# COURSE DATA

## DATA SUBJECT

**Code:** 34081
**Name:** Biopharmacy and Pharmacokinetics
**Cycle:** Undergraduate Studies
**ECTS Credits:** 10.5
**Academic year:** 2025-26

## STUDY (S)

| Degree | Center | Acad. year | Period |
|---|---|---|---|
| 1201 - Degree in Pharmacy | Facultat de Farmàcia i Ciències de l'alimentació | 3 | Annual |
| 1211 - Double Degree in Pharmacy and Human Nutrition and Dietetics | Facultat de Farmàcia i Ciències de l'alimentació | 3 | Annual |

## SUBJECT-MATTER

| Degree | Subject-matter | Character |
|---|---|---|
| 1201 - Degree in Pharmacy | Biopharmaceutics and pharmacokinetics | COMPULSORY |
| 1211 - Double Degree in Pharmacy and Human Nutrition and Dietetics | Asignaturas obligatorias del PDG Farmacia-Nutrición Humana y Dietética | COMPULSORY |

## COORDINATION

PERIS RIBERA JOSE ESTEBAN

# SUMMARY

Pharmacokinetics deals with the changes of drug concentration in the drug product and changes of concentration of a drug and/or its metabolite (s) in the human or animal body following administration, i.e. the changes of drug concentration in the different body fluids and tissues in the dynamic system of liberation, absorption, distribution, body storage, binding, metabolism, and excretion. It is interrelated with biopharmaceutics, pharmacology and therapeutics

Biopharmaceutics deals with the physical and chemical properties of the drug substance, the dosage form, and the body and the biological effectiveness, of a drug and/or drug product upon administration, i.e., the drug availability to the human or animal body from a given dosage form, considered as a drug delivery system. The time course of the drug in the body and the quantification of the drug concentration pattern are explained by pharmacokinetics.

The application of pharmacokinetics focuses on two areas: the development of new drugs and the optimization of dosing regimens of drug treatments, both objectives are complemented by Pharmaceutical Technology and Clinical Pharmacy, respectively.

# PREVIOUS KNOWLEDGE

### RELATIONSHIP TO OTHER SUBJECTS OF THE SAME DEGREE

There are no specified enrollment restrictions with other subjects of the curriculum.

### OTHER REQUIREMENTS

Knowledge of mathematics, statistics, physical chemistry, physiology and anatomy is recommended.

## COMPETENCES / LEARNING OUTCOMES

### 1201 - Degree in Pharmacy

Act with autonomy in learning, making informed decisions in different contexts, issuing judgements based on experimentation and analysis, and transferring knowledge to new situations.

Apply such knowledge to the professional world, contributing to the development of human rights, democratic principles, principles of equality between women and men, solidarity, environmental protection and promotion of a culture of peace with a gender pe

Collaborate effectively in work teams, assuming responsibilities and leadership roles and contributing to collective improvement and development.

Contribute to the design, development and implementation of solutions that respond to social demands, taking into account the Sustainable Development Goals as a reference.

Demonstrate critical and self-critical thinking in the field of the degree programme, considering aspects such as professional ethics, moral values and the social implications of the different activities carried out.

Develop skills to update knowledge and undertake further studies, including pharmaceutical specialisation, scientific research, technological development and teaching.

Gather and transmit information in English at a level of proficiency equivalent to B1 of the Council of Europe.

Intervene in health promotion and disease prevention activities in the individual, family and community spheres, with a comprehensive and multiprofessional vision of the health-disease process.

Know and understand, within the field of the degree programme, gender inequalities in society; integrate different needs and preferences based on sex and gender into the design of solutions and problem solving.

Know how to communicate effectively, both orally and in writing, adapting to the characteristics of the situation and the audience.

Know how to identify the factors that influence the absorption and distribution of drugs depending on their route of administration.

Know how to interpret, evaluate and communicate relevant data in the different areas of pharmaceutical activity, using information and communication technologies.

Know the biopharmaceutical properties of active principles and excipients, as well as possible interactions

between them.

Module: Pharmacy and Pharmaceutical Technology. Determine bioavailability, evaluate bioequivalence and assess the factors conditioning them.

Module: Pharmacy and Pharmaceutical Technology. Plan and adjust the dosage of medicines based on their pharmacokinetic parameters.

Module: Pharmacy and Pharmaceutical Technology. Understand the processes of release, absorption, distribution, metabolism and excretion of medicines, and factors conditioning absorption and disposition depending on their routes of administration.

Possess and understand knowledge in the different areas of study included in pharmacist training.

Propose creative and innovative solutions to complex situations or problems within the field of knowledge, to respond to diverse professional and social needs.

Transmit ideas, analyse problems and solve them with critical spirit, acquiring teamwork skills and assuming leadership when appropriate.

## DESCRIPTION OF CONTENTS

**1. Introduction**

Biopharmaceutics and pharmacokinetics. Concept, objectives and scope of the discipline. Transit of drug in the body: Liberation, Absorption, Distribution, Metabolism, Excretion and Response (LADMER). Equivalence of drugs. Equivalents chemical, biological and therapeutic. Bioavailability. One order, zero-order and mixed order kinetics. Usual kinetics of ADMER processes. Linear kinetics. Limiting factors. Data for the study of LADMER. Compartmental analysis and simplifications.

**2. Linear pharmacokinetics. One compartment open model**

**Intravenous administration.**

Pharmacokinetic parameters: elimination rate constant, half-life and volume of distribution. Clearance. Extraction rate. Equivalences between pharmacokinetic parameters. Plasma concentration-time profiles: intravenous bolus administration and intravenous infusion.

**Extravascular administration.**

Pharmacokinetic parameters: absorption rate constant, absorption half-life, Cmax, tmax, lag time and bioavailability in magnitude. Plasma concentration-time profiles: single dose and multiple dosage regimens. Determination of absorption rate constants from oral absorption data. Method of residuals. Cumulative absorption method or Wagner-Nelson method. Influence of the route of drug administration and dosage form on plasma concentration-time profiles.

**3. Linear pharmacokinetics: Two compartment open model**

**Intravenous administration.**

General equation of the plasma concentration-time curve. Pharmacokinetic parameters. First order transfer rate constants from central to peripheral, and from peripheral to central compartment. Apparent volumes of distribution: concept and calculation. Drug clearance: equivalence with pharmacokinetic parameters.

**Extravascular administration.**

Bateman function. Determination of absorption rate constants from oral absorption data. Method of residuals. Cumulative absorption method or Loo-Riegelman method. Collapse of the plasma concentration

time curve.

**4. Non-linear pharmacokinetics**

Concept and causes of non-linear pharmacokinetics. Detection methods. Non-linear elimination processes. Pharmacokinetic parameters. One compartmen non-linear model: general equation of the plasma concentration-time profile after intravenous and extravascular administration. Non-linear two-compartment model: simplifications. Relationship between pharmacokinetic parameters and dose. Pharmacokinetics of the metabolite. Metabolite plasma concentration-time profile. Linear and Nonlinear kinetics.

**5. Pharmacokinetics /pharmacodynamic models**

Response models. Direct response. Indirect response. Empirical pharmacodynamic models. Mathematical modelling of dose-effect-time data. Linear model, log-linear model, maximum effect. Pharmacokinetic-pharmacodynamic modeling (PK/PD). Link models. Direct link. Indirect link: the effect-compartmental model.

**6. Dosage regimen design**

Dosage regimens schedules: basic parameters. One compartment model: repetitive intravenous injections, intermittent intravenous infusion and multiple-oral dose regimen. Plasma drug concentration-time curves. Steady-state: maximum and minimum plasma drug concentrations at steady state. Two compartmental model: repetitive intravenous injections. Plasma drug concentration-time curves.

Individualization of drug dosage regimens. Dose determination. Effect of changing dose and dosing interval on minimum and maximum concentrations at steady-state. Determination of frequency of drug administration. Determination of both dose and dosage interval.

Therapeutic drug monitoring. Nomograms and tabulations in designing dosage regimens. Population Pharmacokinetics: Bayesian approach. Dosing of drugs in specific population groups of patients: infants, pregnant women, the elderly, the obese, and patients with renal impairment and hepatic disease.

**7. Non-compartmental pharmacokinetics**

Concept. Statistical moment theory. Mean residence time (MRT). Area under the curve plasma concentration-time. Volume of distribution. Clearance. Relationships with compartmental pharmacokinetic parameters.

**8. Bioavailability and bioequivalence**

Definitions. Purpose of bioavailability studies. Relative and absolute availability. Methods for assessing bioavailability. Clinical significance of bioavailability studies.

Bioequivalence studies. Design and evaluation of bioequivalence studies. Data assessment. Bioequivalence study submission and drug review process. Clinical significance of bioequivalence studies. Generic substitution.

**9. Biopharmaceutical factors of ADME processes**

Absorption of drugs. Routes of administration. Circulation and recirculation of drugs in the body, sites of loss. Absorption mechanisms. Passive absorption. Convective transport. Active transport. Facilitated transport. Other absorption mechanisms. Distribution of drugs. Binding of drugs to plasma proteins. Calculation of protein binding.

Pharmacokinetic importance of protein binding. Disease and protein binding. Displacement from protein binding. Uptake of drugs by red blood cells.

Drug biotransformation. Liver Physiology. Biotransformation reactions. Intrinsic clearance. Factors able to influence drug metabolism. Sources of variability in drug biotransformation activity. Drug interactions. Pharmacokinetic and clinical implications.

Renal excretion of drugs. Renal excretion mechanisms. Renal clearance: determination. Factors influencing renal clearance. Glomerular filtration of drugs. Passive diffusion. Renal excretion. Other excretion routes: biliary, salivary, exhaled air, sweat and mamary.

**10. Routes of drug administration**

Parenteral administration. Injection sites. Absorption sites: physiological features. Parenteral absorption kinetics from aqueous solutions. Factors influencing parenteral bioavailability.

Oral administration. Gastrointestinal physiology. Places of oral drug absorption. Factors influencing drug

absorption. General recommendations for oral drug administration. Biopharmaceutical Classification System.
Other administration routes. Rectal, vaginal, perlingual, buccal, sublingual, nasal, otic and ocular.
Transdermal administration. Routes of exposure: their importance compared. Percutaneous absorption kinetics. Factors influencing the permeability through the skin: biological, physicochemical and dependent on the vehicle. Percutaneous formulations and discussion.

# WORKLOAD

## PRESENCIAL ACTIVITIES

| Activity | Hours |
|---|---|
| Tutorials | 5,00 |
| Theory | 66,00 |
| Seminar | 10,00 |
| Laboratory | 16,00 |
| Computer classroom practice | 8,00 |
| **Total hours** | **105,00** |

## NON PRESENCIAL ACTIVITIES

| Activity | Hours |
|---|---|
| Attendance at other activities | 0,00 |
| Individual or group project | 10,00 |
| Independent study and work | 80,00 |
| Preparation of lessons | 30,00 |
| Preparation for assessment activities | 20,00 |
| Resolution of case studies | 17,50 |
| **Total hours** | **157,50** |

# TEACHING METHODOLOGY

1. Lectures.
2. Problem solving: Discussion and problem solving exercises in pharmacokinetics.
3. Laboratory practice.
4. Computer practice.
5. Tutorials

# EVALUATION

| | Evaluation system | Evaluation criteria | % calification |
|---|---|---|---|
| Theory evaluation | Written exam: Short questions and multiple choice questions related with the contents of the | -Precise answers<br>-Clear concepts<br>-Consistent reasoning<br>-Correct presentation | 80 |

| | | | |
|---|---|---|---|
| | lectures and problem solving classes | | |
| Problem evaluation | Written exam: problem solving related with the contents of the lectures and problem solving classes | -Clear concepts<br>-Consistent reasoning<br>-Correct presentation | 10 |
| Laboratory and computer practice evaluation | Written exam: short questions and problem solving<br>Control of attendance | -Teamwork and participative attitude<br>-Skills in laboratory work<br>-Work with order and cleanliness<br>-Proper disposal of waste-<br>-Successful completion of practice<br>-Reflective attitude concerning the results<br>-Order and clarity in the resolution of the practice<br>-Mandatory attendance of all sessions | 8 laboratory<br>2 computer |
| Each item requires a mark of at least 50% | | | |

When a student does not take the theory exam at the first regular call for the academic year but has been evaluated in any of the rest educational activities (problems, laboratory practice, informatics practices, tutorials) the qualification report will say "No presented". However, if at the second call, the student does not attend the theory exam, the qualification report will say "Fail", and the mark will be calculated according to the percentages allocated to each of the activities carried out. In summary: the second not attended call will qualify only students who had not attended any of the activities making up the subject.

Evidence of copying or plagiarism in any of the assessable tasks will result in failure to pass the subject and in appropriate disciplinary action being taken. Please note that, in accordance with article 13. d) of the Statute of the University Student (RD 1791/2010, of 30 December), it is the duty of students to refrain from using or participating in dishonest means in assessment tests, assignments or university official documents.

In the event of fraudulent practices, the "**Action Protocol for fraudulent practices at the University of Valencia"** will be applied (ACGUV 123/2020): https://www.uv.es/sgeneral/Protocols/C83sp.pdf

## REFERENCES

Aguilar A, Montejo M, Martin F, Caamaño M
Biofarmacia y Farmacocinética. Ejercicios y Problemas Resueltos, 3ª Edición
Elsevier, 2025

Amidon G, Bermejo M
Biofarmacia Moderna versión 6.
TSRLinc. 2003

http://www. tsrlinc.com/mbindex.htm
Doménech, J., Martínez Lanao, J., Plá Delfina, JM
Biofarmacia y Farmacocinética. Volumen I: Farmacocinética
Editorial Síntesis. 1997

Doménech, J., Martínez Lanao, J., Plá Delfina, JM
Biofarmacia y Farmacocinética. Volumen II: Biofarmacia.
Editorial Síntesis. 1998

Doménech-Berrozpe J, Martínez-Lanao JM, Peraire Guitard C
Tratado general de Biofarmacia y Farmacocinética. Volumen I. LADME. Análisis farmacocinético. Biodisponibilidad y bioequivalencia.
Editorial Síntesis, 2013
Doménech-Berrozpe J, Martínez-Lanao JM, Peraire Guitard C
Tratado general de Biofarmacia y Farmacocinética. Volumen II. Vías de administración de fármacos: aspectos biofarmacéuticos. Farmacocinética no lineal y clínica.
Editorial Síntesis, 2013

Gibaldi, M
Biopharmaceutics and Clinical Pharmacokinetics.
Lea and Febiger. Filadelfia, 1991
Hedaya, MA
Basic Pharmacokinetics
CRC Press. 2007
Jambhekar SS, Breen PJ
Basic Pharmacokinetics, 2nd Edition
Pharmaceutical Press, 2012
Jiménez, NV, Casabó, VG, Sancho, V
Manual de procedimientos para la farmacocinética clínica.
Edita Afaphe, 1997
Ritschel WA, Kearns GL
Handbook of basic pharmacokinetics.
American Pharmacist Association, 2004
Shargel L, Yu ABC
Applied biopharmaceutics and pharmacokinetics, 7th edition
McGraw-Hill Education, 2016