

## 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	FW02	lecturer-in-charge
De Spiegeleer, Bart	FW02	co-lecturer

**Offered in the following programmes in 2024-2025**

	crdts	offering
<a href="#">Master of Science in Teaching in Health Sciences(main subject Pharmaceutical Sciences)</a>	4	A
<a href="#">Master of Science in Drug Development</a>	4	A
<a href="#">Exchange Programme Faculty of Pharmaceutical Sciences</a>	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.