

**Instructor:**

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**TA:** TBA

**Scope and objectives**

This course aims to equip students with the knowledge in pharmaceutical technology. Theory and practice in the manufacture of active pharmaceutical ingredients (APIs), characterization of APIs, formulation of various pharmaceutical dosage forms (e.g., tablets, capsules, emulsions, creams, controlled release formulations) are covered. In addition, the course discusses future trends in industry on selected topics such as continuous manufacturing, quality-by-design, and process analytical technologies.

**Content**

Part 1: The manufacture and properties of Active Pharmaceutical Ingredients (APIs).

- Overview of pharmaceuticals and pharmaceutical industry; role of chemical engineer in pharmaceutical industry.
- Importance, discovery, and synthesis of APIs.
- Solid-state properties and industrial formation and separation of solid APIs.
- Future trends in the manufacture of APIs.

Part 2: Formulation of APIs into drug products.

- Overview and selection of pharmaceutical dosage forms.
- Emulsions and creams
- Tablets and capsules
- Controlled release formulations
- Guest lecture(s)

**Grading**

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|---|--------------------|
| • 3 x Homework                                      | 25% (10% + 2×7.5%) |
| • Participation in in-class tutorials (unannounced) | 10%                |
| • Mid-term quiz (closed book)                       | 15%                |
| • Spring-term final exam (closed book)              | 50%                |

The homework assignments will be distributed via Canvas and must be submitted via Canvas before the deadline. Group study is encouraged, but any submitted work needs to be your own work. Plagiarism and academic dishonesty will not be tolerated in any shape or form. It is good to work collaboratively, because this is how professional engineers work in practice often as well (do learn from each other!), however, every student needs to write up his/her own final answers individually. Your paper is for your eyes only. In cases of plagiarism, no distinction will be made

between those who copied work from classmates (or other sources) and those who offered their work to others so that it could be copied. Duplicating parts of the homework of others may lead to an F grade for all students involved. Late submissions can be submitted for 50% credit up to one week after the deadline and 0% thereafter. You are allowed to use generative AI only for the purposes of language editing, and it must be properly acknowledged. Content generation through AI is not permitted (and not expected to be helpful for the assessment of this course). All papers will be screened with Turnitin upon submission through Canvas.

Several short in-class tutorials will be conducted to practice the teaching material. The date of these tutorials will not be announced upfront. They will be conducted during regular classes when certain parts of the teaching material have been covered. Participation in these tutorials will contribute to 10% of your final course grade. You will need to submit your work in-class (handwritten or digitally through Canvas). It will not be possible to participate remotely or submit your work after class. You will need to attend class regularly to get these participation marks.

The final examination is closed-book/closed-notes and covers the complete course.

The lectures will be in Room G009A (CYT building) on Tuesday and Thursday of every week from 04:30pm - 05:50pm. A tentative timetable is provided below. Please check Canvas regularly for any updates.

### **Textbooks**

- Aulton ME & Taylor KMG. (2018) Aulton's Pharmaceutics, 5th Edition -- The Design and Manufacture of Medicines. Churchill Livingstone, London, U.K. [This textbook is online available via the HKUST library website]
- Blacker AJ & Williams MT. (2011) Pharmaceutical Process Development: Current Chemical and Engineering Challenges edited by A. John Blacker and Michael T. Williams. Royal Society of Chemistry, Cambridge, U.K. [Available in HKUST e-library: <https://lbdiscover.ust.hk/bib/991005328029703412>]

Background reading:

- Am Ende, DJ (2011) Chemical engineering in the pharmaceutical industry: R&D to manufacturing. Hoboken, New Jersey, Wiley, 2011. [Available in HKUST e-library: <https://lbdiscover.ust.hk/bib/991012622743203412>]

### Tentative timetable

	<b>Date &amp; Time</b>	<b>Topics (tentative)</b>	<b>Notes</b>
<b>Week 1</b>	Sep 5, 2023 16:30 – 17:50 Sep 7, 2023 16:30 – 17:50	Introduction General principles of drug delivery and action	Welcome!
<b>Week 2</b>	Sep 12, 2023 16:30 – 17:50 Sep 14, 2023 16:30 – 17:50	Overview of pharmaceutical industry  Active Pharmaceutical Ingredients (APIs) - Impact, discovery, synthesis, environment, safety	
<b>Week 3</b>	Sep 19, 2023 16:30 – 17:50 Sep 21, 2023 16:30 – 17:50	Active Pharmaceutical Ingredients (APIs) - Impact, discovery, synthesis, environment, safety	
<b>Week 4</b>	Sep 26, 2023 16:30 – 17:50 Sep 28, 2023 16:30 – 17:50	Solid-state properties of APIs	Homework 1 distributed*
<b>Week 5</b>	Oct 3, 2023 16:30 – 17:50 Oct 5, 2023 16:30 – 17:50	Solid-state properties of APIs  Industrial formation and purification of APIs	
<b>Week 6</b>	Oct 10, 2023 16:30 – 17:50 Oct 12, 2023 16:30 – 17:50	Industrial formation and purification of APIs  Future trends in the manufacture of APIs	
<b>Week 7</b>	Oct 17, 2023 16:30 – 17:50 Oct 19, 2023 16:30 – 17:50	Future trends in the manufacture of APIs	Submission of Homework 1 (18/10/2023 at 23:59)* Homework 2 distributed*
<b>Week 8</b>	Oct 24, 2023 16:30 – 17:50 Oct 26, 2023 16:30 – 17:50	<b>Mid-term quiz (in-class, Oct 24, 16:30)</b>  Solutions, emulsions, and creams	

<b>Week 9</b>	Oct 31, 2023 16:30 – 17:50 Nov 2, 2023 16:30 – 17:50	Solutions, emulsions, and creams	
<b>Week 10</b>	Nov 7, 2023 16:30 – 17:50 Nov 9, 2023 16:30 – 17:50	<b><u>Guest Lecture:</u></b> Prof. Aviva Chow, Department of Pharmacology and Pharmacy, Li Ka Shing Faculty of Medicine, The University of Hong Kong. Topic: Dosage form design	Submission of Homework 2 (8/11/2023 at 23:59)*
<b>Week 11</b>	Nov 14, 2023 16:30 – 17:50 Nov 16, 2023 16:30 – 17:50	Solid-dosage forms	Homework 3 distributed*
<b>Week 12</b>	Nov 21, 2023 16:30 – 17:50 Nov 23, 2023 16:30 – 17:50	Controlled-release formulations	
<b>Week 13</b>	Nov 28, 2023 16:30 – 17:50 Nov 30, 2023 16:30 – 17:50	Controlled-release formulations	Submission of Homework 3 (29/11/2023 at 23:59)*
Exam period	TBA	On-campus exam of all course material	closed book / closed notes

\* Homework distribution/submission dates in the Syllabus are tentative. Final dates will be announced in the Assignments on Canvas.