or share any course or student materials or videos without the explicit permission of the instructor.

### ***Absences***

Attendance in each laboratory session is mandatory. Attendance in each lab (and the lab tour, if applicable), will be recorded. If you miss a lab or lab tour due to medical, personal, family, or other unavoidable reasons, you must provide supportive documentation (e.g. the University of Toronto Self-Declaration of Illness form on ACORN) to the course Instructor for consideration of accommodation. The declaration is available on ACORN under the Profile and Settings menu. If accommodation is granted, you can make a request the course coordinator to complete a make-up assignment on the same topic of the missed course material. The final mark on the make-up assignment will have the same weighting as the missed lab period(s).

Otherwise, if you miss a single laboratory session, you will obtain a zero for that laboratory. If you miss one laboratory session of a laboratory that spans more than one session, your final mark will be multiplied by the ratio of the number of sessions you attended, provided that you participate in writing the final report. Students must attend and complete at least 80% of the in-person lab periods (typically 20 out of 24) in order to complete PHC340H1.

## VI. TECHNOLOGY REQUIREMENTS

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### REQUIRED EQUIPMENT

- **A laptop or desktop computer** is required for this course.
- **A working webcam** may be helpful for some aspects of this course, if synchronous lectures are hosted. The built-in webcam on a laptop or desktop is acceptable.
- **A lab coat and safety glasses** will be required to participate in lab activities. Closed-toed shoes, and clothing covering your legs are also required. Further details will be provided during the introductory safety lecture and in the PHC340 Laboratory Manual.
- Specific guidance from the U of T Vice-Provost, Students regarding student technology requirements is available here: <https://www.vicereprovoststudents.utoronto.ca/covid-19/tech-requirements-online-learning/>
- Advice for students more broadly regarding online learning is available here: <https://onlinelearning.utoronto.ca/getting-ready-for-online/>

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This course requires the use of computers, and technical issues are possible. When working on an assignment, students are responsible for scheduling enough time to allow for reasonable delays due to technical difficulties to be overcome, so such issues will not be acceptable grounds for deadline extension. Particularly, maintaining an up-to-date independent backup copy of your work is strongly recommended to guard against *e.g.* hard-drive failures, corrupted files, lost computers, etc.

We appreciate that students may experience a range of circumstances that shape their ability and/or decision to participate in course activities using video. We are committed to creating equitable and inclusive learning and teaching spaces. In support of this commitment we feel it is important to give participants the choice to turn their video on/off.

For General technology concerns, please contact the Information Commons Help Desk via (416) 978-HELP (4357) OR by e-mailing [help.desk@utoronto.ca](mailto:help.desk@utoronto.ca). They are open evenings and weekends. <https://oneresearch.library.utoronto.ca/ic-faq-categories/about-and-hours-service>

Please contact the course co-ordinator with course-specific technology concerns. Please be as detailed as possible with your question by including the time/date, detailed description of the problem, web browser and device you were using (*e.g.* laptop/tablet etc.) and include screenshots/error message etc.

## VII. INSTITUTIONAL POLICIES AND SUPPORT

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### ACADEMIC INTEGRITY

Academic integrity is essential to the pursuit of learning and scholarship in a university, and to ensuring that a degree from the University of Toronto is a strong signal of each student's individual academic achievement. As a result, the University treats cases of cheating and plagiarism very seriously. The University of Toronto's Code of Behaviour on Academic Matters (<https://governingcouncil.utoronto.ca/secretariat/policies/code-behaviour-academic-matters-july-1->



[2019](#)) outlines the behaviours that constitute academic dishonesty and the processes for addressing academic offences. Potential offences include, but are not limited to:

***In practical work:***

1. Using someone else's ideas or words without appropriate acknowledgement.
2. Submitting your own work in more than one course without the permission of the instructor.
3. Making up sources or facts.
4. Obtaining or providing unauthorized assistance on any report. **Please note that the use of websites (such as Chegg.com or the course discussion board) to post virtual laboratory report material/questions or to post/access answers to questions is an academic offence under the University of Toronto's Code of Behaviour on Academic Matters. Alleged instances of this nature are forwarded to the Faculty of Arts & Science Student Academic Integrity office.**

***On quizzes, tests, and examinations:***

1. Using or possessing unauthorized aids. **Please note that the use of websites (such as Chegg.com or the course discussion board) to post quiz/term test questions or to post/access answers to questions is an academic offence under the University of Toronto's Code of Behaviour on Academic Matters. Alleged instances of this nature are forwarded to the Faculty of Arts & Science Student Academic Integrity office.**
2. Looking at someone else's answers or collaborating/discussing answers during a quiz or term test.
3. Misrepresenting your identity.

***In general academic work:***

1. Falsifying institutional documents or grades.
2. Falsifying or altering any documentation required by the University.
3. Sharing solutions for any material handed in that is assessed individually.

All suspected cases of academic dishonesty will be investigated following procedures outlined in the Code of Behaviour on Academic Matters. If you have questions or concerns about what constitutes appropriate academic behaviour or appropriate research and citation methods, you are expected to seek out additional information on academic integrity from your instructor or from other institutional resources (see <https://www.academicintegrity.utoronto.ca/>).

**VERIFICATION OF ACADEMIC ORIGINALITY:** Normally, students will be required to submit their course essays to the University's plagiarism detection tool for a review of textual similarity and detection of possible plagiarism. In doing so, students will allow their essays to be included as source documents in the tool's reference database, where they will be used solely for the purpose of detecting plagiarism. The terms that apply to the University's use of this tool are described on the Centre for Teaching Support & Innovation web site (<https://uoft.me/pdt-faq>).

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Students with diverse learning styles and needs are welcome in this course. The University of Toronto is committed to accessibility: if you require accommodations for a disability, or have any other accessibility concerns about the course, please contact [Accessibility Services](#) as soon as possible.

**ACCOMMODATIONS FOR RELIGIOUS OBSERVANCES**

Following the University's policies, reasonable accommodations will be made for students who observe religious holy days that coincide with the due date/time of an assignment, tutorial, class or laboratory

session. Students must inform the instructor **before** the session/assignment date to arrange accommodations.

### **ACCESSIBILITY NEEDS**

Students with diverse needs are welcome in this course. The University of Toronto is committed to accessibility: if you require accommodations for a disability, or have any other accessibility concerns about the course, please contact Accessibility Services as soon as possible.

### **ADDITIONAL SERVICES & SUPPORT**

The following are some important links to help you with academic and/or technical service and support:

- General student services and resources at [Student Life](#)
- Full library service through [University of Toronto Libraries](#)
- Resources on conducting online research through [University Libraries Research](#)
- Resources on academic support from the [Academic Success Centre](#)
- Learner support at the [Writing Centre](#)
- Information for [Technical Support/Quercus Support](#)

### **ACKNOWLEDGEMENT OF TRADITIONAL LANDS**

We wish to acknowledge this land on which the University of Toronto operates. For thousands of years, it has been the traditional land of the Huron-Wendat, the Seneca and, most recently, the Mississaugas of the Credit River. Today, this meeting place is still the home to many Indigenous people from across Turtle Island and we are grateful to have the opportunity to work on this land.