

COURSE: ANALYSIS OF PHARMACEUTICAL PRODUCTS

SUBJECT: Environmental, Food and Pharmaceutical Analysis

MODULE: Specific

PROGRAM: University Master's Degree in Analytical Chemistry

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GENERAL FEATURES *

Type: Basic Training Compulsory Elective

Master's thesis work, Practicum

Duration: Semester

Semester / s: 2

Number of ECTS credits: 5

Language / s: Spanish, Catalan, English

DESCRIPTION

BRIEF DESCRIPTION AND JUSTIFICATION (The meaning of the course in relation to the program. Between 100 and 200 words.)

The analysis techniques are applied to the pharmaceutical field within the GMP environment and are mainly supported by the European pharmacopoeia, the American pharmacopoeia and the ICH harmonization standards.

The subject provides students with the knowledge that will allow them to understand the objective, the procedures, the results and the need to carry out a rigorous analytical work in the development, production and conservation of drugs.

COMPETENCES (Of course you put in relation to the skills pre-assigned in the field.)

Basic competences

CB6 - Have and understand knowledge which provides the ground or opportunity to be innovative in the development and/or application of ideas, often in a research context

CB8 - Integrate knowledge and deal with the complexity of formulating judgments based on information which, being incomplete or limited, includes reflections on social and ethical responsibilities related to the application of their knowledge and judgments

CB9 - Communicate conclusions, and the reasons that sustain them, to specialized and non-specialized audiences in a clear and unambiguous way.

CB10 - Understand the need for life-long learning in a self-directed or autonomous way.

General competences

CG1 - Ability to lead, direct and manage projects in academic or business environments adapting to the structures, needs and ways of operation of each institution

Specific competences

E15 - Demonstrate advanced knowledge of analytical methods for the characterization of raw materials, formulated products, active pharmaceutical ingredients and excipients, and the

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identification and quantification of impurities, enantiomers and degradation products present in pharmaceutical samples

E16 - Ability to interpret the analytical results obtained in pharmaceutical samples (raw materials, formulated products, active pharmaceutical ingredients, excipients) and in the determination of impurities, enantiomers and degradation products in these samples

Transversal competences

T1 - Ability to communicate in English and use English as a working language

T3 - Ability to assess the impact of the use of chemistry in the sustainable development of the society

PREREQUISITES * (Modules, materials, disciplines or expertise needed to track the subject. Contain subjects that must have been completed can be made.)

Students who have accessed the master's degree from bachelor's degrees in chemistry will not need any additional training complement. For the other degrees, they must have previously studied subjects that included basic contents of instrumental analytical chemistry and structural elucidation (including mass spectrometry).

CONTENTS (Sections that make up the syllabus, to a second level of detail.)

- 1) The environment.
 - Analysis in the GMP environment.
 - European and American Pharmacopoeia and ICH Standards.
- 2) The substances.
 - Analysis of active ingredients and excipients.
 - Analysis of raw materials and formulated products.
 - Analysis of impurities and degradation products.
 - Analysis of enantiomers.
- 3) The stages of preparation and measurement in the analysis procedures.
 - Sampling and storage.
 - Preparation of standards and samples (dilution, concentration, purification, derivatization).
 - Measurement and quantification.
 - Results analysis.
- 4) The instrumental analysis techniques.
 - Application of conventional, coupled and automated instrumental techniques.
 - Analysis techniques specific to the pharmaceutical field.

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5) The studies.

Stability of drugs.

Pharmacokinetic, bioavailability and bioequivalence studies.

METHODOLOGY

TRAINING ACTIVITIES * (Complete the table relating activities, workload in ECTS credits, and skills.)

Training Activities	ECTS	Competences
Sessions of exposition of concepts	31 / 1.15	E15, E16, T3
Sessions solving exercises, problems and cases	4 / 0.15	E15, E16, T3
Seminars	2 / 0.07	E15, E16, T3
Presentations	4 / 0.1	E15, E16, T1, T3
Activities of personal study by students	90 / 3.33	E15, E16, T3
Evaluation activities (exams, monitoring controls ...)	4 / 0.15	E15, E16, T3
TOTAL	135/5	

TEACHING METHODOLOGY (Justifying the teaching methods used in relation to the competences and contents of the course. Between 100 and 200 words.)

- Sessions of exposition of concepts: Exposition of contents through presentation or explanation (possibly including demonstrations) by a professor.
- Sessions solving exercises, problems and cases: Solving exercises, approach / problem solving and presentation / discussion of cases by a professor with the active participation of students.
- Seminars: Statement made by a teacher in order to review, discuss and answer questions about materials and topics presented in the sessions of exposure sessions concepts and solving exercises, problems and cases.
- Presentations: Oral presentation to a professor and possibly other students by a student. It can be a paper prepared by the student by searching the published literature or a summary of a practical or project undertaken by the student.
- Activities of personal study by students: Personal work required of the student to acquire the competences of each subject and assimilate the knowledge presented in the sessions of exposition of concepts and of solving exercises, problems and cases, using, when necessary, the consultation recommended material.
- Evaluation activities: Oral and/or written statements made during a semester or after it.

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EVALUATION

ASSESSMENT SYSTEM * (Complete the table relating evaluation methods, competences and weight in the course grade.)

Evaluation Methods	%	Competences
Final Exam	50%	E15, E16, T3
Monitoring activities	25%	E15, E16, T3
Projects and presentations	20%	E15, E16, T1, T3
Participation	5%	E15, E16, T1, T3

LEARNING OUTCOMES (Explanation of the embodiments that allow the student skills assessment, relating them to the skills and methods of assessment.)

The student must demonstrate knowledge of the main sampling methods of pharmaceutical matrices. (E15, E16)

The student must demonstrate knowledge of the main general analytical methods for the determination of chemical compounds in pharmaceutical matrices. (E15, E16)

The student must demonstrate knowledge of specific analytical methods for the determination of chemical compounds in pharmaceutical matrices. (E15, E16)

The student must demonstrate his ability to interpret the results obtained in the determination of chemical compounds in pharmaceutical matrices. (E16, T3)

The student must demonstrate knowledge of the main standards that are applied in the pharmaceutical analysis. (E15)

The student must be able to communicate effectively both orally and in writing, to communicate in English and to use English as a working language, and to work in a multidisciplinary environment individually or as a member of a team. (T1, CG1)

The student must be able to develop learning skills and recognize the need for ongoing training for their proper professional development. (CB10).

QUALIFICATION (Explanation of the computer system of the course grade.)

The grade of this course is obtained:

Final exam	50%
Monitoring activities	25%
Projects and presentations	20%
Participation	5%

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- The **final exam** includes theoretical and practical aspects.
- **Monitoring activities** include works (exercises, problems and cases) that perform and deliver the students during the course.
- The **projects** include problems and cases that students solve outside of class schedules. Each student presents one of their project.
- The **participation** includes attendance, initiative and the attitude shown by the student in relation to the teacher and their peers.

ASSESSMENT OF THE COMPETENCES (Define calculation expressions for each competence and the relevant evaluation methods.)

The competences are evaluated with the qualification of the subject

BIBLIOGRAPHY (Recommended and accessible to students.)

European Pharmacopoeia (in digital format, current version)

American Pharmacopoeia USP (in digital format, online)

DOCUMENT HISTORY

PREVIOUS CHANGES (You set the date and author / s, the most recent first)

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LAST REVISION (Indicate date and author / s.)

January 2016 (Dr. Francesc Broto)