

CLINICAL PHARMACOKINETICS OF ANTINEOPLASTIC DRUGS

1.- General information

Code	303008	Plan		ECTS	3
Type	Elective	Course	2025/2026	Periodicity	1 st Semester
Language	English				
Department	Pharmaceutical Sciences				
Virtual Platform	https://studium.usal.es/				

1.1.- Faculty

Professor Coordinator	Dra. Amparo Sánchez Navarro				
Department	Pharmaceutical Sciences				
Research area	Pharmacy and Pharmaceutical Technology				
Center	Faculty of Pharmacy				
Tutorials	Appointment by email				
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Professor	Dra. Marina Holgado Madruga				
Department	Physiology and Pharmacology				
Research area	Pharmacology				
Center	Faculty of Medicine				
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Tutorials	Appointment by email				
E-mail	mholgado@usal.es	Phone	923294500 Ext.:1488		

Professor	Dra. Maria José García Sánchez				
Department	Pharmaceutical Sciences				
Research area	Pharmacy and Pharmaceutical Technology				
Center	Faculty of Pharmacy				
URL Web	https://produccioncientifica.usal.es/investigadores/56899/detalle				
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BIOLOGY AND CLINICAL CÁNCER MÁSTER DEGREE

Professor	José Germán Sánchez Hernández		
Department	Pharmacy at the University Hospital of Salamanca		
Research area	Pharmacy and Pharmaceutical Technology		
Center	University Hospital of Salamanca		
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Professor	Hinojal Zazo Gómez		
Department	Pharmaceutical Sciences		
Research area	Pharmacy and Pharmaceutical Technology		
Center	Faculty of Pharmacy		
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2.- Previous recommendations

A degree on life sciences topics.

3.- Aims of the subject

To provide theoretical and practical knowledge about antineoplastic drugs oriented to the study of its pharmacokinetics (PK) and the main factors responsible for PK variability.

To acquire the ability to apply “in silico” and TDM tools to incorporate PK variability for precision dosage in the clinical practice.

Specific aims:

- To know the mechanism of action of the main antineoplastic drugs used in the clinical practice
- To understand the population pharmacokinetic (PopPK) modeling and simulation methodology and the factors with a relevant impact on patient exposure to drug (demographics, physiopathological, genetics, etc.)
- To study the concepts and tools regarding TDM of antineoplastic drugs in the clinical routine
- To learn about physiological based pharmacokinetic (PBPK) modeling and simulations approach and its application to in silico clinical trials
- To achieve a holistic knowledge on the operation in a hospital pharmacy service for development, validation and follow-up of oncological therapies.

4.- Skills to be acquired / Learning outcomes
Skills
4.1: Basic skills: <ul style="list-style-type: none"> • Understanding the usefulness of clinical PK to evaluate factors with a significant impact on the response to pharmacological treatments • Application of dosage individualization PK tools in the oncological patient • Ability to use the PopPK models to improve the efficacy and safety of treatments with antineoplastic drugs • Application of PBPK models for “first-in-human” dose estimation and dosage individualization in oncologic patients • Pharmacy validation and follow-up of oncological therapies in a University Hospital
4.2: Specific skills: <ul style="list-style-type: none"> • Interpretation and aplicación of TDM results to optimize and individualize pharmacological treatments with antineoplastic drugs • Using pharmacokinetic information to select the dosage regimen with the optimal benefit/risk ratio for antineoplastic drugs • Ability to perform clinical trials in virtual populations • Understanding the application of PK models for dosage optimization • Understanding the multidisciplinary of the clinical team involved in the validation and follow-up of onco-hematologic therapies
4.3: Transferable skills:

5.- Contents (Syllabus)
TOPICS (LECTURES): <ol style="list-style-type: none"> 1. Mechanism of action of the main anticancer drugs used in the clinical practice 2. Clinical pharmacokinetics: basic concepts and application to antineoplastic drugs 3. Population pharmacokinetics (PopPK) 4. Physiological Based Pharmacokinetics (PBPK) 5. Model-informed precision dosing and follow-up criteria in oncologic treatments
SEMINARS and HANDS-ON: <ol style="list-style-type: none"> 1. Data handling and Bayesian estimation 2. Implementation of population pharmacokinetic models 3. Parameters estimation of antineoplastic drugs: case reports 4. Application of PBPK models to oncology patients 5. In silico clinical trials 6. Development and validation of the oncology therapy in a hospital pharmacy service

6.- Teaching methodology
<ul style="list-style-type: none"> • Introductory activity • Lectures • Seminars

- Hands-on
- Case reports discussions
- Focused activities: presentation, analysis and proposals related to scientific papers

6.1.- Estimated learning time					
		Hours tutored by the teacher		Individual work (hours)	TOTAL HOURS
		Attendance required (hours)	Distance learning (hours)		
Lectures		11	8	10	29
Practices	- In classroom				
	- In laboratory				
	- In computer classroom	6			6
	- Countryside				
	- Others (specify)				
Seminars		4		2	6
Work presentations and debates		7		8	15
Tutorials		2		2	4
Online activities					
Work preparation			5	7	12
Other activities					
Exams - evaluation		3			3
TOTAL		33	13	29	75

7.- Materials, other bibliographical, electronic references or any other type of resource
<p>Individualizing Dosage Regimens of Antineoplastic Agents. In Individualized Drug Therapy for Patients: Basic foundations, Relevant software and clinical applications. Ed. Jelliffe R and Neely M. Elsevier. 281-306, 2017.</p> <p>A First Course in Pharmacokinetics and Biopharmaceutics by David Bourne: http://www.boomer.org/c/p4/</p> <ul style="list-style-type: none"> • Therapeutic Drug Monitoring • Clinical Pharmacokinetics • British Journal of Clinical Pharmacology

8.- Assessment
<p>8.1: Assessment Criteria:</p> <ul style="list-style-type: none"> • Continuous follow-up of the knowledge, skills and abilities acquired by the students. • Student participation will be highly appreciated and positively taking into account. • Attendance and active participation in lectures and seminars (hands-on). • Comments and proposals to the case-studies. • Scientific accuracy of the commentaries and answers to the questions. • Presentation and debate of a scientific paper. <p>8.2: Assessment Systems:</p> <p>8.3: General Considerations and Recommendations for Assessment and Resit:</p> <ul style="list-style-type: none"> • Active participation in the proposed activities • Debate about the multidisciplinary of the oncological treatments.

9.- Weekly Teaching Schedule