Reg No: KEGC81/20201

Faculty of Health, Science and Technology
Chemistry

Syllabus

Pharmaceuticals - chemical analysis in projects C

Course Code:	KEGC81
Course Title:	Pharmaceuticals - chemical analysis in projects C *Läkemedel - kemisk analys i projektform C*
Credits:	30
Degree Level:	Undergraduate level
Progressive Specialisation:	First cycle, has at least 60 credits in first-cycle course/s as entry requirements (G2F)

Major Field of Study:
KEA (Chemistry)

Course Approval
The syllabus was approved by the Faculty of Health, Science and Technology 2020-03-11, and is valid from the Spring semester 2020 at Karlstad University.

Prerequisites
Registered on Drug Analysis - Bachelor Programme in Chemistry, including 75 ECTS credits in Chemistry and 15 ECTS credits in Mathematics with Applications in Chemistry completed, or 75 ECTS credits in Chemistry, including completed courses in Analytical Chemistry (7.5 ECTS credits), Biochemistry (7.5 ECTS credits), Physical Chemistry (7.5 ECTS credits), and Mathematics with basic statistics (15 ECTS credits), or equivalent

Learning Outcomes
Part 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 on analytical methods of quality control,
3. give an account of advanced theories and models of separation in the chromatographic analytical separation process,
4. give an account of modern applications of liquid chromatography, from the perspectives of both theory and experiment,
5. perform and give an account of the different types of sample preparation depending on analysis and sample matrix components.
6. give an account of the most common sources of interference and deformation in the analysis and the analytical separation system and how these can best be avoided,
7. give an account of the possibilities and limitations of modern instrumental separation techniques, and
8. conduct methods development and optimise a complete analysis method, including sampling, sample preparation, separation method, and detection technique on a basis of a given task.

Part 2: Chemical analysis project
Upon completion of the course, students should be able to:
9. select and apply classical univariate statistical methods for evaluating laboratory data and analytical results,
10. select and apply classical univariate statistical methods for quality control in different chemistry contexts,
11. apply modern methods of analysis, classification, and calibration to multivariate data,
12. plan, conduct, and evaluate factored trial series for screening, optimisation, and robustness tests of various analytical chemistry applications,
13. use project methodology and an inclusive approach,
14. give an account of given examples of chemical-technical production processes,
15. give an account of quality systems in the pharmaceutical industry,
16. explain molecular correlation in systems relevant for pharmaceuticals,
17. provide a general overview of drug metabolism,
18. give an account of stability and stability testing of pharmaceuticals,
19. use knowledge of quality systems to conduct method development and optimisation of bioanalysis and product analysis in groups,
20. present experimental and theoretical work orally and in writing within given time limits, and
21. identify the need for further knowledge to develop their competence.

Content
Instruction is in the form of theoretical and laboratory components, with a special focus on laboratory sessions.

Part 1 covers the following:
- survey of analytical separation processes from a regulatory perspective,
- enhanced modern analytical separation theory,
- various liquid chromatography techniques,
- modern chromatography matrices,
- modern trends in separation processes such as environmentally-friendly chromatography techniques, supercritical fluid chromatography, miniaturisation, and separation under high pressure,
- survey of empirical and mechanistic modelling of separation processes
- validation of chemical analysis methods,
- sample preparation of analysis components/pharmaceuticals from different sample matrices/preparation formats, and
- detection principles based on molecular spectroscopy and mass spectrometry.

Part 2 covers the following:
- 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 correlation 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 first part of the course, the theoretical components are applied to a given laboratory task which students are given when the course begins and which is presented before laboratory work is initiated. This task is focused on quality control of pharmaceuticals. The participants are expected to work independently to plan and write laboratory instructions which have to be approved before the laboratory session begins. Students then present the results of the laboratory work in writing.

In the second part of the course, 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
Part 1
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.

Part 2
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 special pedagogical 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.

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

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