VNIVERSITAT DE VALÈNCIA

Course Guide
34099 Analysis and Control of Pharmaceuticals and Cosmetic Products

COURSE DATA

Data Subject	
Code	34099
Name	Analysis and Control of Pharmaceuticals and Cosmetic Products
Cycle	Grade
ECTS Credits	4.5
Academic year	2023 - 2024

Study (s)

Degree	Center	Acad. year	Period
1201 - Degree in Pharmacy	Faculty of Pharmacy and Food Sciences	5	First term

Subject-matter

Degree	Subject-matter	Character
1201 - Degree in Pharmacy	32 - Analysis and control of drugs and cosmetics	Optional

Coordination

Name	Department
CARRASCO CORREA, ENRIQUE JAVIER	310 - Analytical Chemistry

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 (RD 1393/2007) // LEARNING OUTCOMES (RD 822/2021)

1201 - Degree in Pharmacy

- Reinforce the acquisition of the general competences of the Curriculum of Degree in Pharmacy.
- Know to organize and manage a quality control laboratory.

- Know and understand how to apply validation methods to analytical and quality assurance methodologies.
- Know how to use analytical methodologies of interest in analytical quality control of pharmaceuticals and cosmetics.
- Know the parameters that define the quality of raw materials as well as the stages for its proper identification, treatment, manipulation and conservation.
- Know how to apply methods of analysis to establish the identity and purity in intermediates and final products in its different administration forms.
- Know the procedures to control impurities derived from the manufacturing process and contamination of final products.
- Know how to apply analytical methods for cosmetic ingredients and forbidden and/ or restricted substances in cosmetic products.

LEARNING OUTCOMES (RD 1393/2007) // NO CONTENT (RD 822/2021)

After this course, the student must be capable of:

- To establish habits of study and work for a successful professional and personal development.
- To develop the aptitude to work in team.
- To develop the skill to argue from rational criteria in a group or seminar.
- To develop the critical capacity for processing the information.
- To improve written presentations and oral communications.
- To know and use the diverse sources of information, both the traditional bibliography and those based on new technologies of information and communication.
- To explain the importance of the quality control in the analytical laboratory, as well as the procedures and statistical tools necessary to carry out this control
- To organize and manage a quality control laboratory.
- To validate analytical methods.
- To handle properly the information concerning the official methods of analysis of pharmaceutical and cosmetic products and to be able to apply such methods to the analysis and quality control of the aforementioned products.
- To select and use the analytical methods of interest for the analytical control of quality of pharmaceuticals, for the identification and quantification of active principles, excipients and impurities.
- To select and use the analytical methods of interest in the analytical control of quality of cosmetic products, for the identification and quantification of allowed restricted and prohibited ingredients.

To carry out the quality control of pharmaceutical and cosmetic products, as well as of the raw materials and intermediate products.

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 genito urinary, 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

ACTIVITY	Hours	% To be attended
Theory classes	20,00	100
Laboratory practices	15,00	100
Seminars	5,00	100
Tutorials	2,00	100
Development of group work	6,00	0
Development of individual work	4,00	0
Study and independent work	30,00	0
Readings supplementary material	1,50	0
Preparation of evaluation activities	10,00	0
Preparing lectures	5,00	0
Preparation of practical classes and problem	10,00	0
TOTAL	**108,50**	

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

Basic

- Pharmaceutical Analysis, D.G. Watson, Elsevier 2005.
- 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

Additional

- 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).