CBE 4404A  Downstream Processing in Pharmaceutical manufacturing

Description
The objective of this course is to introduce upper year chemical/biochemical engineering students to pharmaceutical manufacturing. An overview of the pharmaceutical industry and its regulations will be presented followed by the basic concepts of the major manufacturing methods and their component unit operations. Examples of the manufacturing of selected pharmaceutical drugs will be presented.

Prerequisites
CBE 3322A/B, CBE 3323A/B, CBE 3324A/B, CBE 3325A/B.

Unless you have either the requisites for this course or written special permission from your Dean to enroll in it, you will be removed from this course and it will be deleted from your record. This decision may not be appealed. You will receive no adjustment to your fees in the event that you are dropped from a course for failing to have the necessary prerequisites.

Corequisites
None

Antirequisites
None

Contact Hours
3 lecture hours and 1 tutorial hour, 0.5 course.

Instructor
Dr. L. Briens (SEB2084) Telephone: 519-661-2111 ext: 88849 email: lbriens@uwo.ca

Undergraduate Assistant
Brandy Hunter (TEB 477) Telephone: 519-661-2111 ext: 82131 email: cbeundergraduate@uwo.ca
**Required Text**
None

**Reference Texts**
None

**Course Notes**
Course notes will be available for download from the course website.

**Units**
SI units will be used in lectures and examinations

**General Learning Objectives**

<table>
<thead>
<tr>
<th>A knowledge base for engineering</th>
<th>A</th>
<th>Individual and team work</th>
<th>I</th>
<th>Economics and project management</th>
<th>I</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem analysis</td>
<td>A</td>
<td>Communication skills</td>
<td>I</td>
<td>Life-long learning</td>
<td>I</td>
</tr>
<tr>
<td>Investigation</td>
<td>A</td>
<td>Professionalism</td>
<td>B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Design</td>
<td>A</td>
<td>Impact of engineering on society and the environment</td>
<td>n.e.</td>
<td></td>
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<tr>
<td>Use of engineering tools</td>
<td>A</td>
<td>Ethics and equity</td>
<td>n.e.</td>
<td></td>
<td></td>
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</tbody>
</table>

Key:
- B: evaluated at introductory level
- I: evaluated at intermediate level
- A: evaluated at advanced level
- n.e.: not evaluated

**Specific Learning Objectives**

- Overview of the pharmaceutical industry.
- Regulations and Safety Issues.
- Mixing
  - Functions and characteristics of the components of pharmaceutical mixtures.
  - Principles of mixing.
  - Types of mixers.
  - Monitoring mixing.
- Granulation.
  - Dry granulation.
  - Wet granulation.
  - Oven drying.
  - Fluid bed drying.
  - Monitoring granulation and drying.
- Tabletting.
  - Functions and stages of the tablet compression process.
  - Overview of tabletting equipment.
  - Examination of dies and punches.
- Coating.
  - Principles of coating.
  - Coating materials.
- Spray coating.
- Fluid bed coating.
- Encapsulation.
  - Manufacture of hard-shell capsules.
  - Manufacture of soft gel capsules.
- New directions in pharmaceuticals.

**Evaluation**
The final course mark will be determined as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Assignments</td>
<td>20%</td>
</tr>
<tr>
<td>Project</td>
<td>30%</td>
</tr>
<tr>
<td>Final Examination</td>
<td>50%</td>
</tr>
</tbody>
</table>

The final examination will be limited open-book and will be 3 hours in length.

**Notes**
1) **Students must pass the final examination to pass this course.** Students who fail the final examination will be assigned 48% if the aggregate mark is higher than 50%, or the examination mark, whichever is less.
2) Assignments are to be handed in digitally through OWL. **Late assignments will receive a mark of zero.**
3) **Students must pass the project to pass this course.** The project will be submitted electronically and will be checked for plagiarism using software provided by The University of Western Ontario. Projects showing plagiarism levels above 35% (excluding bibliographic materials and small word matches) will receive a mark of zero. Late projects will be deducted 10% per day past the assigned deadline.

**Repeating All Components of the Course**
In accordance with Senate and Faculty Policy, students who have failed an Engineering course (i.e. <50%) must repeat all components of the course. No special permissions will be granted enabling a student to retain laboratory, assignment or test marks from previous years. Previously completed assignments and laboratories cannot be resubmitted for grading by the student in subsequent years.

**Use of English**
In accordance with Senate and Faculty Policy, students may be penalized up to 10% of the marks on all assignments, tests, and examinations for the improper use of English. Additionally, poorly written work with the exception of the final examination may be returned without grading. If resubmission of the work is permitted, it may be graded with marks deducted for poor English and/or late submission.

**Attendance**
**Attendance in all lectures is mandatory.** Any student who, in the opinion of the instructor, is absent too frequently from class or laboratory periods in any course, will be reported to the Dean (after due warning has been given). On the recommendation of the Department concerned, and with the permission of the Dean, the student will be debarred from taking the regular examination in the course.

**Cheating**
University policy states that cheating is a scholastic offence. The commission of a scholastic offence is attended by academic penalties, which might include expulsion from the program. If you are caught cheating, there will be no second warning (see Scholastic Offence Policy in the Western Academic
Plagiarism
Students must write their essays and assignments in their own words. Whenever students take an idea or a passage from another author, they must acknowledge their debt both by using quotation marks where appropriate and by proper referencing such as footnotes or citations. Plagiarism is a major academic offence (see Scholastic Offence Policy in the Western Academic Calendar).

The University of Western Ontario has software for plagiarism checking. Students may be required to submit their work in electronic form for plagiarism checking.

Conduct
Students are expected to arrive at lectures on time, and to conduct themselves during class in a professional and respectful manner that is not disruptive to others.

Sickness and Other Problems
Students should immediately consult with the instructor or Department Chair if they have any problems that could affect their performance in the course. Where appropriate, the problems should be documented. The student should seek advice from the Instructor or Department Chair regarding how best to deal with the problem. Failure to notify the Instructor or Department Chair immediately (or as soon as possible thereafter) will have a negative effect on any appeal.

Please contact the course instructor if you require material in an alternate format or if any other arrangements can make this course more accessible to you. You may also wish to contact Services for Students with Disabilities (SSD) at 661-2111 x 82147 for any specific question regarding an accommodation.

Notices
Students are responsible for regularly checking their Western email and notices posted on the course web site.

Consultation
Students are encouraged to discuss problems with their teaching assistant and/or instructor in tutorial sessions. Office hours will be arranged for the students to see the instructor and teaching assistants. Other individual consultation can be arranged by appointment with the appropriate instructor.

Accreditation (AU) Breakdown
Engineering Science  =  60%
Engineering Design  =  40%
If, on medical or compassionate grounds, you are unable to write term tests or final examinations or complete course work by the due date, you should follow the instructions listed below. You should understand that academic accommodation will not be granted automatically on request. You must demonstrate to your department (or the Undergraduate Services office if you are in first year) that there are compelling medical or compassionate grounds that can be documented before academic accommodation will be considered. Different regulations apply to term tests, final examinations and late assignments. Read the instructions carefully. (see the 2016 Western Academic Calendar).

A. **GENERAL REGULATIONS & PROCEDURES**

1. Check the course outline to see if the instructor has a policy for missed tests, examinations, late assignments or attendance.

2. Bring your request for academic accommodation to the attention of the Chair of the department (or the Undergraduate Services office if you are in first year) prior to the scheduled time of the test or final examination or due date of the assignment. If you are unable to contact the relevant person, leave a message with the appropriate department (or Undergraduate Services office, if you are in first year). The addresses, telephone and fax numbers are given at the end of these instructions. Documentation must be provided as soon as possible.

3. If you decide to write a test or an examination you should be prepared to accept the mark you earn. Rewriting tests or examinations or having the value of a test or exam reweighted on a retroactive basis is not permitted.

B. **TERM TESTS**

1. If you are unable to write a term test, inform your instructor and the Chair of your Department (or the Undergraduate Services Office if you are in first year) prior to the scheduled date of the test. If the instructor is not available, leave a message for him/her at the department office and inform the Chair of the Department (or the Undergraduate Services Office if you are in first year).

2. Be prepared to provide supporting documentation to the Chair and the Undergraduate Services Office (see next page for information on documentation).

3. Discuss with the instructor if and when the test can be rescheduled. **N.B.** The approval of the Chair (or the Undergraduate Services Office if you are in first year) is required when rescheduling term tests.

C. **FINAL EXAMINATIONS**

1. If you are unable to write a final examination, contact the Undergraduate Services Office PRIOR TO THE SCHEDULED EXAMINATION TIME to request permission to write a Special Final Examination. If no one is available in the Undergraduate Services Office, leave a message clearly stating your name & student number (please spell your full name).

2. Be prepared to provide the Undergraduate Services Office with supporting documentation (see next page for information on documentation) the next day, or as soon as possible (in cases where students are hospitalized). The following circumstances are not considered grounds for missing a final examination or requesting special examinations: common cold, sleeping in, misreading timetable and travel arrangements.

3. In order to receive permission to write a special examination, you must obtain the approval of the Chair of the Department and the Associate Dean and in order to apply you must sign a "Recommendation for a Special Examination Form" available in the Undergraduate Services Office. The Undergraduate Services Office will then notify the course instructor(s) and reschedule the examination on your behalf.

**N.B.** It is the student's responsibility to check the date, time and location of the special examination.

D. **LATE ASSIGNMENTS**

1. Advise the instructor if you are having problems completing the assignment on time (prior to the due date of the assignment).

2. Be prepared to provide documentation if requested by the instructor (see reverse side for information on documentation).

3. If you are granted an extension, establish a due date. The approval of the Chair of your Department (or the Associate Dean if you are in first year) is not required if assignments will be completed prior to the last day of classes.

4. i) Extensions beyond the end of classes must have the consent of the instructor, the department Chair and the Associate Dean. Documentation is mandatory.

   ii) A Recommendation of Incomplete Form must be filled out indicating the work to be completed and the date by which it is due. This form must be signed by the student, the instructor, the department Chair and the Associate Dean.
SHORT ABSENCES

If you miss a class due to a minor illness or other problems, check your course outlines for information regarding attendance requirements and make sure you are not missing a test or assignment. Cover any readings and arrange to borrow notes from a classmate.

EXTENDED ABSENCES

If you are absent more than one week or if you get too far behind to catch up, you should consider reducing your workload by dropping one or more courses. (Note drop deadlines listed below). You may want to seek advice from the academic counsellor in your Department or the counsellors in the Undergraduate Services Office if you are in first year.

DOCUMENTATION

If you consulted an off-campus doctor or Student Health Services regarding your illness or personal problem, you must provide the doctor with a Student Medical Certificate to complete at the time of your visit and then bring it to the Department (or the Undergraduate Services Office if you are in first year). This note must contain the following information: severity of illness, effect on academic studies and duration of absence.

In Case of Serious Illness of a Family Member: Provide a Student Medical Certificate to your family member's physician to complete and bring it to the Department (or the Undergraduate Services Office if you are in first year).

In Case of a Death: Obtain a copy of the death certificate or the notice provided by the funeral director's office. You must include your relationship to the deceased and bring it to the Department (or the Undergraduate Services Office if you are in first year).

For Other Extenuating Circumstances: If you are not sure what documentation to provide, ask the Departmental Office (or the Undergraduate Services Office if you are in first year) for direction.

Note: Forged notes and certificates will be dealt with severely. To submit a forged document is a scholastic offence (see below).

ACADEMIC CONCERNS

You need to know if your instructors have a policy on late penalties, missed tests, etc. This information may be included on the course outlines. If not, ask your instructor(s).

You should also be aware of attendance requirements in some courses. You can be debarred from writing the final examination if your attendance is not satisfactory.

If you are in academic difficulty, check out the minimum requirements for progression in the calendar. If in doubt, see your academic counsellor.

Calendar References: Check these regulations in your 2016 Western Academic Calendar available at www.westerncalendar.uwo.ca.

Absences Due to Illness - page 117
Academic Accommodations for Students with Disabilities - page 118
Academic Accommodations for Religious Holidays - page 119
Incomplete Standing - page 104
Scheduling of Term Assignments – page 97
Scholastic Offences - page 113
Special Examinations - page 132

Note: These instructions apply to all students registered in the Faculty of Engineering regardless of whether the courses are offered by the Faculty of Engineering or other faculties in the University.

Drop Deadlines: First term half course (i.e. “A” or “F”): November 5, 2016
Full courses and full-year half courses (i.e. “E”, “Y” or no suffix): November 30, 2016
Second term half or second term full course (i.e. “B” or “G”): March 7, 2017

Undergraduate Services Office: SEB 2097 telephone: (519) 661-2130 fax: (519) 661-3757
Dept. of Chemical and Biochemical Engineering: TEB 477 telephone: (519) 661-2131 fax: (519) 661-3498
Dept. of Civil and Environmental Engineering: SEB 3005 telephone: (519) 661-2139 fax: (519) 661-3779
Dept. of Electrical and Computer Engineering, Software Engineering: TEB 279 telephone: (519) 661-3758 fax: (519) 850-2436
Mechatronics Engineering: TEB 3002 telephone: (519) 661-4122 fax: (519) 661-3020
Dept. of Mechanical and Materials Engineering: SEB