UNIVERSIDAD DE CASTILLA - LA MANCHA

GUÍA DOCENTE

1. General information

Course: PHARMACEUTICAL TECHNOLOGY III
Type: CORE COURSE
Degree: 376 - UNDERGRADUATE DEGREE PROGRAMME IN PHARMACY
Center: 14 - FACULTY OF PHARMACY
Year: 5
Main language: Spanish
Use of additional languages:
Web site:

Code: 14340
ECTS credits: 6
Academic year: 2023-24
Group(s): 10
Duration: First semester
Second language: English
English Friendly: Y
Bilingual: N

Lecturer: **JOAQUIN GONZALEZ FUENTES** - Group(s): **10**

Building/Office	Department	Phone number	Email	Office hours
Facultad de Farmacia AB. Despecho 3.8	CIENCIAS MÉDICAS	2236	joaquin.gfuentes@uclm.es	Monday to Wednesday. 16:00-19:00. by appointment by email

Lecturer: **MANUEL JESUS SANTANDER ORTEGA** - Group(s): **10**

Building/Office	Department	Phone number	Email	Office hours
Facultad Farmacia. 3.1	CIENCIAS MÉDICAS	2239	manuel.santander@uclm.es	Monday to Wednesday. 16:00-19:00. by appointment by email

2. Pre-Requisites

There are no prerequisites but it is recommended:
- Basic training in Physics and Chemistry to know the characteristics and properties of chemical products, bases of physical and physicochemical processes necessary in the sequence of operations for the manufacture and control of medicinal products.physicochemical processes necessary in the sequence of operations for the manufacture and control of medicinal products.- Statistical training involved in the manufacture of medicines.
- Basic training in physiology and pharmacology for the knowledge of the place and form of action of drugs in order to choose the appropriate route of administration and pharmaceutical form for each drug.
administration and appropriate pharmaceutical form for each active ingredient.
If there are any changes in the planning due to unforeseen circumstances, students will be informed of these changes through the virtual campus.

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 involved in the design, manufacture and evaluation of dosage forms of medicines.and evaluation of the dosage forms of medicines. This knowledge provides the pharmacist with the ability to provide information,patient care and advice on the administration and conservation of medicines.All these characteristics are related to subjects such as Biopharmacy and Pharmacokinetics, Pharmaceutical Biotechnology, Pharmaceutical Technology I and II, leading the student to acquire the necessary knowledge and skills for the administration and conservation of medicines.II, leading the student to acquire the necessary training to successfully deal with the administration of drugs with effective, safe and stable pharmaceutical forms

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.
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.

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.

To know and to develop good manufacturing practiques (GMP) for the different activities to develop in Pharmaceutical Industry, pharmacy and hospital Pharmacy Service.

Know the vehiculizacion nanoparticles as forms of drugs.

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: DESIGN OF PHARMACEUTICAL PLANTS

- **Unit 1.1** Design of pharmaceutical plants based on GMP.
- **Unit 1.2** Air treatment systems in the pharmaceutical industry.
- **Unit 1.3** Water production systems in the pharmaceutical industry

Unit 2: SCALING AND PRODUCTION IN THE PHARMACEUTICAL INDUSTRY

- **Unit 2.1** Scale-up of the production of solid oral dosage forms (I)
- **Unit 2.2** Scale-up of the production of solid dosage forms for oral administration (II).
- **Unit 2.3** Industrial processing of solid dosage forms for oral administration.
- **Unit 2.4** Industrial processing of liquid oral dosage forms.
- **Unit 2.5** Industrial processing of parenteral liquid forms.

Unit 3: QUALITY CONTROL IN THE PHARMACEUTICAL INDUSTRY

- **Unit 3.1** Planning and Control of the Production Process.
- **Unit 3.2** Sampling Methods in the Pharmaceutical Industry.

Unit 4: QUALITY MANAGEMENT AND VALIDATION IN THE PHARMACEUTICAL INDUSTRY

- **Unit 4.1** Quality management in the pharmaceutical industry.
- **Unit 4.2** Introduction to the study of validation in the pharmaceutical industry.
- **Unit 4.3** Approval and validation of suppliers.
- **Unit 4.4** Validation of analytical and bioanalytical methods.
- **Unit 4.5** Validation of cleaning methods in the pharmaceutical industry.

Unit 5: AUDITS AND SELF-INSPECTIONS

- **Unit 5.1** Audits and Self-Inspections

Unit 6: DERMOPHARMACY AND SANITARY PRODUCTS

- **Unit 6.1** Dermopharmacy and Medical Devices

ADDITIONAL COMMENTS, REMARKS

PRACTICAL SCRIPT

Practical 1: Determination of the design space of Theophylline extended release matrix tablets (FarAlb-Comp 50 mg).

Practical 2: Preparation of Theophylline extended-release hard capsules (FarAlb-Cap 50 mg).

Practical 3: Pharmacotechnical control of extended-release theophylline hard capsules (FarAlb-Cap 50 mg).

Practice 4: Effect of compression conditions on critical quality attributes in the development of immediate release Theophylline tablets.

Practical 5: Development of standard operating procedures for the development of magistral formulae and officinal preparations.

The material provided in class or through ICT tools by the teacher is intellectual material of the teacher and, therefore, cannot be distributed. Likewise, students are reminded that it is not permitted to record classes without the teacher's permission.

7. Activities, Units/Modules and Methodology

Training Activity	Methodology	Related Competences (only degrees before RD 822/2021)	ECTS	Hours	As	Com	Description
							The availability of teaching resources will be accessible on the Moodle platform prior to the the start of the activities. In addition, students will have access to complementary bibliographic and audiovisual material (books, review articles, videos) in the university library on the Albacete campus. The teaching

Class Attendance (theory) [ON-SITE]	Combination of methods	B01 B02 B03 B05 EFT01 EFT02 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	1.44	36	Y	N	methodology through a combination of methods will include the lecture method expository/lecture method together with case studies. The active student participation in face-to-face teaching in workshops and seminars will be assessed using ICT tools. Cooperative work both in the classroom and outside the classroom will be materialised in the preparation and defence of work, as well as in the resolution of problems and/or cases that will be presented orally. The grades obtained in these activities will be taken into account in the final assessment of the course.
Class Attendance (practical) [ON-SITE]	Practical or hands-on activities	B01 B02 B03 B05 EFT01 EFT02 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	0.8	20	Y	Y	Practical teaching will be given in small groups within the periods established in the academic calendar and which do not coincide with other other teaching activities. It will take place in classrooms and/or laboratories, all of them equipped with the appropriate adequate means to achieve the proposed objectives. These activities are COMPULSORY, so that the student will not be able to pass the the course if they are not done properly.
Study and Exam Preparation [OFF-SITE]	Self-study	B01 B02 B03 B05 EFT01 EFT02 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	3.6	90	Y	N	Students may request personal tutorials personal tutorials on the contents of the subject by arranging the interview with the corresponding corresponding teacher.
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	Y	Specific dates have been set aside in the academic calendar for specific dates have been set aside in the academic calendar for assessment tests that do not coincide with other teaching activities
		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%	Theoretical knowledge is assessed, as well as its application to the resolution of problems and practical cases.
Laboratory sessions	20.00%	20.00%	Attendance to the practical laboratory classes is compulsory. The practicals are compulsory activities, so that The existence of an absence without adequate justification, will imply that the student CANNOT pass the course. The grade obtained will represent 20 % of the final grade of the course. The application in the laboratory of the knowledge previously learned, the student's attitude and the proper preparation of the laboratory notebook will be considered . In the event that the student does not pass the practical block in the ordinary exam, he/she will have another opportunity in the final exam of the extraordinary exam to pass the subject. Once the practical block has been passed, the obtained grade will be retained for the following two academic years.
Assessment of active participation	10.00%	10.00%	The teacher advises the student to attend regular attendance at the Face-to-face activities during the course. It will be valued positively the resolution of issues and problems by part of the student, the presentation and public defense of work, as well as their active participation and attitude in class and Tutorials. These activities are not mandatory.
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:

In this modality, the subject will follow a system of continuous evaluation, adapted to the regulatory standards of the University of Castilla-La Mancha.
The final grade will take into account, proportionally, the average of the written tests (70%), the performance of the laboratory practices (20%)
and participation in seminars or other activities proposed in class (10%).
It will be assumed that all students opt for the continuous modality, unless otherwise informed (non-continuous modality) through a
Email addressed to the teacher responsible for the subject until 50% of all evaluable activities have been completed or the
Class period is over.
The subject will be passed as long as a final average grade equal to or greater than 5 out of 10 is obtained between the different blocks (Theoretical, Practical and
Participation). It will be possible to add the marks obtained from the Theoretical and Practical block from a grade of 4 out of 10.
EVALUATION THEORETICAL MODULE (70% of the final grade). It will consist of a partial test (continuous evaluation) and a final test. Both will be able to include theoretical concepts, topics treated in the practices or in the different teaching activities, problems or clinical cases, etc. The student who pass the 4 in the partial test, you can decide if you examine the whole subject, or overcome the contents corresponding to the partial face test
At the final test, in this case each test will have a value of 50%. This decision will have to be notified to the teacher responsible for the subject via email at least 2 weeks before the date of the second final test. To be able to choose to add the note corresponding to the theoretical block of the subject through continuous evaluation, a minimum grade of 4 must be obtained in each of the tests.
EVALUATION PRACTICAL MODULE (20% of the final grade). Attendance at internships is MANDATORY. It will be evaluated by submitting a laboratory notebook and an examination of knowledge, although attitude in the laboratory, compliance with safety standards and management of residues may also be considered in the qualification. To pass the practical module, a grade of AT LEAST 5 POINTS MUST BE OBTAINED. The Qualification may be kept during the following two academic years, if the student so states in writing to the responsible teacher. For
To be able to choose to add the note of the practical block to the rest of the blocks, a minimum grade of 4 must be obtained in this block of the subject.
EVALUATION MODULE OF ACTIVITIES (10% of the final grade). Your evaluation will be in the classroom through the realization of proposed activities by the teacher. They are NOT MANDATORY. It will only be taken into account once the theoretical-practical block has been passed. The qualification will be able to
Keep during the following two academic years, if the student so states in writing to the responsible teacher. If a student could not
Carry out any of the evaluable activities of the block of activities in person, for justified reasons, you can request the teacher to
Carrying out another non-face-to-face activity, of which they will be evaluated, to achieve the competences.
In the event that the student does not reach the grade required to pass the ordinary call, and has to make the extraordinary, the qualification of the Theoretical and practical blocks can be kept only if a minimum grade of 4 points has been reached. The activity note is not subject to this rule. It is recalled that the material prepared by the teacher and made available to students on the Virtual Campus platform is the property of the teacher,
So taking it out of that context and making it available to people outside that platform will be considered plagiarism. Likewise, the realization of the Different tests with unauthorized aid or material will be considered fraud. In accordance with the provisions of the Regulation of evaluation of the student, the test in which fraud has been detected will be considered invalid and will be graded with fail (0), including as fraudulent act
Any type of plagiarism detected.

Non-continuous evaluation:

subject can follow a non-continuous evaluation system, adapted to the regulatory norms of the University of Castilla-La Mancha.
The final grade will take into account, proportionally, the average of the written tests (70%), the completion of laboratory practices (20%)
and participation in seminars or other activities proposed in class (10%).
The subject will be passed as long as a final average grade equal to or greater than 5 out of 10 is obtained among the different blocks (Theoretical, Practical and
Stake). It will be possible to add the marks obtained from the Theoretical and Practical block from a mark of 4 out of 10.
THEORETICAL MODULE EVALUATION 70% of the final mark. It will consist of 1 FINAL TEST that may include theoretical concepts, practical cases, problems etc To pass the theoretical module, a qualification of AT LEAST 5 POINTS must be obtained.
PRACTICAL MODULE EVALUATION (20% of the final mark). Attendance at practices is MANDATORY. It will be evaluated by presenting a laboratory notebook and a knowledge test, although the attitude in the laboratory, compliance with safety regulations and management of residues may also be considered in the qualification. To pass the practical module, a qualification of AT LEAST 5 POINTS must be obtained. The
The grade may be kept for the following two academic years, if the student so states in writing to the responsible professor.
EVALUATION OF THE ACTIVITIES MODULE (10% of the final mark). Its evaluation will be in the classroom by carrying out the proposed activities by the teacher. They are NON-MANDATORY. It will only be taken into account once the theoretical-practical block has been passed. The rating can be retain it for the next two academic years, if the student states so in writing to the responsible professor. If a student could not carry out any of the evaluable activities of the block of activities in person, for justified reasons, you can ask the teacher for the carrying out another non-contact activity, of which they will be evaluated, to achieve the competencies.
In the event that the student does not reach the grade required to pass the ordinary call, and has to take the extraordinary one, the qualification of the Theoretical and practical blocks can only be retained if a minimum score of 4 points has been reached. The activity note is not subject to this rule.
It is recalled that the material prepared by the teacher and made available to students on the Virtual Campus platform is the property of the teacher, so taking it out of that context and making it available to people outside that platform will be considered plagiarism. Likewise, carrying out different tests with unauthorized aid or material will be considered fraud. In accordance with the provisions of the Evaluation Regulation of the student, the test in which fraud has been detected will be considered invalid and will be graded with fail (0), including as a fraudulent act
any type of plagiarism detected.

Specifications for the resit/retake exam:

The final grade will take into account, proportionally, the average of the written tests (70%), the completion of the laboratory practices (20%) and the participation in seminars or other activities proposed in class (10%). It will be possible to add the marks obtained from the Theoretical and Practical block from a grade of 4 out of 10.
The subject will be passed as long as a final average grade equal to or greater than 5 out of 10 is obtained among the different blocks (Theoretical, Practical and Stake). It will be possible to add the marks obtained from the Theoretical and Practical block from a mark of 4 out of 10.
THEORETICAL MODULE EVALUATION 70% of the final mark. It will consist of 1 FINAL TEST that may include theoretical concepts, practical cases, problems etc A qualification of AT LEAST 5 POINTS is required to pass the theoretical module.
PRACTICAL MODULE EVALUATION (20% of the final mark). For those students who have failed the practical module, they will be able to repeat the exam of practical knowledge in the EXTRAORDINARY CALL. A score of AT LEAST 5 POINTS is required to pass the practical module.
EVALUATION OF THE ACTIVITIES MODULE (10% of the final mark). THE QUALIFICATION OBTAINED DURING THE ORDINARY CALL IS MAINTAINED
It will only be taken into account once the theoretical-practical block has been passed. The qualification can be kept during the two academic years following, if the student manifests it.
It is recalled that the material prepared by the teacher and made available to students on the Virtual Campus platform is the property of the teacher, for taking it out of that context and making it available to people outside of that platform will be considered plagiarism. Likewise, the realization of the different Testing with unauthorized aid or material will be considered fraud. In accordance with the provisions of the Student Assessment Regulations, the test in the one that has been detected fraud will be considered invalid and will be qualified with suspense (0), including any type of plagiarism as a fraudulent act detected.

Specifications for the second resit / retake exam:
Only students who meet the requirements set out in the Student Assessment Regulations of the University will be able to access this call.
University of Castilla-La-Mancha which 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
Study and Exam Preparation [AUTÓNOMA][Self-study]	90
Formative Assessment [PRESENCIAL][Assessment tests]	4

General comments about the planning: Check schedules on the website of the Faculty of Pharmacy and virtual Campus. The planning of the The subject will be carried out during the development of the course with the help of the virtual platform of the UCLM. The time schedule may be modified against unforeseen causes.

Global activity

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

10. Bibliography and Sources

Author(s)	Title/Link	Publishing house	Citv	ISBN	Year	Description
Benitez Palomeque, E.	Good Manufactering Practices. La gestión técnica en la fabricación de medicamentos. Consejos prácticos.	Ed. Centro de Estudios Superiores de la Industria Farmacéutica	Madrid	84-921046-0-0	1996	
Cole, G.	Pharmaceutical production facilities: design and applications. 2ª edición.	CRC Press		0-7484-0438-4	1998	
S. Cox Gad	Pharmaceutical Manufacturing Handbook: Regulations and Quality	Wiley		978-0-470-25959-7	2008	
Salazar Macián, R.	Tecnología Farmacéutica Industrial, vol. I y II	Romargraf S.A.	Barcelona	84-931913-4-5	2003	
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Salazar Macián, R.	Cualificación y validación: elementos básicos de la calidad y productividad	Romargraf S.A.	Barcelona	978-84-931913-8-2	2007	
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Y. Qiu	Developing Solid Oral Dosage Forms	Elsevier		978-0-444-53242-8	2013	
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	Formulario Nacional	Ministerio de Sanidad y Consumo		978-84-7978-813-1	2007	
	Formulario Nacional , 2ª edición				2015	
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	Medscape DrugInfo					
	http://search.medscape.com/reference-search					
	Pharmaceutical manufacturing handbook : production and proce	Wiley-Interscience,		978-0-470-25958-0	2008	
	Portal farmacéutico. Bases de datos del CGCOF (BOT)					
	http://www.portalfarma.com/Paginas/default.aspx					
	Real Farmacopea Española. 5ª Edición.	Ministerio de Sanidad, Servicios Sociales e Igualdad. Madrid			2015	
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	Tratado de Tecnología Farmacéutica. Volumen II:	Sintesis		9788490771020	2016	