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: Pharmaceutical preformulation and formulation

Teachers: Parojčić V. Jelena, Ibrić R. Svetlana, Đuriš D. Jelena, Cvijić V. Sandra, Corrigan I. Owen

Course status: Mandatory modules, module: Pharmaceutical Technology

Semester: I	**Year of studies:** I
ECTS points: 10	**Course code:** ДФТ1ОМ1

Requirements: no

Course aims:

Introduction to the importance of preformulation studies in the early stages of drug product development and formulation factors affecting drug product performance and its biopharmaceutical characterization as the foundation for independent research work.

Course outcomes:

Understanding and application of pharmaceutical preformulation and formulation principles in drug product development and biopharmaceutical characterisation

Course contents:

Importance of preformulation studies in candidate drug selection and early development. Role of preformulation studies in the early phases of drug product development. Physicochemical characteristics of active pharmaceutical substances and excipients. pKa value determination. Partition coefficient. Drug solubility (solubility determination, solubility prediction, influence of excipients on drug solubility). Solid state characteristics; Crystal state and structural analysis (polymorphism and the related phenomena, evaluation of thermodynamic stability of different polymorphs, salts and co-crystals, solvates, hydrates, amorphous material). Solid state characterization (x-ray diffraction, IR spectroscopy, near IR spectroscopy, Raman spectroscopy, NMR). Crystal morphology assessment (microscopy, SEM, AFM). Hygroscopicity. Thermal analysis. Particle size; determination of particle size distribution and specific surface area. Drug stability and its importance in pharmaceutical formulation development. Biopharmaceutical approaches in pharmaceutical development: solubility and dissolution; physiological aspects of drug release and drug dissolution testing; biorelevant dissolution testing; the principles of drug absorption; evaluation of drug absorption potential. Biopharmaceutical classification system. Physiological factors influencing drug bioavailability administered by different routes of administration. Drug dissolution in vitro and in vivo. Drug dissolution from different dosage forms. In vitro - in vivo correlation. Principles of different dosage forms development. Regulatory aspects of pharmaceutical development. QbD concept in pharmaceutical development. Principles of drug product optimisation. Experimental design - principles and application in pharmaceutical development.

Recommended literature:

1. Gibson M. Pharmaceutical preformulation and formulation, 2nd ed. Informa Healthcare, 2009;
2. Florence and Attwood. Physicochemical Principles of Pharmacy, Pharmaceutical press, 2006;
3. Aulton ME. Pharmaceutics - the science of dosage form design, 2nd ed. Churchill Livingstone, 2002;
4. Enczclopedia of pharmaceutical Technology, Swarbrick J., Boylan J.C:, second edition, marcel Dekker Inc., New York, Basel, 2002;
5. Pharmaceutical Dissolution Testing, editors Jennifer J. Dressman, Johannes Kramer, Informa Healthcare, 2005;
6. Physiological Pharmaceutics: Barriers to Drug Absorption, by Neena Washington, Clive Washington, Clive Wilson, CRC 2000;

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

Teaching methods:

Lectures, interactive lectures, simulation workshops, seminars

Grading system:

Pre-exam (homeworks and presentations) up to 50 points; Final written exam up to 50 points.

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

Course title: Theoretical aspects of liquid and semisolid pharmaceutical dosage forms

Teachers: Savić D. Snežana, Đekić M. Ljiljana, Krajišnik R. Danina

Course status: Mandatory modules, module: Pharmaceutical Technology

Semester: I	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1ОМ2

Requirements: /

Course aims:

Knowledge of theoretical and practical aspects of colloidal systems / conventional and nanodispersed systems such as emulsions and suspensions, and techniques for their characterization for the purpose of formulation of stable, efficient and safe conventional and advanced dosage forms/drug carriers.

Course outcomes:

The students are able to solve a research problem in the field of colloidal systems / conventional and nanodispersed systems i.e., in formulation development of conventional and advanced pharmaceutical dosage forms/drug carriers and know techniques for their characterization.

Course contents:

Dispersions. Theories on stabilisation of different colloidal systems: DLVO theory, theory of steric and electrosteric stabilisation. Characteristics of colloids. Zeta potential. Physical stability of colloidal systems for pharmaceutical application. Phenomenon on the surfaces and interfaces. Rheology of the pharmaceutical systems. Surfactants. Micellization, solubilization. Liquid crystals state. Dispersions. Suspensions. Mechanisms of stabilisation of suspensions. Emulsions and mechanisms of stabilisation of emulsions. Nanoemulsions obtained by high-energy and low-energy emulsification methods. Nanosuspensions - suspensions of nanocrystals. Nanoparticles - liquid dispersions of nanoparticles. Techniques for characterisation of colloids with different dispersity grade and consistency: photon correlation spectroscopy, laser diffraction analysis, microscopy (light, polarizing, and transmission electron microscopy), Cryo-electron microscopy, fluorescent microscopy, Raman spectroscopy, Atomic force microscopy, Differential scanning calorimetry, Thermogravimetric analysis, Rheological characterisation, x-ray diffraction.

Recommended literature:

1. Vuleta G, Milić J, Primorac M, Savić S. Farmaceutska tehnologija I, Farmaceutski fakultet Beograd, 2012.

2. Florence & Attwood. Physicochemical Principles of Pharmacy, Pharmaceutical Press 2009.

3. Gibson M. Pharmaceutical Preformulation and Formulation, Informa Healthcare 2009.

4. Savić S. Fizičkohemijski aspekti i in vitro/in vivo karakterizacija emulzionih sistema sa nejonskim emulgatorima tipa šećernog etra. Farmaceutski fakultet Beograd, 2004. 5. Selected journal papers: Advanced Drug Delivery Reviews, European Journal of Pharmaceutics and Biopharmaceutics, European Journal of Pharmaceutics, Internaional journal of Pharmaceutics, Current Opinion in Colloid and Interface Science, Advances in Colloid and Interface Science.

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

Teaching methods:

Lectures, interactive methods, seminars.

Grading system:

Pre-commitments: seminar - maximum 50 points; exam (written/test): maximum 50 points

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

Course title: Formulation and characterization of pharmaceutical dosage forms for cutaneous application

Teachers: Vuleta M. Gordana, Đekić M. Ljiljana, Savić D. Snežana

Course status: Mandatory modules, module: Pharmaceutical Technology

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1ОМ3

Requirements: Preformulation and formulation research and development, Theoretical aspects of liquid and semisolid pharmaceutical dosage forms

Course aims:

Introduction in theoretical and practical aspects of dermal and transdermal drug delivery, influence of the factors relevant for selection of optimal formulation of the dosage form, biopharmaceutical aspects of cutaneous drug application and current methods for in vitro and in vivo characterization of pharmaceutical preparations for cutaneous application.

Course outcomes:

The students are able to apply theoretical and practical aspects of formulation of dosage forms for cutaneous application and methods for their characterization, through an individual research work.

Course contents:

Considerations on the importance of the design and development of pharmaceutical preparations for cutaneous application. Specificity of the cutaneous dosage forms development. Criteria for selection of: pharmaceutical excipients regarding a pharmaceutical dosage form type or skin desease type (skin condition), aspects of dermal and transdermal drug delivery. Influence of the vehicle of the semi-solid preparations for cutaneous application on drug release and effects in local therapy. Theoretical aspects of penetration, permeation and percutaneous absorption of the drugs and physical and chemical approaches for skin barrier properties modification, in order to affect the diffusion rate of a permeant. Chemical penetration enhancers od the drugs. Biological and physico-chemical factors relevant for percutaneous penetration and permeation. Principles of development of pharmaceutical preparations for cutaneous application: ointments, creams, gels. Transdermal drug delivery systems: transdermal patches (basic types: drug-in-adhesive type, matrix type, reservoir type) and other systems (application of microneedles). In vitro and in vivo methods for characterization of pharmaceutical dosage forms for cutaneous application. In vitro diffusion models (with different membranes) for evaluation of drug release and percutaneous penetration/permeation.

Recommended literature:

1. Vuleta G, Milić J, Primorac M, Savić S. Farmaceutska tehnologija I, Farmaceutski fakultet Beograd, 2012.

2. Gibson M. Pharmaceutical Preformulation and Formulation, Informa Healthcare 2009.

3. Niazi S. Handbook of Pharmaceutical Manufacturing Formulations: Semisolid Products, CRC Press, 2004. Savić S.

4. Remington: The Science and Practice of Pharmacy, 22nd ed., Pharmaceutical Press, 2012.

5. Allen LV, Popovich NG, Ansel HC. Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincot Williams & Wilkins, Philadelphia, 2005.

6. Voight R. Pharmazeutische Technologie, Deutscher Apotheker Verlag, Stuttgart, 2006.

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

Teaching methods:

Lectures, interactive methods with problem simulations, individual research work.

Grading system:

Pre-commitments: seminars (minimum 30 points); exam (written) (minimum 70 points).

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

Course title: Theoretical aspects of parenteral and ophthalmic preparations

Teachers: Milić-Aškrabić R. Jela, Krajišnik R. Danina

Course status: Mandatory modules, module: Pharmaceutical Technology

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1ОМ4

Requirements: non

Course aims:

Knowledge of formulation theoretical and practical aspects of parenteral and ophthalmic preparations, which will serve to doctoral students as the basis for their application in independent researches within the doctoral studies in pharmaceutical sciences – elective module/area pharmaceutical technology as well as in the future professional activities.

Course outcomes:

Application of advanced knowledge related to theoretical and practical aspects of the formulation of parenteral and ophthalmic preparations and methods for their characterization within the independent researches.

Course contents:

Formulation considerations of parenteral preparations: physiological, physicochemical and pharmaceutical technological requirements. The requirement for sterility of parenteral preparations – the impact on formulation and principles of the preparation development. Excipients for parenteral preparations and factors significant for their choice. Strategies for formulation of parenteral dosage forms with poorly soluble active substances, unstable molecules and macromolecules. Novel drug carriers for parenteral administration. Methods for the characterization of various pharmaceutical formulations/drug carriers for the parenteral administration during preformulation and formulation. Quality requirements for the parenteral preparations. Factors important for the stability of parenteral preparations. Compatibility problems related to interaction of parenteral preparations and containers as well as mixing of several parenteral preparations. Factors relevant for formulation of ophthalmic preparations (anatomical and physiological features of the eye, the physicochemical properties of the drug substance). Types and characteristics of the pharmaceutical dosage forms for application to the eyeball and in the conjunctival sac. Excipients in ophthalmic preparations and factors significant for their choice. Quality requirements for the ophthalmic preparations. Approach for optimizing ocular drug availability in the local administration. Novel dosage forms and drugs carriers for ophthalmic administration. Methods for the characterization of some pharmaceutical formulations/drug carriers for ophthalmic administration during preformulation and formulation.

Recommended literature:

1. Pharmaceutical preformulation and formulation, 2nd ed., Mark Gibson (Ed..), Informa Healthcare, New York, 2009
2. Avis K.E. and Avis A.E. Pharmaceutical Dosage Forms: Parenteral Medications, Lippincott Williams &Wilkins, 1992
3. Remington: The Science and Practice of Pharmacy, 22nd ed. Pharmaceutical Press, Gurnee, 2012
4. Encyclopedia of Pharmaceutical Technology, Swarbrick J., Boylan J.C., second edition, vol. 1-3, Marcel Dekker Inc., New York, Basel, 2002
5. Katdare A., Chaubal M.V. (eds.), Excipient Development for Pharmaceutical, Biotechnology and Drug Delivery Systems, informa healthcare, New York, London, 2006
6. Avis K.E, Sterile Pharmaceutical Products: Process Engineering Applications, CRC, 1995
7. Turco S.J., Sterile Dosage Forms Their Preparation and Clinical Application, Lippincott Williams &Wilkins, 1994

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

Teaching methods:

Lectures, interactive sessions

Grading system:

Exam prerequisites: 50 points; Final exam: 50 points

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

Course title: Theoretical Aspects of Solid Dosage Forms

Teachers: Đurić R. Zorica, Parojčić V. Jelena, Ibrić R. Svetlana, Đuriš D. Jelena, Vasiljević D. Dragana

Course status: Mandatory modules, module: Pharmaceutical Technology

Semester: III	**Year of studies:** II
ECTS points: 5	**Course code:** ДФТ2ОМ1

Requirements: previously completed course Preformulation and Formulation Research and Development

Course aims:

To provide students with knowledge about theoretical and practical aspects of formulation of solid dosage forms, so that they can acquire competences to perform independent research activities within doctoral studies in Pharmaceutical Sciences – Modul Pharmaceutical Technology, and later on, related research activities in practice.

Course outcomes:

Application of theoretical and practical aspects of formulation and manufacturing procedures of solid dosage forms, and methods for their characterization in the independent research activities.

Course contents:

Modern approaches in the formulation of solid dosage forms. Solid dispersions (methods of preparation, characterization). Hard capsules. Soft capsules. Fast-dissolving solid oral dosage forms. Powder characterization (particle size, flowability, density, porosity). Compressibility and compactibility. Theoretical aspects of compression. Analysis of the material characteristics which are important for the compression. Compaction simulators. Basic principles of the formulation of inhalation powders (particle size, disposition in the lungs, impaction). Pelets. Characteristics of the pharmaceutical excipients for solid dosage forms. Multifunctional excipients. Characteristics of pharmaceutical operations in the preparation (production) of solid dosage forms. Milling. Mixing. Granulation (hot-melt granulation, fluidized-bed granulation, granulation in high-shear mixers). Tableting. Extrusion. Spheronization. Equipment for the manufacturing of solid dosage forms. Tablet machines: instrumentation of tablet machines. Fluidized-bed granulation: types and characteristics of the equipment. Concept of continuous production of solid dosage forms. Application of spray drying in the production of solid dosage forms. Application of lyophilization in the production of solid dosage forms. Analysis of solid dosage forms. Principles of Process Analytical Technology–PAT in the production of solid dosage forms. Process control in the production of solid dosage forms.

Recommended literature:

1. Handbook of Pharmaceutical Granulation Technology, Second Edition by Dilip M. Parikh (Editor), Taylor & Francis, 2005.
2. Pharmaceutical Powder Compaction Technology. Editors: G Alderborn, C Nystrom, New York: Marcel Dekker, 1995.
3. Pharmaceutical Principles of Solid Dosage Forms by Jens T. Carstensen, Informa Health Care 1993.
4. Handbook of Pharmaceutical Excipients by Raymond C. Rowe, Paul J. Sheskey, Siân C. Owen, 4th edition, McGraw-Hill 2005.
5. Pharmaceutical Dosage Forms-tablets by Herbert A. Lieberman, Leon Lachman, Joseph B. Schwartz, Informa Health Care, 1990.
6. Encyclopedia of Pharmaceutical Technology, Swarbrick J., Boylan J.C., second edition, Marcel Dekker Inc., New York, Basel, 2002.

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

Teaching methods:

Theoretical classes, interactive classes including demonstrations and simulation integrated with problem-based learning, laboratory and computer practical classes.

Grading system:

Pre-exam requirements: practical work/elaborate study/seminar paper – maximum 50 points; final exam: written – maximum 50 points.

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

Course title: Theoretical Aspects of Modified Release Dosage Forms/Drug Delivery Systems

Teachers: Primorac M. Marija, Ibrić R. Svetlana, Đekić M. Ljiljana, Cvijić V. Sandra

Course status: Mandatory modules, module: Pharmaceutical Technology

Semester: III	**Year of studies:** II
ECTS points: 5	**Course code:** ДФТ2ОМ2

Requirements: none

Course aims:

To provide students with knowledge about theoretical and practical aspects of the formulation of modified release dosage forms/drug delivery systems for different dosage routes, so that they can acquire competences to perform independent research activities within doctoral studies in Pharmaceutical Sciences – Modul Pharmaceutical Technology.

Course outcomes:

Application of theoretical and practical knowledges regarding formulation of modified release dosage forms/drug delivery systems in the independent research activities within doctoral studies, and later on in practise.

Course contents:

Formulation approaches for modified release dosage forms. Mechanisms of modified drug release (practical examples). Diffusion-controlled drug release. Dissolution-controlled drug release. Swelling-controlled drug release. Osmosis-controlled drug release. Programmed drug release. Matrix type drug delivery systems. Pharmaceutical excipients for oral modified release dosage forms. Modified release dosage forms for the use in the mouth. Multiparticulate drug delivery systems. Modern aspects of the formulation of drug delivery systems. Ocular, intravaginal/intrauterine, peroral, parenteral, pulmonary, buccal, nasal and transdermal drug delivery systems. Chronotherapeutic drug delivery systems: classes and characteristics. Target drug delivery systems. Colon-specific drug delivery systems. Colloidal drug carriers. Biopharmaceutical aspects of oral modified release preparations. Specificities of modified release dosage forms assessment.

Recommended literature:

1. Wen H., Park K., Oral Controlled Release Formulation Design and Drug Delivery, John Wiley & Sons, New Jersey, 2010.

2. Allen L.V., Popovich N.G., Ansel H.C., Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, Lippincot Williams&Wilkins, Philadelphia, 2005.

3. Encyclopedia of Pharmaceutical Technology, Swarbrick J., Boylan J.C., second edition, vol. 1-3, Marcel Dekker Inc., New York, Basel, 2002.

4. Rathbone M.J., Hadgraft J., Roberts M.S., Modified-Release Drug Delivery Technology, Marcel Dekker, Inc., New York, Basel, 2003.

5. Одабрани радови из часописа: Advanced Drug Delivery Reviews, European Journal.

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

Teaching methods:

Theoretical classes, interactive classes, seminars.

Grading system:

Pre-exam requirements: seminar paper – maximum 50 points; final exam: written – maximum 50 points.

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

Course title: Physico-chemical phenomena and instrumental methods

Teachers: Mirjana B. Medenica, Nataša D. Pejić

Course status: elective, module: Pharmaceutical Technology

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1И1

Requirements: no

Course aims:

Introduction to the selected physical and chemical phenomena and instrumental techniques which candidates will use in his doctoral dissertation

Course outcomes:

Knowledge of the theoretical principles of physical and chemical phenomena, as well as performing selected techniques and methods during the experimental work, and in the interpretation of the obtained results.

Course contents:

Selected topics of colloid chemistry : kinetic, electrical and optical properties of colloids, surfactants. Theoretical aspects of rheology : Newtonian and Non-Newtonian systems, viscoelastic systems. Physicochemical surface properties: surface tension, adsorption, wetting . Chemical Kinetics: Theoretical aspects and analysis of kinetic data.

X-ray powder diffraction analysis: principles, instrumentation, sample preparation, the use of structural analysis, monitoring the conversion of solid phase during the production of the drug, the determination of impurities.

Absorption (atomic and molecular absorption spectrophotometry), fluorimetry and Raman spectroscopy methods: principles, techniques and instrumentation applications. Infrared spectroscopy with Fourier transform : principle, instrumentation, application to the analysis of the active principle in a solid and semisolid pharmaceutical formulations. Mass spectrometry: principles, instrumentation and applications. Nuclear magnetic resonance imaging: principles, applications for the confirmation of the chemical structure and the analysis of the active principle. Turbidimetry and nephelometry: application to the determination of the concentration of the system , and solubilization.

Thermal methods of analysis (thermogravimetry and differential scanning calorimetry) principles, instrumentation, sample preparation, interpretation of thermogram, the application for the determination of physicochemical properties of different pharmaceutical products, the stability of the active principles and excipients and water content. Selected methods for the electrochemical determination of ingredients in pharmaceutical products (e.g., water) , as well as the characteristics of the surfactants.

Recommended literature:

. Skoog D, Holler FJ, Niemen TA. Principles of Instrumental Analysis (5th ed.). Philadelphia: Sounders College Publishing; 1998.

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

Teaching methods:

Lectures, interactive lectures.

Grading system:

Pre-exam (homeworks and presentations) up to 50 points; Final written exam up to 50 points.

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

Course title: Formulation and characterization of herbal medicines

Teachers: Vuleta M. Gordana, Kundaković D. Tatjana, Vasiljević D. Dragana

Course status: elective, module: Pharmaceutical Technology

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1И2

Requirements: Pharmaceutical preformulation and formulation

Course aims:

Introduction to the theoretical and practical aspects of the formulation, and the specific characteristics of herbal medicines.

Knowledge of the active ingredients of plant origin (herbal drugs, herbal drugs preparation), their chemical composition and stability, in order to select the most appropriate formulation of the pharmaceutical form , and

herbal drug, as well as the production procedure.

Course outcomes:

Knowledge of the chemical and other properties of the active substances of plant origin and specific characteristics of plant drugs, important to select the most appropriate formulation and the appropriate herbal medication, for a particular route of administration, as well as a method for their characterization.

Course contents:

Introduction to herbal medicines and specificity of this group of products.

Active components (herbal drug preparations, herbal drugs) and their chemical composition. The most important aspects of herbal drugs and herbal drug preparations. Herbal extracts. Methods selection and conditions of extraction depending on the desired characteristics of the extracts. Considerations relevant for the development of the pharmaceutical formulation of the drug for a particular plant routes of administration.

Specific features of the development of herbal medicines and herbal medicines characteristics.

The criteria for the choice of auxiliary substances (excipients) in relation to the physicochemical properties and stability of the active ingredients of plant origin (herbal drug preparations, herbal drugs), pharmaceutical form of the medicinal product and the production process of plant medicine. Modern pharmaceutical forms of herbal medicines.

Methods for characterization of herbal medicines.

Recommended literature:

1. Vuleta G, Milić J, Primorac M, Savić S, Farmaceutska tehnologija I, Farmaceutski fakultet, Beograd, 2012.
2. ESCOP Monographs. Stuttgart: Georg Thieme Verlag, 2003.

3.Community Monographs: www.ema.europa.eu

4. Voigt R, Pharmazeutische Technologie, Deutscher Apotheker Verlag, Stuttgart, 2006.

5. Vallisuta O, Olimat S. (Ed). Drug Discovery Research in Pharmacognosy. InTech, Rijeka, 2012

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

Teaching methods:

Lectures, work in group, seminars

Grading system:

Pre-commitments: practical work/display problems/essay - maximum 40 points;

final exam: Oral - maximum 60 points

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

Course title: Pharmacokinetics

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

Course status: elective, module: Pharmaceutical Technology

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1И3

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 in drug development, different designs of pharmacokinetic trial depending on the phase of drug development, for performing and critical appraisal of clinical pharmacokinetics and bioequivalence trials.

Course outcomes:

On completion of the course, the student will be able to apply drug's pharmacokinetic and metabolism characteristics into the decision-making process related to drug's development and critically appraise pharmacokinetic and bioequivalence studies.

Course contents:

Prediction of pharmacokinetic processes, metabolism and parameter values based on physico-chemical characteristics of a drug candidate. Assessment of ADME processes of the drug candidate. Prediction of the pharmacokinetics in humans (allometric approach, physiological models). Pharmacokinetic profiles and parameters depending on the route of drug administration. Pharmacokinetics of biological drugs. Pharmacokinetics of modified release drug preparations. Regulatory aspects in pharmacokinetic trials. Preparing reasearch protocol for clinical pharmacokinetic and bioequivalence studies according to regulatory aspects. Design of pharmacokinetic and bioequivalence trials. Performing pharmacokinetic and bioequivalence trials. Calculation of pharmacokinetic parameters using different pharmacokinetic approaches to data analysis. Data interpretation, statistical tests in analysing pharmacokinetic parameters from pharmacokinetic and bioequivalence trials. Interpretation of the pharmacokinetic and statistic results. Preparing the report of pharmacokinetic and bioequivalence trials. Critical appraisal of pharmacokinetic and bioequivalence trials.

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

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

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: Pharmaceutical Analysis and Quality Control

Teachers: Anđelija M. Malenović, Biljana S. Stojanović

Course status: elective, module: Pharmaceutical Technology

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1И4

Requirements: /

Course aims:

Acquiring knowledge from pharmaceutical analysis important for quality control in development and formulations of drugs, as well in quality control of final medical product

Course outcomes:

Getting knowledge on quality of medical products including knowledge on methods nedded for quality control

Course contents:

The methods important for drug analysis during formulation development. Separation methods for drug analysis in formulation development. Chromatographic parameters and criteria for the evaluation of chromatographic analysis quality. The types of chromatographic methods. Characteristics of the stationary phase and selection of the proper type . Modifications of mobile phases (ion-pair chromatography, ion suppression). Ultra High Performance Liquid Chromatography, characteristics and possibilities for application. Development of chromatographic methods for a particular analysis. Discussion on the implications to the method characteristics (sample properties, detector types, solution stability, selection of the stationary phase and mobile phase, etc). Other chromatographic methods important for estimation of product quality in different phases of formulation development with special attention on gas chrohroamtographic methods and iinverse gas chromatographic methods.

The principles and theoretical foundations of thermal analysis. Evaluation of thermal analysis methods: thermogravimetry - TG, derivative thermogravimetry - DTG , thermogravimetric analysis - TGA, differential thermal analysis - DTA and differential scanning calorimetry - DSC. Possibilities and importance of application of TGA for drug characterization and importance for formulation development.

Quality control and definition of specifications in different phases of development, drug manufacturing and drug release. Compendial methods and validation of new qualitative and quantitative methods for drug anaysis. Legislative and evaluation of product quality.

Recommended literature:

1. Kazakevich, Y., Lobrutto, R., Editors: HPLC for pharmaceutical scientist. John Wiley & Sons, Inc., New York,USA 2007.

2. Ahuja, S.: Chromatography and separation science. Volume 4 of Separation science and technology, Academic Press, San Diego, USA 2003.

3. Craig, D. Q. M., Reading, M.: Thermal Analysis of Pharmaceuticals. CRC Press is an imprint of Taylor & Francis Group, an Informa business, Boca Raton, USA, 2007.

4. Gabbott P., Editor: Principles and Applications of Thermal Analysis, Blackwell Publishing Ltd ,Oxford, UK 2008.

5. Ahuja, S., Scipynski, S., Editors: Handbook of Modern Pharmaceutical Analysis. Academic Press, San Diego, 2001.

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

Teaching methods:

Lectures, workshops, seminars, interactive teaching and internet.

Grading system:

Pre-exam engagements: 30 points Final exam: 70 points

University of Belgrade Faculty of Pharmacy	DOCTORAL ACADEMIC STUDIES	

Course title: Drug Stability

Teachers: Ibrić R. Svetalana

Course status: elective, module: Pharmaceutical Technology

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1И5

Requirements: Pharmaceutical preformulation and formulation

Course aims:

Introduction into drug stability and evaluation of drug stability

Course outcomes:

Application of techniques for evaluation of drug stability.

Course contents:

Investigation into drug stability in preformulation and formulation stages of drug development. Introduction into methods for drug stability evaluation. Functional changes in farmaceutical dosage forms in time. Effects of packaging on drug stability. Stabilization of drugs in dosage forms. Estimation of shelf life (pratical examples). Regulatory requirements for drug stability.

Recommended literature:

1. Stability of Drugs and Dosage Forms by Yoshioka, Sumie.; Stella, Valentino J. New York Kluwer Academic Publishers, 2002.

2. Chemical Stability of Pharmaceuticals: A Handbook for Pharmacists by Kenneth Antonio Connors, Informa Health Care, 2000.

3. Drug Stability, Principles and Practices, Kenneth Antonio Connors, Wiley-IEEE, 1986.

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

Teaching methods:

Lectures, interactive lectures, simulation workshops

Grading system:

Pre-exam (homeworks and presentations) up to 30 points; Final written exam up to 70 points.

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

Course title: Application of optimization techniques in Pharmaceutical Technology

Teachers: Ibrić R. Svetlana, Đuriš D. Jelena

Course status: elective, module: Pharmaceutical Technology

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1И6

Requirements: /

Course aims:

Introduction into experimental design and artificial neural network and their application in pharmaceutical technology

Course outcomes:

Certain experimental design techniques, as well as artificial networs, student may apply in own research.

Course contents:

Fundamentals of experimental design. Screening experimental design. Fractional experimental design. Analysis of factor effects. Full factorial desing. Response surface methodology application. Mixture experimental design. Fundamentals in artificial neural networks and their application in pharmaceutical technology. Multilayer perceptron. Generalizer Rgression Neural Network. Dynamic artificial neurla networks.

Recommended literature:

1. Djuris J. (Ed.) Computer aided applications in pharmaceutical technology. Woodhead Publishing, Cambridge, United Kingdom. 2013.

2. Ибрић С. Примена математичке теорије експеримената у фармацеутској технологији, Констиси, Београд, 2006.

3. Lewis G.A. (Ed.) Pharmaceutical Experimental Design. Marcel Dekker. New York, 1999.

4. Rajasekaran S, Vijayalakshmi Pai GA. Neural networks, fuzzy logic and genetic algorithms: synthesis and applications. Prentice-Hall, New Delhi, India, 2003.

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

Teaching methods:

Lectures, interactive lectures, simulation workshops

Grading system:

Pre-exam (homeworks and presentations) up to 30 points; Final written exam up to 70 points.

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

Course title: Methodologies in Biopharmaceutical Drug Characterization

Teachers: Parojčić V. Jelena, Cvijić V. Sandra, Owen I. Corrigan

Course status: elective, module: Pharmaceutical Technology

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** ДФТ1И7

Requirements: none

Course aims:

A student should get to know the methodology and application of biopharmaceutical drug characterization in order to be able to perform independent research activities within doctoral studies in Pharmaceutical Sciences – Modul Pharmaceutical Technology, and later on, related research activities in practice.

Course outcomes:

The application of various methods in biopharmaceutical drug characterization.

Course contents:

Biopharmaceutics Drug Classification Systems. Present techniques for solubility determination. In vitro, in vivo and in silico methods for the prediction/determination of drug permeability. In vitro and in vivo methods for determination of drug dissolution rate from different pharmaceutical preparations. Biorelevant media. In vitro, in vivo and in silico methods for the assessment of food effects on oral drug absorption. Recent methods for the evaluation of the influence of transporters on oral drug absorption. In silico absorption prediction. Mathematical modeling of drug absorption process. In vitro-in vivo correlation: Application of linear and nonlinear models. Biopharmaceutical characterization of herbal drugs. Regulatory aspects and the importance of biopharmaceutical drug characterization.

Recommended literature:

1. Drug Bioavailability: Estimation of Solubility, Permeability, Absorption and Bioavailability, H. Waterbeemd, H. Lennernäs, P. Artursson, editors, Wiley-VCH, Weinheim. 2006.

2. Biopharmaceutics applications in drug development, R. Krishna, L.Yu, editors, Springer, New York. 2008.

3. Pharmaceutical Dissolution Testing, J. Dressman, J. Kramer, editors, Taylor and Francis Group, Boca Raton. 2005.

4. Physiological Pharmaceutics: Barriers to Drug Absorption, N. Washington, C. Washington, C. Wilson, Taylor & Francis Series in Pharmaceutical Sciences. 2001.

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

Teaching methods:

Theoretical classes, interactive classes including demonstrations, problem based learning.

Grading system:

Pre-exam requirements: practical work/elaborate study/seminar paper – maximum 40 points; final exam: written – maximum 60 points.

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

Course title: Polymers for pharmaceutical/medical applications

Teachers: Milić-Aškrabić R. Jela, Krajišnik R. Danina

Course status: elective, module: Pharmaceutical Technology

Semester: III	**Year of studies:** II
ECTS points: 5	**Course code:** ДФТ2И1

Requirements: no

Course aims:

Advancement of knowledge related to the types and characteristics of the polymers used in the formulation of pharmaceutical dosage forms/drug carriers, as well as the factors relevant for polymer selection, which would serve as a basis for individual research within the doctoral studies and future professional activities.

Course outcomes:

Ability to apply the acquired knowledge to individual consideration of polymeric material characteristics relevant for their application in formulation of pharmaceutical dosage forms/drug carriers.

Course contents:

Polymers in medical/biomedical products: reasons and objectives of the application. The types and properties of polymer materials for pharmaceutical application (conventional dosage forms, drug carriers of drugs and therapeutic systems).

Characteristics and application of: hydrophilic polymers, hydrogels (cross-linked hydrated polymer), micelle-forming polymers (self-associative polymers). Characteristics of biodegradable polymers. Polymers that change structure and properties in response to environmental factors ("Smart"/" Intelligent " polymers). Methods for polymers characterization in drug preformulation and formulation studies. GRAS (Generally Recognized As Safe) status of polymers. Correlation between a polymer structure and properties - significance for drug carriers. Polymer-drug conjugates (polymer therapeutics).

Recommended literature:

1. Kwon G.S. (ed.), Polymeric Drug Delivery Systems, Taylor S. Francis, Boca Raton, London, 2005.
2. Remington: The Science and Practice of Pharmacy, 22nd ed. Pharmaceutical Press, Gurnee, 2012.
3. Fried, J. R., Polymer Science and Technology, Prentice Hall, New Jersey, 2003.
4. Rowe R.C., Sheskey P.J., Owen S.C., (eds.), Handbook of Pharmaceutical Excipients. Pharmaceutical Press and American Pharmacists Association, London, Washington 2008.
5. Malmsten M. Surfactants and Polymers in Drug Delivery, Marcel Dekker Inc, New York, 2002.
6. Evans D. and Wennerström H., The colloidal Domain-Where Physics Chemistry, Biology, and Techology Meet ,Wiley-VCH, New York, 1999.
7. Pürma J., Polymeric Surfactants, Marcel Dekker,New York,1992.

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

Teaching methods:

Lectures, interactive sessions

Grading system:

Exam prerequisites: 50 points; Final exam: 50 points.

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

Course title: Drug delivery carriers

Teachers: Primorac M. Marija, Đekić M. Ljiljana

Course status: elective, module: Pharmaceutical Technology

Semester: III	**Year of studies:** II
ECTS points: 5	**Course code:** ДФТ2И2

Requirements: Preformulation and formulation research and development

Course aims:

Knowledge of characteristics and application of novel drug carriers (liposomes, elastic vesicular carriers, microparticles, nanoemulsions, microemulsions, polymeric micelles, dendrimers, cyclodextrins and solid dispersions). Introduction in methods for physico-chemical and biopharmaceutical characterisation of drug delivery carriers. Introduction in major strategies for development of pharmaceutical formulations with drug delivery carriers.

Course outcomes:

The students know charcteristics and application of novel drug carriers (liposomes, elastic vesicular carriers, microparticles, nanoemulsions, microemulsions, polymeric micelles, dendrimers, cyclodextrins and solid dispersions). They are familiar with the methods for physico-chemical and biopharmaceutical characterisation of drug delivery carriers. The students are introduced in major strategies for development of pharmaceutical formulations with drug delivery carriers.

Course contents:

Liposomes - types, characteristics and applications. Elastic vesicular carriers (transfersomes, ethosomes and invasomes). Microparticles (microcapsules and microspheres) - characteristics and applications. Nanoparticles (polymeric nanoparticles and solid lipid nanoparticles) - characteristics and applications. Nanoemulsions. Microemulsions. Polymeric micelles. Dendrimers. Cyclodextrins. Solid dispersions. Physicochemical and biopharmaceutical characterisation of liposomes, elastic vesicular carriers, microparticles, nanoemulsions, microemulsions, polymeric micelles, dendrimers, cyclodextrins and solid dispersions by applying different techniques (photon correlation spectroscopy, fourier transform infrared spectroscopy (FT-IR), differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), scanning electron microscopy (SEM), transmission electron microscopy (TEM), optical microscopy, polarising light microscopy, rheological characterisation). Major approaches in development of pharmaceutical formulations with drug delivery carriers for different routes of application.

Recommended literature:

1. Fanun M, Colloids in Drug Delivery, CRC Press/Taylor and Francis Group, Boca Raton, 2010.

2. Rathborne MJ, Hadgraft J, Roberts MS, Modified-Release Drug Delivery Technology, Marcel Dekker, Inc., New York, Basel, 2003. 3. Encyclopedia of Pharmaceutical Technology, Swarbrick J, Boylan JC, second edition, vol. 1-3, Marcel Dekker Inc., New York, Basel, 2002. 4. Gibson M. Pharmaceutical Preformulation and Formulation, Informa Healthcare 2009.

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

Teaching methods:

Lectures, interactive methods, problem-based learning.

Grading system:

Pre-commitments: seminars - 50 points; exam (written): 50 points

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

Course title: Selected chapters of pharmaceutical biotechnology

Teachers: Savić D. Snežana

Course status: elective, module: Pharmaceutical Technology

Semester: III	**Year of studies:** II
ECTS points: 5	**Course code:** ДФТ2И3

Requirements: Passed exams at compulsory courses of the module Pharmaceutical Technology at I and II school year of doctoral studies.

студија

Course aims:

The aim of the course is to provide the participant with knowledge of preparation/manufacturing procedures, characterization techniques, properties, carrier systems, efficacy and safety aspects of proteins/peptide drugs and monoclonal antibodies.

Course outcomes:

By the end of this course participant should have a knowledge on preparation procedures, characterization techniques and administration of biological drugs/biopharmaceutics in human medicine.

Course contents:

Administration and distribution routes for proteins – parenteral rout, oral rout, alternative administration routes; Carrier systems and mechanisms for targeted drug delivery – colloidal particulate systems, mechanical pumps, biosensor pumps, osmotic-dependent systems, microencapsulated secretor cells; Excipients in formulation of biologics/biopharmaceutics; Microbiological quality of protein drugs; Monoclonal antibodies (mAbs) as carrier systems, human and humanized antibodies, biospecific antibodies, immunoconjugates; Pharmaceutical consideration of monoclonal antibodies-based drugs (examples). Regulatory affairs in marketing authorization of biologics and biosimilars; Stabilization techniques for improvement of proteins and mAbs: mutagenesis of primary sequences, pegylation technique, encapsulation technique into micro- and nanosystems. Some examples of biopharmaceutics: insulins, erythropoietins, colony-stimulating factors, coagulation factors, mAbs, vaccines produced by biotechnology procedures.

Recommended literature:

1.Crommelin DJA, Sindelar RD. eds Pharmaceutical Biotechnology. 2nd ed. Philadelphia, Penn: Taylor&Francis , Inc; 2012.

2. Allen LV, Popovich NG, Ansel HC. Eds Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 8th ed. Philadelphia, Lippincott Williams&Wilkins, 2010.

3. Groves M. Pharmaceutical Biotechnology, 2nd Ed., Taylor&Francis Group LLC, New York, 2006.

4. Selected papers from international peer review journals: Journal of Biotechnology, Nature Biotechnology, Trends in Biotechnology.

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: maximal 70 points.

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

Course title: Micro- and nanoencapsulation of drug substances

Teachers: Đekić M. Ljiljana, Krajišnik R. Danina

Course status: elective, module: Pharmaceutical Technology

Semester: III	**Year of studies:** II
ECTS points: 5	**Course code:** ДФТ2И4

Requirements: Preformulation and formulation research and development

Course aims:

Knowledge of characteristics of micro- and nanoencapsulated drugs (pharmaceutical technology and biopharmaceutical aspects). Introduction in preparation methods for potential drug carriers such as microemulsions, nanoparticles, liposomes, nanoemulsions, microemulsions and micelles, procedures for micro- and nanoencapsulation of the drugs and principles of analitical techniques suitable for their physico-chemical and biopharmaceutical characterisation. Introduction in major strategies for development of pharmaceutical formulations with micro- and nanoencapsulated drug substances.

Course outcomes:

The student knows pharmaceutical technology and biopharmaceutical aspects of micro- and nanoencapsulated drugs, knows and understands procedures of preparation of functional microparticles, nanoparticles, liposomes, nanoemulsions, microemulions and micelles and micro- and nanoencapsulation of the drugs; knows principles of analytical techniques suitable for physicochemical and biopharmaceutical characterisation of potential drug carriers such as microparticles, nanoparticles, lipsomes, nanoemulsions, microemulsions and micelles; knows current approaches in development of pharmaceutical formulations with micro-/nanoencapsulated drug substances.

Course contents:

Approaches for improvement of pharmaceutical technology characteristics and biopharmaceutical profile of the drugs by micro-/nanoencapsulation. Major methods of preparation of functional microparticles, nanoparticles, liposomes, nanoemulsions, microemulsions and micelles (precipitation, coacervation, polymerization, surfactant self-assembly); phase behaviour of multicomponent systems comprising pharmaceutical excipients such as surfactants, and lipids, and applicability of phase behaviour studies in development of drug delivery carriers of nanoemulsion, microemulsion, micelles and liposome types. Major mechanisms of micro-/nanoencapsulation of the drugs (conjugation, adsorption, solubilization, dispersing). Methods for isolation/purification of micro-/nanoencapsulated drugs and strategies for their stabilisation. Analytical techniques suitable for physicochemical and biopharmaceutical characterisation of potential drug carriers such as microparticles, nanoparticles, liposomes, nanoemulsions, microemulsions and micelles, for different routes of administration (photon correlation spectroscopy, fourier transform infrared spectroscopy (FT-IR), differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), scanning electron microscopy (SEM), transmission electron microscopy (TEM), optical microscopy, polarising light microscopy, rheological characterisation). Major approaches in development of pharmaceutical formulations with micro-/nanoencapsulated drug substances.

Recommended literature:

1. Gad SC, Pharmaceutical Manufacturing Handbook: Production and Processes, Jonh Wiley & Sons, 2009.

2. Benita S. Microencapsulation: Methods and Industrial Applications (2nd ed.), Taylor & Francis, 2006.
3. Fanun M. Colloids in Drug Delivery, CRC Press / Taylor & Francis Group, Boca Raton, 2010.
4. Gibson M. Pharmaceutical Preformulation and Formulation, Informa Healthcare 2009.

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

Teaching methods:

Lectures, interactive methods, problem-based learning.

Grading system:

Pre-commitments: seminars - 30 points; exam (written): 70 points

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

Course title: Advanced concepts in data analysis

Teachers: Đuriš D. Jelena, Ibrić R. Svetlana

Course status: elective, module: Pharmaceutical Technology

Semester: III	**Year of studies:** II
ECTS points: 5	**Course code:** ДФТ2И5

Requirements: /

Course aims:

Introduction into multivariate analyisis, machine learning techniques, expert systems, in silico tools and their application in pharmaceutical technology

Course outcomes:

Certain techniques and tools student may apply in own research

Course contents:

Multivariate analysis (chermometry in classification and/or regression), factor analysis, principal component analysis. Machine learning methods (fuzzy logic, decision trees, genetic algorithms, genetic programming, self-organizing maps). Expert systems and in silico tools. Application of these methods and tools in drug formulation.

Recommended literature:

1. Djuris J. (Ed.) Computer aided applications in pharmaceutical technology. Woodhead Publishing, Cambridge, United Kingdom. 2013.

2. Ибрић С. Примена математичке теорије експеримената у фармацеутској технологији, Констиси, Београд, 2006.

3. Balakin KV. (Ed.) Pharmaceutical Data Mining. John Wiley & Sons, Inc., Hoboken, New Jersey, 2010.

4. Ekins S. (Ed.) Computer applications in pharmaceutical research and development. John Wiley & Sons, Inc., Hoboken, New Jersey, 2006.

5. Rajasekaran S, Vijayalakshmi Pai GA. Neural networks, fuzzy logic and genetic algorithms: synthesis and applications. Prentice-Hall, New Delhi, India, 2003.

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

Teaching methods:

Lectures, interactive lectures, simulation workshops

Grading system:

Pre-exam (homeworks and presentations) up to 30 points; Final written exam up to 70 points.