

Course syllabus

Läkemedelsformulering och produktion Drug Formulation and Production

KLGN60, 7,5 credits, A (Second Cycle)

Valid for: 2022/23

Faculty: Faculty of Engineering, LTH

Decided by: PLED B/K

Date of Decision: 2022-04-11

General Information

Main field: Pharmaceutical Technology.

Compulsory for: B4-l, K4-l, MLAK1

Elective for: N5-nbm

Language of instruction: The course will be given in English

Aim

The aim of this course is to give, based on basic knowledge of chemistry and chemical engineering give, a deepend understanding of formulation and production of pharmaceutical.

Learning outcomes

Knowledge and understanding

For a passing grade the student must

- Have knowledhe about how to design different pharmaceutical formulations, including choice of ingredients, quality aspects and production methods.
- be able to evaluate how pharmaceutical components are taken up by the body
- have knowledge about the quality system used in pharmaceutical industry
- understand how to characterise a pharmaceutical product including physical characterisation and in vitro release

- understand issues related to development of pharmaceutical products and be able to design a stability investigation.
- Have knowledge about pharmacokinetics

Competences and skills

For a passing grade the student must

- be able to document their work according to the standard present in pharmaceutical industry
- be able to use and understand the terminology that are standard in the pharmaceutical industry
- be able to estimate what formulation that are suitable for different chemical compounds and therapeutic situations
- be able to present work orally and as a poster
- be able to independently plan and execute laborative work

Judgement and approach

For a passing grade the student must

- comprehend the correlation between patient compliance and the choice of pharmaceutical product to develop.
- comprehend why there are such hard quality demands on the pharmaceutical industry and to understand the ethical demands that involved in pharmaceutical development.

Contents

The course describes pharmaceutical products and production with an emphasis on physicochemical and chemical engineering questions. It also describes what happens to the drug product in the living organism when administered through different routes. The course focuses on different pharmaceutical formulations such as solutions, suspensions, emulsions, granulates, tablets, capsules, aerosols, creams etc.

Furthermore the course will give an overview of the quality aspects of pharmaceutical industry, and special requirements on pharmaceutical industry when it comes to demands from authorities both Swedish and international. The laboratory assignments will illustrate important formulation aspects and how to evaluate quality and physical chemical properties of the formulation. Furthermore they will illustrate different quality documents in the industry.

Examination details

Grading scale: TH - (U,3,4,5) - (Fail, Three, Four, Five)

Assessment: Oral individual presentation of home exam, quiz exam, active participation in case work and laborative work, written laboratory reports according to industry and poster presentation in group of a project. Final grade is based on the individual presentation of the individual presentation of home exam.

The examiner, in consultation with Disability Support Services, may deviate from the regular form of examination in order to provide a permanently disabled student with a form of examination equivalent to that of a student without a disability.

Parts

Code: 0120. **Name:** Drug Formulation Oral Exam and Assignments.

Credits: 4. **Grading scale:** TH. **Assessment:** Grades are judged on quality on oral

presentation. **Contents:** Oral presentation of exam and quiz.

Code: 0220. **Name:** Project.

Credits: 2. **Grading scale:** UG. **Assessment:** active participation in project and discussions concerning the project. Poster **Contents:** A project where the students should describe a drug product based on an active substance and how to produce this. choose patient group and discuss ethical issues concerning the choices made.

Code: 0320. **Name:** Practical Assignment.

Credits: 1,5. **Grading scale:** UG. **Assessment:** Production master Plan and report for one laborative assignment Participate i seminar **Contents:** Two laborative assignments

Admission

Assumed prior knowledge: KFKF01 Molecular Driving Forces 2: Interactions and Dynamics

The number of participants is limited to: No

The course overlaps following course/s: KLG027, KLGN35

Reading list

- Aulton: Pharmaceuticals, The Design and Manufacture of Medicines. Churchill Livingstone, ISBN: 0443101086/9780443101083. Older or newer versions of Aulton's text book will also work.
- Distributed papers during the course and course compendium.

Contact and other information

Course coordinator: Professor Marie Wahlgren,
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Course administrator: Peter Jensen, peter.jensen@food.lth.se

Course homepage: <http://www.food.lth.se>