SUBJECT: PROCESS CHEMISTRY

MATTER: Process Chemistry
MODULE: Drug design and production Mention
STUDIES: Degree in Pharmacy

GENERAL FEATURES*

Type: ☐Basic Training,☒ Compulsory, ☐Elective
☐Final degree work, ☐Supervised practices
☐Practices oriented to the Mention

Duration: Semester **Semester / s**: S9
Number of ECTS credits: 6
Languages: English

DESCRIPTION

BRIEF DESCRIPTION AND JUSTIFICATION

The mission of the chemical process is to find the ideal industrial synthesis for a NCE taking into account factors such as safety, environmental considerations and price.
The aim of this course is to provide chemical language, knowledge and development principles of organic synthesis processes on an industrial scale, particularly within the environment of the pharmaceutical industry.
Consequently, the course focuses on the production of drugs at a relatively small scale (tens to hundreds of Kg) and not about the manufacture of organic compounds at the level of hundreds of tons. Special attention is devoted to the selection of reagents and solvents commonly used in industry.

POWERS *

General skills:

- G-1 Identify, design, obtain, analyze, control and produce drugs, medicines and other health products and raw materials of interest for human or veterinary use.
- G-10 Design, apply and evaluate reagents, methods and preclinical and clinical analytical techniques, knowing the basics of clinical analysis and the characteristics and contents of the reports of laboratory diagnosis.
- G-16 Demonstrate ability for oral and written communication in English.

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Specific skills:

- E-Q1 Identify, design, obtain, analyze and produce the active ingredients, pharmaceuticals and other products and materials of sanitary interest.
- E-Q5 Know the physico-chemical properties of the substances used in the manufacture of drugs.
- E-Q8 Know and understand the nature and behavior of functional groups in organic molecules.

Transversal skills Master Level:

- T-1M Have advanced knowledge and demonstrate, in a scientific and technological research or a highly specialized context, a detailed and informed understanding of the theoretical and practical aspects and about the methodology of work in one or more fields of study.
- T-2M Being able to control and predict the evolution of complex situations and make judgments based on incomplete information by developing new and innovative working methodologies adapted to scientific/research, technological or professional, multidisciplinary in general, field in which the activity is developed.
- T-3M Demonstrate sufficient autonomy to participate in research projects and scientific or technological collaborations within its thematic scope, in interdisciplinary contexts and, where appropriate, with a high component of knowledge transfer.

PREVIOUS REQUIREMENTS*

It is recommended to have previous knowledge in Organic Chemistry and Structural Determination

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CONTENTS

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METHODOLOGY

TRAINING ACTIVITIES

Training activities * (GF Memory)	Training activities (Sigma)	ECTS credits *	Competences
Theoretical sessions	Sessions of exposition of concepts	1.8	G-1, G-10, G-16, E-Q1, E-Q5, E-Q8, T-1M, T-2M, T-3M
Solving exercises and problems	-	-	-
Knowledge integrating activities: cases, seminars, directed work and cooperative learning	Seminars	0.4	G-1, G-10, G-16, E-Q1, E-Q5, E-Q8, T-1M, T-2M, T-3M
Practical sessions: laboratory or simulations	Practical / laboratory work	-	-
-	Presentations (3)	-	-
Personal study by students	Activities of personal study by students	3.7	G-1, G-10, G-16, E-Q1, E-Q5, E-Q8, T-1M, T-2M, T-3M
Evaluation activities	Evaluation activities (testing, monitoring controls ...)	0.1	G-1, G-10, G-16, E-Q1, E-Q5, E-Q8, T-1M, T-2M, T-3M
	TOTAL	6.0	

GF: Degree in Pharmacy
(1) In the GF the "cases" epigraph of the subject file in Sigma is included in" Knowledge integrating activities"
(2) Does not apply to GF, activities to answer questions from the students are included in " Personal study by students"
(3) In the GF the "presentations" epigraph of the subject file in Sigma is included in" Knowledge integrating activities"

EXPLANATION OF TEACHING METHODS

1. **Expository method.** Participatory lecture, work through expositions of different theoretical and practical contents involving the student with the combination of activities and exercises in the classroom. Encouraging students to ask questions that conduct personal reasoning. Content impartition, explanation and demonstration of skills, abilities and knowledge in the classroom or through audiovisual media.

5. **Learning based on problems or cases,** allowing students to experience, test and inquire about the nature of situations, phenomena and daily activities promoting analysis, teamwork and decision-making.

6. **Cooperative learning,** getting students to take responsibility for their own learning and their peers in a strategy of shared responsibility to achieve group goals.

7. **Evaluation activities.** Exercises to evaluate the degree of assumption of competencies (knowledge, skills, values) by students. Continuously or timely.

EVALUATION

EVALUATION METHODS

Evaluation Methods * (GF Memory)	Evaluation methods (Sigma)	Weight * (2)	Competences
Final exam	Final exam	50%	G-1, G-10, G-16, E-Q1, E-Q5, E-Q8, T-1M, T-2M T-3M
-	Exam / partial / s (1)	-	-
Monitoring of learning (including controls, cases, exercises, problems, participation, Online self-assessment)	Follow-up activities	25%	G-1, G-10, G-16, E-Q1, E-Q5, E-Q8, T-1M, T-2M, T-3M
Project and presentations	Project and presentations	25%	G-1, G-10, G-16, E-Q1, E-Q5, E-Q8, T-1M, T-2M, T-3M

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Practical or experimental work	Experimental or field work	-	-
TFG evaluation	Projects	-	-
External practices (supervised practices and mention-oriented practices)	Evaluation from the company or institution	-	-
-	Participation (1)	-	-
		100%	

GF: Degree in Pharmacy
1) In the GF the "Examination / partial / is" and "Participation" epigraphs of the subject file in Sigma are included in "Monitoring of Learning"
(2) The values may range ± 5% from the value set in the GF memory (final sum 100%)

LEARNING OUTCOMES

- Knowing the principles of process chemistry.
- Knowing how to use the principles of the development of synthetic processes for industrial scale production of drugs or organic compounds of interest.
- Demonstrate the ability to select industrializable synthetic routes in a multidisciplinary environment individually or as a team member.
- Demonstrate understanding of the impact of the development of synthesis processes on an industrial scale in the production of pharmaceuticals and organic compounds of interest and the importance of working in a professional environment and ethically responsible.

QUALIFICATION

The qualification of this subject is obtained:

Final exam (EF)	50%
Follow-up activities (AS)	25%
Project and presentations (T)	25%

All are rated over 10.

In order to be able to take the final exam, it is essential that the qualification of the project and presentations (T) be greater than or equal to 5.0. Otherwise, the qualification of the project and presentations must be previously recovered.

The final qualification (NF) is calculated by the following formula.

Note = 50% EF + 25% AS + 25% T

The final exam qualification must be equal to or greater than 5 to average in the formula for calculating the final qualification.

The subject is approved if the final qualification is equal to or greater than five.

Second convocatory

If you have not reached the minimum qualification of 5.0, you must take a recovery exam (ER) (from which you will get an ER qualification) that replaces EF. The qualifications obtained in AS and T are maintained.

The final qualification is calculated:

NF = 50% ER + 25% AS + 25% T

The final exam qualification must be equal to or greater than 5 to average in the formula for calculating the final qualification.

The subject is approved if the final qualification is equal to or greater than five.

Next convocatories

In case of not passing the subject in second convocatory, no qualification will be kept for the next course and will be evaluated in a single final exam that includes all the contents of the subject.

The subject is approved if the final qualification is equal to or greater than five.

SKILLS EVALUATION

For the evaluation of skills G-1, G-10, G-16, E-Q1, E-Q5, E-Q8, T-1M, T-2M T-3M the qualification of the subject will be used as indicator.

BIBLIOGRAPHY

BASIC BIBLIOGRAPHY:

- Course materials (available in Moodle platform)
- NG Anderson, Practical Process Research & Development, Academic Press, San Diego2000.
- ICH guidelines (http://www.ich.org)
- *European Pharmacopeia* (Http://www.pheur.org)
- *US Pharmacopeia* (Http://www.usp.org)

COMPLEMENTARY BIBLIOGRAPHY:

- Oljan Repic. Principles of Process Research and Chemical Development in the Pharmaceutical Industry, Wiley Interscience, 1997.
- W. Cabri, R. Difabio. From Bench to Market: The Evolution of Chemical Synthesis,Oxford University Press, Oxford2000.
- S. Lee, G. Robinson. Process Development: Fine Chemicals from Grams to Kilograms,Oxford University Press, Oxford1997.
- K. Carpenter, JH Atherton. Process Development: Physicochemical Concepts,Oxford University Press, Oxford1997.

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DOCUMENT HISTORY

PREVIOUS CHANGES
March 2018, Dr. Ana Cuartero

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July 2018, Dr. Xavier Berzosa