COURSE DATA

Data Subject	
Code	34083
Name	Toxicology
Cycle	Grade
ECTS Credits	9.0
Academic year	2021 - 2022

Study (s)

Degree	Center	Acad. year	Period
1201 - Degree in Pharmacy	Faculty of Pharmacy and Food Sciences	4	Annual

Subject-matter

Degree	Subject-matter	Character
1201 - Degree in Pharmacy	23 - Toxicology	Obligatory

Coordination

Name	Department
RUIZ LEAL, MARIA JOSE	265 - Prev. Medicine, Public Health, Food Sc.,Toxic. and For. Med.

SUMMARY

Toxicology course (34083) is an obligatory subject on the third year of the Degree of Pharmacy, which is taught in the Faculty of Pharmacy, University of Valencia. This course has a total of 9 ECTS taught during a year. The main objective of this subject is to obtain a toxicological training that allows to interpret scientific data relative to drugs.

The knowledge will be provided to the students on basic toxicology, mechanisms of toxicity, evaluation of the toxicity, toxicity of drugs and sanitary products as potential agents with adverse effects when used in a correct therapeutic guideline or as responsible for acute intoxication. As well as the knowledge on the methodologies that allow to decrease toxic concentrations in biological samples, environmental foods and samples, to assure levels that provide a well-being to the population.

PREVIOUS KNOWLEDGE

Relationship to other subjects of the same degree

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

Other requirements

To study toxicology, the knowledge of a number of basic concepts of biology, physiology, chemistry and biochemistry are needed. These concepts are part of the contents of the subjects taught during the previous courses in the Graduate.

1201 - Degree in Pharmacy

- To possess and to understand the knowledge in the different areas of study included in the formation of the pharmacist.
- To know how interpret, value and communicate relevant data in the different aspects of pharmaceutical activity, making use of information and communication technologies.
- Skill to communicate ideas, analyze problems and solve them with a critical mind, achieving team-working abilities and assuming leadership whenever required.
- Development of skills to update their knowledge and undertake further studies, including pharmaceutical specialization, scientific research and technological development, and teaching.
- Know how to apply the scientific method and acquire skills in the management of legislation, information sources, bibliography, elaboration of protocols and other aspects that are considered necessary for the design and critical evaluation of preclinical and clinical trials.
- To promote the rational use of medicines and health products
- To develop communication and information skills, both oral and written, to deal with patients and other health professionals in the center where they carry out their professional activity. To promote the capacity of work and collaboration in multidisciplinary teams and those related to other health professionals.
- To recognize personal limitations and the need to keep up to date professional competence, paying particular attention to the self-learning of new knowledge based on available scientific evidences.
- To develop in students an understanding of the risks associated with the use of chemical substances and laboratory procedures.
- Basic knowledge in clinical management, health economics and efficient use of health resources.
- Module: Medicine and Pharmacology - Promoting the rational use of drugs and medical devices.
- Module: Medicine and Pharmacology ? Assessing toxicological effects of substances applying relevant assays.

- Module: Medicine and Pharmacology - Knowing the analytical techniques related to laboratory, toxic, food and environmental diagnosis.
- Assessing the therapeutic and toxic effects of substances with pharmacological activity
- Knowledge of the basic concepts of Toxicology
- Knowledge of different toxicokinetic processes (absorption, distribution, metabolism and excretion) and ecotoxicokinetics
- Knowledge of nature, mechanisms of action and effect of toxics. Searching solutions in case of intoxication
- Drug safety considering their physical and chemical properties and potential risks associated with their use.
- Designing and assessing toxicological assays
- Carry out the activities of the clinical and social pharmacy. Pharmaceutical care in relation to the safety of drugs and medical devices
- Assessing toxic effects of substances with pharmacological activity: side effects of drugs. Acute and chronic intoxications.
- Knowledge of analytical techniques related to laboratory diagnosis in drug-induced intoxications
- Knowing and manage the basic information sources related to Toxicology

During this course, students should acquire the following abilities and skills:

• Knowledge on basic toxicology

• Ability to raise and solve basic toxicological problems, relating to chemical properties and structures of drugs and sanitarian products.

• Skill and ability to solve toxicological problems

• Knowledge of the toxicological aspects through the possibilities that Internet provides, and capacity of relation of the presence of drugs and sanitary products in the organism with the adverse effects that they can cause.

• Ability to perform experimental work and to encourage students to continue the scientific and research activity.

DESCRIPTION OF CONTENTS

1. Introduction to toxicology

Toxicology. Introduction. Historic evolution of toxicology. Related sciences. Related disciplines of toxicology. References. Toxicological concepts. Types of intoxications. Dose-response and dose-effect relationships. Selectivity, sensibility and security margin.

2. Toxicokinetics

Phases of toxic action. Exposure phase. Pathways for xenobiotics. Transport mechanisms of toxins through biological membranes. Absorption. Distribution, fixation and excretion of toxins. Toxicokinetics. Compartmental models. Toxicokinetic parameters. Biotransformations of toxins. Phase 1 reaction: oxidation, reduction, hydrolysis and hydration. Reactions Phase 2: Sulfation, glucuronidation, acetylation, methylation, conjugation with glutathione and amino acids. Mechanisms of toxicity. Apoptosis and necrosis. Nonspecific toxicity. Reversible and irreversible specific toxicity. Immune reactions. Immune mechanisms. Types of allergies. Inhibition, activation and enzyme induction. Factors that modify toxicity. Factors that depend on the individual. Genetic factors. Environmental factors and social factors.

3. Assessment of Toxicology

Methods in toxicology testing. Alternative methods. In vitro test systems. Biological substrates and toxicity endpoints. Studies of general effects: acute toxicity and repeated doses toxicity. Tests of specific effects: Antagonism or synergism studies, and skin, eyes and behaviour tests. Carcinogenicity, mutagenicity, teratogenicity, Reproductive and Developmental Toxicity. Risk assessment and security estimation.

4. Side effects of drugs and other basic medicines classified by therapeutic groups

Adverse drug reactions. Criteria to determine an adverse reaction. Studies of pharmacovigilance. Methodology in pharmacotherapy follow-up. Introduction to the Dáder method. Classification of negative outcomes of the pharmacotherapy /drug treatment. Clinical case. Adverse drug reactions in the nervous system. Adverse drug reactions on the musculoskeletal system. Adverse drug reactions on the digestive system and metabolism. Adverse drug reactions that act on the cardiovascular system. Adverse drug reactions that act on the respiratory system. Adverse drug reactions of the anti-infective therapy of systemic use. Antineoplastic drug. Hormonal therapy. Drug interactions.

5. Side effects of drugs in organs and systems

Adverse drug reaction on the central and peripheral nervous system. Adverse drug reaction on arteries and pulmonary capillaries. Pulmonary veno-occlusive disorders. Bronchial tube and lower tract.
Adverse drug reaction on the cardiovascular system. Hypertension, peripheral vasoconstriction and low blood pressure. Adverse drug reaction on the digestive system. Adverse drug reaction and mechanisms of toxic action on the liver. Adverse drug reaction and mechanisms of toxic action on the kidney. Adverse

drug reaction on blood and hematopoietic organs. Anaemia, Neutropenia, agranulocytosis and thrombocytopenia. Secondary haematological tumours. Disorders of Haemostasis. Drug adverse reaction of the medicaments on the skin. Cutaneous elementary injuries. Adverse drug reaction on the endocrine system. Adverse reactions on the hypophysis, adrenal glands, thyroid and pancreas. Adverse drug reaction on the locomotor system. Adverse drug reaction on the sense organs. Toxic effects on the organs of the vision. Toxic effects on the organ of hearing and balance. Toxic effects on taste and smell organ.

6. Clinical toxicology

Epidemiology of acute intoxications. Antagonists and Antidotes. Assistance and treatment of acute intoxication. Acute drug intoxication. Acute intoxication of domestic use products: Caustics and Pesticides. Drug addiction.

7. Food and environmental toxicology

Occurrence of toxic chemicals in food and environment. Mechanisms of action of toxic chemicals, toxic effects to humans and development of preventive measures before any serious damage.

8. Analytical toxicology

Chemical - toxicological analysis. Sample collection and different toxicological analyses. Chain of custody. Immunochemical tests.

9. Laboratory

There will be 3,5 hours / session. Practices are of obligatory assistance. Practice manual is supplied directly in the laboratory. Students will handle in a report once realized the practices and they will have to overcome a written exam.

1. Pharmaceutical toxicology and databases
1.1. Security in the use of chemical products
1.2. Toxicological databases in Internet
2. Drug extraction from biological fluids
2.1. Identification of toxics
3. Determination of salicylic acid
4. Determination of alcohol in serum by gas chromatography (GC)
5. Determination of benzodiacepines in plasma by LC
6. Determination of trazodone in plasma by colorimetry
7. Determination of phenothiazines in urine by chromatography
8. Determination of theophylline in serum by LC.
9. Determination of paracetamol in plasma by LC.
10. Determination of atmospheric SO2
11.-Determination of fluorides in urine

WORKLOAD

ACTIVITY	Hours	% To be attended
Theory classes	49,00	100
Laboratory practices	28,00	100
Seminars	6,00	100
Tutorials	3,00	100
Development of group work	10,00	0
Development of individual work	10,00	0
Study and independent work	15,00	0
Readings supplementary material	10,00	0
Preparation of evaluation activities	15,00	0
Preparing lectures	55,00	0
Preparation of practical classes and problem	10,00	0
Resolution of case studies	10,00	0
TOTAL	**221,00**	

TEACHING METHODOLOGY

The development of the course is structured as follows:

Theoretical classes: 2 hours per week in which the teacher provides students with an overview of the topic, and the information necessary to understand the contents of the subject. The students are encouraged to search supplementary information. It is recommended to review the material before going to the classroom.

Specialized tutoring (sessions in group): Small groups of students are ideal for students to raise questions or issues that they arise throughout the development of the theoretical classes.

Laboratory classes: small groups of students work with the laboratory manual and resolve the problems that are raised. Class attendance is mandatory. Each student group shows their results and discusses their toxicological interpretation. Laboratory classes include toxicological information from internet and databases in Toxicology.

Seminars: a small working group is directed by a professor. The group works according to a basic guides and rules. The results are exposed and critical analysis should be made in class with all the students. The group is supervised by the professor periodicallya and guides them in the search of bibliographic sources and in their critical analysis.

Both in the theoretical and practical sessions, examples of the applications of the subject's content will be given in relation to the Sustainable Development Goals (SDG), as well as in the topics proposed for the expository seminars. The goal is to integrate the application of the SDGs into toxicology lessons to provide students with related knowledge and skills, as well as to promote reflection and criticism. Of the 17 SDG, special emphasis will be placed on the following toxicology-related goals: SDG 3, SDG 4, SDG 5, SDG 12, SDG 13 and SDG 17.

EVALUATION

In order to sit for the final written exam, it is mandatory to have completed the laboratory practices.

The **10**% of the grade will be obtained as a result of the preparation and presentation of **seminars and tutorials**. Mark of this section will be kept two consecutive years (for those students who do not pass the subject in the first enrollment). Lack of regular attendance to class or tutoring will be reflected negatively on the score for this section.

About **25**% of the grade corresponds to **laboratory practices** which attendance is mandatory. It includes the participation and preparation of laboratory practical classes, which are assessed by a written exam during the last day of the laboratory practices and will represent 5% of the mark, which will be kept two years (for those students who do not pass the subject in the first enrollment). The other 20% of the mark corresponds to questions and a practice case which will be evaluated on the written final exam.

To evaluate the **theoretical contents**, there will be a midterm exam, corresponding to the first part of the program, in which they could eliminate contents from 5 out of 10 and that represent **25%** of the final grade. The grade of the mild-term exam is kept for the examination of the second round (June-July). Students who have removed contents in the first midterm exam will be assessed only on the final exam of the second part of the theoretical contents, those who have failed the midterm exam go with all the theoretical contents to the final exam.

The other **40**% of the grade will be obtained from the results obtained in the exam corresponding to the **theoretical contents** of the second part of the program (second semester). To pass the theoretical contents you must have 4 out of 10.

It is mandatory to have passed the theoretical exam and have completed the laboratory practice to add seminars to the grade. To pass the subject, you must obtain a grade of 5 or higher in the final exam.

Those students who fail the course in the first call, they keep the grade of seminars for the second round (June-July).

The student who does not take the theoretical exam and has conducted seminars or practices during the academic year, in the first call will be considered "Not Submitted", and in the second call as "Not Sibmitted".

REFERENCES

Basic

- Ballantine B, Marss T, Syversen T. 2000. General and applied toxicology. McMillan Reference Ltd., London
- Bataller R. 2004. Toxicología Clínica, Servicio de Publicaciones Universidad de Valencia, Valencia
- Bello J, López de Cerain A. 2001. Fundamentos de Ciencia Toxicológica. Díaz de Santos, Madrid
- Flórez J. (editor). Farmacología humana 6ª ed. Elsevier Masson, 2013
- Krishnan K, Andersen ME. 2001. Principles and Methods of Toxicology. Taylor & Francis, 4ºed., London
- Klaassen CD, Watkins JB. 2005. Casarett y Doull. Fundamentos de Toxicología. Mc Graw-Hill Interamericana, Madrid
- El manual Merck de diagnóstico y tratamiento. 2007. Elsevier España, Madrid
- Niesink RJM, de Vries J, Hollinger MA. 1996. Toxicology. Principles and Applications. CRC Press, Boca Raton, Florida
- Rang & Dale. Farmacología.9ª ed. Elsevier, 2019
- Repetto Jiménez M, Repetto Kuhn G. 2009. Toxicología Fundamental. 4 ed. Díaz de Santos, Madrid
- Gil Hernández F, Pla Martínez A, Hernández Jerez A. 2019. Manual de toxicología. 2 ed. Editorial técnica Avicam
- Nogué Xarau, X. 2019. Toxicología clínica. Ed. Elsevier España, SLU
- Lee A. 2007. Reacciones adversas de los medicamentos. 1º edición. Pharma editores

Additional

- Agencia Española de Medicamentos y Productos Sanitarios, http://aemps.es/
- European Medicines Agency, www.ema.europa.eu/
- International Vademecum, www.vademecum.es/
- Catálogo de especialidades farmacéuticas. Consejo General de Colegios Oficiales de Farmacéuticos (Blot plus 2.0) 2013:, http://www.portalfarma.com/
- e-libros disponibles a través del Servicio de Biblioteca y Documentación de la Universidad de Valencia, http://trobes.uv.es/
- Asociación Española de Toxicología, http://www.aetox.es
- Portal de búsqueda de información toxicológica, http://busca-tox.com

- Revista de Toxicología, https://rev.aetox.es/wp/

ADDENDUM COVID-19

This addendum will only be activated if the health situation requires so and with the prior agreement of the Governing Council

1. General concepts

All the contents initially programmed in the teaching guide are maintained. Thus, 100% of the curriculum is covered, guaranteeing the achievement of the learning objectives. The student will organize his autonomous learning with the materials uploaded to the virtual classroom.

2. Volume of work and temporary planning of teaching

The teaching guide establishes 49 hours of theory classes in the classroom, 28 hours of practical classes in the laboratory, 6 hours of seminars and 3 hours of tutorials.

The weight of the different activities that add up to the hours of dedication in ECTS credits marked in the original teaching guide is maintained.

Teaching timetables are maintained, both in terms of days and hours for theory, seminars, tutorials and practices.

*The first **theory classes** of the course will take place in the classroom. The rest of the class schedules will be maintained by synchronous videoconferences or voice-over videos. The students will have to do autonomous work with the materials uploaded to the virtual classroom.*

*The **laboratory practices** will be carried out in a face-to-face way, respecting the capacity of the students in the laboratory. The computer practices will be done through synchronous videoconferences.*

*The **seminars** will be presented in class either in person or by synchronous video conference.*

*The system of virtual **tutorials** is maintained through e-mail (attention of the professor within 48 hours), for the resolution of specific doubts. Tutorials will take place in the classroom, as the small groups have the capacity allowed by the UV.*

3. Teaching methodology

***Theory**: The materials for these sessions will have been previously uploaded to the virtual classroom: the same materials provided in the original guide for face-to-face teaching but adapted by incorporating explanatory notes and locutions so that the student can access them at any time. Synchronous video conferences will be held to explain concepts that need to be clarified, using the virtual classroom forum to answer questions.*

For the continuous evaluation, the tool will be used in the virtual classroom and Kahoot questionnaires at established times.

***Seminars**: The seminars will be presented in class in a face-to-face manner or by synchronous video conference so that all the students on the course can access them.*

***Tutorials**: the virtual tutorial system is maintained via e-mail (attention of the teaching staff within 48 hours), for the resolution of specific doubts.*

Tutorials will take place in the classroom, as the small groups meet the capacity allowed by the UV.

***Practices**: there will be classroom practices respecting the capacity of the students in the laboratory. In order to carry out the practices, the materials for these sessions will be previously uploaded to the virtual classroom (practice booklet, presentations with explanations or locutions, links and videos explaining the techniques/methods used) adapted to the non-presential modality, as well as problems solved together with proposed problems that must be solved and handed in through the virtual classroom "task" option. The resolution of doubts will be carried out by means of synchronous videoconference.*

4. Evaluation

In order to pass the course, it is essential to attend the laboratory practices.

The percentage of each section in the evaluation is maintained: 65% of the theory mark (25% of the first partial mark and 40% of the second partial mark), 10% of the seminar mark, 25% of the practice mark.

*The **theory** mark and its percentage (65%) are maintained. In this section, continuous assessment activity is incorporated with a percentage of 10% that was not contemplated in the original guide. The weight of the theory exam is reduced from 65% to 55%.*

*The **seminar** mark and its percentage (10%) are maintained. To get the maximum from this section is a prerequisite for 100% attendance of the scheduled activity, which will be recorded in the classroom (face to face) or in the Blackboard Collaborate platform on the day of the activity through synchronous video conferencing.*

*The **laboratory practice** mark and its percentage (25%) are maintained. To get the maximum from this section is a prerequisite for 100% attendance of the scheduled activity which will be recorded in the classroom (face to face) or in the Blackboard Collaborate platform on the day of the synchronous video conference.*

If a person does not have the means to establish this connection and access the virtual classroom, they should contact the professor by e-mail at the time of publication of this annex to the teaching guide.

The exam will be held in person.

5. Bibliography

The recommended readings available in UV subscribed databases (requiring VPN in some cases) and those recommended by teachers are maintained.