POLI ESCOLA SUPERIOR SAÚDE TÉCNICO GUARDA	**SUBJECT DESCRIPTION**	**MODELO** PED.015.03

Course	**Pharmacy - 1st Cycle**					
Subject	**Pharmaceutical Technology**					
Academic year	2023/24	*Curricular year*	3rd	*Study period*	1st semester	
Type of subject	Compulsory	*Student workload (H)*	Total: 121,5	Contact: T: 22,5; TP: 22,5; PL: 10; S:7,5	*ECTS*	4,5
Professor(s)	Filipa Alexandra Mascarenhas Melo					
☐ *Area/Group Coordinator* ☒ *Head of Department* *(select)*	André Ricardo Tomás dos Santos Araújo Pereira					

PLANNED SUBJECT DESCRIPTION

1. LEARNING OBJECTIVES

Through the study of pharmaceutical technology, students are expected to achieve the following objectives:

O1 – Apply the knowledge acquired in the curricular unity of Galenic Pharmacy;
O2 – Know the structure of the Pharmaceutical Industry;
O3 – Understand the importance of the implementation of GMPs;
O4 – Integrate the entire process that goes from the reception of the raw materials to the output of the finished product in the Pharmaceutical Industry;
O5 – Make the transposition from the technology at laboratory scale to the technology at industrial scale, identifying the main critical steps.

2. PROGRAMME

1) Pharmaceutical Operations at industrial scale: pharmaceutical technology used in the preparation of the most common pharmaceutical forms
2) Pharmaceutical Systems: immediate versus modified release systems
3) Pharmaceutical development of medicines for human use and main considerations in the development of medicines for specific populations
4) Medicine stability studies: stability protocols, conservation conditions and parameters to be studied
5) Good Manufacturing Practice of medicines for human and veterinary use (GMPs)
6) Quality control in the production of medicines: control of raw materials, control in process and control of the finished product
7) Validation of manufacturing processes and analytical methods

LABORATORIAL CONTENT
Quality control tests of solid oral forms (dissolution, disintegration and friability)
Stability tests

3. COHERENCE BETWEEN PROGRAMME AND OBJECTIVES

The syllabus explained contribute to the acquisition of certain skills, namely to provide students with knowledge of the characteristics of the pharmaceutical industry, in particular with regard to its organization and mode of operation, linking them to the legal framework in which it should take place and to the quality requirements faced.
In this CU, the students acquire knowledge about the pharmaceutical operations at industrial scale, about the technology employed in the conception of pharmaceutical systems and about the pharmaceutical development, that allowed them to understand the structure of the pharmaceutical industry and the implementation of pharmaceutical development, stability and quality control protocols, in compliance with the Good Manufacturing Practice of Medicines.
In this curricular unit it is also promoted the student interest in autonomous learning, through continuous research in technical books and scientific journals.

4. MAIN BIBLIOGRAPHY

- Prista, L.; Alves, A.; Morgado, R., Lobo, J. (2003-2006). Tecnologia Farmacêutica. Fundação Calouste Gulbenkian. 6ª-8ª ed. vols. I, II e II.
- Souto, E. B., & Lopes, C. M. (2011). Novas formas farmacêuticas para administração de fármacos, Edições Universidade Fernando Pessoa.
- Lachman, L., Lieberman, H. A., Kanig, J. L., Pinto, J. F., & Fernandes, A. I. H. D. (2001). Teoria e prática na indústria farmacêutica, Vols. 1 e 2.
- Handbook of Pharmaceutical Excipients. (2009). London: The Royal Pharmaceutical Society of Great Britain and The American Pharmaceutical Association, sixth edition.
- Farinha, A.; Tavares, P.; Sarmento, M.J. (2001). Estabilidade de Medicamentos: Conceitos e Metodologias. Boletim do Laboratório de Estudos Farmacêuticos, 30.
- EMEA/CHMP/167068/2004 - Note for guidance on pharmaceutical development
- EMEA/CPMP/QWP/122/02 - Guideline on stability testing: Stability testing of existing active substances and related finished products

5. TEACHING METHODOLOGIES (INCLUDING EVALUATION)

The CU includes theoretical and theoretical-practical components. The theoretical evaluation consists of two written tests. The theoretical-practical assessment consists of continuous assessment and the preparation and presentation of two assignments: one on the formulation and testing of different types of tablets and the other on new therapeutic systems for the delivery of active ingredients. The practical-laboratory evaluation consists of the elaboration of reports. The theoretical, continuous, group work and reports assessments have a weighting of 70%, 5%, 10% and 15%, respectively. The approval in the curricular unit is achieved with a final grade equal to or greater than 9.5 (on a scale of 0-20), obtained by the sum of the different evaluation components. It is also necessary to obtain a minimum mark of 8 in each of the assessment components (T, TP and PL).
In case the students have approved the theoretical-practical and laboratory component but not the theoretical one, the grade obtained in the work with a weighting of 10% and 15%, respectively, remains during the normal and resource examination periods of the same year, it being only necessary that students take an examination of the theoretical component.

6. COHERENCE BETWEEN TEACHING METHODOLOGIES AND OBJECTIVES

The teaching methodologies are considered to be consistent with the objectives of the course. Theoretical classes with an expository methodology, which are always intended to be participatory, are the first approach to the content in which students are encouraged to ask questions and make reasoning based on the previous knowledge they had and acquired throughout the semester, being fundamental to achieving the objectives related to knowledge and memorization of concepts. On the other hand, the theoretical-practical classes in which questions are solved and scientific articles and guidelines are analyzed, related to the knowledge acquired in the theoretical classes, are very important for developing the capacity for scientific reasoning, critical analysis and integration of knowledge and for achieving the objectives related to attitudes and behaviors. Guidance is also given in researching scientific information for group work. In practical-laboratory classes, experimental quality control activities applicable to the pharmaceutical industry are carried out. In seminar classes, students will have to present some of the work proposed at the beginning of the semester, allowing them to develop their autonomy and consolidate the objectives related to attitudes and behavior. External speakers will also be invited to present seminars on relevant topics in the field of Pharmaceutical Technology. As part of this course, a study visit to the pharmaceutical industry and/or a Drug Technology Development Laboratory is also planned.

7. ATTENDANCE

The limit of absences must not exceed 25% of the total number of theoretical-practical and practical hours that are allocated in the study plan.

DATE

2 de outubro de 2023

SIGNATURES

Professor

Filipa Alexandra Mascarenhas Melo
(Filipa Alexandra Mascarenhas Melo)

Head of Department

André Ricardo Tomás dos Santos Araújo Pereira
(André Ricardo Tomás dos Santos Araújo Pereira)