

## STUDY PROGRAMME STRUCTURE

Study program Toxicological risk assessment represents specialized academic study that lasts for one year i.e. two semesters (60 ECTS). The proposed study program will allow students to master the knowledge and skills in the field of toxicological risk assessment better in order to work in the pharmaceutical and chemical industry, health and/or regulatory authorities. Upon completing the program, the student receives a specialist of pharmacy degree.

Right to enroll in specialized academic studies have the candidates who graduated from the Faculty of Pharmacy, or candidates who have completed the School of Medicine, Faculty of Dentistry, Faculty of Veterinary Medicine, Faculty of Biology, Faculty of Technology and Metallurgy, Faculty of Agriculture and Faculty of Chemistry.

The proposed study program consists of a total of 8 courses, 6 mandatory (General Toxicology - 8 ECTS Principles of Ecotoxicology - 7 ECTS, Environmental Pollutants - 8 ECTS, Toxicity Tests - 6 ECTS, Toxicological Risk Assessment - 9 ECTS, Project - 8 ECTS) and 2 elective courses from 4 available (Pharmaceutical Waste, Toxicovigilance, Regulatory Toxicology, Exposure Assessment). The number of points for each course was determined in relation to the tasks that the student needs to do to achieve the objective and learning outcome. Student receives ECTS after passing the final course exam. The project work is done in the 2nd semester and defended at the end of specialization, after passing all the exams according to the curriculum.

The study program includes the following content: 1. introduction to toxicology, doses in toxicology, ADME processes and toxicokinetics, mechanisms of action and target organs of toxicity, 2. toxicology of the main pollutants: air pollutants, toxic metals, pesticides, persistent organic pollutants, 3. introduction to ecotoxicology, fate and behavior of toxic substances in the environment, ecotoxicological risk assessment, green chemistry, medical and pharmaceutical waste, 4. acute toxicity tests, eye and skin irritation tests, skin sensitization test, repeated doses studies, carcinogenicity/mutagenicity tests, reproductive toxicity tests, reproductive toxicity test, developmental toxicity tests; ecotoxicity studies: toxicity tests in birds, aquatic organisms, bees, beneficial arthropods, earthworms, soil macro- and microorganisms, micro- and mesocosms study, 5. terminology in toxicological risk assessment, data analysis, hazard assessment, dose-response relationships evaluation, deterministic and probabilistic exposure assessment, risk characterization, the application of @RISK software package, the classification and labeling of toxic substances, risk assessment of exposure to environmental contaminants, risk assessment in toxicologically relevant impurities in medicines, safety assessment of cosmetic products, 6. legislative basis of toxicological

risk assessment in the evaluation of medicine dossiers, plant protection products, consumer products and biocides.

#### Teaching methods

The teaching is carried out using the following methods: lectures, interactive sessions, case studies, panel discussions, workshops, on-line learning, and independent students' research.

## PURPOSE OF STUDY PROGRAMME

The aim of the specialized academic study program Toxicological risk assessment at the Faculty of Pharmacy is to educate specialists and to enable them reaching expertise in toxicology and human health risk assessment due to exposure to environmental contaminants.

The purpose of the study program Toxicological risk assessment is to provide professional education and expertise in the field of risk assessment to human health due to the (potential) exposure to various toxic substances, in the area of the regulatory based quality assurance of the release of medicinal products, medical devices, customer products, food, plant protection products, biocides and other chemicals on the market, also in the process of medical, pharmaceutical and other hazardous waste management, which is indeed scarce in competent staff.

Therefore, the study program has been developed in accordance with the specific needs for risk assessment implementation in accordance with the number of laws: the Law on Medicines and Medical Devices ("Official Gazette of RS", 30/2010), the Law on Health Safety of Customer Products ("Off. Gazette of RS "no. 92/2011), the Law on Safety and Health at Work (" Off. Gazette. RS ", no. 101/2005 and 91/2015), the Law on Food Safety (" Off. Gazette of RS ", no. 42/2009), the Law on Plant Protection Products ( "Off. Gazette of RS", no. 41/2009), the Law on Biocides ( "SL. Gazette of RS", no. 36/2009, 88/2010, 92 / 2011 and 25/2015), the Law on Chemicals ( "Off. Gazette of RS", no. 36/2009, 88/2010, 92/2011, 93/2012 and 25/2015), the Law on Waste Management ( "Off. Gazette RS ", no. 36/2009, 88/2010 and 14/2016), etc.

The proposed study program provides an opportunity for professional development of staff working in the field of legislation: pharmacists and other health care workers who work on registration of drugs and evaluation of toxicologically significant impurities, safety assessment of cosmetic products; master of pharmacy, master of pharmacy-medical biochemistry, other health professions who work on the evaluation of exposure to toxic substances in the workplace, food safety, on the assessment of toxicology dossiers of pesticides and chemicals.

This program enables the training of staff who work in the pharmaceutical, chemical and pesticide industry, in the development and production of medicines, medical devices, cosmetics, pesticides and other chemicals used for various purposes.

Furthermore, the exposure assessment of the general population and specific subpopulations to toxic substances and mixtures, as well as ecotoxicological risk assessment represent permanent activities implemented with the aim to ensure the safety, hygiene and health protection, and sustainable development of the environment. Hence, continual training of experts in these areas is of public interest.

The purpose of the study program is development of the professionals who will master the basic theoretical principles and methods of toxicological risk assessment regardless the scenarios, patterns and sources of exposure. Throughout the study program, students gain knowledge and skills that qualify them for the work in the pharmaceutical and chemical industries, medical institutions, Medical Agencies, Environmental Protection Agencies, Ministry of Health, Agriculture and Environmental Protection, etc.

Study program provides acquisition of the following competencies:

- identification of relevant data sources, their analysis, and critical evaluation,
- analysis and critical evaluation of published research results,
- toxicological evaluation,
- adequate approach and understanding of the legislative practice,
- teamwork,
- decision making,
- work on pollution prevention and on dissemination of relevant information,
- organizational and management skills.

## GOALS OF THE STUDY PROGRAMME

The primary purpose of the proposed specialized academic study program Toxicological risk assessment is to train professionals working in the field of pharmacy and dealing with exposure assessment to toxic substances, and human health risk assessment. The primary objective of the study program, in general, is accomplished by acquiring knowledge and skills in the field of basic principles of toxicology and ecotoxicology, criteria and methods used to examine the toxicity and ecotoxicological properties of chemicals, theoretical and practical basis of toxicological risk assessment, as well as in the area of hazard identification, dose-response assessment, exposure assessment, risk characterization and classification and labeling of chemicals.

Attending specialized academic studies Toxicological risk assessment expands students' fundamental knowledge in the particular fields and later enables them to implement this knowledge in their professional work. Candidates will be trained for independent and teamwork, critical thinking and independent decision-making in complex situations in the process of risk assessment.

Diplomas obtained in this field will be recognized by the European institutions, allowing students to pursue further professional development or scientific training (doctoral study) in the area of pharmacy and related disciplines both on national and foreign universities.

Specific objectives include:

- acquiring knowledge in the field of regulatory toxicology, understanding of national, European and international laws and by-laws;
- acquiring knowledge in toxicology and ecotoxicology, understanding the importance and principles of toxicological risk assessment;
- gaining knowledge in the field of risk assessment of specific pollutants of living and working environment (air pollutants, persistent organic pollutants - organohalogen compounds, toxic metals, pesticides)
- acquiring knowledge and skills to critically assess the quality and results of toxicity and ecotoxicity tests;
- acquiring knowledge in the field of risk assessment of toxicologically significant contaminants in medicines;
- acquiring knowledge in the field of toxicological risk assessment of cosmetic products;
- gaining knowledge in the field of toxicological risk assessment of plant protection products and biocides, including the dossier assessment;
- mastering the methods of risk analysis; training in the models use, interpretation of the results of toxicological risk assessment, and providing possible solutions, if the risk exists;
- critical evaluation of the data, studies and the results of scientific research in the field of toxicology;
- training for the exposure scenarios design and the appropriate design of the risk assessment;

## COMPETENCIES OF GRADUATED STUDENTS

### *Description of general and course specific competencies of students*

After completing the study program graduate possesses the following general abilities: synthesis, analysis and evaluation of the relevant information, mastering the research methods, procedures and processes, development of critical approach, application of acquired knowledge in the practice, particularly in the specific problems solving and finding concrete practical solutions, the ability to identify new professional challenges and to independently seek for their solution, the development of professional ethics, the development of communicational skills and public presentation skills, ability to teamwork, the successful implementation of informational and communicational technologies, permanent monitoring of the scientific and professional achievements and the lifelong knowledge acquiring.

In addition to these general competencies, student acquires the following subject-specific competences as well: thorough knowledge and understanding of national, European and international legislation and subordinate legislation in the field of toxicology; integrating the knowledge in the area of legislation, toxicology, ecotoxicology and risk assessment; analyses of the results of toxicity and ecotoxicological tests; creating exposure scenarios and problem solving using appropriate methods of risk assessment; ability to work with databases, ability to critically evaluate information, as well as the capacity to apply models used in exposure assessment and the interpretation of results.

#### *Description of learning outcomes*

The proposed study program will enable graduates to master better the knowledge and skills necessary to work in the pharmaceutical and chemical industry, health and/or regulatory authorities.

Students who complete the study program of specialist academic study Toxicological Risk Assessment will be capable of:

- create adequate exposure scenario related to the characteristics of the exposed population, route, source, duration and the frequency of exposure to toxic substances,
- properly analyze and apply the results of toxicity and ecotoxicological tests,
- correctly select data and methods to be implemented to carry out the toxicological risk assessment and interpret the results reviewing the scope and nature of the risk,
- application of theoretical knowledge in practice, with an ability to critically analyze and understand the full meaning of the principle: toxicological risk assessment - evidence based,
- understanding the legislative toxicological risk assessment framework,
- participate in health promotion, environmental protection and prevention of the risks of exposure to toxic substances.

## CURRICULUM

The study program Toxicological Risk Assessment represents a specialized academic study course lasting one year, or two semesters (60 ECTS). The proposed study program consists of a total of 8 courses: 6 mandatory (General Toxicology - 8 ECTS Principles of Ecotoxicology - 7 ECTS, Environmental Pollutants - 8 ECTS, Toxicity Tests - 6 ECTS, Toxicological Risk Assessment - 9 ECTS, Project - 8 ECTS) and 2 elective courses from 4 available (Pharmaceutical Waste, Toksicovigilance, Regulatory Toxicology, Exposure Assessment). Elective courses in the study program are represented with 23.3% (14 ECTS).

The total number of hours is 600 per annum. In the first semester, there are 3 mandatory courses with the total of 120 hours of active teaching (lectures and practice) and one elective course with 30 hours of active teaching while in the second semester there are two compulsory subjects (120 hours of active teaching), one elective course with 30 hours of active teaching and project preparation.

The teaching in the study program is carried out through the following methods: lectures, interactive teaching, case studies, panel discussions, workshops, on-line learning, and independent students' research.

Evaluation of the knowledge required for each mandatory course is conducted through the written exam, and for elective courses through the oral exam. Each course has its grading system determined which includes credits for pre-exam activities and the final exam.

The student is required to pass all the exams according to the curriculum, in order to start with the preparation and defense of the project task. The project task has an experimental character (candidate should independently conduct a risk assessment for a certain exposure scenario based on the acquired knowledge) and its scope is defined by the Rule book on specialized academic studies. The defense of the project task is carried out in front of the commission consisting of at least three members


### Semesters and year of studies timetables


Code	Course title	Sem.	L	E	Oth	R	ECTS	
<b>FIRST YEAR</b>								
1	63ПРО1ОТ	General Toxicology	I	30	15	30	30	8
2	63ПРО1ПЕ	Principles of Ecotoxicology	I	15	15	30	30	7
3	63ПРО1ЖС	Environmental Contaminants	I	30	15	30	30	8
4		Elective block 1/4	I	15	15	15	15	7
<b>Total number in the first semester</b>				<b>90</b>	<b>60</b>	<b>105</b>	<b>105</b>	<b>30</b>
5	63ПРО2ТЕ	Toxicity Tests	II	15	30	15	15	6
6	63ПРО2ПР	Toxicological Risk Assessment	II	30	45	15	15	9
7		Elective block 1/4	II	15	15	15	15	7
8	63ПРО2ПЗ	Project work	II					8
<b>Total number in the second semester</b>				<b>60</b>	<b>90</b>	<b>45</b>	<b>45</b>	<b>30</b>
<b>Total number in the first year</b>				<b>150</b>	<b>150</b>	<b>150</b>	<b>150</b>	<b>60</b>
Active classes: L-Lectures, E-Exercises, Oth-Other forms of teaching (seminars, presentations, homeworks, on-line forum), R-research work.								

### List of elective courses

Code	Course title	Semester	ECTS	Discipline	
1	63ПРИ2ФО	Pharmaceutical Waste	I/II	7	Toxicological risk assessment
2	63ПРИ2ТВ	Toxicovigilance	I/II	7	Toxicological risk assessment
3	63ПРИ2ЛТ	Regulatory Toxicology	I/II	7	Toxicological risk assessment
4	63ПРИ2ПИ	Exposure Assessment	I/II	7	Toxicological risk assessment
Total ECTS*				14	


\* Students get to choose 2 courses

<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> General Toxicology			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Mirjana M. Đukić, Zorica L. Bulat, Danijela D. Đukić-Ćosić, Marijana M. Ćurčić, Aleksandra A. Buha			
<b>Course status:</b> mandatory			
<b>Semester:</b> I		<b>Year of studies:</b> I	
<b>ECTS points:</b> 8		<b>Course code:</b> 63ΠΡΟ10Τ	
<b>Requirements:</b> /			
<b>Course aims:</b> Acquirement of knowledge in general toxicology, dosis in toxicology, mechanisms of toxicity, toxicity end points and absorption, distribution, metabolism and excretion of toxic substances.			
<b>Course outcomes:</b> Use of knowledge from the general toxicology to analyse dose-response, ADME processes, toxicokinetics and to assess toxicity end points and target organs..			
<b>Course contents:</b> <i>Lectures</i> Risk Assessments - basic terms and definitions. Dose-response relationship. Doses in toxicology, relevance and evaluation in risk assessment, advantages and limitations. Benchmark dose, its definition, evaluation, softwares for its calculation. Dose extrapolation for genotoxic carcinogens. ADME processes. Toxicokinetics, parameters and models. Mechanisms of toxicity: covalent binding for cellular macromolecules, receptors, enzymes inhibition, adverse effect of xenobiotics on ionic transporters, oxidative stress, interactions with bioelements, necrosis and apoptosis. Systemic toxicity, target organs: hematotoxicity, hepatotoxicity, nephrotoxicity, neurotoxicity, pulmototoxicity. Toxic responses. Basic principles of therapy and antidotes. <i>Practical classes</i> Toxicological data basis. Doses calculation in toxicology by means of probit analysis. Examples of different toxicokinetic models. Identification of toxicity mechanisms, target organs and critical toxic effects.			
<b>Recommended literature:</b> 1. Timbrell JA. Introduction to Toxicology, CRC Press, 3th edition, 2002. 2. Casarett and Doull's Toxicology: The Basic Science of Poisons. Ed.: Curtis D. Klaassen, McGraw-Hill Companies, Inc., USA, 8th edition, 2013. 3. Boelsterli UA. Mechanistic toxicology. The molecular basis of how chemicals disrupt biological targets. Ed.: Boelsterli UA. Informa healthcare, 2009.			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 30		<b>Practical classes:</b> 15	
<b>Research work:</b> 30		<b>Other forms of teaching:</b> 30	
<b>Teaching methods:</b> Lectures, Practical work; Workshop, Homework, Individual research			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	15	Practical	
Practical classes	15	Written	70
Workshops		Oral	
Colloquia			
Seminars			
Other activities			

<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> Principles of Ecotoxicology			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Dragana L. Vujanović, Zorica L. Bulat, Danijela D. Đukić-Ćosić, Marijana M. Ćurčić, Aleksandra A. Buha			
<b>Course status:</b> mandatory			
<b>Semester:</b> I		<b>Year of studies:</b> I	
<b>ECTS points:</b> 7		<b>Course code:</b> 63ΠΡΟ1ΠΕ	
<b>Requirements:</b> /			
<b>Course aims:</b> Acquirement of knowledge in ecotoxicology, toxicity tests, parameters of ecotoxicity, ecotoxicological risk assessment.			
<b>Course outcomes:</b> Use of knowledge in ecotoxicology to analyse results of ecotoxicity tests and exposure scenario. Ability to evaluate risk, to calculate relevant parameters, and to present the results of ecotoxicological risk assessment.			
<b>Course contents:</b> <i>Lectures</i> Basic terms and definitions in ecotoxicology. Pollutants of soil, water, sediment and air, and relevant phenomena. Relevant parameters and doses/concentrations in ecotoxicology. Ecotoxicity tests, indicator species. Fate and behaviour in the environment, degradation and related factors. Ecotoxicological risk assessment; risk assessment phases, cumulative risk assessment. Parameters in ecotoxicological risk assessment, concept and guidance values; TER (Toxicity Exposure Ratio) and HQ (Hazard Quotient). <i>Practical classes</i> Ecotoxicity tests - calculation of LD50, LC50, ED50 in acute tests; assessment of NOEC in subchronic tests. Fate and behaviour of toxic substances in the environment: bioaccumulation assessment, degradation half time in related environmental compartments. Examples of ecotoxicological risk assessment - calculation of Toxicity Exposure Ratio (TER) and Hazard Quotient (HQ).			
<b>Recommended literature:</b> 1. Connell DW, Lam P, Richardson B, Wu R. Introduction to Ecotoxicology, Wiley-Blackwell, 1999. 2. Hoffman DJ, Rattner BA, Burton GA, Cairns J. Handbook of Ecotoxicology, 2nd edition, CRC Press LLC, USA, 2003. 3. Walker CH, Hopkin SP, Sibly RM, Peakal DB. Principles of ecotoxicology. 4th edition. Taylor and Francis, 2012.			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 15		<b>Practical classes:</b> 15	
<b>Research work:</b> 30		<b>Other forms of teaching:</b> 30	
<b>Teaching methods:</b> Lectures, Practical work; Workshop, Homework, Individual research			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	25	Practical	
Practical classes	25	Written	50
Workshops		Oral	
Colloquia			
Seminars			
Other activities			





<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> Environmental Contaminants			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Zorica L. Bulat, Danijela D. Đukić-Ćosić, Marijana M. Ćurčić, Aleksandra A. Buha			
<b>Course status:</b> mandatory			
<b>Semester:</b> I		<b>Year of studies:</b> I	
<b>ECTS points:</b> 8		<b>Course code:</b> 63ПРО1ЖС	
<b>Requirements:</b> /			
<b>Course aims:</b> Analyses of toxicological profiles of the most relevant environmental chemicals.			
<b>Course outcomes:</b> Use of knowledge in critical evaluation of toxicity and dose-response relationship, target organs and mechanisms of toxicity of environmental contaminants.			
<b>Course contents:</b> <i>Lectures</i> Toxicology/Toxicological risk assessment of environmental contaminants - toxicological relevance, toxicokinetics, molecular mechanisms of action, toxicity, target organs: air pollutants - CO, CO <sub>2</sub> , NO <sub>x</sub> , SO <sub>2</sub> ; persistent organic pollutants - polychlorinated and polybrominated biphenyls, polychlorinated dibenzodioxines, polychlorinated dibenzofuranes and polybrominated diphenylethers; toxic metals - lead, cadmium, mercury and arsenic; pesticides - organochlorines, organophosphates, carbamates, pyrethroids, bispyridinium and triazine herbicides. <i>Practical classes</i> Analyses of toxicological profiles of environmental contaminants - acute and chronic toxicity, mechanisms of toxicity, carcinogenicity, genotoxicity, reproductive toxicity, developmental toxicity.			
<b>Recommended literature:</b> 1. Marquardt H, Schafer SG, McClellan R, Welsch F: Toxicology. Academic Press, USA, 1999. 2. Derelanko MJ, Hollinger MA. Handbook of toxicology, third edition. Ed.: Derelanko MJ, Hollinger MA. CRC Press LLC, Boca Raton, USA, 2014. 3. Handbook of Human Toxicology. Ed.: Massaro EJ, CRC Press LLC, USA, 1997.			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 30		<b>Practical classes:</b> 15	
<b>Research work:</b> 30		<b>Other forms of teaching:</b> 30	
<b>Teaching methods:</b> Lectures, Practical work; Workshop, Homework, Individual research			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	20	Practical	
Practical classes	20	Written	60
Workshops		Oral	
Colloquia			
Seminars			
Other activities			

<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> Toxicity Tests			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Zorica L. Bulat, Danijela D. Đukić-Ćosić, Marijana M. Ćurčić, Aleksandra A. Buha			
<b>Course status:</b> mandatory			
<b>Semester:</b> II		<b>Year of studies:</b> I	
<b>ECTS points:</b> 6		<b>Course code:</b> 63ΠΡΟ2ΤΕ	
<b>Requirements:</b> /			
<b>Course aims:</b> Acquiring knowledge about criteria and methods used for chemicals toxicity testing, development of skills for presenting the results of toxicity and ecotoxicity.			
<b>Course outcomes:</b> Critical assessment of the quality and the results of toxicity testing.			
<b>Course contents:</b> <i>Lectures</i> Acute oral, dermal and inhalation toxicity tests, acute eye/skin irritation/corrosion, skin sensitisation. Subacute, subchronic and chronic toxicity tests. Carcinogenicity tests. Genotoxicity/mutagenicity tests. Reproductive toxicity tests. Developmental toxicity tests. Other tests-neurotoxicity. Ecotoxicity tests: birds, aquatic organisms, bees, arthropodes, earthworms, soil micro- and macro-organisms, micro- and mesocosmos studies. <i>Practical classes</i> Quality analysis of toxicity tests. Critical evaluation of toxicity tests results.			
<b>Recommended literature:</b> 1. EU Test Method Regulation, Council Regulation (EC) No 440/2008. 2. Hayes AW. Principles and methods in toxicology. Ed. Hayes AW. Taylor and Francis 2001. 3. Jacobson-Kram D and Keller K. Toxicological testing handbook Principles, applications and Data Interpretation. Eds.: Jacobson-Kram D and Keller K. Informa healthcare, 2006.			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 15		<b>Practical classes:</b> 30	
<b>Research work:</b> 15		<b>Other forms of teaching:</b> 15	
<b>Teaching methods:</b> Lectures, Practical work; Workshop, Homework, Individual research			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	10	Practical	
Practical classes	10	Written	
Workshops		Oral	50
Colloquia	30		
Seminars			
Other activities			

<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> Toxicological Risk Assessment			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Zorica L. Bulat, Danijela D. Đukić-Čosić, Marijana M. Čurčić, Aleksandra A. Buha			
<b>Course status:</b> mandatory			
<b>Semester:</b> II		<b>Year of studies:</b> I	
<b>ECTS points:</b> 9		<b>Course code:</b> 63ΠΡΟ2ΠΡ	
<b>Requirements:</b> /			
<b>Course aims:</b> Acquiring knowledge and skills regarding: hazard identification, dose-response and exposure assessment; Role of risk assessment in regulatory toxicology; risk communication			
<b>Course outcomes:</b> Competent individual and team work in: scenario development, data quality assessment, selection of adequate methods and models for human health risk assessment, risk interpretation and communication.			
<b>Course contents:</b> <i>Lectures</i> Toxicological risk assessment - introduction to concept and paradigm. Phases in risk assessment: Hazard identification. Dose-response assessment. Exposure assessment. Risk characterization. Risk assessment methodologies: deterministic and probabilistic approach. Risk assessment of non-carcinogenic substances. Risk assessment of carcinogenic and genotoxic substances. Aggregative risk assessment. Cumulative risk assessment. Integrative risk assessment. Risk assessment in legislative toxicology. Classification and labeling of chemicals. <i>Practical classes</i> Basic calculations in toxicological risk assessment - aggregative, integrative and cumulative risk assessment. Risk calculation for carcinogenic/genotoxic substances using slope factor. Probabilistic risk assessment using @RISK software. Operator exposure assessment. Reference values/health based guidance values. Classification and labeling of chemicals. Critical data evaluation and dossier development.			
<b>Recommended literature:</b> 1. Paustenbach DJ. Human and ecological risk assessment. Ed.: Paustenbach DJ. John Wiley and Sons, Inc., New York, USA, 2002. 2. Toxicology and Risk Assessment of Chemicals, Nielsen E, Ostergaard G, Laarsen JC. Informa Helthcare 2008. 3. Toxicology and Risk Assessment: A comprehensive introduction. Graim H, Snider R. John Wiley and Sons, 2008. 4. Toxicological profiles. Public Health Service, Agency for Toxic Substances and Disease Registry. 5. Health Safety Guides, WHO 6. Environmental Health Criteria, WHO/IPCS 7. Toxicological Risk Assessment of Chemicals : a practical guide. Nielsen E, Ostergaard G, Laarsen JC. Informa Helthcare 2008.			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 30		<b>Practical classes:</b> 45	
<b>Research work:</b> 15		<b>Other forms of teaching:</b> 15	
<b>Teaching methods:</b> Lectures, Practical work; Workshop, Homework, Individual research			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	20	Practical	
Practical classes	20	Written	60
Workshops		Oral	

Colloquia			
Seminars			
Other activities			


<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> Pharmaceutical Waste			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Zorica L. Bulat, Danijela D. Đukić-Ćosić, Marijana M. Ćurčić, Aleksandra A. Buha			
<b>Course status:</b> elective			
<b>Semester:</b> I/II		<b>Year of studies:</b> I	
<b>ECTS points:</b> 7		<b>Course code:</b> 63ПРИ2Ф0	
<b>Requirements:</b> /			
<b>Course aims:</b> Acquiring knowledge and skills on waste management, particularly concerning pharmaceutical waste.			
<b>Course outcomes:</b> Safe management of pharmaceutical waste.			
<b>Course contents:</b> <i>Lectures</i> Types and categories of hazardous waste. Medical waste. Methods and procedures of pharmaceutical waste management. Treatment of pharmaceutical waste. The role of pharmacist in pharmaceutical waste management. Classification and labelling of medical waste. <i>Practical classes</i> Characterization and classification of medical waste. Procedures for safe handling and disposal of pharmaceutical waste.			
<b>Recommended literature:</b> 1. Jaqueline Vaughn. Waste mangement. A reference handbook. ABC Clio INC. 2009. 2. Mulder JG and Dencker L. Pharmaceutical Toxicology Ed.: Mulder JG and Dencker L. Pharmaceutical Press, 2006. 3. Zakon o upravljanju otpadom "Službeni glasnik RS ", br. 36/2009, 88/2010 и 14/2016.			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 15		<b>Practical classes:</b> 15	
<b>Research work:</b> 15		<b>Other forms of teaching:</b> 15	
<b>Teaching methods:</b> Lectures, Practical work; Workshop, Homework, Individual research			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	10	Practical	
Practical classes	10	Written	
Workshops		Oral	50
Colloquia	30		
Seminars			
Other activities			

<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> Toxicovigilance			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Zorica L. Bulat, Danijela D. Đukić-Ćosić, Marijana M. Ćurčić, Aleksandra A. Buha			
<b>Course status:</b> elective			
<b>Semester:</b> I/II		<b>Year of studies:</b> I	
<b>ECTS points:</b> 7		<b>Course code:</b> 63ПРИ2ТВ	
<b>Requirements:</b> /			
<b>Course aims:</b> Acquiring knowledge about toxicovigilance: identification of relevant parameters for analysis of poisoning incidence rate and their correlation.			
<b>Course outcomes:</b> Evaluation of parameters relevant for analysis of poisoning incidence rate and their correlation.			
<b>Course contents:</b> <i>Lectures</i> Concept of toxicovigilance - role and relevance. Parameters of analysis in toxicovigilance. Role of pharmacist and Poison Control Centre: information, education and prevention. Global monitoring of hazardous effects: data bases. <i>Practical classes</i> Analysis of data published by Poison Control Centres.			
<b>Recommended literature:</b> 1. Gupta SK, Singh U, Velpandian T. Analytical Toxicology for Poisoning Management and Toxicovigilance. Alpha Science International. 2002.			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 15		<b>Practical classes:</b> 15	
<b>Research work:</b> 15		<b>Other forms of teaching:</b> 15	
<b>Teaching methods:</b> Lectures, Practical work; Workshop, Homework, Individual research			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	10	Practical	
Practical classes	10	Written	
Workshops		Oral	50
Colloquia	30		
Seminars			
Other activities			

<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> Regulatory Toxicology			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Zorica L. Bulat, Danijela D. Đukić-Ćosić, Marijana M. Ćurčić, Aleksandra A. Buha			
<b>Course status:</b> elective			
<b>Semester:</b> I/II		<b>Year of studies:</b> I	
<b>ECTS points:</b> 7		<b>Course code:</b> 63ПРИ2ЛТ	
<b>Requirements:</b> /			
<b>Course aims:</b> Information on legislative aspect of toxicological risk assessment.			
<b>Course outcomes:</b> Adequate interpretation and application of laws and sublaws in safe management of chemicals.			
<b>Course contents:</b> <i>Lectures</i> Law on chemicals. Law on biocides. Law on plant protection products. Law on waste management. Law on medicines and medicinal products. Law on items of general use.  <i>Practical classes</i> Legislative in practice. Building the dossier and safety data sheet. Qualitative and quantitative evaluation of a dossier.			
<b>Recommended literature:</b> 1. Zakon o hemikalijama ("Službeni glasnik RS", br. 36/ 09 i 88/10) 2. Zakon o biocidnim proizvodima ("Službeni glasnik RS ", br. 36/09 i 88/10) 3. Zakon o sredstvima za zaštitu bilja ("Službeni glasnik RS", br. 52/10) 4. Zakon o upravljanju otpadom ("Službeni glasnik RS", br. 36/09 i 88/10) 5. Zakon o zdravstvenoj zaštiti ("Službeni glasnik RS" , br. 107/05 i 72/09) 6. Zakon o zdravstvenoj ispravnosti predmeta opšte upotrebe ("Službeni glasnik RS" , br. 92/11)			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 15		<b>Practical classes:</b> 15	
<b>Research work:</b> 15		<b>Other forms of teaching:</b> 15	
<b>Teaching methods:</b> Lectures, Practical work; Workshop, Homework, Seminars			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	10	Practical	
Practical classes	10	Written	
Workshops		Oral	50
Colloquia	30		
Seminars			
Other activities			

<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> Exposure assessment			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Zorica L. Bulat, Danijela D. Đukić-Ćosić, Marijana M. Ćurčić, Aleksandra A. Buha			
<b>Course status:</b> elective			
<b>Semester:</b> I/II		<b>Year of studies:</b> I	
<b>ECTS points:</b> 7		<b>Course code:</b> 63ПРИ2ПИ	
<b>Requirements:</b> /			
<b>Course aims:</b> Acquiring knowledge about the factors that influence the exposure assessment.			
<b>Course outcomes:</b> Use of knowledge in critical analysis of the exposure parameters and data reliability.			
<b>Course contents:</b> <i>Lectures</i> Factors influencing exposure assessment: population / subpopulation, source, pathway, frequency, duration of exposure. Scenario of acute and chronic exposures and relevant parameters. Development of data basis. Development of exposure algorithm. Exposure models. Deterministic and probabilistic exposure assessment: strengths and limitations, results interpretation. Exposure assessment and legislation. <i>Practical classes</i> Work with database. Analysis of the data and their distribution. Exposure factors and their impact on exposure assessment. Assessment of uncertainties. Case reports.			
<b>Recommended literature:</b> 1. Nielsen E, Ostergaard G, Laarsen JC. Toxicology and Risk Assessment of Chemicals A Practical Guide. Informa Helthcare 2010. 2. Liou P, Weisel C. Exposure Science Basic Principles and Applications. Elsevier 2014.			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 15		<b>Practical classes:</b> 15	
<b>Research work:</b> 15		<b>Other forms of teaching:</b> 15	
<b>Teaching methods:</b> Lectures, Practical work; Workshop, Homework, Seminars			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	10	Practical	
Practical classes	10	Written	
Workshops		Oral	50
Colloquia	30		
Seminars			
Other activities			



<b>University of Belgrade</b> <b>Faculty of Pharmacy</b>	<b>Specialized academic study</b> <b>TOXICOLOGICAL RISK ASSESSMENT</b>		
<b>Study programme:</b> Toxicological Risk Assessment			
<b>Course title:</b> Project			
<b>Teachers:</b> Biljana M. Antonijević, Vesna J. Matović, Zorica L. Bulat, Danijela D. Đukić-Ćosić, Marijana M. Ćurčić, Aleksandra A. Buha			
<b>Course status:</b> mandatory			
<b>Semester:</b> II		<b>Year of studies:</b> I	
<b>ECTS points:</b> 8		<b>Course code:</b> 63ΠΡΟ2Π3	
<b>Requirements:</b> /			
<b>Course aims:</b> Project work should include overall knowledge gained in the course of specialized studies and result in theoretical knowledge use in solving the particular scenario of toxicological risk assessment.			
<b>Course outcomes:</b> Use of theoretical knowledge in toxicological risk assessment and proposing recommendations for risk management.			
<b>Course contents:</b> <i>Lectures</i> <i>Practical classes</i>			
<b>Recommended literature:</b>			
<b>The total of active learning classes</b>			
<b>Lectures:</b> 0		<b>Practical classes:</b> 0	
<b>Research work:</b> 0		<b>Other forms of teaching:</b> 0	
<b>Teaching methods:</b> Project represents individual research work in which student should apply the methodology of the toxicological risk assessment. Student prepares the project in the written form which contains the following chapters: introduction, theoretical part, experim			
<b>Grading system</b>			
<b>Exam prerequisites</b>	<b>Points</b>	<b>Final exam</b>	<b>Points</b>
Active participation in lectures	0	Practical	
Practical classes		Written	50
Workshops		Oral	50
Colloquia			
Seminars			
Other activities			