COURSE DATA

DATA SUBJECT

Code: 34099
Name: Analysis and Control of Pharmaceuticals and Cosmetic Products
Cycle: Undergraduate Studies
ECTS Credits: 4.5
Academic year: 2025-26

STUDY (S)

Degree	Center	Acad. year	Period
1201 - Degree in Pharmacy	Facultat de Farmàcia i Ciències de L'alimentació	5	First quarter

SUBJECT-MATTER

Degree	Subject-matter	Character
1201 - Degree in Pharmacy	Analysis and control of drugs and cosmetics	ELECTIVES

COORDINATION

LERMA GARCIA MARIA JESUS

SUMMARY

Analysis and Control of Pharmaceuticals and Cosmetic Products is an optional course of 4.5 credits ECTS of the 5th year of the Degree in Pharmacy.

According to the skills assigned to the pharmacists, the chemical analysis appears as a discipline necessary for the accurate development of their professional activity. In 2nd year of the Degree in Pharmacy is studied the core obligatory course Chemical Analysis, of 9 ECTS, in which are given and developed the principles, basic concepts and methodology of chemical analysis, as well as the fundamentals and applications of the main methods of analysis. The course *Analysis and Control of Pharmaceuticals and Cosmetic Products* starts from the knowledge and skills acquired in the course *Chemical Analysis* to get in the specific areas of the pharmaceuticals and of the cosmetic products.

The analysis and control of pharmaceuticals is necessary to assure the quality of the pharmaceutical products.

The Law 25/90, of December 20, of the Medicine in second Title, second chapter, establishes, among others, the conditions of evaluation, authorization and registration of the pharmaceutical products. This law details along its articles the ways to achieve the proper quality in all activities related with pharmaceuticals.

One of the guarantees of pharmaceutical quality is, obviously, the chemical analytical control of all the components of the pharmaceutical product.

The analytical control of cosmetic products is a field of increasing interest and at present there exists a European law that regulates the prohibited and restricted ingredients in cosmetic products, and there is a increasing effort for the development of methods to control these products.

The objective of the learning process for this course is claimed to get the students into basic training for analysis and control of pharmaceuticals and cosmetic products, skills of great usefulness in these fields.

The general aims of this subject are to get the student into basic knowledge on the organization and management of quality control laboratories, the relevance of the analytical properties of the methodologies involved in the quality control of pharmaceuticals and cosmetic products, the basic principles involved in the validation of analytical methods, the use of equipments as well as the main methods used in the control of raw materials, intermediate products and final products of either pharmaceuticals and cosmetic products.

Along with the topics, the concepts taught in the subject will be related to those objectives of sustainable development that are part of the 2030 Agenda.

PREVIOUS KNOWLEDGE

RELATIONSHIP TO OTHER SUBJECTS OF THE SAME DEGREE

There are no specified enrollment restrictions with other subjects of the curriculum.

OTHER REQUIREMENTS

Prior knowledge: Chemical nomenclature and formulation. Stoichiometric calculations. Performing calculations and least squares regression. Basic statistical treatment of analytical results. Basic concepts of chemical analysis.

COMPETENCES / LEARNING OUTCOMES

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Act with autonomy in learning, making informed decisions in different contexts, issuing judgements based on experimentation and analysis, and transferring knowledge to new situations.

Apply analytical methods for cosmetic ingredients and substances prohibited and/or restricted in cosmetic products.

Apply methods for analysing the identity, purity and richness of intermediates and final products in their different forms of administration.

Be able to analyse active ingredients, pharmaceuticals and other products and materials of health interest.

Collaborate effectively in work teams, assuming responsibilities and leadership roles and contributing to collective improvement and development.

Contribute to the design, development and implementation of solutions that respond to social demands, taking into account the Sustainable Development Goals as a reference.

Demonstrate critical and self-critical thinking in the field of the degree programme, considering aspects such as professional ethics, moral values and the social implications of the different activities carried out.

Know and apply methods for the validation of analytical methods and quality assurance.

Know and understand, within the field of the degree programme, gender inequalities in society; integrate different needs and preferences based on sex and gender into the design of solutions and problem solving.

Know how to communicate effectively, both orally and in writing, adapting to the characteristics of the situation and the audience.

Know how to organise and manage a quality control laboratory.

Know how to use analytical methodologies of interest in the analytical quality control of medicines and cosmetic products.

Know the parameters defining the quality of raw materials, as well as the stages for their identification, treatment, handling and preservation.

Know the procedures for controlling impurities from production processes and contamination of finished products.

Module: Biology. Know and understand the microbiological control of medicines.

Propose creative and innovative solutions to complex situations or problems within the field of knowledge, to respond to diverse professional and social needs.

Reinforce the acquisition of the general competences of the curriculum.

DESCRIPTION OF CONTENTS

1. Quality and quality control

Quality and quality control. Quality in quality control of the pharmaceuticals and cosmetic products. Organization and management of quality in a laboratory.

2. Quality control in pharmaceutical industry

Quality control in pharmaceutical industry. Responsible organisms. General concepts and current legislation. Quality control of the raw materials, intermediate products and final products in pharmaceutical industry. Identification and quantification of active principles, excipients and impurities.

3. Official methods of analysis in pharmaceutical industry

Official methods of analysis in pharmaceutical industry. Pharmacopoeias. Validation of methods.

4. Non-official methods of confirmed guarantee for the analysis of pharmaceuticals

Non-official methods of confirmed guarantee for the analysis of pharmaceuticals. Methods based on analytical spectrometry, electroanalytical, and chromatographic and related techniques. Main applications in quality control of pharmaceuticals (cardiovascular, antiinfectious, dermatological, antidiabetic, related to the system genitourinary, system skeletal muscle, nervous central system, etc.).

5. Quality control in cosmetic industry

Quality control in the cosmetic industry. Responsible organisms. General concepts and current legislation. Quality control of the raw materials, intermediate products and products ended in the cosmetic industry. Identification and quantification of authorized, restricted and prohibited ingredients.

6. Official methods of analysis in cosmetic industry

Official methods of analysis in cosmetic industry. European regulation. Validation of methods.

7. Not-official methods of confirmed guarantee for the analysis of cosmetic products

Not-official methods of confirmed guarantee for the analysis of cosmetic products. Methods based on analytical spectrometry, electroanalytical, chromatographic and related techniques. Main applications in quality control of cosmetic products (colorant, preservatives, perfumes, sun protection products, hygiene and cleaning products, hair products, decorative cosmetics, etc.).

8. Applications of UV/V spectrometry in quality control of pharmaceuticals and cosmetic products

Applications of UV/V spectrometry in quality control of pharmaceuticals and cosmetic products. - Simultaneous determination of mixtures of maleate of phenylamine and clorhydrate of phenylefrinr in pharmaceuticals for the treatment of cold.

9. Applications of molecular fluorescence in quality control of pharmaceuticals and cosmetic products

Applications of molecular fluorescence in quality control of pharmaceuticals and cosmetic products. - Determination of furosemide in diuretics by molecular fluorescence.

10. Applications of atomic spectrometry in quality control of pharmaceuticals and cosmetic products

Applications of atomic spectrometry in quality control of pharmaceuticals and cosmetic products - Determination of alkaline elements in pharmaceutical products by flame atomic emission spectrometry.

11. Applications of liquid chromatography in quality control of pharmaceuticals and cosmetic products

Applications of liquid chromatography in quality control of pharmaceuticals and cosmetic products. - Determination of UV filters in sunscreens by liquid chromatography with UV detector.

12. Applications of gas chromatography in quality control of pharmaceuticals and cosmetic products

Applications of gas chromatography in quality control of pharmaceuticals and cosmetic products. - Determination of menthol and camphor in anti-cellulite products by gas chromatography with FID detector.

WORKLOAD

PRESENCIAL ACTIVITIES

Activity	Hours
Tutorials	2,00

Theory	23,00
Seminar	5,00
Laboratory	15,00
Total hours	**45,00**

NON PRESENCIAL ACTIVITIES

Activity	Hours
Attendance at other activities	0,00
Individual or group project	10,00
Independent study and work	31,50
Preparation of lessons	15,00
Preparation for assessment activities	10,00
Resolution of case studies	0,00
Total hours	**66,50**

TEACHING METHODOLOGY

During classes of theory a global vision of the topic to treat will be presented and the main fundamentals for resolution of model problems related by the theoretical contents will be given.

In the classes of laboratory demonstrations the teacher will introduce the principles and experimental methodology to be applied, as well as of the analytical instrumentation to be used. The students will perform the practices using the laboratory scripts, and they will do the necessary calculations. The students will deliver the analytical reports.

In the tutorials, practical cases will be debated and the ability of the student for the resolution of cases will be evaluated.

In the seminars each other practical cases related to the contents of the classes will be treated. At least one hour will be devoted to presentations of works in order to evaluate transverse skills.

EVALUATION

The assessment of student learning will take into account all the aspects outlined in the methodology section of this teaching guide.

In the examination, questions related to class of theory, tutorials, seminars and laboratory practice will be included.

FIRST CALL

Final score:

Proposed activities in seminars and tutorials: 15% (Active participation, preparation and works presentations)

Activities of Laboratory Practice: 20% (Lab work: 5%, results: 10%; questions: 5%)

Examination: 65%

The minimum score on each of these three parts must be equal to or greater than 4.5 to average.

The minimum overall grade to pass the subject is 5.0.

Students who do not perform during the course of the minimum of activities in seminars and tutorials required by the teacher or who score in the activities below 5.0 will be evaluated solely for the other two parts, scoring in examining this case 80% of the final grade. Other students can also choose this type of evaluation.

Before each laboratory session, a questionnaire with 5 questions related to the practice to be carried out will be answered. The score of the questionnaire, which will go from 0 to 1, will be multiplied by the work note in the laboratory, as a corrector.

Students who do not perform the laboratory practices required by the professor and those who obtain a rating below 5.0 will have to do and to pass a practical laboratory examination. These practices are mandatory and therefore non-recoverable, according to what is established in Article 6.5 of the Evaluation and Grading Regulations of UV for Bachelor's and Master's degrees. In the event that, for justified reasons, you are unable to attend any of these activities, you will need to communicate it with sufficient advance notice. This way, the subject coordinator will be able to assign the student to a session in another group.

Evidence of copying or plagiarism in any of the assessable tasks will result in failure to pass the subject and in appropriate disciplinary action being taken. Please note that, in accordance with article 13. d) of the Statute of the University Student (RD 1791/2010, of 30 December), it is the duty of students to refrain from using or participating in dishonest means in assessment tests, assignments or university official documents.

In the event of fraudulent practices, the **Action Protocol for fraudulent practices at the University of Valencia** will be applied (ACGUV 123/2020):

https://www.uv.es/sgeneral/Protocols/C83sp.pdf

SECOND CALL

The rating is obtained by applying the same criteria as in the first

REFERENCES

- Pharmaceutical Analysis, D.G. Watson, Elsevier 2005.
- Los estudiantes podrán consultar en el Aula Virtual otras publicaciones consideradas de interés por los profesores (tales como artículos publicados en revistas científicas, relacionados con el análisis y control de medicamentos y de productos cosméticos).
- Modern Methods of Pharmaceutical Analysis, vol. III, R.E. Schirmer, CRC Press 2000, Boca Raton, Florida.
- Análisis y control de medicamentos, R. Salazar, Romargraf, S.A., 2005
- Real Farmacopea Española y Suplementos. Ministerio de Sanidad y Consumo. Madrid Guidelines ICH Secretariat. IFPMA Ginebra
- Remington ¿The Science and Practice of Pharmacy¿, Ed. A.R. Gennaro, Philadelphia College of Pharmacy and Science Philadelphia 2000
- Agencia española de medicamentos y productos sanitarios: http://www.aemps.es/
- ICH: http://www.ich.org/
- ICH harmonisation for better health: http://www.ich.org/
- Métodos oficiales de análisis de productos cosméticos, Ed. Agencia Española de Medicamentos y Productos Sanitarios, Madrid, 1998
- Analysis of Cosmetic Products, Ed. A. Salvador, A. Chisvert, Elsevier, 2007