University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Methodology of scientific research

Teachers: Savić M. Miroslav, Krajnović M. Dušanka, Kotur-Stevuljević M. Jelena, Bogavac-Stanojević B. Nataša

Course status: Mandatory common, module: Doctoral academic studies

Semester: I	**Year of studies:** I
ECTS points: 5	**Course code:** Д1О31

Requirements: none

Course aims:

The aim of this course is to provide participants with general scientific skills in order to formulate a scientific problem and plan the experiment, as well as to understand the complete process of preparation and publication of scientific research results

Course outcomes:

By the end of this course participants will be able to summarize and apply the principles of the methodology of scientific-researh work and scientific writing

Course contents:

Science and scientific method. Problem and scientific problem. Hypothesis. Hypothesis verification: scientific observation and scientific experiment. Common methodology of scientific research in biomedicine. Classification of research. Experimental research in laboratory. Animal experiments. Types of studies in epidemiological investigations. Ethics and biomedical investigations. Ethical codex of scientific-researh work. Generation of biomedical information. Communications. Networks. Internet. Internet search engines. Authorship/co-authorship. Role and duties of principal investigator. Protection of intellectual property. Classification of scientific work. Writing of scientific and professional papers. Literature citing. Review process. Oral presentation of scientific work (adaptation to audience and situation). Designing PowerPoint slides for a scientific presentation. Introduction to writing of project proposals. Master's thesis and doctoral dissertation.

Recommended literature:

1 Cargill, M, O'Connor P. Writing scientific research articles: Strategy and steps. John Wiley & Sons, 2013.

2. Baumgartner TA, Hensley LD. Conducting and Reading Research in Health and Human performance. Mc Graw Hill, Boston, 2006

3. Machin D, Campbell MJ. Design of studies for medical research. John Wiley & Sons, Hoboken, 2005.

4. Peat J, Elliot E, Baur L, Keena V. Scientific writing – easy when you know how. BMJ Books, London, 2002.

5. Albert T. The A-Z of medical writing. BMJ Books, London, 2000.

6. Hudson Jones A, McLeallan F. Ethical Issues in Biomedical Publication. Baltimore: John Hopkins University Press, 2000.

The total of active learning classes	**Lectures:** 30
	Individual research work: 30

Teaching methods:

Lectures and study-research work

Grading system:

Seminar: 30 points; written exam: 70 points

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Statistics in research

Teachers: Bogavac-Stanojević B. Nataša, Kotur-Stevuljević M. Jelena

Course status: Mandatory common, module: Doctoral academic studies

Semester: I	**Year of studies:** I
ECTS points: 5	**Course code:** Д1О32

Requirements: One semester of undergraduate studies in mathematics and statistics
pharmaceutical / medical biochemistry / medicine

Course aims:

Understanding advanced statistical methods. Applying advanced statistical analyses in scientific research.

Course outcomes:

After completing the course students will be trained to:

- Recognizing the type of statistical analysis
- Interpret the significance of the obtained statistical indicators and discuss the results,
- Understand the importance of the application of statistical methods in the scientific research,
- Use statistical software in the data analysis

Course contents:

One-way analysis of variance (ANOVA). Two-way analysis of variance. ANOVA with replication. Post-hoc tests. Simple linear regression analysis. Multiple regression analyses. Logistic regression. Analysis of covariance. Nonparametric analysis of variance. Nonparametric correlation. Chi-square test. Confidence interval.

Student's research: Solving different statistical problems and tasks.

Recommended literature:

1. Sheskin DJ. Handbook of parametric and nonparametric statistical procedures Chapman & Hall/CRC, Washington, D.C., 2000.
2. Vitingoff E, Shiboski SC, Glidden DV, McCulloch CE. Regression Methods in Biostatistics,Springer Science + Business Media, New York, 2005.
3. Selvin S. Statistica Analysis of Epidemiological Data, Oxfor University Press, Oxford, 1996.
4. Tamhane AJ, Dunlop DD. Statistics and Data Analysis, Prentice Hall, Upper Saddle River, NJ, 2000.

The total of active learning classes	**Lectures:** 30
	Individual research work: 30

Teaching methods:

Lectures, computer exercises, solving practical problems

Grading system:

The presence at lectures: 30 points; Written Exam: 70 points.

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Seminar 1

Teachers: Ivanović P. Darko, Zečević L. Mira, Malenović M. Anđelija, Stojanović S. Biljana, Miletić Đ. Ivanka, Šobajić S. Slađana, Stanković M. Ivan, Đorđević I. Brižita, Vuleta M. Gordana, Milić R. Jela, Primorac M. Marija, Savić D. Snežana, Vasiljević D. Dragana, Krajišnik R. Danina, Đekić M. Ljiljana, Spasić M. Slavica, Jelić-Ivanović D. Zorana, Spasojević-Kalimanovska V. Vesna, Stojanov D. Marina, Ignjatović D. Svetlana, Topić S. Aleksandra, Dopsaj B. Violeta, Bogavac-Stanojević B. Nataša, Kotur-Stevuljević M. Jelena, Tasić M. Ljiljana, Marinković D. Valentina, Krajnović M. Dušanka, Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina, Kovačević N. Nada, Petrović D. Silvana, Maksimović A. Zoran, Kundaković D. Tatjana, Drobac M. Milica, Ugrešić D. Nenad, Stepanović-Petrović M. Radica, Savić M. Miroslav, Ilić V. Katarina, Novaković N. Aleksandra, Tomić A. Maja, Leposavić M. Gordana, Arsenović-Ranin M. Nevena, Stojić-Vukanić M. Zorica, Plećaš-Solarović A. Bosiljka, Pešić P. Vesna, Nedeljković S. Miodrag, Milenković T. Marina, Antić Stanković A. Jelena, Parojčić V. Jelena, Ibrić R.Svetlana, Đuriš D.Jelena, Grbić V. Sandra, Đurić R. Zorica, Vladimirov M.Sote, Agbaba D. Danica, Bulat L. Zorica,

Matović J. Vesna, Antonijević M. Biljana, Vujanović L. Dragana, Đukić M. Mirjana

Course status: Mandatory common, module: Doctoral academic studies

Semester: I	**Year of studies:** I
ECTS points: 5	**Course code:** Д1О33

Requirements: none

Course aims:

This course aims to enable the participant to: search the scientific literature effectively and thoroughly; perform a critical analysis of publications relevant for his/her study field; apply the principles of making a successful oral presentation in English.

Course outcomes:

By the end of this course participants will be able to: search the scientific literature effectively and thoroughly; perform a critical analysis of publications relevant for his/her study field; apply the principles of making a successful oral presentation in English

Course contents:

Collecction of pertinent literature (by use of bibliographic databases, web sites of publishers, general search engines). Preparation of personal databases. Contextual analysis of key publications in a field. Preparation and presentation of the published results.

Recommended literature:

1. Alley M. The craft of scientific presentations. Critical steps to succeed and critical errors to avoid. Springer-Verlag New York, Inc., 2003.
2. Original scientific papers and review articles in the field of the participant's research activity.

The total of active learning classes	**Lectures:** 30
	Individual research work: 60

Teaching methods:

Study-research work

Grading system:

Seminar: 70 points; written exam: 30 points

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Seminar 2

Teachers: Ivanović P. Darko, Zečević L. Mira, Malenović M. Anđelija, Stojanović S. Biljana, Miletić Đ. Ivanka, Šobajić S. Slađana, Stanković M. Ivan, Đorđević I. Brižita, Vuleta M. Gordana, Milić R. Jela, Primorac M. Marija, Savić D. Snežana, Vasiljević D. Dragana, Krajišnik R. Danina, Đekić M. Ljiljana, Spasić M. Slavica, Jelić-Ivanović D. Zorana, Spasojević-Kalimanovska V. Vesna, Stojanov D. Marina, Ignjatović D. Svetlana, Topić S. Aleksandra, Dopsaj B. Violeta, Bogavac-Stanojević B. Nataša, Kotur-Stevuljević M. Jelena, Tasić M. Ljiljana, Marinković D. Valentina, Krajnović M. Dušanka, Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina, Kovačević N. Nada, Petrović D. Silvana, Maksimović A. Zoran, Kundaković D. Tatjana, Drobac M. Milica, Ugrešić D. Nenad, Stepanović-Petrović M. Radica, Savić M. Miroslav, Ilić V. Katarina, Novaković N. Aleksandra, Tomić A. Maja, Leposavić M. Gordana, Arsenović-Ranin M. Nevena, Stojić-Vukanić M. Zorica, Plećaš-Solarović A. Bosiljka, Pešić P. Vesna, Nedeljković S. Miodrag, Milenković T. Marina, Antić Stanković A. Jelena, Parojčić V. Jelena, Ibrić R.Svetlana, Đuriš D.Jelena, Grbić V. Sandra, Đurić R. Zorica, Vujić B. Zorica, Čudina A. Olivera, Bulat L. Zorica, Matović J. Vesna, Antonijević M. Biljana, Vujanović L. Dragana, Đukić M. Mirjana

Course status: Mandatory common, module: Doctoral academic studies

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** Д1О34

Requirements: none

Course aims:

This course aims to enable the participant to: search the scientific literature effectively and thoroughly; perform a critical analysis of publications relevant for his/her study field; upgrade his/her capacities for giving a successful oral presentation in English.

Course outcomes:

By the end of this course participants will be able to: search the scientific literature effectively and thoroughly; perform a critical analysis of publications relevant for his/her study field; apply the principles of making a successful oral presentation in English

Course contents:

Collecction of pertinent literature (by use of bibliographic databases, web sites of publishers, general search engines). Preparation of personal databases. Contextual analysis of key publications in a field. Preparation and presentation of the published results.

Recommended literature:

1. Alley M. The craft of scientific presentations. Critical steps to succeed and critical errors to avoid. Springer-Verlag New York, Inc., 2003.

2. Original scientific papers and review articles in the field of the participant's research activity.

The total of active learning classes	**Lectures:** 30
	Individual research work: 60

Teaching methods:

Study-research work

Grading system:

Seminar: 70 points; written exam: 30 points

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Seminar 3

Teachers: Ivanović P. Darko, Zečević L. Mira, Malenović M. Anđelija, Stojanović S. Biljana, Miletić Đ. Ivanka, Šobajić S. Slađana, Stanković M. Ivan, Đorđević I. Brižita, Vuleta M. Gordana, Milić R. Jela, Primorac M. Marija, Savić D. Snežana, Vasiljević D. Dragana, Krajišnik R. Danina, Đekić M. Ljiljana, Spasić M. Slavica, Jelić-Ivanović D. Zorana, Spasojević-Kalimanovska V. Vesna, Stojanov D. Marina, Ignjatović D. Svetlana, Topić S. Aleksandra, Dopsaj B. Violeta, Bogavac-Stanojević B. Nataša, Kotur-Stevuljević M. Jelena, Tasić M. Ljiljana, Marinković D. Valentina, Krajnović M. Dušanka, Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina, Kovačević N. Nada, Petrović D. Silvana, Maksimović A. Zoran, Kundaković D. Tatjana, Drobac M. Milica, Ugrešić D. Nenad, Stepanović-Petrović M. Radica, Savić M. Miroslav, Ilić V. Katarina, Novaković N. Aleksandra, Tomić A. Maja, Leposavić M. Gordana, Arsenović-Ranin M. Nevena, Stojić-Vukanić M. Zorica, Plećaš-Solarović A. Bosiljka, Pešić P. Vesna, Nedeljković S. Miodrag, Milenković T. Marina, Antić Stanković A. Jelena, Parojčić V. Jelena, Ibrić R.Svetlana, Đuriš D.Jelena, Grbić V. Sandra, Đurić R. Zorica, Vujić B. Zorica, Čudina A. Olivera, Bulat L. Zorica, Matović J. Vesna, Antonijević M. Biljana, Vujanović L. Dragana, Đukić M. Mirjana

Course status: Mandatory common, module: Doctoral academic studies

Semester: III	**Year of studies:** II
ECTS points: 5	**Course code:** Д2О31

Requirements: none

Course aims:

This course aims to enable the participant to: search the scientific literature effectively and thoroughly; perform a critical analysis of publications relevant for his/her study field; upgrade his/her capacities for giving a successful oral presentation of results of personal reserch activities

Course outcomes:

By the end of this course participants will be able to: search the scientific literature effectively and thoroughly; perform a critical analysis of publications relevant for his/her study field; apply the principles of making a successful oral presentation in English

Course contents:

Collecction of pertinent literature (by use of bibliographic databases, web sites of publishers, general search engines). Preparation of personal databases. Contextual analysis of key publications in a field. Preparation and presentation of the published results.

Recommended literature:

1. Alley M. The craft of scientific presentations. Critical steps to succeed and critical errors to avoid. Springer-Verlag New York, Inc., 2003.

2. Original scientific papers and review articles in the field of the participant's research activity.

The total of active learning classes	**Lectures:** 30
	Individual research work: 60

Teaching methods:

Study-research work

Grading system:

Seminar: 70 points; written exam: 30 points

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Seminar 4

Teachers: Ivanović P. Darko, Zečević L. Mira, Malenović M. Anđelija, Stojanović S. Biljana, Miletić Đ. Ivanka, Šobajić S. Slađana, Stanković M. Ivan, Đorđević I. Brižita, Vuleta M. Gordana, Milić R. Jela, Primorac M. Marija, Savić D. Snežana, Vasiljević D. Dragana, Krajišnik R. Danina, Đekić M. Ljiljana, Spasić M. Slavica, Jelić-Ivanović D. Zorana, Spasojević-Kalimanovska V. Vesna, Stojanov D. Marina, Ignjatović D. Svetlana, Topić S. Aleksandra, Dopsaj B. Violeta, Bogavac-Stanojević B. Nataša, Kotur-Stevuljević M. Jelena, Tasić M. Ljiljana, Marinković D. Valentina, Krajnović M. Dušanka, Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina, Kovačević N. Nada, Petrović D. Silvana, Maksimović A. Zoran, Kundaković D. Tatjana, Drobac M. Milica, Ugrešić D. Nenad, Stepanović-Petrović M. Radica, Savić M. Miroslav, Ilić V. Katarina, Novaković N. Aleksandra, Tomić A. Maja, Leposavić M. Gordana, Arsenović-Ranin M. Nevena, Stojić-Vukanić M. Zorica, Plećaš-Solarović A. Bosiljka, Pešić P. Vesna, Nedeljković S. Miodrag, Milenković T. Marina, Antić Stanković A. Jelena, Parojčić V. Jelena, Ibrić R.Svetlana, Đuriš D.Jelena, Grbić V. Sandra, Đurić R. Zorica, Vujić B. Zorica, Čudina A. Olivera, Bulat L. Zorica, Matović J. Vesna, Antonijević M. Biljana, Vujanović L. Dragana, Đukić M. Mirjana

Course status: Mandatory common, module: Doctoral academic studies

Semester: IV	**Year of studies:** II
ECTS points: 5	**Course code:** Д2О32

Requirements: none

Course aims:

This course aims to enable the participant to: search the scientific literature effectively and thoroughly; perform a critical analysis of publications relevant for his/her study field; upgrade his/her capacities for giving a successful oral presentation of results of personal reserch activities; prepare publications containing the results obtained in the performed personal investigation

Course outcomes:

By the end of this course participants will be able to: search the scientific literature effectively and thoroughly; perform a critical analysis of publications relevant for his/her study field; apply the principles of making a successful oral presentation and preparing publications containing the personal results

Course contents:

Collecction of pertinent literature (by use of bibliographic databases, web sites of publishers, general search engines). Preparation of personal databases. Contextual analysis of key publications in a field. Preparation and oral and written presentation of the personal results.

Recommended literature:

1. Alley M. The craft of scientific presentations. Critical steps to succeed and critical errors to avoid. Springer-Verlag New York, Inc., 2003.
2. Original scientific papers and review articles in the field of the participant's research activity.

The total of active learning classes	**Lectures:** 30
	Individual research work: 60

Teaching methods:

Study-research work

Grading system:

Seminar: 70 points; written exam: 30 points

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Pharmacokinetics and metabolism during drug development and drug use

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: Mandatory modules, module: Pharmacokinetics and Clinical Pharmacy

Semester: I	**Year of studies:** I
ECTS points: 10	**Course code:** ДФК1ОМ1

Requirements: none

Course aims:

The aim of the course is to provide students with relevant tools needed for understanding the importance of the pharmacokinetics and drug metabolism during drug development, different designs of pharmacokinetic trials depending on the phase of drug development, importance of pharmacokinetic principles in drug therapy and individualization of dosage regimen.

Course outcomes:

On completion of the course, the student will be able to understand and apply drug's pharmacokinetic and metabolism characteristics into the decision-making process related to drug development and individualization of dosing regimen.

Course contents:

Regulatory aspects of the pharmacokinetic studies. Pharmacokinetic study design depending on the phase of drug development. Preclinical in vitro pharmacokinetic and metabolism studies of drug candidate. Preclinical pharmacokinetic studies in experimental animals. In vitro-in vivo correlation of metabolism. Prediction of pharmacokinetic processes, metabolic pathways and parameters values based on physico-chemical characteristics of a drug candidate. Prediction of the pharmacokinetics in humans (allometric approach, physiological models). Clinical pharmacokinetic studies. Assessment of ADME processes of the drug candidate. Izoenzymes CYP450. Induction and inhibition of enzyme systems, extrahepatic drug metabolism. Drug metabolism kinetics. Pharmacological and toxicological significance of drug metabolism. Drug metabolism in vivo. Examination of the drug's potential for pharmacokinetic interactions, and consequently adverse drug effects. Prediction of drug-drug interactions on metabolism level. Calculation of pharmacokinetic parameters using different softwares for pharmacokinetic data analysis. Data interpretation, interpretation of the pharmacokinetic parameters' values. Bioequivalence studies. Correlation between drug's pharmacokinetics and pharmacodynamics. Pharmacokinetic principles in individualization of drug therapy. Application of pharmacokinetic parameters in dosage regimen adjustments.

Recommended literature:

1. Shargel L, Wu-Pong S, Yu A. Applied Biopharmaceutics & Pharmacokinetics, 6th ed. McGraw-Hill, 2012.

2. Rowland M, Tozer TN. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, 4th ed. Lippincott Williams & Wilkins, 2011.

3. Krishna R (ed). Applications of Pharmacokinetic Principles in Drug Development, 1st ed. Springer, 2003.

4. Coleman M. Human drug metabolism, 2nd ed. Wiley, 2010.

5. Zhang D, Zhu M, Humphreys WH (eds). Drug Metabolism in Drug Design and Development, 1st ed. Wiley, 2007.

The total of active learning classes	**Lectures:** 60
	Individual research work: 60

Teaching methods:

Theoretical lectures, problem-based learning.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Selected chapters of clinical pharmacy

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: Mandatory modules, module: Pharmacokinetics and Clinical Pharmacy

Semester: I,II	**Year of studies:** I
ECTS points: 10	**Course code:** ДФК1ОМ2

Requirements: none

Course aims:

The aim of the course is to provide students with relevant tools needed for understanding drug-related problems of patients with various diseases and specific needs as well as drug-related problems of specific patient populations. Student will acquire knowledge about identification and drug-related problem solving in practice as well as monitoring of patient outcomes.

Course outcomes:

On completion of the course, the student will be able to apply the knowledge, identify and solve drug-related problems of patients in practice and monitor patient outcomes.

Course contents:

Types of drug-related problems. Identifcation of drug-related problems. Interventions for problem solution. Methods of monitoring patient outcomes. Clinical pharmacy in the treatment of diseases of the cardiovascular system, respiratory system, central nervous system, gastrointestinal system, endocrine system and the musculo-skeletal system. Clinical pharmacy in the treatment of infectious diseases and cancers, anemia, and electrolyte abnormalities. Specifics of pharmacotherapy in elderly patients and children. The therapeutic approach to patients with altered renal and/or liver function. Specifics of pharmacotherapy and identification of drug-related problems in pregnant women and nursing mothers. Laboratory parameters to monitor the safety and efficacy of therapy. Analysis of case studies involving the identification of drug-related problems, interventions for problem solving, the assessment of laboratory parameters and outcome monitoring plan for multimorbid patients who receive treatment for diseases of the cardiovascular system, respiratory system, central nervous system, gastrointestinal system, endocrine system, musculo-skeletal system, cancer, infectious diseases, and/or renal and hepatic insufficiency.

Recommended literature:

1. Dodds L. Drugs in Use. Clinical Case Studies for Pharmacists, Pharmaceutical Press 4th ed, 2009.

2. Walker R, Whittlesea C. Clinical Pharmacy and Therapeutics, Churchill Livingstone 5th ed, 2012.

3. Greene R, Harris N. Pathology and Therapeutics for Pharmacists: a Basis for Clinical Pharmacy Practice, Pharmaceutical Press, 3rd ed, 2008.

The total of active learning classes	**Lectures:** 60
	Individual research work: 60

Teaching methods:

Theoretical lectures, problem-based learning, seminars.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Planning pharmacokinetic studies

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: elective, module: Pharmacokinetics and Clinical Pharmacy

Semester: II	**Year of studies:** I
ECTS points: 15	**Course code:** ДФК1И1

Requirements: Pharmacokinetics and metabolism during drug development and drug use

Course aims:

The aim of the course is to provide students with relevant tools needed for performing and critical appraisal of pharmacokinetic and bioequivalence studies.

Course outcomes:

On completion of the course, the student will be able to perform and critically appraise (pre)clinical pharmacokinetic and bioequivalence studies.

Course contents:

Regulatory aspects of the pharmacokinetic preclinical and clinical studies. Pharmacokinetic and bioequivalence study design. Preparation of research protocols for conducting pharmacokinetic preclinical and clinical studies according to the regulatory aspects. Preparation of research protocols for bioequivalence studies according to the regulatory aspects. Importance of pharmacokinetics drug profile in the process of planning and conducting pharmacokinetic trials. Implementation of protocols for clinical pharmacokinetic studies. Performing bioavailability and bioequivalence studies. Collection and data analysis during pharmacokinetic (pre)clinical studies. Types of pharmacokinetic data analysis and calculation of the pharmacokinetic parameters. Statistical methods and tests during pharmacokinetic and bioequivalence studies. Interpretation of the (pre)clinical pharmacokinetic studies results. Preparation of a report based on the results of clinical pharmacokinetic studies. Critical appraisal of the results of pharmacokinetic and bioequivalence studies.

Recommended literature:

1. Chow S-C, Liu J-P. Design and Analysis of Clinical Trials: Concepts and Methodologies, 2nd ed, Wiley-Interscience, 2003.

2. Piantadosi S. Clinical Trials: A Methodologic Perspective 2nd ed, Wiley-Interscience, 2005.

3. Chow S-C, Liu J-P. Design and Analysis of Bioavailability and Bioequivalence Studies, 3rd ed. Chapman and Hall/CRC, 2008.

4. Hauschke D, Steinijans V, Pigeot I. Bioequivalence Studies in Drug Development: Methods and Applications, 1st ed. Wiley, 2007.

The total of active learning classes	**Lectures:** 90
	Individual research work: 90

Teaching methods:

Theoretical lectures, problem-based learning.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.

University of Belgrade Faculty of Pharmacy	DOCTORAL ACADEMIC STUDIES	

Course title: Pharmacokinetic drug variability

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: elective, module: Pharmacokinetics and Clinical Pharmacy

Semester: II	**Year of studies:** I
ECTS points: 15	**Course code:** ДФК1И2

Requirements: Pharmacokinetics and metabolism during drug development and drug use

Course aims:

The aim of the course is to provide students with relevant tools needed for understanding drugs' variability in pharmacokinetic processes, and importance of therapeutic drug monitoring during certain drugs therapy.

Course outcomes:

On completion of the course, the student will be able to access the impact of various factors on the pharmacokinetic drug variability and apply the principles of dosing regimen adjustments of selected drugs based on the data during therapeutic drug monitoring.

Course contents:

Clinically significant sources of pharmacokinetic variability. Physiological factors as a sources of pharmacokinetic variability. Pathological factors as a sources of pharmacokinetic variability. External factors as a sources of pharmacokinetic variability. Requirements for the therapeutic drug monitoring. Preparation of blood sampling protocol as a part of therapeutic drug monitoring process. Therapeutic drug monitoring in specific patients' populations. Initial dosing regimen and its adjustment in obese patients, pregnant women, pediatric and geriatric population of patients, patients with impaired renal, liver function using the principles of clinical pharmacokinetics. Principles of individualization of dosing regimen based on measured drug levels of selected drugs: antibiotics, antiepileptic drugs, immunosuppressive drugs, digoxin, lithium, theophylline. Case studies involving the application of clinical pharmacokinetics principles in of dosing regimen individualization.

Recommended literature:

1. Bauer L. Applied Clinical Pharmacokinetics, 2nd ed. McGraw-Hill Medical, 2008.

2. Burton ME, Shaw LM, Schentag JJ, Evans WE. Applied Pharmacokinetics and Pharmacodynamics: Principles of Therapeutic Drug Monitoring, 4th ed. Lippincott Williams & Wilkins, 2005.

3. Winter M. Basic Clinical Pharmacokinetics, 5th ed. Lippincott Williams & Wilkins, 2009.

4. Rowland M, Tozer TN. Clinical Pharmacokinetics and Pharmacodynamics: Concepts and Applications, 4th ed. Lippincott Williams & Wilkins, 2011.

5. Murphy JE. Clinical Pharmacokinetics, 5th ed. American Society of Health-System Pharmacists, 2011.

The total of active learning classes	**Lectures:** 90
	Individual research work: 90

Teaching methods:

Theoretical lectures, problem-based learning.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Drug interactions and adverse outcomes, drug safety and pharmacovigilance

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: elective, module: Pharmacokinetics and Clinical Pharmacy

Semester: II	**Year of studies:** I
ECTS points: 15	**Course code:** ДФК1И3

Requirements: none

Course aims:

The aim of the course is to enable students to acquire knowledgde for assessment of clinical importance of drug interactions and adverse drug effects in order to improve treatment safety.

Course outcomes:

On completion of the course, the student will be able to apply the knowledge and assess clinical importance of drug interactions and adverse effects of drugs with the aim of improving treatment safety.

Course contents:

The research of pharmacodynamic and pharmacokinetic drug interactions. Assessment of drug interactions based on the results of laboratory tests. Assessment of clinical importance of drug interactions. Investigation of adverse effects of drugs. Predisposing factors for the occurrence of adverse drug reactions. Methods for monitoring adverse drug reactions. The importance of monitoring adverse drug reactions (pharmacovigilance). Recording and analysis of adverse drug reactions. The role and importance of research in pharmacovigilance. The study of side effects of drugs which are used in the treatment of diseases of the central nervous system, cardiovascular system, respiratory, system gastrointestinal system, endocrine system, malignant and infectious diseases. Safe use of drugs in pregnancy and childhood. Case study analysis - identification and prevention of adverse outcomes of interactions in patients treated for diseases of the cardiovascular system, respiratory system, central nervous system, gastrointestinal system, endocrine system, musculo-skeletal system, cancer, infectious diseases, and/or renal and hepatic insufficiency. Design of clinical studies for investigation of interactions in clinical practice. Critical assessment of published studies of clinically important drug-drug, drug- food and drug- dietary supplement interactions. Critical assessment of published studies on the adverse reactions of drugs.

Recommended literature:

1. Tatro D. Drug Interaction Facts™: Published by Facts & Comparisons (Drug Interaction Facts), Lippincott Williams & Wilkins; 2012.

2. Baxter K ed. Stockley s Drug Interactions, Pharmaceutical Press, 2012.

3. PDR Guide to Drug Interactions, Side Effects, and Indications, Thomson Healthcare; 62nd ed, 2007.

The total of active learning classes	**Lectures:** 90
	Individual research work: 90

Teaching methods:

Theoretical lectures, problem-based learning, seminars.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Planning of clinical studies in clinical pharmacy research

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: elective, module: Pharmacokinetics and Clinical Pharmacy

Semester: II	**Year of studies:** I
ECTS points: 15	**Course code:** ДФК1И4

Requirements: none

Course aims:

The aim of the course is to enable students to acquire knowledgde about planning, conducting and critical appraisal of clinical studies in pharmacy and medicine.

Course outcomes:

On completion of the course, the student will be able to apply the knowledge and plan, conduct and critically appraise clinical studies in pharmacy and medicine.

Course contents:

Classification and design of clinical studies. Objectives of health research. Development of methodology to explore specific clinical problems - research setting, the selection of design of clinical studies for conducting research, estimation of the number of subjects and methods of randomization. Setting criteria for inclusion and exclusion of subjects. Research focused on exposure, disease, population. Cohort studies, case - control, cross-sectional studies. Randomized controlled clinical trials. Meta - analysis. The reliability and applicability of the results of clinical studies. Methods of randomization and allocation. Determining the number of participants. Recruitment of participants. Ethics in performing clinical studies. Qualitative Research. The use of questionnaires in health care research, advantages and disadvantages. Health services research, clinical audit, quality assurance services. Pharmacoeconomic analysis. Planning a cost-minimization analysis, cost-benefit analysis, analysis of the cost- utility analysis and cost benefit ratio. The use of techniques for decion making relying on cost/benefit in pharmacoeconomic analyzes. The use of discounting in pharmacoeconomic analyzes. Analysis of results, expected outcomes .

Recommended literature:

1. Brody T. Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines. Academic Press; 1st ed. 2011.

2. Chow S-C, Liu JP. Design and Analysis of Clinical Trials: Concepts and Methodologies, Wiley-Interscience; 2 Sub edition, 2003.

3. Bowling A. Research Methods in Health: Investigating Health and Health Services. Open University Press; 3rd ed, 2009.

4. Arnold RJ. Pharmacoeconomics: From Theory to Practice. CRC Press; 1st ed, 2009.

The total of active learning classes	**Lectures:** 90
	Individual research work: 90

Teaching methods:

Theoretical lectures, problem-based learning, seminars.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Selected chapters of pharmacology

Teachers: Savić M. Miroslav, Stepanović-Petrović M. Radica

Course status: elective, module: Pharmacokinetics and Clinical Pharmacy

Semester: II	**Year of studies:** I
ECTS points: 15	**Course code:** ДФК1И5

Requirements: none

Course aims:

The aim of this course is to provide participants with knowledge necessary for understanding the basic characteristics of pharmacological profiles of prototype drugs in selected pharmacotherapeutic groups, based on in vitro and in vivo data obtained from preclinical as well as clinical studies.

Course outcomes:

Ability to independently interpret the results of basic preclinical studies of drugs. Ability for critical appraisal of the completeness of the available pharmacological profile of a drug. Appraisal of preclinical research data in the context of the findings of research in humans. Comprehension of benefits and risks of drugs in the selected pharmacotherapeutic group.

Course contents:

Target sites for drug action. Integration of nervous, endocrine and immunological regulation of a multicellular organism. Mechanisms of action of neurotransmitters, hormones and local mediators. Interaction drug-mechanisms of biological regulation. Mechanisms of signal transduction. Receptors, ion channels, enzymes, transporters. In vitro investigation of drug affinity and efficacy. Efficacy and potency. Agonists, inverse agonists, antagonists. Dose-response relationship, quantal and graded. Tolerance and resistance to drug action. Principles of drug investigation on animals. Primary pharmacodynamic investigations. Secondary pharmacodynamic investigations. Safety pharmacology. Toxicological profile of drugs. Acute toxicity. Toxicity of repeated administration. Mutagenicity. Teratogenicity. Carcinogenicity. Interpretation of the results obtained from toxicological studies and data extrapolation on humans. Estimation of efficacy and safety of drugs. Clinical and pharmacoepidemiological studies. Pharmacological profile of the drug. Mechanisms of action, pharmacological effects, therapeutic use and adverse effects of the therapeutic group of research interest for the candidate.

Recommended literature:

1.Rang HP, Dale MM, Ritter JM, Flower RJ, Henderson G. Rang and Dale's Pharmacology. 7th edition, Churchill Livingstone Elsevier, 2011.

2. Brunton LL, Chabner BA, Knollmann BC (eds). Goodman&Gliman's the Pharmacological Basis of Therapeutics, 12th editon. McGraw Hill, 2011.

3. Kenakin T. A Pharmacology Primer: Theory, Applications and Methods, 2nd edition. Academic Press, London, 2006

4. Katzung BG (ed). Basic&Clinical Pharmacology, 12th ed, Lange Medical Books/McGraw-Hill Medical Publishing Division, New York, 2012.

5. Hacker M, Bachmann K, Messer W. Pharmacology Principles and Practice. Academic Press, Amsterdam, 2009.

The total of active learning classes	**Lectures:** 90
	Individual research work: 90

Teaching methods:

Lectures, workshops and seminars

Grading system:

Seminar: 30 points; written exam: 70 points

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Methodology in pharmacokinetic studies and methodological aspects during modelling process

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: elective, module: Pharmacokinetics and Clinical Pharmacy

Semester: III	**Year of studies:** II
ECTS points: 15	**Course code:** ДФК2И1

Requirements: Pharmacokinetics and metabolism during drug development and drug use

Course aims:

The aim of the course is to provide students with relevant tools needed for understanding the methodological issues in pharmacokinetic data analysis.

Course outcomes:

On completion of the course, the student will be able to assess and apply optimal approach pharmacokinetic parameters calculation, and to use pharmacokinetic softwares for data modelling and simulation.

Course contents:

Different approaches in calculating pharmacokinetic parameters that characterize ADME processes of I and 0 order. Noncompartmental pharmacokinetic data analysis. Compartmental pharmacokinetic data analysis. Solving practical assignements and calculation of pharmacokinetic parameters by application of compartmental data analysis using the pharmacokinetic softwares. Solving practical assignements and calculation of pharmacokinetic parameters by application of noncompartmental data analysis using the pharmacokinetic softwares. Interpretation of pharmacokinetic parameters values of biological drugs. Linear, generalized linear and nonlinear models of combined effects. Bayesian modelling of pharmacokinetic data. Methods for parameters estimation in population pharmacokinetic analysis. Physiologicaly based (perfusion) models for each of ADME process. Pharmacokinetic-pharmacodynamic (PK/PD) modelling. Principles of data simulation. Using different pharmacokinetic softwares for pharmacokinetic parameters' calculation, and sources in pharmacokinetic drug variability. Application of developed pharmacokinetic models in predicting drug's concentration profile following specific dosing regimen. Application of developed pharmacokinetic models in predicting drug's concentration profile and efficacy/safety profile following specific drug's dosing regimen.

Recommended literature:

1. Rosenbaum S. Basic Pharmacokinetics and Pharmacodynamics: An Integrated Textbook and Computer Simulations, 1st ed. Wiley, 2011.

2. Bonate PL. Pharmacokinetic-Pharmacodynamic Modeling and Simulation, 2nd ed. Springer, 2011.

3. Ette EI, Williams PJ. Pharmacometrics: The Science of Quantitative Pharmacology, 1st ed. Wiley-Interscience, 2007.

4. Gabrielsson J, Weiner D. Pharmacokinetic and Pharmacodynamic Data Analysis: Concepts and Applications, 4th ed. Swedish Pharmaceutical Press, 2007.

5. Peters SA. Physiologically-Based Pharmacokinetic (PBPK) Modeling and Simulations: Principles, Methods, and Applications in the Pharmaceutical Industry, 1st ed. Wiley, 2012.

The total of active learning classes	**Lectures:** 90
	Individual research work: 90

Teaching methods:

Theoretical lectures, problem-based learning.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Methodology in clinical pharmacy research

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: elective, module: Pharmacokinetics and Clinical Pharmacy

Semester: III	**Year of studies:** II
ECTS points: 15	**Course code:** ДФК2И2

Requirements: Selected chapters of clinical pharmacy

Course aims:

The aim of the course is to enable students to acquire knowledgde about different methodological approaches of clinical pharmacy research.

Course outcomes:

On completion of the course, the student will be able to apply the knowledge and select appropriate methodology for planning and conducting clinical pharmacy research. Moreover, students will be able to perform critical appraisal of the research methodology in clinical pharmacy.

Course contents:

Methodology of research on effectiveness, safety and pharmacoeconomics of treatment. Questionnaires as research methods for the assessment of adherence, quality of life, efficacy and safety of treatment. Semi-structured interview. Creating a questionnaire, contents, types of questions, anonymity, type of response, wording of questions, the order of questions. Assessing the validity, reliability and sensitivity of questionnaire for use in clinical pharmacy research. Tests of significance and correlation. Cronbach α and internal consistency. Factor analysis. The development of questionnaires for the evaluation of adherence, quality of life, safety, and efficacy of treatment for patients suffering from diseases of the cardiovascular system, respiratory system, central nervous system, gastrointestinal system, endocrine system, musculo-skeletal system, cancer, infectious diseases, and/or renal and hepatic insufficiency. The use of questionnaires in clinical practice. Critical assessment of validated questionnaires used in clinical pharmacy research. Development and validation of methods for assesment of drug concentrations, biological markers, and/or laboratory parameters in biological material. Development and validation of pharmacoeconomic studies. One-way and two-way sensitivity analysis. Decision tree and Markov models. Significance and correlation testing of obtained data. Development of methodology for conducting pharmacoeconomic analysis. Critical evaluation of pharmacoeconomic studies in the literature.

Recommended literature:

1. Fayers P, Machin D. Quality of Life: The Assessment, Analysis and Interpretation of Patient-reported Outcomes. Wiley; 2nd ed, 2007.

2. Jacobsen K. Introduction to Health Research Methods. Jones & Bartlett Learning; 1st ed, 2011.

3. Swartz ME, Krull IS. Handbook of Analytical Validation. CRC Press; 1st ed, 2012.

4. Drummond MF, Sculpher MJ, Torrance GW, O'Brien BJ. Methods for the Economic Evaluation of Health Care Programmes, Oxford University Press; 3rd ed, 2005.

The total of active learning classes	**Lectures:** 90
	Individual research work: 90

Teaching methods:

Theoretical lectures, problem-based learning, seminars.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Pharmacokinetics of biological drugs

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: elective, module: Pharmacokinetics and Clinical Pharmacy

Semester: III	**Year of studies:** II
ECTS points: 15	**Course code:** ДФК2И3

Requirements: Pharmacokinetics and metabolism during drug development and drug use

Course aims:

The aim of the course is to provide students with relevant tools needed for understanding characteristics and factors that contribute to pharmacokinetics of biological drugs.

Course outcomes:

On completion of the course, the student will be able to understand pharmacokinetic characteristics in development of biological drug, and to individualize dosing regimen based on pharmacokinetic and/or pharmacokinetic-pharmacodynamic studies results.

Course contents:

The importance and place of pharmacokinetics in development of biological drugs. Regulatory aspects in pharmacokinetic studies of biological drugs. Association between pharmacokinetics and technology and pharmacodynamics of biological drugs. Bioanalytical methods used in the pharmacokinetic studies for measuring biological drugs levels in biological samples and their validation according to regulatory requirements. Pharmacokinetic characteristics of proteins, and peptides. Pharmacokinetic characteristics of monoclonal antibodies. Pharmacokinetic characteristics of oligonucleotides. Pharmacokinetic characteristics of viral and non-viral gene delivery vectors. Pharmacokinetic data analysis and interpretation of the pharmacokinetic parameters' values of biological drugs. Solving practical assignements and calculation of pharmacokinetic parameters using pharmacokinetic softwares. Interpretation of pharmacokinetic parameters values of biological drugs. Dosing regimen adjustments based on data on measured biological drugs' concentrations. Biosimilar drugs. Design of pharmacokinetic studies for biological drugs and its variability pharmacokinetic processes. Modelling process and interpretation of final pharmacokinetic-pharmacodynamic models of the selected biologic drugs using pharmacokinetic softwares. Modelling process and interpretation of final physiologicaly based (perfusion) models of the selected biologic drugs using pharmacokinetic softwares.

Recommended literature:

1. Meibohm B. Pharmacokinetics and Pharmacodynamics of Biotech Drugs, 1st ed. Wiley-Blackwell, 2006.

2. Kontermann R. Therapeutic Proteins: Strategies to Modulate Their Plasma Half-lives, 1st ed. Wiley-Blackwell, 2012.

The total of active learning classes	**Lectures:** 90
	Individual research work: 90

Teaching methods:

Theoretical lectures, problem-based learning.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.

University of Belgrade Faculty of Pharmacy	**DOCTORAL ACADEMIC STUDIES**	

Course title: Monitoring of adherence, efficacy and safety

Teachers: Miljković R. Branislava, Vezmar Kovačević D. Sandra, Vučićević M. Katarina

Course status: elective, module: Pharmacokinetics and Clinical Pharmacy

Semester: III	**Year of studies:** II
ECTS points: 15	**Course code:** ДФК2И4

Requirements: Selected chapters of clinical pharmacy

Course aims:

The aim of the course is to enable students to acquire knowledgde for monitoring and critical assesment of adherence, efficacy and safety of drugs.

Course outcomes:

On completion of the course, the student will be able to apply the knowledge and monitor and critically asess adherence, efficacy and safety of treatment.

Course contents:

Treatment outcomes. The causes of the unsatisfactory adherence and/or lack of efficacy and safety of therapy. Treatment errors and methods for prevention. Methods for monitoring of compliance, adherence, concordance. The importance of valid and reliable monitoring of patient outcomes. Assessing the validity, reliability and sensitivity of measuring instruments for monitoring adherence, efficacy and safety. Methods for improving the quality of life of the patient. The role of research in improving the outcome of treatment. The development of methods for monitoring of adherence, efficacy and safety of patients with diseases of the cardiovascular system, respiratory system, central nervous system, gastrointestinal system, endocrine system, musculo-skeletal system, cancer, infectious diseases, and/or renal and hepatic insufficiency. Strategies for improving the degree of adherence, efficacy and safety of treatment. Particularities of adherence monitoring, effectiveness and safety of the treatment of diseases of the central nervous system, cardiovascular system, respiratory system, musculo-skeletal system, and the gastrointestinal system. Critical evaluation of published research in the field of monitoring of adherence, efficacy and safety of treatment. Critical assessment of quality of life studies. Critical assessment of the validity, reliability and sensitivity of instruments for monitoring adherence, efficacy and safety.

Recommended literature:

1. Fayers P, Machin D. Quality of Life: The Assessment, Analysis and Interpretation of Patient-reported Outcomes. Wiley; 2nd ed, 2007.

2. Walker R, Whittlesea C. Clinical Pharmacy and Therapeutics, Churchill Livingstone 5th ed, 2012.

3. Kane RL, Radosevich DM. Conducting Health Outcomes Research. Jones & Bartlett Learning; 1st ed, 2010.

The total of active learning classes	**Lectures:** 90
	Individual research work: 90

Teaching methods:

Theoretical lectures, problem-based learning, seminars.

Grading system:

Pre-exam activities - seminar 30 points. Final exam 70 points.