| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Pharmaceutical legislation and professional duties of qualified person

**Teachers:** Valentina D. Marinković, Dušanka M. Krajnović

**Course status:** mandarory

| **Semester:** I | **Year of studies:** I |
|---|---|
| **ECTS points:** 10 | **Course code:** 6ПЛО1Ф3 |

**Requirements:** /

**Course aims:**

The adoption of content and understanding of the pharmaceutical legislation and regulatory requirements in the development, transfer, production, release and recall of drugs from the market, as well as professional role of the person responsible for batch release on the market.

**Course outcomes:**

The ability of implementation and enforcement of regulatory requirements in all phases of the life cycle of drug products.

**Course contents:**

*Lectures*

National an European legislation (EU Directives, laws, regulations, directives); Manufacturing and distribution authorization (requests and responsibilities); Inspection for medicines and medical devices (organization and mutual recognition (PICs)); Batch release certification;Critical events and recall of a medicine from labour market; Initiative for harmonization of the legislation (ICH directives);

Legal, professional and ethical duties of the QP. Delegation of responsibilities and duties; Routine obligations of the QP and certification of the batch of manufactured medicines; Batch records review (electronic records and signatures); Regulatory adjustment (relation of the QP and regulatory authorities); Preparation and management of the inspection by the regulatory authorities; Place of QP inside the company (organizational structure).

*Practical classes*

Declaration of conformity for starting materials; Delivery under quarantine; Management review and continual improving. Release of non-registered medicine on the market.

**Recommended literature:**

1.Tasić Lj, Marinković V. Kvalitet u farmaciji -od teorije do prakse. Beograd: Farmaceutski fakultet, 2012.

2. Pharmaceutical Quality System, Oliver Schmidt, Informa Healtcare USA, Inc, 2008

3. 1. Rules and Guidance for Pharmaceutical Manufacturers and Distributors, MCA, UK, 2002.

4. ICH guidances www.ich.org

5. EudraLex – Volume 4 Good Manufacturing Practice (GMP) Guidelines ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

**The total of active learning classes**

| **Lectures:** 2 | **Practical classes:** 1 |
|---|---|
| **Research work:** 2 | **Other forms of teaching:** 1 |

**Teaching methods:**

Lectures (ex catedra) practice: case studies, workshops, panel discussion, homework .

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |

| | | |
|---|---|---|
| Other activities | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Quality Management System

**Teachers:** Valentina D. Marinković, Đurić R Zorica, Ljiljana M. Tasić

**Course status:** mandatory

| **Semester:** I | **Year of studies:** I |
|---|---|
| **ECTS points:** 12 | **Course code:** 6ПЛО1СК |

**Requirements:** /

**Course aims:**

Acquiring of professional knowledge and skills for application of the requests of the Good Manufacturing Practice and of the basic principles of the Total Quality Management.

**Course outcomes:**

Capability of implementation and carrying out of the requests of the Good Manufacturing Practice and of the basic principles of the Total Quality Management.

**Course contents:**

*Lectures*

Quality philosophy and models of quality management; Basic elements of quality management efficient system in pharmaceutical industry; Concepts of a QA, GMP and QC; the Good practice in production, distribution and quality control of medicines (GMP, GDP, GCLP.); Premises and equipment (plant, storage, laboratory); Key personal (training system); Documentation of quality system; Quality specification; Calibration and maintenance (plans, contracts, exceptions); Validation and qualification in the pharmaceutical industry; Internal audit; System of changes control; Deviations management; System of corrective and preventive measurements; Product quality report (Annual products review); Analysis of trends and atypical results; Contract manufacturing and analysis; Quality by design – basic principles of development of processes and methods (ICH Q8); Risk management – identification, estimation, control and mitigation (ICH Q9); Pharmaceutical quality system (ICH Q10); Integrated management systems (GMP, ISO 9001, ISO 14001, OHSAS 18001).

*Practical classes*

Case stusies: deviation management, change control, CAPA system, SWOT analysis

**Recommended literature:**

1.Tasić Lj, Marinković V. Kvalitet u farmaciji -od teorije do prakse. Beograd: Farmaceutski fakultet, 2012.

2. Pharmaceutical Quality System, Oliver Schmidt, Informa Healtcare USA, Inc, 2008 3. Lee TH, Shiba S, Wood Rc. Integrated management systems- A Practical Approach to transforming organisations. New York: John Wiley & Sons Inc 1999.

4. ICH guidances www.ich.org

5. EudraLex – Volume 4 Good Manufacturing Practice (GMP) Guidelines ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm

**The total of active learning classes**

| **Lectures:** 30 | **Practical classes:** 30 |
|---|---|
| **Research work:** 30 | **Other forms of teaching:** 15 |

**Teaching methods:**

Lectures (ex catedra) practice: case studies, workshops, panel discussion, homework .

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |

| | | |
|---|---|---|
| Other activities | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Pharmaceutical-Medicinal chemistry

**Teachers:** Vujić B. Zorica, Brborić S. Jasmina, Erić M. Slavica

**Course status:** mandatory

| **Semester:** I | **Year of studies:** I |
|---|---|
| **ECTS points:** 8 | **Course code:** 6ПЛО1ФХ |

**Requirements:** /

**Course aims:**

Gaining additional knowledge of: acid-base and physicochemical properties of pharmacologically active compounds, structure-activity relationship (SAR), rational drug design. Improving knowledge of: functional groups chemistry, chemical stability of pharmaceuticals, degradation reactions, chemical aspect of metabolism. Understanding drug targets, receptors, signal transduction, drug receptor interaction, mechanisms of drug action.

**Course outcomes:**

By the end of the course student will be able:

-To apply what he learned to assessment of the physicochemical properties of substances for pharmaceutical use;

-To evaluate critically current research in medicinal chemistry;

-To understand the mechanism of in vivo and in vitro stability;

-To recognize possible physicochemical incompatibilities;

-To answer rationally the “why” and “how” questions related to drug action;

-To improve cognitive skills (thinking and analysis) on particular subject.

**Course contents:**

*Lectures*

Physicochemical properties of drugs: ionization properties, lipophilicity, solubility, rational drug design, structure-activity relationship (SAR). Biotransformation of drugs, phase I reactions, phase II reactions, drug incompatibility chemistry, stereochemical aspects of drug metabolism, metabolic stability, isomerism, pro drug approaches. The molecular mechanism of drug action, targets for drug action, receptors (metabotropic, ionotropic, transmembrane receptors with enzymatic cytosolic domains, intracellular receptors), signal transduction, drug - receptor interaction, dose-response relationships, quantal dose biological response relationships.

*Practical classes*

Explanation the development of a given drug.

Description the structure - activity relations of examples.

Discussion about possible metabolism pathway of given drug.

Interpretation of molecular mechanism of action of given examples.

Searching relevant literature for information in relation to the project.

Summarization the found data and presentation them in a power point presentation to their fellow students.

**Recommended literature:**

1. Wilson’s and Gisvold’s Textbook of Organic Medicinal and Pharmaceutical Chemistry, 12th Ed., Lippincott Williams & Willkins, 2011

2. Gareth Thomas, Medicinal Chemistry, An introduction, John Wiley & Sons, Ltd, 2002

3. Williams DA, Lemke TL, Foye’s Principles of Medicinal Chemistry, 7th Ed., 2012

4. Thomas Nogrady; Medicinal Chemistry, A Biomedical Approach, 2nd edition, Oxford University Press, New York

5. Donald Cairns, Essentials of Pharmaceutical Chemistry, Pharmaceutical Press, 2002

6. Comprehensive Medicinal Chemistry II, Volume 5: ADME-Tox Approches, Elsevier 2006, Editors in Chief: John B. Taylor and David J. Triggle

7. Povl Kragsgaard-Larsen, Ulf Madsen and Kristian Stromgaard, eds. Textbook of Drug Design and Discovery, CRC Press, 4th Ed., 2009

8. Graham L. Patrick, An Introduction to Medicinal Chemistry, Oxford University Press, 4th Ed., 2009
9. Sirius Analytical Instruments Ltd. www.sirius-analytical.com
10. http://www.rpsgb.org.uk/worldofpharmacy/workingwithotherbodies/qualifiedpersonscheme/study

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 22.5 | **Practical classes:** 22.5 |
| **Research work:** 22.5 | **Other forms of teaching:** 22.5 |

**Teaching methods:**
Lectures, problem solving, discussion group, student research project, analysis of scientific paper, seminars.

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 10 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 30 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Active pharmaceutical ingredients and excipients

**Teachers:** Agbaba D. Danica, Vladimirov M. Sote, Čudina A. Olivera, Malenović M. Anđelija

**Course status:** mandatory

| | |
|---|---|
| **Semester:** II | **Year of studies:** I |
| **ECTS points:** 8 | **Course code:** 6ПЛО2АС |

**Requirements:** /

**Course aims:**

Acquiring additional knowledge on the effects of synthesis and modification of the synthesis process (generic drugs), active pharmaceutical ingredients and excipients, their physicochemical properties, and the quality of the final product.

**Course outcomes:**

Application of the acquired knowledge to the assessment of the data on the quality of pharmaceutical ingredients. Recognition of the importance of the quality of pharmaceutically active ingredients and excipients to ensure the quality of the final product.

**Course contents:**

*Lectures*

Generic medicines. Starting materials, reagents, solvents, and catalysts in the process of synthesis. Characterization of starting substances and intermediates, validation and evaluation of critical phases, intermediates, residual solvents. Genotoxicity. Confirmation of the structure of substances for pharmaceutical use, physicochemical and biological characteristics. Physicochemical characteristics of solid state and methods of its testing, polymorphism, crystal and amorphous state. Reference standards and materials. Chemical stability of substances for pharmaceutical use, the origin of impurities (known impurities, potential impurities, specified and non-specified impurities), refining of substances for pharmaceutical use. Relationship between characteristics of substances for pharmaceutical use and the quality of final products. Good manufacturing practice in manufacturing of substances for pharmaceutical use. Spatial and equipment requirements. Stability testing of pharmaceutical substances. Degradation pathway and degradation profiles of substances for pharmaceutical use. Kinetics of the degradation reactions. Selection of a method for identification and quantification of impurities. Quality control of substances for pharmaceutical use. Reduced sampling and reduced testing. Qualification of the manufacturer as key activity in providing the quality of raw materials.

*Practical classes*

Development and validation of stability indicating method.

**Recommended literature:**

1. Pharmaceutical Substances, Synthesis, Patents, Applications,

Axel Kleemann and Jurgen Engel, 4th Edition, Thieme,Stuttgart, 2009

2. Stanley H. Nusim, Active Pharmaceutical Ingredients, Second Edition: Development, Manufacturing, and Regulation (Drugs and the Pharmaceutical Sciences), Taylor & Francis Group, Boca Raton, Florida, USA, 2005

3. Ira R. Berry, Daniel Harpaz, Validation of Active Pharmaceutical Ingredient, CRC Press, Boca Raton, Florida, USA, 2001

4. ICH Q7, Good Manufacturing Practice for Active Pharmaceutical Ingredients, CPMP/ICH/4106/00)

5. ICH Q11, Development and Manufacture of Drug Supstance, Draft version

6. Satinder Ahuja, Impurities evaluation of pharmaceuticals, Marcel Dekker Inc., New York, USA, 1998.

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 15 | **Practical classes:** 15 |
| **Research work:** 30 | **Other forms of teaching:** 15 |

**Teaching methods:**

Lectures, practical laboratory work, interactive teaching and research work

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Pharmaceutical development

**Teachers:** Parojčić V Jelena, Ibrić R Svetlana, Đurić R Zorica

**Course status:** mandatory

| | |
|---|---|
| **Semester:** II | **Year of studies:** I |
| **ECTS points:** 10 | **Course code:** 6ПЛО2ФЛ |

**Requirements:** /

**Course aims:**

To provide advanced knowledge related to modern pharmaceutical dosage forms, dosage form development and optimization and the influence of formulation factors on drug efficiency and safety.

**Course outcomes:**

Critical evaluation of the influence of formulation factors on drug quality, efficiency and safety; Interpretation of the results of biopharmaceutical drug characterisation.

**Course contents:**

*Lectures*

Preformulation studies. Drug solubility and dissolution rate. Partition coefficient. Particle size. Crystalline structure and polymorphism. Solid state characterization.

Formulation studies. QbD as the modern concept of pharmaceutical development. Optimization techniques in formulation development. Design Space. Application of mathematical models and expert systems in formulation development. Modern pharmaceutical dosage forms. Characteristics of modern excipients. Biopharmaceutical aspects in formulation development. Biopharmaceutical drug characterization.

Preformulation studies. Drug solubility and dissolution rate. Partition coefficient. Particle size. Crystalline structure and polymorphism. Solid state characterization.

Formulation studies. QbD as the modern concept of pharmaceutical development. Optimization techniques in formulation development. Design Space. Application of mathematical models and expert systems in formulation development. Modern pharmaceutical dosage forms. Characteristics of modern excipients. Biopharmaceutical aspects in formulation development. Biopharmaceutical drug characterization.

*Practical classes*

Application of mathematical models and expert systems in formulation development. Writing Pharmaceutical development report

**Recommended literature:**

1. Mark Gibson, Pharmaceutical Preformulation and Formulation, 2nd Ed, Informa Healtheare, 2009
2. ICH Q8 Pharmaceutical Development

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 15 | **Practical classes:** 30 |
| **Research work:** 30 | **Other forms of teaching:** 30 |

**Teaching methods:**

Interactive lectures; Problem based learning, Computer simulation,

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |

| | | |
|---|---|---|
| Other activities | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Pharmaceutical Industry and Environmental Management

**Teachers:** Valentina D. Marinković, Ljiljana M. Tasić

**Course status:** elective

| | |
|---|---|
| **Semester:** III | **Year of studies:** II |
| **ECTS points:** 6 | **Course code:** 6ПЛИ233 |

**Requirements:** /

**Course aims:**

Acquiring of professional knowledge and skills for environment management system in the Pharmaceutical Industry.

**Course outcomes:**

Capability of implementation and carrying out of the standard requests for environment management system (EMS).

**Course contents:**

*Lectures*

Register of ecology aspects and influences in the Pharmaceutical industry. Ecology laws and legal regulations. Ecology management programmes. Ecology structure, responsibility and communication. Personnel training, conscious and competency. Documentation of ecology management – MSDS.

Medical and pharmaceutical waste – collection, categorization, destruction. Preparation and reaction in emergency cases. Monitoring and measurements. Reconsideration by the Management and continued improvements. Principals of the ISO 14001 standard – implementation and certification.

*Practical classes*

Crisis management plan. Corrective and preventive actions in EMS.

**Recommended literature:**

1.Tasić Lj, Marinković V. Kvalitet u farmaciji -od teorije do prakse. Beograd: Farmaceutski fakultet, 2012.

2. Global Environmental Health in the 21 st Century – from governmental regulation to corporate social responsibility, M. Harrison and C. Coussann, 2007, National Academic Press

3.ISO 14000/ISO14001 Environmental Management Guide

4.www.iso1400/14001 - enviromental-management.com

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 1 | **Practical classes:** 1 |
| **Research work:** 1 | **Other forms of teaching:** 1 |

**Teaching methods:**

Lectures (ex catedra) practice: case studies, workshops, panel discussion, homework .

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Preclinical and clinical drug research

**Teachers:** Branislava R. Miljković, Miroslav M. Savić, Silva Lj. Dobrić

**Course status:** elective

| | |
|---|---|
| **Semester:** II | **Year of studies:** I |
| **ECTS points:** 6 | **Course code:** 6ПЛИ2ПИ |

**Requirements:** /

**Course aims:**

Acquiring the additional knowledge on regulatory requirements for conducting preclinical and clinical drug testing; on the most important methods and tools for conducting these studies, including the ethical and legal issues, as well as on the methods of evaluation of the obtained results.

**Course outcomes:**

Comprehension of the methodology and importance of preclinical and clinical drug testing, in the drug development phase, as well as in the post-marketing drug surveillance.

**Course contents:**

*Lectures*

Drug discovery and development. Pharmacological screening. Pharmacokinetic testing. Toxicology testing. Good laboratory practice in preclinical drug testing. Principles of clinical drug testing. Phases and types of clinical drug testing. Studies of drug bioavailability and bioequivalence. Planning of clinical drug testing. Ethics in clinical drug research. Pharmacovigilance. Legal regulation of clinical drug research.

*Practical classes*

Case studies

**Recommended literature:**

1.Rang HP. Drug discovery and development. Edinburgh, Churchil Livingstone, 2006.

2.Hodgson E. A textbook of modern toxicology. 3rd ed. Toronto, John Wiley & Sons, 2004.

3.Chow SC, Liu J. Design and Analysis of Bioavailiability and Bioequivalence Studies. 3rd ed. CRC Press, London, 2009.

4.European Medicines Agency, Committee for Proprietary Medicinal Products. Guideline on the Investigation of Bioequivalence. (CPMP/EWP/QWP/1401/98** Corr).

5.US Department of Health and Human Services Food and Drug Administration. Center for Drug Evaluation and Research. Guidance for Industry. Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Consideration. March 2003.

6. Emanuel EJ, Grady C, Crouch RA, Lie R, Miller F Wendler D. The Oxford Textbook of Clinical Research Ethics. Oxford, Oxford University Press, 2008.

7. Senn S. Statistical Issues in Drug Development, 2nd ed. Chichester, John Wiley & Sons, 2007.

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 30 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

Lectures, interactive teaching and research work

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 10 | Written | 50 |
| Colloquia | | Oral | |

| | | |
|---|---|---|
| Seminars | 30 | |
| Other activities | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Pharmaceutical marketing

**Teachers:** Tasic M. Ljiljana, Dusanka M. Krajnovic

**Course status:** elective

| | |
|---|---|
| **Semester:** I | **Year of studies:** I |
| **ECTS points:** 6 | **Course code:** 6ПЛИ2ФК |

**Requirements:** /

**Course aims:**

Introduction to the philosophy and methodology of market research of pharmaceuticals, health and pharmaceutical services. Introduction to the regulatory and ethical framework of pharmaceutical marketing practices and the concept of social marketing. introduction of market and the methodology for health promotion and disease prevention. Basics of pharmacoepidemiology and pharmacovigilance.

**Course outcomes:**

Developing the techniques of segmentation and market research. Critical analysis of marketing, post-marketing, pharmacoeconomic and similar studies. Developing of knowledge and skills in the design, implementation and evaluation of promotional campaigns (approaches: producers, users / consumers, and society). Ability to analyze regulatory and ethical standards, and lounching the products toward the professionals and the general public.

**Course contents:**

*Lectures*

General principles of pharmaceutical marketing (manufacturers, patients and society aspects); marketing mix , models, methods and techniques of marketing. Marketing and its role. General concepts of marketing. Market segmentation. Strategy and tactics. Analysis of client needs (prescribers, financiers, users - patients). Market research of drugs versus analytical marketing. Principles in pharmacoepidemiology and pharmacovigilance. Posmarketing monitoring of medicines. Public health marketing (social marketing). General concepts of social marketing. Components and techniques of social marketing. Regulation and ethics in advertising and marketing of pharmaceutical products and services.

*Practical classes*

As part of the practical classes there you will examine, analyze and discuss about practical examples of theoretical lessons. Creating a mission, vision, strategy and tactics of the organization. Segmentation of the market, analysis of target markets, analyzis of customer needs. Market research using the methods: Boston Consulting Group matrix, SWOT analysis, benchmarking and portfolio analysis. Making the plans for a promotional campaign (products and services). Critical analysis of pharmacoepidemiological studies. Critical analysis of marketing activities in terms of ethical principles, regulatory framework and sers protection.

**Recommended literature:**


1. Kotler P. Маркетинг менаџмент. Београд: Дата статус; 2006.
2. Tasic Lj. Farmaceutski menadzment i marketing.Beograd: Placebo; 2007.
3. Spilker B. Multinational Pharmaceutical Companies: principles and practices. 2nd ed. Boston: Ravens press; 1994.
4. Dogramatzis D. Pharmaceutical Marketing a Practical Guide. Denver: Interpharm Press; 2002.
5. Beauchamp T, Bowie N, Arnold D. Ethical theory and business. 8th ed. New Jersey: Prentice Hall; 2007.


**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 15 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

Ex cathedra lectures, practical classes (case studies, workshops, panel discussions, homework assignments, on-line forum and training); Evaluation of Teaching: written-final test and practical exam-verbally.

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 10 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Veterinary medicines

**Teachers:** Parojčić V. Jelena, Vasiljević M. Dragana

**Course status:** elective

| | |
|---|---|
| **Semester:** II | **Year of studies:** I |
| **ECTS points:** 6 | **Course code:** 6ПЛИ2ВЛ |

**Requirements:** /

**Course aims:**

To provide advanced knowledge related to veterinary drug administration, veterinary dosage forms, methods for their evaluation and relevant regulatory guidelines for veterinary medicines manufacture and marketing authorisation.

**Course outcomes:**

Understanding of formulation and manufacturing principles applied to specific dosage forms used in veterinary medicine. Critical evaluation of the influence of formulation and drug manufacture on dosage form characteristics. Ability to suggest relevant methodology for veterinary medicines testing and evaluate the results obtained.

**Course contents:**

*Lectures*

Characteristics of drug administration in veterinary medicine. Types and characteristics of veterinary dosage forms. Manufacture and quality control of veterinary dosage forms. Registration of veterinary medicines. Regulatory guidelines relevant to veterinary medicines production and distribution.

*Practical classes*

Discussion on the regulatory and legal requirements related to development, manufacture and marketing authorisation of veterinary medicines

**Recommended literature:**

Steven B. Kayne and Michael H. Jepson Veterinary Pharmacy, Pharmaceutical Press, 2004; Yolande Bishop The Veterinary Formulary, 6th edition, Pharmaceutical Press, 2004; James Swarbrick, James C. Boylan, Encyclopedia of Pharmaceutical Technology, Second edition, Volume 3, Marcel Dekker Inc., New York and Basel, 2002, Релевантни законски и регулаторни документи.

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 15 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

Interactive lectures; Problem based learning, Computer simulation,

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Drug Manufacture

**Teachers:** Parojčić V Jelena, Ibrić R Svetlana, Đurić R Zorica

**Course status:** mandatory

| **Semester:** III | **Year of studies:** II |
|---|---|
| **ECTS points:** 10 | **Course code:** 6ПЛО3ПЛ |

**Requirements:** /

**Course aims:**

To provide advanced knowledge level related to identification and monitoring of critical manufacturing factors influencing drug quality, efficiency and safety.

**Course outcomes:**

Identification of critical process parameters, process monitoring and evaluation in accordance with the relevant regulatory requirements and guidelines; Competent decision making on the influence of process parameters on drug quality, efficiency and safety.

**Course contents:**

*Lectures*

Facilities design and equipment for drug manufacture. Pharmaceutical utility systems (HVAC, water systems, compressed air). Unit operations and equipment for drug manufacture. Scale-up. Technology transfer. Drug manufacture planning and organization. Manufacturing documentation. Yield and balance of consumed material (reconciliation). Validation of facilities, equipment and utility systems. Process validation. Cleaning validation. Drug packaging and labeling. Process Analytical Technology. Concept of continuous manufacture.

*Practical classes*

Unit operations and equipment for drug manufacture. Scale-up. Technology transfer. Drug manufacture planning and organization. Manufacturing documentation.

**Recommended literature:**

1. Mark Gibson, Pharmaceutical Preformulation and Formulation, 2nd Ed, Informa Healthcare, 2009
2. G.C. Cole, Pharmaceutical Production Facilities: Design and Application, Informa Healthcare, 1998
3. L.L. Augsburger, Pharmaceutical Dosage Forms: Tablets 3-Volume set, Informa Healthcare, 2008
4. S.C. Gad, Pharmaceutical Manufacturing Handbook, Informa Healthcare; 2004
5. P. Cloud, Pharmaceutical Equipment Validation, Informa Healthcare, 1998

**The total of active learning classes**

| **Lectures:** 30 | **Practical classes:** 30 |
|---|---|
| **Research work:** 30 | **Other forms of teaching:** 45 |

**Teaching methods:**

Interactive lectures; Problem based learning, Computer simulation,

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Pharmaceutical microbiology

**Teachers:** Marina T. Milenković, Marinković D. Valentina

**Course status:** mandatory

| | |
|---|---|
| **Semester:** IV | **Year of studies:** II |
| **ECTS points:** 8 | **Course code:** 6ПЛ03ФМ |

**Requirements:**

**Course aims:**

To provide knowledge and skills regarding microbiological methods, testing and quality control in pharmaceutical manufacturing, which will ensure product and process integrity in accordance with the contemporary regulatory requirements.

**Course outcomes:**

Analysis and critical estimation of applied methods and results of microbiology testing in environmental monitoring, quality of starting materials and final products.

**Course contents:**

*Lectures*

Classification of microorganisms . Microorganisms in the environment and their relevance to pharmaceutical process. Methods of identification of microorganisms. Rapid enumeration and identification methods. Microbial contamination control in Pharmaceutical Industry (microbial monitoring of water, microbiological environmental monitoring ). Bioburden test; Sampling for microbiological testing. Sterilization and disinfection. Selection and use of conservancy and disinfection agents.

Microbiological supports (making and control of accuracy). Bacterial endotoxins, pirogenes. Microbiological tests in medicine control (sterility testing, microbiological purity, testing of preservative efficiency, determining of antibiotics content). Validation of microbiological methods.

*Practical classes*

Microbiological tests in medicine control (sterility test Ph Eur 2.6.1. , Microbiological examination of non-sterile products : total viable aerobic count Ph Eur 2.6.12., Microbiological examination of non-sterile products:

test for specified micro-organisms, Ph Eur 2.6.13.).

**Recommended literature:**

1. Stephen P. Denyer, Norman Hodges, Sean P. Gorman, Brendan F. Gilmore: Hugo & Russell's Pharmaceutical microbiology, 8th edition, Wiley-Blackwell, 2011.

2. L. Clonth, Microbial Limit and Bioburden tests: Validation Approach and Global Requirements, CRS Press, 2008

3. M. C. Easter, Rapid Microbiological Methods in Pharmaceutical Industry, Interpharm/CRS, 2003.

4. N.A. Halls, Microbiological contamination control in pharmaceutical clean-room, CRS Press, 2004.

5. N. Hodges, G. Hanlon, Industrial Pharmaceutical Microbiology Standards& Controls, Euromed Communications Ltd, 2003.

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 15 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 30 |

**Teaching methods:**

teaching, seminars, practice

**Grading system:**

maximal number of points 100

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |

| | | |
|---|---|---|
| Seminars | 20 | |
| Other activities | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Production of sterile drug dosage forms - conventional and biological drugs

**Teachers:** Milić R. Jela, Savić D. Snežana, Krajišnik R. Danina, Marinković D. Valentina, Stojić-Vukanić M. Zorica, Arsenović Ranin M. Nevena

**Course status:** elective

| | |
|---|---|
| **Semester:** IV | **Year of studies:** II |
| **ECTS points:** 6 | **Course code:** 6ПЛИЗПС |

**Requirements:** /

**Course aims:**

Advancement of professional knowledge related to formulation and production/critical manufacturing factors (aseptic conditions) influencing quality and safety of sterile pharmaceutical drug dosage forms including biological drugs.

**Course outcomes:**

Application of the acquired knowledge in fulfillment of the relevant regulatory requirements for good practices in the manufacture and quality control of sterile conventional drug dosage forms and biological drugs and a critical assessment of the effects of environmental conditions, the composition of the formulation and manufacturing process on the quality, efficacy and safety of sterile drug products.

**Course contents:**

*Lectures*

Pharmaceutical legislation (regulatons) in the field of sterile drug products. Regulatory requirements for facilities, equipment and personnel in the manufacturing of sterile dosage forms. Validation of space, equipment, support systems and procedures in the production of sterile drug products. Risk analysis - application in manufacture of sterile conventional and biological drugs. Consideration of aspects important for the performance of microbiological tests in the manufacturing of sterile medicinal products. Specific aspects for formulation of sterile conventional and biological drugs for various routes of administration. Fundamentals of rDNA technology and monoclonal antibodies preparation (case studies). Factors to be considered in manufacturing (conditions and actions) for products subject to terminal sterilization and aseptic products that are produced . Characterization and bioanalytical aspects of biologic drugs: the example of recombinant proteins. Biosimilar drugs. Packaging and labeling of sterile pharmaceuticals. The transfer of sterile drug dosage form (lab scale formula) from laboratory to industrial scale (Scale - up).

*Practical classes*

practical exercises and seminars.Discussion on the relevant requirements related to formulation, development and manufacture aspects of of sterile pharmaceutical drug dosage forms including biological drugs

**Recommended literature:**


1. Sterile Drug Products: Formulation, Packaging, Manufacturing and Quality (Drugs and the Pharmaceutical Sciences) by Michael J. Akers, Informa Healthcare, New York, 2010.

2. Handbook of Pharmaceutical Manufacturing Formulations: Sterile Products (Volume 6 of 6) ,Sarfaraz K. Niazi, CRC Press, 2004

3. Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control from Manufacturer (Drugs and the Pharmaceutical Sciences), Sidney H. Willig, Marcel Dekker, 2000

4. Microbial Contamination Control in Parenteral Manufacturing (Drugs and the Pharmaceutical Sciences), Kevin L. Williams, Marcel Dekker, 2004

5. Quality Rules in Sterile Products Manufacture, John Sharp, Informa Healthcare, 2009

6. Sterilization Validation and Routine Operation Handbook by Anne F. Booth , Technomic Publishing, 2001

7. Pharmaceutical Biotechnology: Concepts and Applications, Gary Walsh (ed), Wiley, 2007.

8. Pharmaceutical Biotechnology: Drug, Discovery and Clinical Applications. Kayser O, Warzecha H. (eds) 2nd edition, 2012, Wiley, 235-254.


**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 30 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

Lectures, interactive teaching and research work

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Pharmaceutical Packing

**Teachers:** Jela R. Milić, Biljana S. Stojanović

**Course status:** elective

| | |
|---|---|
| **Semester:** III | **Year of studies:** II |
| **ECTS points:** 6 | **Course code:** 6ПЛИЗМП |

**Requirements:** /

**Course aims:**

Improving of professional knowledge on type of material for packaging of medicines and medical devices, as well as on packing control.

**Course outcomes:**

Knowing of the packaging materials, types and characteristics of material for packaging requests for packaging material testing and of testing capability of appropriate material for packaging of medicines and medical devices.

**Course contents:**

*Lectures*

Types and characteristics of packaging material. Selecting of packaging material. Request for packaging material control. Potential interaction of packing material with formulation components. Materials for packaging of blood and other biological drugs and their testing. Potential toxic materials. Materials for packaging of medical gases, packaging quality control, accuracy of marking and keeping.

*Practical classes*

Selecting of packaging material, potential interaction of packing material with formulation components - practical experience.

**Recommended literature:**

1. Bauer. Pharmaceutical Packaging Handbook, Informa Healthcare, 2009

2. O. G. Piringer, A. L. Baner. Plastic Packaging: Interactions with Food and Pharmaceuticals, Willey-VCH, 2008

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 15 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

Lectures, interactive teaching and research work

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Herbal products

**Teachers:** Nada N. Kovačević, Zoran A. Maksimović

**Course status:** elective

| **Semester:** IV | **Year of studies:** II |
|---|---|
| **ECTS points:** 6 | **Course code:** 6ПЛИЗБП |

**Requirements:** /

**Course aims:**

Improving of professional knowledge and skills related to specificities in production, quality control, marketing authorisation and post-marketing monitoring of herbal products (herbal medicinal products, traditional herbal medicinal products and herbal dietary supplements).

**Course outcomes:**

Capability of implementation and carrying out of the requests of the national and European regulation in production, control and marketing of herbal medicinal products, traditional herbal medicinal products and herbal dietary supplements, as well as post-marketing monitoring.

**Course contents:**

*Lectures*

Rational phytotherapy. Categories of herbal products (herbal medicinal products, traditional herbal medicinal products and herbal dietary supplements). National and European legal regulation related to different categories of herbal products.

Definition, quality, assurance and control of pharmaceutically quality of active components of natural origin: herbal drugs and preparations of herbal drugs. Development of herbal medicinal products, traditional herbal medicinal products and herbal dietary supplements (combination of active/therapeutic components). Specificities in production of active components of natural origin. Control of interproducts and final products. Documentation for marketing authorisation. Reclaiming and advertisement. Pharmacovigilance of herbal medicinal products.

*Practical classes*

National and European legal regulation related to different categories of herbal products - practical aspects.

**Recommended literature:**

1. European Pharmacopoeia - 6th edition, 2006. EDQM, Strasbourg

2. Directive 2004/24/ec of the European parliament and of the council amending, as regards traditional herbal medicinal products

3. Good manufacturing practice – annex 7.

4. EMA/HMPC/CVMP/287539/2005 Rev. 1 (Guideline on declaration of herbal substances and herbal preparations 1 in herbal medicinal products 2/traditional herbal medicinal products)

5. Doc.Ref. EMEA/HMPS/236916/2005 (guideline on good agricultural and collection practice (gacp) for starting material of herbal origin).

6. Guideline on quality of herbal medicinal products 1 /traditional herbal medicinal products

7. Doc.Ref. EMEA/HMPS/CHMP/CVMP/214869/2006 (guideline on quality of combination herbal medicinal products / traditional herbal medicinal products)

8. Doc.Ref. EMEA/HMPS/71049/2007 (guideline on the use of the ctd format in the preparation of a registration application for traditional herbal medicinal products).

**The total of active learning classes**

| **Lectures:** 30 | **Practical classes:** 15 |
|---|---|
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

lecture, case study, analyses of products, seminars

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 5 | Practical | |
| Practical classes | 10 | Written | 50 |
| Colloquia | | Oral | 20 |
| Seminars | | | |
| Other activities | 15 | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Pharmaceutical supply chain management

**Teachers:** Valentina D. Marinković, Ljiljana M. Tasić

**Course status:** elective

| **Semester:** III | **Year of studies:** II |
|---|---|
| **ECTS points:** 6 | **Course code:** 6ПЛИЗУС |

**Requirements:** /

**Course aims:**

Acquiring of additional knowledge about the principles and procedures of pharmaceutical Supply Chain with the purpose of assuring quality of products. Planning and organization of activities in a procedure of storage, distribution and sales. Sales and Operations Planning.

**Course outcomes:**

Efficient organization of activities related to planning, supply, storage and distribution of medicines and medical devices.

Critical estimation all factors in chain of supplay for drug release on the market.

**Course contents:**

*Lectures*

General concepts of management and parts supply chain of drugs and medical devices. Methods of market research suppliers. Planning, purchasing and supply in all segments of the supply chain. Globalization and autsor in the pharmaceutical industry. Autsors control activities. Key indicators-performance-determination and monitoring. Good practice in warehousing, distribution and transport of drugs and medical devices. Employees, facilities and equipment storage. Methods and conditions for keeping certain types of products. Automatic storage processes. Information systems with electronic data processing storage and distribution of drugs. Transport and handling of starting materials, intermediate products, final products and equipment for the production of drugs. Documentation of performance, quality and status of product. Roles and responsibilities of the QP release of raw materials, semi finished and finished products proizvoda.

*Practical classes*

Withdrawaled final products from the market due to complaints and counterfeit drugs. Supply contract and Quality Contract with outsoursed companies. QP Declaration.

**Recommended literature:**

1.Tasić Lj, Marinković V. Kvalitet u farmaciji -od teorije do prakse. Beograd: Farmaceutski fakultet, 2012.

2. Tasić Lj. Farmaceutski menadžment i marketing. Beograd: Placebo; 2007.

3. Lee TH, Shiba S, Wood Rc. Integrated management systems- A Practical Approach to transforming organisations. New York: John Wiley & Sons Inc 1999.

4. Hedley R. Supply chain manahgement in the drug industry- Delivery Patient Value for Pharmaceuticals and Biologics. New Jersey: John Wiley & Sons Inc 2011.

**The total of active learning classes**

| **Lectures:** 15 | **Practical classes:** 15 |
|---|---|
| **Research work:** 15 | **Other forms of teaching:** 30 |

**Teaching methods:**

Lectures (ex catedra) practice: case studies, workshops, panel discussion, homework .

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |

| | | |
|---|---|---|
| Seminars | 20 | |
| Other activities | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Pharmaceutical analysis

**Teachers:** Mira L. Zečević, Anđelija M. Malenović, Biljana S. Stojanović

**Course status:** mandatory

| **Semester:** IV | **Year of studies:** II |
|---|---|
| **ECTS points:** 10 | **Course code:** 6ПЛО4ФА |

**Requirements:** /

**Course aims:**

Understanding the principles of modern pharmaceutical analysis, critical analysis and professional interpretation of the results, as well as the application of the principles of good laboratory practice and the quality assurance in the laboratory. Training for individual and team work.

**Course outcomes:**

Application of acquired knowledge and skills in the interpretation of the results of pharmaceutical analysis and forming of critical thinking in the area of drugs control with the aim of ensuring quality, efficacy and safety of drugs.

**Course contents:**

*Lectures*

Highlights on modern pharmaceutical analysis. An overview of pharmaceutical test methods. Spectroscopic, chromatographic and hyphenated techniques in a pharmaceutical analysis. Compendial testing. Pharmaceutical-technological methods of analysis. Specifications - analytical procedures and acceptability criteria; development and validation of a pharmaceutical test methods. Mathematical-statistical models (experimental design) in development, optimization and validation of the method. Sampling, laboratory testing, issuing of the analysis final certificate. API sampling, excipients, inter-, semi-, and final products. Forming of a representative sample; sampling plans. Application of a Good laboratory practice and of quality assurance in a pharmaceutical analysis. Standard operative procedures. Organization of control process. Coordination of control and production. Managing results out of the specification (OOS); managing unexpected results (OOS): managing results out of trend (OOT). Analytical methodology transfer. Pharmaceutical analysis documentation.. Testing of stability of pharmaceutical forms; degradation products; identity and purity requirements, isolation and identification. Formal studies of stability. Regulatory directives on stability.

*Practical classes*

Analysis IR, NIR, NMR / MS data. Analysis of pharmaceutical ingredients and pharmaceutical dosage forms.

**Recommended literature:**


1. S. Ahuja and S. Scypinski, Handbook of Modern Pharmaceutical Analysis, Volume 10, 2010, Academic Press, San Diego, USA.
2. J. Ermer, J. Miller, Method validation in pharmaceutical analysis, Wiley-VCH, Darmastadt, 2005
3. Richard G. Brereton, Chemometrics, Data Analysis for the Laboratory and Chemical Plant, John Wiley & Sons Ltd, 2003.
4. L. Ohanneisan, A. J. Steeter, Handbook of Pharmaceutical Analysis, Marcel Dekker, 2002.
5. ICH Q 6A, Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances
6. Investigation Out of Specifications (OOS) Test Results for Pharmaceutical Production, Septembar 1998 (Draft)


**The total of active learning classes**

| **Lectures:** 30 | **Practical classes:** 30 |
|---|---|
| **Research work:** 15 | **Other forms of teaching:** 30 |

**Teaching methods:**

Lectures, practical laboratory work, interactive teaching and research work

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |

| | | | |
|---|---|---|---|
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Dietary Supplements

**Teachers:** Sobajic S Sladjana, Stankovic M Ivan, Djordjevic I Brizita, Kovacevic Nada

**Course status:** elective

| | |
|---|---|
| **Semester:** IV | **Year of studies:** II |
| **ECTS points:** 6 | **Course code:** 6ПЛИ4ДС |

**Requirements:** /

**Course aims:**

Students will get the knowledge in the area of production, quality assurance and release of dietary supplements to the market.

**Course outcomes:**

Students will be able to understand and implement requirements of national and EU legislative on dietary supplements.

**Course contents:**

*Lectures*

Definition and history of dietary supplements; Quality management of dietary supplement production; international standards and requirements for dietary supplements; types of dietary supplements; plant-based supplements; dosage forms of dietary supplements.

*Practical classes*

international standards and requirements for dietary supplements - practical aspect

**Recommended literature:**

1 . J.K.Ransley, J.K. Donnelly, N.W.Read, Springer 2001; Dietary supplements, Pamela Mason, Pharmaceutical Press, 2007);

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 15 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

Lectures, interactive teaching and research work

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Application of optimization techniques in pharmaceutical research and development

**Teachers:** Mira L. Zečević, Anđelija M. Malenović, Biljana S. Stojanović, Svetlana R. Ibrić

**Course status:** elective

| | |
|---|---|
| **Semester:** IV | **Year of studies:** II |
| **ECTS points:** 6 | **Course code:** 6ПЛИ4ОТ |

**Requirements:** /

**Course aims:**

Acquiring of additional knowledge on application of optimization techniques in developing and optimization of formulation and manufacturing process, optimization and validation of methods for pharmaceutical analysis.

**Course outcomes:**

Application of acquired knowledge from the area of optimization techniques (experimental design and methods of mechanical learning) in planning of experiments for formulation research, manufacturing process, methods of optimization and validation, as well as interpretation of obtained results.

**Course contents:**

*Lectures*

Experimental design. Basic aspects. Design types. Selection of factors, defining of an experiment plan and performing of an experiment. Selective design. Analysis of the factor effects. Methodology of a response level. Interpretation of obtained effects by statistical methods. Validation of mathematical models. Optimization. Case studies.

Mechanical learning. Basic aspects. Artificial neural networks. Logics stage. Stems of decision. Examples of application in developing of pharmaceutical formulations and processes and in optimization and validation of a method for medicines pharmaceutical analysis.

*Practical classes*

Case studies in application of optimization methods in planing and optimization of pharmaceutical methods

**Recommended literature:**

1. S. N. Deming, S.L. Morgan, Experimental design: a chemometric approach, Elsevier, Amsterdam, Netherlands, 1993.

2. K. Hinkelmann, O. Kempthorne, Design and Analyses of Experiments, John Wiley & Sons, New Jersey, USA, 2005.

3. Y. Vander Heyden, A. Nijhuis, J. Smeyers-Verbeke, B.G.M. Vandeginste, D.L. Massart, Guidance for Robustness/Ruggedness Tests in Method Validation, J. Pharm, Biomed. Anal., 24, 723/753, 2001.

4. J. Ermer, J. H. McB. Miller, Editors: Method Validation in Pharmaceutical Analyses, WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim, 2005.

5. J. N. Miller and J.C. Miller, Statistics and Chemo metrics for Analytical Chemistry, Fifth Edition, 2005., Pearson, Pertice Hall, Harlow

6. K. Velten. Mathematical Modeling and Simulation: Introduction for Scientists and Engineers, Wiley, 2009

7. N. Anthony Armstrong. Pharmaceutical experimental design and interpretation, CRC/Taylor & Francis, 2006.

8. K.V. Balakin, Ed, Pharmaceutical Data Mining, Jonh Wiley & Sons, 2010

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 15 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

Interactive lectures; Problem based learning, Computer simulation

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | 50 |

| | | | |
|---|---|---|---|
| Practical classes | 20 | Written | |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Radiopharmaceuticals

**Teachers:** Brborić S. Jasmina

**Course status:** elective

| | |
|---|---|
| **Semester:** IV | **Year of studies:** II |
| **ECTS points:** 6 | **Course code:** 6ПЛИ4РФ |

**Requirements:** /

**Course aims:**

Acquiring of necessary knowledge about radionuclides and radiopharmaceuticals, about their production, quality control and application in nuclear medicine (in diagnostics and therapy).

**Course outcomes:**

Understanding of basic concepts of radiochemistry and radiopharmacy and application of acquired knowledge in production and quality control of radiopharmaceuticals.

**Course contents:**

*Lectures*

Radioactivity and radioisotopes (radionuclide) for application in nuclear medicine: basic characteristics, production and application, risks of radiation and protective measures.

Radiopharmaceuticals: definitions, characteristics and requirements, methods of labeling and factors of importance for radiolabeling process. Technetium chemistry, preparation of technetium-99m pharmaceuticals. Radiopharmaceutical kits preparing. Quality control of radiopharmaceuticals: physicochemical and biological tests. Quality assurance of radiopharmaceuticals. Monographs of radiopharmaceuticals. Monographs on radiopharmaceuticals in the European Pharmacopeia. European Regulations governing radiopharmaceuticals. Diagnostic uses of radiopharmaceuticals in nuclear medicine. PET radiopharmaceuticals. Therapeutic uses of radiopharmaceuticals.

*Practical classes*

Problem-based learning and structured class discussions. Reading and analysis of original scientific papers relevant to selected topics.

**Recommended literature:**

1. Saha GB. Fundamentals of Nuclear Pharmacy, sixth edition, Springer 2010.

2. Zolle I. Technetium-99m Pharmaceuticals, Preparation and Quality control in Nuclear Medicine, Springer, 2007.

3. Saha GB. Basics of PET imaging: Physics, Chemistry and Regulations, Springer 2005.

**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 15 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

Lectures, interactive teaching and research work

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |
| Other activities | | | |

| University of Belgrade<br>Faculty of Pharmacy | Specialized Academic Studies<br>**RELEASE OF MEDICINAL PRODUCTS ON THE MARKET** | |
|---|---|---|

**Study programme:** Release of medicinal products on the market

**Course title:** Medical devices and medical gases

**Teachers:** Malenović M. Anđelija, Vasiljević D. Dragana

**Course status:** elective

| | |
|---|---|
| **Semester:** IV | **Year of studies:** II |
| **ECTS points:** 6 | **Course code:** 6ПЛИ4МС |

**Requirements:** /

**Course aims:**

Acquiring professional knowledge refered to quality and safety of medical devices and medical gases, as well as introduction to legal regulations related to manufacturing, registration and sale of medical devices and medical gases.

**Course outcomes:**

Application of acquired knowledge on estimation of adequacy of data concerning characteristics, safety and quality of medical devices and medical gases.

**Course contents:**

*Lectures*

The division and classification of medical devices and medical gases. Requirements of the Good Manufacturing Practice for manufacturing of medical devices and medical gases. Bio-compatibility and vigilance. Materials used for manufacturing of medical devices. Functional characteristics of some groups of medical devices. Structure of technical documents. Risk management application on medical devices and medical gases. Quality control of medical gases. Evidence keeping on results of realized testing and sampling procedures, control and testing of medical gases. Approving and supervision of suppliers of initial materials and contracted manufacturers. Implementation of internal trainings and knowledge testing from the area of medical gases quality control.

*Practical classes*

Classification of medical devices. Training in the application procedure for registration in the Register of Medical Devices. Written essay; student research work.

**Recommended literature:**


1. Directive 90/385/EEC of the European parliament and of the council on active implantable medical devices
2. Directive 98/79/EC of the European parliament and of the council on in vitro diagnostic medical devices
3. Directive 93/42/EEC of the European parliament and of the council concerning medical devices
4. Richard Fries, Reliable design of medical devices, Second edition, Taylor & Francis Group, Boca Raton, Florida, USA, 2006.
5. John W, Nicholson, The chemistry of medical and dental materials, The Royal Society of Chemistry, Cambridge, UK, 2002
6. Theodore R. Kucklick, The Medical Device R&D Handbook, Taylor & Francis Group, Boca Raton, Florida, USA, 2006
7. ISO 14971:2000(E), Medcial Devices – Application of Risk Management to Medical Devices.


**The total of active learning classes**

| | |
|---|---|
| **Lectures:** 30 | **Practical classes:** 15 |
| **Research work:** 15 | **Other forms of teaching:** 15 |

**Teaching methods:**

Lectures, practical laboratory work, interactive teaching and research work

**Grading system:**

| Exam prerequisites | Points | Final exam | Points |
|---|---|---|---|
| Active participation in lectures | 10 | Practical | |
| Practical classes | 20 | Written | 50 |
| Colloquia | | Oral | |
| Seminars | 20 | | |

| | | |
|---|---|---|
| Other activities | | |