GHENT UNIVERSITY

Course Specifications

Valid in the academic year 2024-2025

Advanced Drug Analysis and Quality (J000444)

Course size *(nominal values; actual values may depend on programme)*

Credits 4.0 **Study time 120 h**

Course offerings and teaching methods in academic year 2024-2025

A (semester 1)	English	Gent	peer teaching	0.0h
			independent work	
			seminar	
			lecture	
			group work	

Lecturers in academic year 2024-2025

Wynendaele, Evelien	FWO2	lecturer-in-charge
De Spiegeleer, Bart	FWO2	co-lecturer

Offered in the following programmes in 2024-2025	crdts	offering
Master of Science in Teaching in Health Sciences(main subject Pharmaceutical Sciences)	4	A
Master of Science in Drug Development	4	A
Exchange Programme Faculty of Pharmaceutical Sciences	4	A

Teaching languages

English

Keywords

Pharmaceutical analysis, Pharmacopoeia, international quality guidelines for medicines, GMP/GLP incl. substandard and falsified medicines, sampling issues, chemometrics.

Position of the course

This course wants to give insight in the current practices and challenges of pharmaceutical analysis and quality. In addition, attention will be paid to the relation with regulatory affairs, research and development (R&D) and GMP/GLP in an international context.

Contents

The following topics will be handled in this course:
• Importance, structure and practical use of the European Pharmacopoeia.
• Pharmaceutically relevant methods and tests (chemical, physico-chemical, biological and microbiological).
• International analytical and quality guidelines.
• Relation with and considerations at sampling and sample preparation, GMP/GLP, substandard and falsified medicines, experimental designs and data-treatment.
• Seminars on the planning and execution of analytical experiments on medicines, incl. data-handling and reporting.

Initial competences

A profound knowledge of (general and instrumental) analytical chemistry, as well as a basic knowledge of drug development.

Final competences

1 To correctly and efficiently use the formal sources of pharmaceutical analysis (pharmacopoeia and international guidelines).
2 To apply the principles of analytical techniques and quality within an industrial-pharmaceutical R&D and GMP/GLP context.

3 To adequately report pharmaceutical-analytical experiments, inclusive the critical analysis of the results in order to correctly conclude.
4 To collaborate in team and work result-oriented when reporting pharmaceutical-analytical laboratory experiments..

5 To think scientifically about the complexity of a pharmaceutical-analytical decision process.

Conditions for credit contract

Access to this course unit via a credit contract is determined after successful competences assessment

Conditions for exam contract

This course unit cannot be taken via an exam contract

Teaching methods

Group work, Seminar, Lecture, Independent work, Peer teaching

Extra information on the teaching methods

Lectures supported by real-life cases in seminars and prepared by guided self-study. Some reports are being prepared in group.

Study material

Type: Handbook

Name: European Pharmacopoeia
Indicative price: Free or paid by faculty
Optional: no
Language : English
Online Available : Yes

Type: Slides

Name: Slides
Indicative price: Free or paid by faculty
Optional: no
Language : English
Available on Ufora : Yes

References

Several sources are recommended in the course, e.g. Journal of Pharmaceutical Analysis, ICH/EMA/EDQM-websites).

Course content-related study coaching

Possibility to ask questions during or after the classes (orally or email).

Assessment moments

end-of-term and continuous assessment

Examination methods in case of periodic assessment during the first examination period

Written assessment with open-ended questions

Examination methods in case of periodic assessment during the second examination period

Written assessment with open-ended questions

Examination methods in case of permanent assessment

Professional practice, Skills test, Participation, Peer and/or self assessment, Written assessment, Assignment

Possibilities of retake in case of permanent assessment

examination during the second examination period is possible in modified form

Extra information on the examination methods

Theory: periodic, written (open questions). European Pharmacopoeia texts will be given for information.
Seminars: permanent, written (i.a. reports) + examinations. The scoring is based on the interpretation of the results. The examination during the seminars aims at assessing the insight of the student in the principles and background of the exercises. Students who are absent during the seminars need to make up the skipped examination at a later moment. A second examination chance for the seminars involves a number of tests related to the seminars.

Calculation of the examination mark

The final mark is counted by the following weights: theory (written examination) 65%, seminars 35%. If the student obtains a score below 9/20 for one of the separate parts of the evaluation (seminars or theory), then the final examination mark is automatically reduced to the lowest score obtained for one of the separate parts. Students who do not show up at all during the seminars without valid reason can maximally obtain a total score of 5/20, irrespective of their score for the theoretical examination.

Transfer of examination results to the second examination period from the same academic year

- If a student passes the evaluation part continuous assessment in the first examination period, he/she must not repeat this part during the second examination period.
- If a student passes the evaluation part end-of-term assessment, he/she must not repeat this part during the second examination period.

In case a student did not succeed for the whole course unit, he/she can however make use of the full second exam opportunity; considering the last obtained marks will count in the calculation of the final examination mark.