

**Research Methods in Pre-clinical Pharmacology**

Code: 42361  
ECTS Credits: 9

Degree	Type	Year	Semester
4311309 Pharmacology	OT	0	1

The proposed teaching and assessment methodology that appear in the guide may be subject to changes as a result of the restrictions to face-to-face class attendance imposed by the health authorities.

### Contact

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### Teachers

Victoria Clos Guillén

Raimon Guitart Bas

Ana Puigdemont Rodríguez

Pedro José Otaegui Goya

Gianluigi Caltabiano

Miguel Angel Vicente Martínez

Francesc Jiménez Altayo

### Use of Languages

Principal working language: spanish (spa)

### External teachers

A. Casadesús

A. Flores

A. Guzmán

A. Norniella

A. Pujol

E. Piqué

J. Alfons

J. De la Puente

J. Hernández

J. L. Montero

J. Ramis

L. Canut

M. Aulí

M. Borràs

N. Prats

R. Mollà

R. Roca

## Prerequisites

There are no special prerequisites.

## Objectives and Contextualisation

To apply basic pharmacological and methodological knowledge to develop preclinical drug research and interpret the results.

## Competences

- Design and conduct research on drugs.
- Generate innovative ideas.
- Interpret one's own and other results of research on drugs.

## Learning Outcomes

1. Apply models to describe and predict the time course of drug concentrations and their pharmacological response.
2. Generate innovative ideas.
3. Interpret models to describe and predict the time course of drug concentrations and their pharmacological response
4. Plan, design, use and interpret studies (not on humans) with the aim of evaluating the effects of drugs and their mechanism of action.
5. Plan, design, use and interpret studies (not on humans) with the aim of evaluating the time course of drug concentration in biological tissues and its relation to the effects observed.
6. Plan, design, use and interpret studies (not on humans) with the aim of evaluating toxicity and possible adverse reactions.
7. Recognise and apply the ethical and quality requirements for conducting non-clinical research with drugs.

## Content

a) Evaluation and validation of a pharmacological target. Molecular screening: automation and high performance. Levels of pharmacological research: computer (in silico), cells, organs, animals, humans. In vitro studies: molecular for the evaluation of targets, cell cultures (biochemical and molecular), isolated organs (physiological, biochemical and molecular). Ex vivo studies. Methodologies used in in vivo studies: conscious animal and anesthetized animal (measurement of blood pressure). Animal models of diseases induced by administration of compounds, by surgical intervention or by genetic manipulation. Methodologies for studies of psychotropic drugs.

b) In silico studies. In vitro studies: physical-chemical characterization (release, dissolution). In vitro studies: metabolism. In vivo studies: handling of animals, choice of species. In vivo studies: design. Microdialysis techniques. Plasma protein binding. Animal / human extrapolation (allometry): data analysis. Toxicokinetics and special pharmacokinetics.

c) Mechanisms of toxicity. In vitro toxicity studies. In vivo toxicity studies: single administration. In vivo toxicity studies: repeated administration. Toxic-anatomopathology. Reproductive toxicology: infertility, teratogenicity (embryotoxicity). Genotoxicity Carcinogenesis Phototoxicity Immunotoxicity Local tolerability Behavior tests

d) Ethics of animal research. Ethical committees BPLs: Good Laboratory Practices. Guidelines for pre-clinical research of Regulatory Agencies. Legislation. Preclinical information for registration. Study of patent situation.

e) Models, development strategies / techniques: empirical, mechanistic. Theory of statistical moments. Convolution / deconvolution: theory and applications. Non-linear adjustment. Population approximation. Sensitivity analysis and biases: strategies and applications.

## Methodology

The final grade is the arithmetic mean of the grades obtained in the subjects that compose it.

## Activities

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Classroom practices (PAUL)	11	0.44	1, 2, 3, 5, 4, 6, 7
Clinical case seminars (SCC)	4	0.16	1, 2, 3, 5, 4, 6, 7
Master Class (TE)	50	2	1, 2, 3, 5, 4, 6, 7
Practical Experimental Laboratory (PLAB)	3	0.12	1, 2, 3, 5, 4, 6, 7
Type: Supervised			
Review of papers	24	0.96	1, 2, 3, 5, 4, 6, 7
Unscheduled tutorials	3	0.12	1, 2, 3, 5, 4, 6, 7
Type: Autonomous			
Study, written works ...	127	5.08	1, 2, 3, 5, 4, 6, 7

## Assessment

The final grade is the arithmetic mean of the grades obtained in the subjects that compose it.

## Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
Attendance and participation	10 %	0	0	1, 2, 3, 5, 4, 6, 7
Oral presentations	42,5 %	2	0.08	1, 2, 3, 5, 4, 6, 7
Short questions exam	47,5 %	1	0.04	1, 2, 3, 5, 4, 6, 7

## Bibliography

Updated bibliography will be provided for each subject.

General bibliography:

- T.P. Kenakin. Pharmacology in drug discovery. Ed. Elsevier, 2012
- Guia de desarrollos preclínicos. Genoma España. 10 aniversario (2002-2012)
- <http://www.agenciasinc.es/Noticias/Genoma-Espana-publica-una-guia-de-desarrollos-preclinicos>
- Doménech J, Martínez J, Plá JM. Biofarmacia y Farmacocinética Volumen I: Farmacocinética. 1ª Edición. Madrid: Editorial Síntesis, 1997
- Weisman RS, Smith C, Goldfrank LR. Toxicokinetics. Applying pharmacokinetic principles to the poisoned patient. In: Hoffman RS, Goldfrank LR eds. Contemporary management in critical care. Critical Care Toxicology. New York: Churchill Livingstone, 1991 (vol1; no 3): 21-42.
- Young-Jin S, Shannon M. Pharmacokinetics of Drugs in Overdose. Clinical Pharmacokinetics 1992; 23 (2): 93-105.
- Goodman & Gilman: Las Bases Farmacológicas de la Terapéutica Autor/es :Laurence L. Brunton, John S. Lazo, Keith L. Parker, 2008, 11va edición
- Gary C. Rosenfeld, David S. Loose, Pharmacology, 4th Ed. Lippincott Williams & Wilkins
- Weisman RS, Smith C, Goldfrank LR. Toxicokinetics. Applying pharmacokinetic principles to the poisoned patient. Contemporary management in critical care. 2000.
- Fernández, Velázquez Farmacología básica y clínica, 2008 , 18ª Ed.