Reg No: KEAD81/20212

Faculty of Health, Science and Technology
Chemistry

Syllabus

Pharmaceuticals - chemical analysis in projects D

Course Code:	KEAD81
Course Title:	Pharmaceuticals - chemical analysis in projects D *Läkemedel - kemisk analys i projektform D*
Credits:	30
Degree Level:	Master's level
Progressive Specialisation:	Second cycle, has only first-cycle course/s as entry requirements (A1N)

Major Field of Study:
KEA (Chemistry)
KTA (Chemical Engineering)

Course Approval
The syllabus was approved by the Faculty of Health, Science and Technology 2021-02-26, and is valid from the Autumn semester 2021 at Karlstad University.

Prerequisites
Upper secondary level Swedish 3 or Swedish as a Second Language 3 and English 6, plus either

Alternative 1: Admission to the Master of Science programme in Chemical Engineering at Karlstad University with 90 ECTS credits completed in the programme, including Analytical Chemistry 7.5 ECTS credits, Biochemistry 7.5 ECTS credits, and Physical Chemistry 7.5 ECTS credits, plus 15 ECTS credits completed in Mathematics, including basic statistics

or

Alternative 2: Admission to 90 ECTS credits of Chemistry, with 75 ECTS credits completed, including Analytical Chemistry 7.5 ECTS credits, Biochemistry 7.5 ECTS credits, and Physical

Chemistry 7.5 ECTS credits, plus 15 ECTS credits completed in Mathematics, including basic statistics

or equivalent

Learning Outcomes

Module 1 Advanced analytical chromatography - theory and practice
Upon completion of the course, students should be able to:
1. give an account of general analytical processes, and formulate, delimit and interpret an analytical
chemical problem,
2. develop, validate and give an account of the most important regulatory demands placed on
analytical quality control methods,
3. apply advanced theories and models of separation in the chromatographic analytical separation
process,
4. give an account of the most recent applications of liquid chromatography from a theoretical as well
as an experimental perspective,
5. carry out and give an account of different types of sample preparation depending on the type of
analysis and the composition of the test matrix,
6. give an account of the most common sources of interference and deplacement of the analytical
peaks and of the analytical separation system and how to avoid them,
7. give an account of the potentials and limitations of the modern instrumental separation techniques,
8. perform method development of and optimise a complete analysis method including sampling,
sampling preparation, separation method and detection technique in relation to a given task, and
9. assess the robustness, environmental impact and fulfilment of quality requirements of an analysis
method.

Module 2 Chemical analysis in projects
Upon completion of the course, students should be able to:
10. select, assess, and apply classical unvariate statistical methods for evaluating laboratory measurement data and analytical results,
11. select, assess, and apply classical unvariate statistical methods of quality control in various chemistry contexts,
12. apply modern methods of analysis, classification, and calibration to multivariate measurement data,
13. plan, conduct, and evaluate factored trial series for screening, optimisation, and robustness testing of various applications in chemical analysis,
14. use project methodology and an inclusive approach,
15. give an account of given examples of chemical-technical production processes,
16. give an account of quality systems in the pharmaceutical industry,
17. explain molecular interaction in systems relevant for pharmaceuticals,
18. give a general account of drug metabolism,
19. give an account of stability and stability testing of pharmaceutical products,
20. use knowledge of quality systems to complete a group assignment on methodological development and optimisation of bioanalysis and product analysis,

21. present experimental and theoretical work, orally and in writing, and within given time limits,
22. identify their own need for further knowledge and skills development, and
23. assess and evaluate relevant research literature.

Content
The course includes theoretical and laboratory components, with a special emphasis on the latter.

Module 1 Advanced analytical chromatography - theory and practice, 7.5 ECTS cr
- Outline of analytical separation processes from a regulatory perspective
- Advanced modern analytical separation theory
- Different liquid chromatographic variants as reversed-phase chromatography, polar-phase chromatography, hydrophilic interaction chromatography, ion pair chromatography, and chiral
separation of optical isomers
- Modern chromatographic matrices such as pH stable phases, semi-porous phases, monoliths
- Different trends in separation processes: Green modern chromatographic techniques, super critical
fluid chromatography, miniaturisation and separation at high pressure
- Outline of empirical and mechanical modelling of separation processes
- Validation of chemical analysis methods
- Sample preparation of analysis components/pharmaceuticals from different sampling matrices/preparation forms
- Detection principles based on molecule spectroscopy and mass spectroscopy.

Module 2 Chemical analysis in projects, 22.5 ECTS cr
- classical unvariate statistical methods: descriptive statistics, hypothesis testing, sampling theory, variance analysis, and robust methods and their applications,
- modern chemometric multivariate methods for analysis, classification, and calibration, factored trial planning and optimisation,
- project methodology, including an inclusive approach,
- introduction to chemical-technical production processes,
- introduction to molecular interaction from a pharmaceutical perspective,
- introduction to the metabolism of a number of drugs,
- stability testing, stress testing, and common degradation products and production impurities for a number of different drugs, and
- different industrial quality systems for conducting product analysis and bioanalysis.

In the laboratory part of Module 1, students apply the theoretical components to a task that they get at
the beginning of the course and report on it individually before the laboratory session. The task has a
focus on the quality control of pharmaceuticals. Students are expected to plan and author the submitted
laboratory compendium independently before the laboratory session. Students present the result of the
completed laboratory work orally and in writing. In addition, students carry out and report on a risk
assessment with consideration of quality requirements, time limits and the environmental requirements
of an industrial pharmaceutical perspective.

In Module 2, laboratory work is carried out in project form. The students work in groups to acquire knowledge and plan how to complete tasks. As the project progresses, they have to identify their need of further knowledge, and they themselves are in large part responsible for acquiring the knowledge/competence required. In groups, students apply the theoretical course content to the given problems, and present the results orally and in writing.

Reading List
See separate document.

Examination
Module 1 Advanced analytical chromatography - theory and practice
Theory: Assessment is based on an individual written exam and the presentation of a project task, in the
shape of a laboratory manual with references to research articles regarding the selection of analytical
method and its validation.
Laboratory work: Assessment is based on active participation and a written report.

Module 2 Chemical analysis in projects
Theory: Assessment is based on a written exam and hand-in assignments.
Project: Assessment is continuous and based on seminars, written and oral reports, and active
participation in practical course components.

If students have a decision from Karlstad University entitling them to Targeted Study Support due to a documented disability, the examiner has the right to give such students an adapted examination or to examine them in a different manner.

Grades
One of the grades Distinction (VG), Pass (G), or Fail (U) is awarded in the examination of the course. For students in Engineering programmes, one of the grades 5 (Pass with Distinction), 4 (Pass with Some Distinction), 3 (Pass), or U (Fail) is awarded in the examination of the course.

Quality Assurance
Follow-up relating to learning conditions and goal-fulfilment takes place both during and upon completion of the course in order to ensure continuous improvement. Course evaluation is partly based on student views and experiences obtained in accordance with current regulations and partly on other data and documentation. Students will be informed of the result of the evaluation and of any measures to be taken.

Course Certificate
A course certificate will be provided upon request.

Additional information
The local regulations for studies at the Bachelor and Master levels at Karlstad University stipulate the obligations and rights of students and staff.

The course KEAD81 cannot be included in the same degree programme as the courses KEGC41, KEAD41, and KEGC81.

The course may involve up to 25 days of mandatory attendance at Karlstad University.