UNIVERSIDAD DE CASTILLA - LA MANCHA

GUÍA DOCENTE

1. General information

Course: PHARMACEUTICAL TECHNOLOGY I
Type: CORE COURSE
Degree: 376 - UNDERGRADUATE DEGREE PROGRAMME IN PHARMACY
Center: 14 - FACULTY OF PHARMACY
Year: 3
Main language: Spanish
Use of additional languages:
Web site:

Code: 14322
ECTS credits: 6
Academic year: 2022-23
Group(s): 10
Duration: First semester
Second language: English
English Friendly: Y
Bilingual: N

Lecturer: **MARIA FRANCISCA GALINDO ANAYA** - Group(s): **10**

Building/Office	Department	Phone number	Email	Office hours
Facultad de Farmacia 2.17	CIENCIAS MÉDICAS	967599200	maria.galindo@uclm.es	

2. Pre-Requisites

There are no prerequisites but it is recommended:

· Basic Physics and Chemistry training to know the characteristics and properties of chemical products, bases of the physical and physicochemical processes necessary in the sequence of operations for the manufacture and control of medicines.

· Statistical training involved in the manufacture of the medicine.

· Basic training in Physiology and Pharmacology for the knowledge of the place and way of acting of the drugs for the election of the route of administration and adequate pharmaceutical form for each active principle.

stablished

3. Justification in the curriculum, relation to other subjects and to the profession

Pharmaceutical Technology is the discipline of the Pharmacy degree that provides the scientific and technological knowledge that involves the design, elaboration and evaluation of dosage forms of medicines. This knowledge allows the pharmacist the capacity of ir

All these characteristics are related to signatures such as Biopharmacy and Pharmacokinetics, Pharmaceutical Technology II and III, leading the student to acquire the necessary training to successfully face the administration of drugs with effective, safe and stable p

4. Degree competences achieved in this course

Course competences

Code	Description
B01	Proficiency in a second foreign language at level B1 of the Common European Framework of Reference for Languages.
B02	Knowledge of Information and Communication Technologies (ICT).
B03	A correct oral and written communication
B04	Ethical commitment and professional deontology.
B05	Ability to develop those learning skills necessary to undertake further studies.
EFT01	Using statistical analysis applied to pharmaceutical sciences
EFT02	Apply both computational and data processing techniques, for getting information about physical, chemical and biological data
EFT05	Using statistical analysis applied to pharmaceutical sciences
EFT06	Design, optimize and elaborate the pharmaceutical forms guaranteeing their quality, including the formulation and quality control of medicines, the development of master formulas and officinal preparations.
EFT07	Able to apply the quality control process to medical devices, dermopharmaceutical and cosmetic products and package materials.
EFT10	Demonstrate knowlege of the physicochemical and biopharmaceutical properties of drugs and excipients, as well as the possible interaction between them
G01	Identify, design, obtain, analyze, control and produce drugs and medicines, as well as other products and raw materials of sanitary interest for human or veterinary use.
G04	Design, prepare, supply and dispense medicines and other products of health interest.
G13	Develop communication and information skills, both oral and written, to deal with patients and users of the centre where they carry out their professional activity. Promote the capacity to work and collaborate with multidisciplinary teams and those related to other health professionals.
G14	Know the ethical and deontological principles according to the legislative, regulatory and administrative provisions governing professional practice, understanding the ethical implications of health in a changing social context.
G15	Recognise own limitations and the need to maintain and update professional competence, with particular emphasis on self-learning of new knowledge based on scientific evidence.
T01	Critical thinking skills based on the application of the scientific method
T02	Ability to manage quality scientific information, bibliography, specialized databases and resources accessible through the Internet.
T03	Handling of basic and specific software for the treatment of information and experimental results.
T04	Motivation for quality, safety at work and awareness of environmental issues, with knowledge of the internationally recognised systems for the correct management of these aspects.
T05	Organizational, planning and implementation skills.
T06	Ability to address human resources decision-making and management.
T07	Ability to work as a team and, where appropriate, exercise leadership functions, encouraging entrepreneurship.
T08	Develop interpersonal skills and the ability to function in an international and multicultural context.

5. Objectives or Learning Outcomes

Course learning outcomes

Description
To know the controls in raw materials, semi-finished and finished products, as well as the validation of processes in order to ensure the quality of the medicines manufactured.
Understanding the checks necessary to ensure the quality of pharmaceutics skin products, sanitary products, and cosmetics.
Know the vehiculizacion nanoparticles as forms of drugs.
Ability to select the route of administration and the pharmaceutical form.
Ability to work under standards of good laboratory practice (GLP).
Ability to design a pharmaceutical laboratory in response to their facilities and processes necessary to ensure the quality of the products manufactured.
Ability to plan, design and develop preformulation studies of the different pharmaceutical forms and to interpret the results.
To know and to develop good manufacturing practiques (GMP) for the different activities to develop in Pharmaceutical Industry, pharmacy and hospital Pharmacy Service.
Know and understand the fundamentals of the Pharmaceutical Technology
Develop drugs regarding its qualitative and quantitative composition and select the optimal technological processes to be used in its manufacture.

6. Units / Contents

Unit 1: INTRODUCTION TO PHARMACEUTICAL TECHNOLOGY
- **Unit 1.1** Basic concepts of Pharmaceutical Technology. Concept and objectives of the subject. Definitions. Objective of the pharmaceutical forms. Functions and properties of excipients. Bibliographical sources
- **Unit 1.2** GLP and GTP. Pharmacopoeia

Unit 2: QUALITY GUARANTEE AND RULES OF CORRECT MANUFACTURE
- **Unit 2.1** Quality assurance. Concepts: quality, quality control, quality assurance. Good manufacturing standards (NCF or GMP)
- **Unit 2.2** Validation of processes. Organization of quality control systems in the pharmaceutical industry.

Unit 3: BASIC OPERATIONS IN PHARMACEUTICAL TECHNOLOGY
- **Unit 3.1** Spray. Technological and biopharmaceutical importance of particle size. Spraying systems. Factors that influence your choice
- **Unit 3.2** Screening Utility. Theoretical-practical aspects of sifting. Characterization and separation efficiency of the sieve. Screening systems
- **Unit 3.3** Homogenization and mixing. Objectives and utilities. Theoretical-practical aspects of the operation. Mixing systems
- **Unit 3.4** Filtration. Objectives and importance. Theoretical-practical aspects of filtration. Classification of filtration systems
- **Unit 3.5** Sterilization. Sterilization techniques Controls sterility in raw materials, packaging and finished medicine. Requirement of the RFE.
- **Unit 3.6** Water and solvents for use in Pharmacy. Types of water for pharmaceutical use (RFE). Obtaining procedures. Other solvents of greater use in Pharmaceutical Technology (RFE)

Unit 4: PHARMACEUTICAL FORMS OF ORAL ADMINISTRATION
- **Unit 4.1** Introduction to the oral route. Forms of oral administration. Classification. General characteristics. Liquid forms. Solid forms, powders, granules, capsules and tablets
- **Unit 4.2** Oral Liquid Forms Introduction. Types. Advantages and disadvantages. Presentation of liquid pharmaceutical forms. Classification of Oral Liquid Forms
- **Unit 4.3** Oral solutions Definition. Operations and technological processes related to its preparation. Excipients Development and quality control
- **Unit 4.4** Oral suspensions Definition. Operations and technological processes related to its preparation. Excipients Development and quality control.
- **Unit 4.5** Oral emulsions Definition. Operations and technological processes related to its preparation. Excipients Development and quality control
- **Unit 4.6** Capsules Introduction. Advantages and disadvantages. Raw materials used in the manufacture of capsules. Operations and technological processes related to its preparation. Excipients Development and quality control
- **Unit 4.7** Soft gelatin capsules Composition and formulation. Methods of office and industrial elaboration. Filling material. Selection of capsule size. Filling the capsules. Tests and Controls
- **Unit 4.8** Pharmaceutical forms of oral administration. Introduction to the oral route. Forms of oral administration. Classification. General characteristics. Liquid forms. Solid forms, powders, granules, capsules and tablets.
- **Unit 4.9** Hard gelatin capsules, gastro-resistant and modified release. Composition and formulation. Methods of office and industrial elaboration. Filling material. Selection of capsule size. Filling the capsules. Tests and Controls

7. Activities, Units/Modules and Methodology

Training Activity	Methodology	Related Competences (only degrees before RD 822/2021)	ECTS	Hours	As	Com	Description
Class Attendance (theory) [ON-SITE]	Combination of methods	B01 B02 B03 B04 B05 EFT01 EFT02 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	1.44	36	Y	N	

Class Attendance (practical) [ON-SITE]	Practical or hands-on activities	B01 B02 B03 B04 B05 EFT01 EFT02 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	0.8	20	Y	Y	
Formative Assessment [ON-SITE]	Assessment tests	B01 B02 B03 B04 B05 EFT01 EFT02 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	0.16	4	Y	N	
Study and Exam Preparation [OFF-SITE]	Self-study	B01 B02 B03 B04 B05 EFT01 EFT02 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	3.6	90	Y	N	
		Total:	**6**	**150**			
		Total credits of in-class work: 2.4		**Total class time hours: 60**			
		Total credits of out of class work: 3.6		**Total hours of out of class work: 90**			

As: Assessable training activity
Com: Training activity of compulsory overcoming (It will be essential to overcome both continuous and non-continuous assessment).

8. Evaluation criteria and Grading System

Evaluation System	Continuous assessment	Non-continuous evaluation*	Description
Test	70.00%	70.00%	Both the theoretical knowledge and the application of them to problem solving and practical cases
Laboratory sessions	20.00%	20.00%	Attendance at practical laboratory classes is mandatory. Practices are compulsory activities that can not be recovered, so that the existence of a fault without adequate justification will imply that the student CAN NOT pass the subject. The obtained qualification will suppose 20% of the final qualification of the subject. The application in the laboratory of the previously learned knowledge, the attitude of the student and the adequate elaboration of the laboratory notebook individually will be valued. The internship notebook will be qualified as APTO / NOT SUITABLE. It is essential to obtain an APTO in the internship notebook to be able to pass the practical block of the subject, whose final grade will be the grade obtained in the internship exam. In the event that the student does not approve the practical block in ordinary call, will have another opportunity in the final test of the extraordinary call to pass the subject. Once the practical block has been passed, the obtained grade will be retained during the following two academic years.
Assessment of active participation	10.00%	10.00%	
Total:	**100.00%**	**100.00%**	

According to art. 4 of the UCLM Student Evaluation Regulations, it must be provided to students who cannot regularly attend face-to-face training activities the passing of the subject, having the right (art. 12.2) to be globally graded, in 2 annual calls per subject , an ordinary and an extraordinary one (evaluating 100% of the competences).

Evaluation criteria for the final exam:

Continuous assessment:

The subject will be passed when at least 5 POINTS are obtained in the overall score and THEORETICAL AND PRACTICAL MODULES HAVE BEEN PREVIOUSLY SURPASSED.
EVALUATION THEORETICAL MODULE
70% of the final grade. It will consist of 2 PROOF OF PROGRESS (continuous assessment) and / or 1 FINAL PROOF (when continuous assessment is not passed) that may include theoretical concepts, practical cases, problems, etc. To overcome the module by CONTINUOUS EVALUATION, at least 5 POINTS on average must be obtained in the two progress tests. The student can retrieve said module in a FINAL PROOF.
EVALUATION PRACTICAL MODULE
20% of the final grade. The attendance to practices is COMPULSORY and NOT RECOVERABLE. It will be evaluated by presenting a laboratory notebook and a knowledge test, although the attitude in the laboratory, compliance with safety regulations and waste management can also be considered in the qualification. To overcome the practical module, a score of AT LEAST 5 POINTS must be obtained. This qualification will be maintained during the following two academic years.
EVALUATION ACTIVITY MODULE
10% of the final grade. Its evaluation will be in the classroom through the realization of activities proposed by the teacher. They have a NON-COMPULSORY and NON-RECOVERABLE character.
It will only be taken into account once the practical theoretical block has been overcome

Non-continuous evaluation:

Evaluation criteria not defined

Specifications for the resit/retake exam:

The subject will be passed when at least 5 POINTS are obtained in the overall score and THEORETICAL AND PRACTICAL MODULES HAVE BEEN PREVIOUSLY SURPASSED.
EVALUATION THEORETICAL MODULE
70% of the final grade. It will consist of a FINAL PROOF that may include theoretical concepts, practical cases, problems, etc. In order to pass the module of theoretical contents, at least 5 POINTS must be obtained in said test.
EVALUATION PRACTICAL MODULE
20% of the final grade. For those students who have suspended the practical module, they may repeat the practical knowledge exam in the EXTRAORDINARY CALL. A score of AT LEAST 5 POINTS is required to pass the practical module. Those students who have suspended for practical NO ASSISTANCE, in no case may repeat or pass the subject.
EVALUATION ACTIVITY MODULE
10% of the final grade. The possibility of recovering the activity module is not contemplated, so the QUALIFICATION OBTAINED IS MAINTAINED DURING THE ORDINARY CALL.
The qualification may be retained during the following two academic years, if the student so states.

Specifications for the second resit / retake exam:

Only students who meet the requirements set out in the Student Assessment Regulations of the University of Castilla-La Mancha will be able to access this call, they will be evaluated according to the criteria applied in the extraordinary call.

9. Assignments, course calendar and important dates

Not related to the syllabus/contents

Hours	hours
Class Attendance (theory) [PRESENCIAL][Combination of methods]	36
Class Attendance (practical) [PRESENCIAL][Practical or hands-on activities]	20
Formative Assessment [PRESENCIAL][Assessment tests]	4
Study and Exam Preparation [AUTÓNOMA][Self-study]	90

Global activity

Activities	hours
Study and Exam Preparation [AUTÓNOMA][Self-study]	90
Formative Assessment [PRESENCIAL][Assessment tests]	4
Class Attendance (practical) [PRESENCIAL][Practical or hands-on activities]	20
Class Attendance (theory) [PRESENCIAL][Combination of methods]	36
Total horas:	150

10. Bibliography and Sources

Author(s)	Title/Link	Publishing house	Citv	ISBN	Year	Description
Aulton M.E.	La ciencia del diseño de las formas de dosificación.	Elsevier D.L.		84-8174-728-9	2003	
Faulí y Trillo C.	Tratado de Farmacia Galénica.	Luzán 5, S.A. de Ediciones. Madrid.		978-84-7989-0100	1993	
Lieberman H.A., Lachman L., Schwartz J.B.	Pharmaceutical dosage forms. Tables	2nd ed. Marcel Dekke		84-8174-728-9	1989	
Lozano Mª C, Córdoba D, Córdoba M.	Manual Tecnología Farmacéutica	Elsevier D. L.		978-84-8086-600-2	2013	.
Podczeck F., Jones B.E.	Pharmaceutical capsules.	2nd ed Pharmaceutical Press.			2004	
Vila Jato JL	Tecnología Farmacéutica II. Formas farmacéuticas.	Editorial Síntesis D.L.		978-84-7738-538-7	1997	
	Real Farmacopea Española.	5ª Edición. Ministerio de Sanidad y Consumo. Madrid.			2015	
	http://biblioteca.uclm.es/					
	http://.emea.europa.eu: Agencia Europea del Medicamento					
	http://.farmacia.org: Portal farmacéutico					
	http://.fda.gov/caer/drug/defaut.htm: FDA					
	http://.infomedicamento.net: El medicamento en la Red (Apartado de farmacotecnia)					
	http://.medscape.com/druginfo: Medscape DrugInfo					
	http://.portalfarma.es: Bases de datos del CGCOT (BOT)					
Martinez Pacheco Ramón	Tratado de Tecnología Farmacéutica. Volumen III: Formas de dosificación	Síntesis		9788490771037	2017	
Martínez Pacheco Ramón	Tratado de Tecnología Farmacéutica. Volumen I: Sistemas farmacéuticos	Síntesis		9788490771020	2016	
Martínez Pacheco Ramón	Tratado de Tecnología Farmacéutica. Volumen II: Operaciones básicas	Síntesis		9788490770986	2016	