UNIVERSIDAD DE CASTILLA - LA MANCHA

GUÍA DOCENTE

1. General information

Course: PHARMACEUTICAL TECHNOLOGY II
Type: CORE COURSE
Degree: 376 - UNDERGRADUATE DEGREE PROGRAMME IN PHARMACY
Center: 14 - FACULTY OF PHARMACY
Year: 4
Main language: Spanish
Use of additional languages:
Web site:

Code: 14330
ECTS credits: 6
Academic year: 2023-24
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	Mondays and Wednesdays from 16:00-19:00 Make an appointment in advance by email

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	Mondays and Wednesdays from 16:00-19:00 Make an appointment in advance by email

Lecturer: **MARIA VICTORIA LOZANO LOPEZ** - Group(s): **10**

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Facultad Farmacia. 2.4	CIENCIAS MÉDICAS	8238	mvictoria.lozano@uclm.es	Mondays and Wednesdays from 16:00-19:00 Make an appointment in advance 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 the physical and 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 knowledge of the place and form of action of drugs in order to choose the appropriate route of administration and pharmaceutical form for each active ingredient.

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, preparation and evaluation of the dosage forms of medicines. This knowledge enables the pharmacist to provide information, care and advice to patients on the administration and conservation of medicines.

All these characteristics are related to subjects such as Biopharmacy and Pharmacokinetics, Pharmaceutical Technology I and III, leading the student to acquire the necessary training to successfully deal with the administration of drugs with effective, safe and stable dosage 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.
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 select the route of administration and the pharmaceutical form.

Ability to work under standards of good laboratory practice (GLP).

Ability to plan, design and develop preformulation studies of the different pharmaceutical forms and to interpret the results.

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: COLLOIDAL SYSTEMS AS DRUG VECTORS.

Unit 1.1 Objectives and classification. Obtaining methods. Liposomes. Microspheres. Microparticles. Nanoparticles. Nanocapsules.

Unit 1.2 Colloidal systems for topical administration. Colloidal systems for mucosal administration. Colloidal systems for parenteral parenteral administration.

Unit 2: PHARMACEUTICAL FORMS FOR PARENTERAL ADMINISTRATION

Unit 2.1 Parenteral administration forms I: Classification. Requirements. Sterilisation and depyrogenation methods. Methods of isotonisation.

Unit 2.2 Parenteral dosage forms II: Preparation of parenteral dosage forms. Vehicles and additives. Packaging and conditioning. Testing and controls. Seminar on isotony.

Unit 3: PHARMACEUTICAL FORMS FOR PULMONARY ADMINISTRATION. OPERATIONS AND TECHNOLOGICAL PROCESSES RELATED TO THEIR MANUFACTURING. EXCIPIENTS AND QUALITY CONTROL

Unit 3.1 Aerosols. Basic biopharmaceutical and technological requirements. Devices: pressurised canisters, dry powder inhalers and nebulisers. nebulisers. Technological processes for their manufacture. Quality control

Unit 4: PHARMACEUTICAL FORMS AND MANUFACTURING PROCESSES FOR MEDICINAL PRODUCTS FOR SKIN AND MUCOSAL ADMINISTRATION

Unit 4.1 Pharmaceutical forms for cutaneous application. Semi-solid forms. Classification. Technological processes for their manufacture. Quality control. quality control.

Unit 4.2 Pharmaceutical forms for ocular administration. Eye drops. Ophthalmic semi-solid forms.

Unit 4.3 Pharmaceutical forms for nasal and otic administration.

Unit 4.4 Pharmaceutical forms for rectal administration.

Unit 4.5 Pharmaceutical forms for vaginal administration.

Unit 5: MODIFIED-RELEASE MEDICINES.

Unit 5.1 Controlled release systems.Definition, classification and release mechanisms.

Unit 5.2 Modified release oral dosage forms.Osmotic systems.Matrix systems. Other systems. Preparation procedures. Preparation procedures.excipients and adjuvants Quality control.

Unit 5.3 Modified-release parenteral dosage forms. Liquid systems and implants. Biocompatible, bioerosionable and biodegradable systems. biodegradable systems. Preparation procedures. Quality control.

Unit 5.4 Transdermal systems. Classification. Technological processes for their elaboration. Quality control.

Unit 5.5 Modified release systems for other routes. Classification. Basic biopharmaceutical and technological requirements. Vehicles and additives. Quality control.

Unit 6: GALENIC DEVELOPMENT. STAGES IN THE DEVELOPMENT OF A MEDICINAL PRODUCT. PREFORMULATION, FORMULATION AND STABILITY OF MEDICINAL PRODUCTS.

Unit 6.1 Concepts and phases of galenic development.

Unit 6.2 Preformulation I. Objectives.Technological aspects.Physical and physico-chemical characterisation.Compatibility studies.Protein and peptide activeprotein and peptide nature.

Unit 6.3 Preformulation II: Biopharmaceutical aspects.In vitro studies. In vivo studies. Conclusions.

Unit 6.4 Formulation. Design and optimisation of the formulation phase.

Unit 6.5 Stability in solution.Kinetics of degradation processes. Transition state theory. Influence of temperature: activation energy. energy.Accelerated stability studies. Influence of pH, polarity and ionic strength of the medium. Drug degradation mechanisms. Stabilisation procedures.

Unit 6.6 Stability in the solid state. Kinetics of degradation processes. Biopharmaceutical shelf life. ICH regulations.

ADDITIONAL COMMENTS, REMARKS

PRACTICE SCRIPT
- Formulation of colloidal systems.
- Stability of colloidal systems.
- Dissolution study of controlled release forms.
- Pharmaceutical forms for cutaneous application.
- Stability of drugs in solution.

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 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	1.44	36	Y	N	The availability of teaching resources will be accessible on the Moodle platform before starting 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 methodology through a combination of methods will include the 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 of it will be materialised in the preparation and defence of work, as well as in the resolution of problems and/or cases that will be oral presentations. The grades obtained in these activities will be considered for the final assessment of the course.
Class Attendance (practical) [ON-SITE]	Practical or hands-on activities	B01 B02 B03 B04 B05 EFT01 EFT02 EFT05 EFT06 EFT07 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, which do not coincide with other teaching activities. It will take place in classrooms and/or laboratories, equipped with the appropriate means to achieve the proposed objectives. They are COMPULSORY activities, so the student will not be able to pass the the course if they are not properly done.
Formative Assessment [ON-SITE]	Assessment tests	B01 B02 B03 B04 B05 EFT01 EFT02 EFT05 EFT06 EFT07 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	0.16	4	Y	Y	Specific dates have been set in the academic calendar for the assessment tests that do not coincide with other teaching activities.
Study and Exam Preparation [OFF-SITE]	Self-study	B01 B02 B03 B04 B05 EFT01 EFT02 EFT05 EFT06 EFT07 G01 G04 G13 G15 T01 T02 T03 T04 T05 T06 T07 T08	3.6	90	Y	N	Students may request personal tutorials on the contents of the subject by previously arranging the interview with the corresponding teacher.
		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 case studies.
Laboratory sessions	20.00%	20.00%	Attendance to the practical laboratory classes is compulsory. The grade obtained will account for 20 % of the final grade of the course. The application in the laboratory work of the knowledge previously learnt, the student's attitude and the adequate individual preparation of the laboratory notebook will also be considered. The laboratory notebook will be will be graded as PASS/FAIL. It is essential to obtain a PASS grade in the laboratory workbook to pass the practical section of the course, whose final grade will be the one obtained in the practical exam. If the student does not pass the practical section in the ordinary exam, he/she will have another opportunity to pass the course in the final exam of the extraordinary call. Once the practical section has been passed, the grade obtained will be kept for the following two academic years.

Assessment of active participation	10.00%	10.00%	The teacher suggests that the student should attend regularly to the face-to-face activities during the course. The development of questions and problems by the student will be favourably assessed, as well as the presentation and public defence of works, the student's active participation and his/her attitude in class and tutorials. These activities are not compulsory.
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 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%).
It will be assumed that all students opt for the continuous modality, unless otherwise informed (non-continuous modality) by means of a email addressed to the professor responsible for the subject until 50% of all the evaluable activities have been completed or the class period has ended.
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 a partial test (continuous assessment) and a final test. Both may include theoretical concepts, topics covered in practices or in different teaching activities, problems or clinical cases, etc. The student who pass a 4 in the partial test, you can decide whether to take an exam for the entire subject, or eliminate the contents corresponding to the partial test to the final test, in this case each test will have a value of 50%. This decision will have to be notified to the professor responsible for the subject via email at least 2 weeks before the date of the second final test. In order to be able 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.
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 in order to keep it for the following two academic years. The
The grade may be kept for the following two academic years, if the student so states in writing to the responsible professor. For
To be able to choose to add the grade from the practical block to the rest of the blocks, a minimum grade of 4 must be obtained in this block of the subject.
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.

Non-continuous evaluation:

The 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
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 and 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%).
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
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 grade of AT LEAST 5 POINTS is required to pass the practical module and keep it for the following two academic years.
EVALUATION OF THE ACTIVITIES MODULE (10% of the final mark). THE QUALIFICATION OBTAINED DURING THE CALL IS MAINTAINED ORDINARY. 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 those students who meet the requirements stablished by the Student Assessment Regulations of the University of Castilla-La Mancha will be eligible for this call, who 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

General comments about the planning: Consult the timetables on the website of the Faculty of Pharmacy and the Virtual Campus. The planning of the will be carried out during the course with the help of the virtual platform of the UCLM. The timetable may be modified in the event of unforeseen circumstances.

Global activity

Activities	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
Total horas:	150

10. Bibliography and Sources

Author(s)	Title/Link	Publishing house	Citv	ISBN	Year	Description
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Martínez Pacheco R.	Tratado de Tecnología Farmacéutica. Volumen II "Operaciones básicas"	Síntesis		9788490771020	2016	
Rowe R.C.	Handbook of pharmaceutical excipients	5ª Edición. Pharmaceutical Press and the American Pharmacists Association			2005	
Torres Suarez A.	Estabilidad de medicamentos.	Asociación Española de Farmacéuticos de la Industria (AEFI). Madrid			2004	
Uchegbu I.F., Schatzlein A.	Polymers in drug delivery	CRC/Taylor & Francis		978-0-8493-2533-5	2006	
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Vila Jato J.L.	Tecnología Farmacéutica II: Formas farmacéuticas	Editorial Síntesis D.L.			2001	
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	Medscape DrugInfo http://search.medscape.com/reference-search					
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Martínez Pacheco R.	Tratado de Tecnología Farmacéutica. Volumen III "Formas de dosificación"	Síntesis	9788490771037	2017
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Alonso M.J., Csaba N.	Nanostructured Biomaterials for Overcoming Biological Barriers	RSC Publishing	978-1-84973-363-2	2012
Aulton M.E	La ciencia del diseño de las formas de dosificación.	Elsevier D.L.		2004
Faulí y Trillo C.	Tratado de Farmacia Galénica	Luzán 5, S.A. de Ediciones. Madrid		1993
Florence, A. T. (Alexander Taylor)	Physicochemical principles of pharmacy	Pharmaceutical Press	978-0-85369-984-2	2011
Isabel González Álvarez, Miguel Ángel Cabrera Pérez, Maria del Val Bermejo Sanz	Metodologías Biofarmacéuticas en el Desarrollo de Medicamentos	Universitas Miguel Hernández	978-84-16024-16-2	2015