



# KE2330 Sustainable Production of Pharmaceuticals 9.0 credits

Hållbar läkemedelsteknik

This is a translation of the Swedish, legally binding, course syllabus.

## Establishment

Course syllabus for KE2330 valid from Autumn 2011

## Grading scale

A, B, C, D, E, FX, F

## Education cycle

Second cycle

## Main field of study

Chemical Science and Engineering

## Specific prerequisites

\_Admission requirements for programme students at KTH:

\_At least 150 credits from grades 1, 2 and 3 of which at least 110 credits from years 1 and 2, and bachelor's work must be completed, within a programme that includes:

75 university credits (hp) in chemistry or chemical engineering, 20 university credits (hp) in mathematics and 6 university credits (hp) in computer science or corresponding.

\_Admission requirements for independent students:

\_75 university credits (hp) in chemistry or chemical engineering, 20 university credits (hp) in mathematics and 6 university credits (hp) in computer science or corresponding.

Documented proficiency in English corresponding to English B.

# Language of instruction

The language of instruction is specified in the course offering information in the course catalogue.

## Intended learning outcomes

After the course the student should be able to:

- describe a batchwise production plant for production of pharmaceuticals and explain the benefits and drawbacks of this mode of production
- describe the mechanisms and performance of unit operations like agitation and mixing, crystallization, extraction, distillation, drying and chromatography in production of pharmaceuticals
- describe excipients and their function in pharmaceutical dosage forms
- describe and understand manufacturing of pharmaceutical dosage forms, and the mechanisms and performance of important pharmaceutical unit operations
- acquire and evaluate information from technical/scientific literature and other sources of information for the purpose of development and design of new processes, or for improvement or trouble shooting of current processes
- plan, design and perform experiments to develop and design new processes, or for improvement or trouble shooting of current processes
- perform calculations over design, performance, operation and scaleup/scaledown of processes
- analyse processes and propose technically feasible and economically viable solutions to process problems or needs for improvement
- evaluate and prioritize measures to improve processes or product properties from technical, economical, safety and environmental points of view

The course contains group assignments, oral presentations, discussions and written reporting, and accordingly contributes to the corresponding programs goals.

## Course contents

The course focuses on manufacturing of pharmaceuticals, and cover in particular separation processes in the manufacturing of the active pharmaceutical ingredients and pharmaceutical unit operations for solid dosage forms. The course focuses on batch processing and agitated tank operations, in multipurpose, multiproduct plants with emphasis on the influence of physico-chemical and processing conditions on process result and product properties. The course gives a detailed description and analysis of crystallization, agitation and mixing, distillation, drying, extraction and chromatography under these conditions. The course

then continues with a description of in particular solid oral dosage forms, pharmaceutical excipients, and important pharmaceutical unit operations like granulation, grinding and tableting.

The course contains also laboratory exercises. Each exercise includes to design an experimental plan to solve a given problem, laboratory work and analysis of results. A literature review over design and manufacturing of a given solid dosage form is to be performed by each student.

The course contains group assignments, oral presentations, discussions and written reporting, and accordingly contributes to the corresponding programs goals.

## Course literature

Kompendier och särtryck.

Coulson J.M. and Richardson J.F., Chemical Engineering vol. 1, 6:te upplagan, Butterworth Heinemann, 2000

Coulson J.M. and Richardson J.F., Chemical Engineering vol. 2, 5:te upplagan, Butterworth Heinemann, 2002

Aulton, M.E.: Aulton's Pharmaceutics: The Design and Manufacture of Medicines, 3rd ed., Churchill Livingstone, 2007

## Examination

- LIT1 - Literature Review, 1.5 credits, grading scale: P, F
- TEN1 - Examination, 4.5 credits, grading scale: A, B, C, D, E, FX, F
- LAB1 - Experimental Laborations, 3.0 credits, grading scale: P, F

Based on recommendation from KTH's coordinator for disabilities, the examiner will decide how to adapt an examination for students with documented disability.

The examiner may apply another examination format when re-examining individual students.

If the course is discontinued, students may request to be examined during the following two academic years.

## Other requirements for final grade

TEN1 - Examination, 4,5 credits, grading scale: AF

LAB1 - Experimental laboration, 3,0 hp, grading scale: PF

LIT1 - Literature review, 1,5 hp, grading scale: PF

## Ethical approach

- All members of a group are responsible for the group's work.
- In any assessment, every student shall honestly disclose any help received and sources used.
- In an oral assessment, every student shall be able to present and answer questions about the entire assignment and solution.