Teaching guide

IDENTIFICATION DETAILS

Degree:	Pharmacy
Scope	Pharmacy
Faculty/School:	Experimental Sciences
Course:	BIOPHARMACY AND PHARMACOKINETICS
Type:	Compulsory
ECTS credits:	6
Year:	4
Code:	2538
Teaching period:	Seventh semester
Subject:	Biopharmacy and Pharmacokinetics
Module:	Pharmacy and Technology
Teaching type:	Classroom-based
Language:	Spanish
Total number of student study hours:	150

SUBJECT DESCRIPTION

Biopharmacy is the branch of pharmaceutical sciences that studies the relationship between the physico-chemical properties of the drug, its dosage form and the therapeutic effect obtained after its administration. This course will study the different phases that occur from the administration of a drug to its place of action, which will be characterized quantitatively in relation to the passage of time by Pharmacokinetics.

GOAL

Establish the processes that the drug undergoes in the body after its administration and the parameters that characterize them to analyze the appropriateness of the route of administration and the established dosage regimen, taking into account the characteristics of the patient for whom the treatment is designed.

PRIOR KNOWLEDGE

- Mathematics and basic descriptive statistics.
- Chemical kinetics.
- Concepts of Physiology and Pathophysiology to understand the processes that the drug undergoes in the body.
- Excel management

COURSE SYLLABUS

THEORETICAL PROGRAM

TOPIC 1: Introduction to Biopharmacy and Pharmacokinetics.

BLOCK I: LADME SERIES STUDY

TOPIC 2: Drug release. Involved processes and dissolution kinetics. Release studies.
TOPIC 3: Drug absorption (I) Absorption mechanisms and parameters. Biopharmaceutical classification of drugs.
TOPIC 4: Drug absorption (II) Routes of drug administration.
TOPIC 5: Drug distribution. Volume of distribution and binding to plasma proteins.
TOPIC 6: Drug Elimination: (I) Metabolism. Liver clearance. (II) Excretion. Renal clearance.

BLOCK II: PHARMACOKINETICS

TOPIC 7: Pharmacokinetic models. Compartmental analysis.
TOPIC 8: Monocompartment model (I) I.V. administration in bolus. (II) IV infusion administration (III) Extravasal administration.
TOPIC 9: Two-compartment model. (I) I.V. administration in bolus. (II) IV infusion administration (III) Extravasal administration.
TOPIC 10: Kinetics of renal excretion. Distributive and cumulative curves.
TOPIC 11: Multiple-dose kinetics in a monocompartment i.v bolus model. Dosage guidelines and schedules.
TOPIC 12: Non-compartment pharmacokinetics.
TOPIC 13: Nonlinear Pharmacokinetics. Dose-dependent pharmacokinetics. Time-dependent pharmacokinetics.
TOPIC 14: Population Pharmacokinetics. Clinical applications.
TOPIC 15: Physiological and pathological situations that require the adjustment of dosage guidelines. Drug monitoring.
TOPIC 16: Bioavailability and bioequivalence.

PRACTICAL PROGRAM

A dissolution test of a pharmaceutical form and the characterization of its release kinetics will be carried out. Using computer tools, the analysis of the data collected in the laboratory and the simulation of practical cases will be carried out on physiological and pathological situations where it is necessary to readjust dosage regimens.

EDUCATION ACTIVITIES

THEORY CLASSES (AFP1): theoretical content will be taught and will be complemented by interactive audiovisual material and documentation provided through the virtual classroom of the subject.
PRACTICAL CLASSES (AFP2): laboratory sessions and computer room. An internship script will be provided.
EXERCISE AND PROBLEM CLASSES (AFP3): explanation of the methodology for solving exercises and the student will be guided in preparing the work required by the teacher.
SEMINARS AND/OR WORK EXHIBITION (AFP4): Complementary exercises and problems will be proposed through the virtual classroom. In addition, a group work will be proposed that must be defended for subsequent evaluation.
TUTORING (AFP5): individual and/or group to monitor the evolution of learning and guide students throughout the development of the subject. The Virtual Classroom platform will be very useful for the study of the subject and for effective communication between student-teacher and student-student. In the Virtual Classroom, students will have basic information and material and support for classes to promote the study of the subject. It will also allow the submission of scheduled exercises and activities, solved individually and/or in groups.
TAKING EXAMS (AFP6): Students will take exams both on the theoretical content and on the content taught in laboratory practices.

DISTRIBUTION OF WORK TIME

TEACHER-LED TRAINING ACTIVITIES	INDIVIDUAL WORK
66 Horas	84 Horas

LEARNING RESULTS

Schedule and correct the dosage of medications based on their pharmacokinetic parameters.

Know the processes of release, absorption, distribution, metabolism and excretion of drugs, and factors that condition absorption and disposal depending on their routes of administration.

SPECIFIC LEARNING RESULTS

Describe the evolution and elimination of the drug in the body by calculating pharmacokinetic parameters.

Interpret the terms of bioavailability and bioequivalence of drugs.

Explain the variation in bioavailability depending on the route of administration, dosage form, and production process, as well as the influence of inter- to intra-individual factors.

Identify the factors that influence the bioequivalence of drugs.

Argue the need for dosage adjustment in physiological and pathological situations.

Select the most appropriate route of administration of drugs in each case based on its clinical implications.

LEARNING APPRAISAL SYSTEM

The CONTINUOUS EVALUATION system will take into consideration:

SE1 Written or oral, developmental, short answer or test-type tests: 50%
SE2 Daily activities and exercises: 10%
SE3 Individual and group work: 23%
SE4 Attendance and participation in face-to-face classroom activities: 2%
SE8 Attendance and participation in face-to-face activities in the laboratory: 15%

- WRITTEN DEVELOPMENT TEST, SHORT ANSWER OR TEST TYPE: It is an essential requirement to pass the course to obtain a minimum score of 5.0 in this evaluation section.
- DAILY ACTIVITIES AND EXERCISES: activities and exercises will be carried out in the classroom or autonomously that will complement the contents of the exhibition sessions.
- INDIVIDUAL AND GROUP WORKS: exercises and works will be carried out that will complement the contents of the exhibition sessions.
- ATTENDANCE AND PARTICIPATION IN FACE-TO-FACE ACTIVITIES IN THE CLASSROOM: attendance checks will be carried out. Proof of non-attendance will not be accepted except in very exceptional cases.
- ATTENDANCE AND PARTICIPATION IN FACE-TO-FACE ACTIVITIES IN THE LABORATORY: It is an essential requirement to pass the course to obtain a minimum score of 5.0 in this evaluation section. Attendance at all practical sessions (regardless of where they take place: laboratory, computer rooms, etc.) is mandatory. The unjustified absence of any of these sessions leads to the loss of the right to an internship evaluation in the ordinary call and a suspension of the course. Students in this situation should immediately contact the teacher.

ALTERNATIVE EVALUATION SYSTEM FOR 2ND OR SUBSEQUENT ENROLLMENT STUDENTS will take into consideration:
- SE1 Written or oral, developmental, short answer or test-type tests: 50%
- SE2 Daily activities and exercises: 5%
- SE3 Individual and group work: 23%
- SE4 Attendance at two mandatory follow-up tutorials with the teacher: 7%
- SE8 Attendance and participation in face-to-face activities in the laboratory: 15%

Students in second or subsequent enrollment must contact the teacher to request to take advantage of this system.
Passing the subject: to consider the theory (theory exam) and practice (laboratory practice exam) parts for the calculation of the final grade, each of them must be approved. The course is approved with a grade equal to or greater than 5.0. If the theory part is passed but not the practical part, the score of the theoretical exam will be kept

until the extraordinary call. The same will happen if the practical part is approved but not the theoretical part. The grades obtained from the submissions of papers, attendance and face-to-face activities in the classroom will also be kept in the extraordinary call.

*Plagiarism, as well as the use of illegitimate means in evaluation tests, will be sanctioned in accordance with those established in the Evaluation Regulations and the University's Coexistence Regulations."

ETHICAL AND RESPONSIBLE USE OF ARTIFICIAL INTELLIGENCE

1.- The use of any Artificial Intelligence (AI) system or service shall be determined by the lecturer, and may only be used in the manner and under the conditions indicated by them. In all cases, its use must comply with the following principles:
a) The use of AI systems or services must be accompanied by critical reflection on the part of the student regarding their impact and/or limitations in the development of the assigned task or project.
b) The selection of AI systems or services must be justified, explaining their advantages over other tools or methods of obtaining information. The chosen model and the version of AI used must be described in as much detail as possible.
c) The student must appropriately cite the use of AI systems or services, specifying the parts of the work where they were used and describing the creative process followed. The use of citation formats and usage examples may be consulted on the Library website(https://www.ufv.es/gestion-de-la-informacion_biblioteca/).
d) The results obtained through AI systems or services must always be verified. As the author, the student is responsible for their work and for the legitimacy of the sources used.
2.- In all cases, the use of AI systems or services must always respect the principles of responsible and ethical use upheld by the university, as outlined in the Guide for the Responsible Use of Artificial Intelligence in Studies at UFV. Additionally, the lecturer may request other types of individual commitments from the student when deemed necessary.
3.- Without prejudice to the above, in cases of doubt regarding the ethical and responsible use of any AI system or service, the lecturer may require an oral presentation of any assignment or partial submission. This oral evaluation shall take precedence over any other form of assessment outlined in the Teaching Guide. In this oral defense, the student must demonstrate knowledge of the subject, justify their decisions, and explain the development of their work.

BIBLIOGRAPHY AND OTHER RESOURCES

Basic

Camaño Somoza, Manuel. Biopharmacy and Pharmacokinetics: Exercises and Problems Solved/2nd ed. Madrid:Elsevier, 2014.

José Doménech Berrozpe, José Martínez Lanao, Concepción Peraire Guitart (eds.). Biopharmacy and Pharmacokinetics Treaty/Madrid: Synthesis, 2013.