University of Belgrade Faculty of Pharmacy	Specialized Academic Studies **INDUSTRIAL PHARMACY**	

Study programme: Industrial pharmacy

Course title: Drug Formulation

Teachers: Parojčić V Jelena, Ibrić R Svetlana, Đuriš D Jelena

Course status: elective

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** СИФАИ1

Requirements: Research and development in pharmaceutical industry

Course aims:

Acquiring the expertise necessary for the development of advanced pharmaceutical formulations designed for specific patient populations.

Course outcomes:

Knowing the different approaches and guidelines in the development of advanced pharmaceutical dosage forms.

Excipients used in the manufacture of advanced pharmaceutical dosage forms; knowledge of specific technological processes used in the manufacture of modern pharmaceutical dosage forms; A critical assessment of the strengths and weaknesses of different pharmaceutical dosage forms.

Course contents:

Lectures

Formulation development of novel pharmaceutical dosage forms and products. Characteristics of novel excipients. Summary of specific unit operations in production of novel pharmaceutical dosage forms. Pharmaceutical and biopharmaceutical characteristics of modified/controlled release drug delivery systems; preparations of fixed dose combinations; pharmaceuticals for personalized therapy and biologic drugs. Specifics of medicinal preparations for use in pediatric patients. Specifics of medicinal preparations for administration to geriatric patients. Overview of regulatory guidelines for the development of drugs for specific populations. Pharmaceutical and biopharmaceutical characteristics of the medicinal preparations for use in veterinary medicine. The development of methods for characterization and quality assessment of novel pharmaceutical forms and products designed for specific patient populations. The use of in vitro and in silico methods for the development of novel pharmaceutical dosage forms and preparation of drugs intended for the specific patient populations

Practical classes

Literature search, preparation and defense of research paper.

Recommended literature:

1 Drug preformulation and formulation, M. Gibson (published in Serbian), Faculty of Pharmacy, 2012.

2 Handbook of Pharmaceutical Manufacturing Formulations, Sarfaraz K. Niazi, Six Volume Set, CRC Press, London, New York, 2004th

3 Selected articles from the contemporary professional and scientific literature 4. Appropriate EMA and FDA regulatory guidelines

The total of active learning classes

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

Teaching methods:

Grading system:

Grading system:

Exam prerequisites	Points	Final exam	Points
Active participation in lectures	10	Practical	60
Practical classes		Written	
Colloquia	20	Oral	
Seminars			

Other activities		

University of Belgrade Faculty of Pharmacy	Specialized Academic Studies **INDUSTRIAL PHARMACY**	

Study programme: Industrial Pharmacy

Course title: Drug Manufacture

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

Course status: mandatory

Semester: II	**Year of studies:** I
ECTS points: 15	**Course code:** СИФАО4

Requirements: Quality assurance in pharmaceutical industry

Course aims:

The acquisition of professional knowledge and skills to implement in the manufacturing process of drugs

Course outcomes:

The ability to organize and control the production of drugs

Course contents:

Lectures

Technology projects for new production facilities in the industry. Requirements relating to the planning and organization of production. Analyses of occupancy, delays in production and planned offerings. Overview of unit operations for each stage of production of various pharmaceutical dosage forms. Specific features of the manufacturing process of different pharmaceutical dosage forms. Principles of continuous production. New concepts in the pharmaceutical industry. Understanding of the production process - PAT and QbD concept in production. Scale up. Technology transfer. Requirements relating to the contractual production and other activities that manufacturers entrust other organizations. Principles, requirements and rules for process control. Product documentation. Analysis ofproduction processes.Annual review of the product .

Practical classes

Visits to pharmaceutical factory and learning about the production processes in the manufacture of drugs. Tasks for assessment production of documents in the pharmaceutical industry. The tasks that are related to solving problems in the course of transfer technology. Presentation of student term papers relating to the production and process control of different pharmaceutical dosage forms.

Recommended literature:

1. Aulton M.E. Pharmaceutics: The science of dosage form design, second edition, Churchill Livingstone, 2002.

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

3. Pharmaceutical Production: An Engineering Guide, B. Bennet, G. Cole, IChemE, 2003.

The total of active learning classes

Lectures: 45	**Practical classes:** 15
Research work:	**Other forms of teaching:**

Teaching methods:

Grading system:

Grading system:

Exam prerequisites	Points	Final exam	Points
Active participation in lectures	10	Practical	60
Practical classes	10	Written	
Colloquia	10	Oral	
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized Academic Studies **INDUSTRIAL PHARMACY**	

Study programme: Industrial Pharmacy

Course title: Research and development in pharmaceutical industry

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

Course status: mandatory

Semester: I	**Year of studies:** I
ECTS points: 10	**Course code:** СИФАО1

Requirements: none

Course aims:

To provide knowdlegde related to the research and development of human and veterinary drugs

Course outcomes:

Critical evaluation of the influence of formulation factors on drug quality, efficiency and safety; Use of risk analysis techniques.

Course contents:

Lectures

Importance of research and develpment in pharmaceutical industry. Role of intelectual property in research and development in pharmaceutical industry.

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

3. Handbook of Pharmaceutical Manufacturing Formulations, Sarfaraz K. Niazi, Six Volume Set, CRC Press, London, New York, 2004

4. Pharmaceutical Preformulation, Jens T. Carstensen, CRC Press, 2000

5. Pharmaceutical Experimental Design, Gareth A. Lewis, Marcel Dekker, 1999

The total of active learning classes

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

Teaching methods:

Grading system:

Grading system:

Exam prerequisites	Points	Final exam	Points
Active participation in lectures	10	Practical	60
Practical classes	10	Written	
Colloquia	10	Oral	
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized Academic Studies **INDUSTRIAL PHARMACY**	

Study programme: Industrial Pharmacy

Course title: Quality assurance in the pharmaceutical industry

Teachers: Đurić R Zorica, Parojčić V Jelena, Ibrić R Svetlana, Marinković D. Valentina, Đuriš D. Jelena, Milenković T. Marina

Course status: mandatory

Semester: I	**Year of studies:** I
ECTS points: 15	**Course code:** СИФАО2

Requirements: none

Course aims:

To provide knowdlegde related to the quality assurance in the pharmaceutical industry

Course outcomes:

Ability to implement and provide quality assurance in the pharmaceutical industry, making validation protocols and implementation of validation processes; process control and evaluation od process parameters.

Course contents:

Lectures

Regulations in area of production of drugs in EU and Serbia. International guidelines related to the quality assurance and all aspects of drug developments (human and veterinary). Standards used in pharmaceutical industry. GXPs in pharmaceutical industry. GMP for human and veterinary drugs. Quality assurance- definitions and requirements. Requests for personnel employed in the pharmaceutical industry. Requirements for documentation management in the pharmaceutical industry. Control of changes in the pharmaceutical industry. Requirements for space, equipment and support systems in the pharmaceutical industry. Validation master plan. Protocols for qualifications and validation in the pharmaceutical industry. Inspections in the pharmaceutical industry.

Practical classes

Visits to pharmaceutical industry. Introducing to the production of drugs and the ways in which they meet the requirements of good

manufacturing practices. Practiacal examples relating to the management of control of changes in the pharmaceutical industry. Practical examples related to the resolution of deviations in the manufacture of drugs. Presentation of student papers relating to specific requirements of Good Manufacturing Practice and other regulations governing the pharmaceutical industry.

Recommended literature:

1. ISO стандарди система менаџмента (www.iso.org.)
2. ICH Q10 - Pharmaceutical Quality System
3. Volume 1 - EU pharmaceutical legislation for medicinal products for human use (www.ec.europa.eu)
4. Volume 4 - Guidelines for good manufacturing practices for medicinal products for human and veterinary use (www.ec.europa.eu)
5. Volume 5 - EU pharmaceutical legislation for medicinal products for veterinary use (www.ec.europa.eu)
6. Закон о лековима и медицинским средствима, Сл.Глас.РС 30/2010 од 7.5.2010.

The total of active learning classes

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

Teaching methods:

Grading system:

Grading system:

Exam prerequisites	Points	Final exam	Points
Active participation in lectures	10	Practical	60
Practical classes		Written	

Colloquia	20	Oral	
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized Academic Studies **INDUSTRIAL PHARMACY**	

Study programme: Industrial Pharmacy

Course title: Packaging drugs and pharmaceuticals

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

Course status: elective

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** СИФАИ3

Requirements: no

Course aims:

The acquisition of professional knowledge and skills related to the packaging material and modern technology in packaging, quality assurance in the process of packaging and risk management application in packaging of drugs.

Course outcomes:

Application of knowledge in the development of packaging for various pharmaceutical forms and organization of the packaging process.

Course contents:

Lectures

Regulatory requirements for packing material and packing of the drugs. The materials used for the packaging : type and characteristics. The influence on the stability of the drug package. Tests for the packaging material. The development of primary and secondary packaging for various pharmaceutical forms for drugs. Unit operations in packagings of drugs. Packing liquid and semi-solid pharmaceutical gosage forms. Packing of powder. Sterile packaging of pharmaceutical dosage forms.The packaging of capsules and tablets. The specificity of the individual packaging of pharmaceutical dosage forms : PDI, DPI. Modern technologies in packaging. Personalized packaging of drugs. The role of packaging in preventing the possibility of drug counterfeiting . " Blow - seal " technology. Types and characteristics of the machine which are used in the process of packaging medicine . Improvements in the process of primary and secondary packaging .

Practical classes

Case study analysis of various examples of the packaging process in the pharmaceutical industry, as well as the use of different packaging materials. Visits zo the pharmaceutical factory, in order to introduce the process of packaging and labeling of drugs and important aspects of these processes. Preparation and defense of research paper.

Recommended literature:

1. Dean DA, Evans ER, Hall IH. Pharmaceutical Packaging Technology. Taylor & Francis Group. 2000.

2. Theobald N, Winder B. Packaging Closures and Sealing Systems. CRC Press. 2006.

3. Piringer OG, Baner AL. Plastic Packaging: Interaction with Food and Pharmaceuticals. Wiley-ICH. 2008.

The total of active learning classes

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

Teaching methods:

Grading system:

Grading system:

Exam prerequisites	Points	Final exam	Points
Active participation in lectures	10	Practical	60
Practical classes		Written	
Colloquia	20	Oral	
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized Academic Studies **INDUSTRIAL PHARMACY**	

Study programme: Industrial Pharmacy

Course title: Drug Marketing Authorization

Teachers: Ibrić R Svetlana, Parojčić V Jelena, Đuriš D. Jelena

Course status: mandatory

Semester: I	**Year of studies:** I
ECTS points: 5	**Course code:** СИФАО3

Requirements: none

Course aims:

The acquisition of professional knowledge and skills for the procedure, preparation and assessment of documentation on quality of drugs

Course outcomes:

Application of knowledge in the preparation and assessment of documentation on quality of drugs in

purpose of obtaining a marketing authorization licence for drugs and medical devices.

Course contents:

Lectures

European and national regulations related to the procedure and conditions for obtaining the marketing authorization licence of drugs and medical devices. The role of regulatory authorities

(Agency for Medicines and Medical Devices Agency of Serbia , the European Medicines Agency and U.S. Food and Drug Administration) in determining the quality, safety and efficacy of drugs. The license for the drug. Contents of documentation and approval of the drug marketing authorization. Administrative documentation. Content of the CTD file. Documentation related to the drug quality.Preclinical and clinical documentation. Post-approval changes (Variations). The classification of the variations. The bioavailability and bioequivalence. Biowaiver. Evaluation of documentation and problems in assessing documentation. Pharmacovigilance. Drug safety. Periodic safety update report and plan risk management. Systematic control of post-marketing drug monitoring . The role of the Medicines and Medical Devices Agency of Serbia in the disapproval of the promotional materials for drugs and medical devices.

Practical classes

A visit to the Agency for Drugs and Medical Devices of Serbia and introduction to the work and the assessment process. Examples of assessing the documentation on drug quality.

Recommended literature:

1. EMA and FDA guidelines

The total of active learning classes

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

Teaching methods:

Grading system:

Grading system:

Exam prerequisites	Points	Final exam	Points
Active participation in lectures	15	Practical	70
Practical classes		Written	
Colloquia		Oral	
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized Academic Studies **INDUSTRIAL PHARMACY**	

Study programme: Industrial Pharmacy

Course title: Drug Stability

Teachers: Ibrić R Svetlana, Parojčić V Jelena, Đuriš D Jelena

Course status: elective

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** СИФАИ2

Requirements: Research and development in pharmaceutical industry

Course aims:

The acquisition of professional knowledge and skills for the procedure, preparation and evaluation of drug stability studies.

Course outcomes:

Application of knowledge in the process of investigating the stability of drugs.

Course contents:

Lectures

Understanding and predicting the shelf-life of pharmaceutical products. Chemical stability. Physical stability. The most common changes in/on the pharmaceuticals. The influence of formulation and the production process on the stability of drugs.The effect of the characteristics of the solid state on the stability of the drug . Methods of stabilizing medications. The methods for testing the stability of drugs. Protocols for conducting stability studies of drugs. Evaluation of test results the stability of drugs. Extrapolation of the results of stability tests. Report about the examination of the stability of drugs. Stability testing of drugs required during postapproval changes. Photostability testing of drugs.Tests for stability during use (in- use stability) . Stability " in- bulk " . Specifics of the plan , implementation and analysis of results of specific pharmaceutical dosage forms. Chambers for stability testing of drugs.

Practical classes

Preparation and defense of research paper. Mathematical tasks recalculation related to stability testing of drugs. Case studies relating to the stability testing of drugs.

Recommended literature:

1.Guidelines ICH Q1A – ICH Q1F (Stability)

2. Statistical design and analysis od stabilitz studies, Shein-Chung Chow, Chapman&Hall/CRC, New York, 2007.

3. Drug Stability: Principles and Practices, Jens T. Carstensen, Christopher Rhodes, Marcel Dekker, New York, 2000.

4. Stability of Drugs and Dosage Forms, Sumie Yoshioka, Valentino J. Stella, Kluwer Academic, New York 2000.

5. Pharmaceutical Stress Testing: Predicting Drug Degradation Steven W. Baertschi, Taylor & Francis, 2005.

The total of active learning classes

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

Teaching methods:

Grading system:

Grading system:

Exam prerequisites	Points	Final exam	Points
Active participation in lectures	10	Practical	60
Practical classes		Written	
Colloquia	20	Oral	
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized Academic Studies **INDUSTRIAL PHARMACY**	

Study programme: Industrial Pharmacy

Course title: Risk Management

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

Course status: elective

Semester: II	**Year of studies:** I
ECTS points: 5	**Course code:** СИФАИ4

Requirements: Quality assurance in pharmaceutical industry

Course aims:

The acquisition of professional knowledge and skills to prepare for the risk analysis techniques and principles of risk management in the pharmaceutical industry.

Course outcomes:

Application of knowledge in the analysis and control of risk in the pharmaceutical industry.

Course contents:

Lectures

Regulations and standards for risk management. The process of risk management in the pharmaceutical industry. Role of risk management in the pharmaceutical development and quality assurance. Phases of risk management. Techniques for assessing risk. Risk matrix : a combination of the probability , consequences and possibilities of detection risk. Control Strategy. Communication and presentation of risk. Methods and tools of risk management: process maps and diagrams, Ishikawa diagrams, preliminary risk analysis, impact analysis (and criticism) in the event of default, the analysis of the tree disadvantages, hazard analysis and critical control points. Examples of the application of risk management in the folowing: pharmaceutical industry in the management of quality; pharmaceutical development ; characteristics of facilities, equipment and related systems ; materials management ; production; packaging and labeling ; as well as the activities of regulatory bodies (inspection , assessment documentation).

Practical classes

Case study analysis for risk assessment for individual processes in the pharmaceutical industry. The application of techniques for risk analyzing in the pharmaceutical industry. Preparation and defense of research paper.

Recommended literature:

1. Guideline ICH Q 9 - Quality Risk Management, 2006.

2. James L. Vesper. Risk Assessment and Risk Management in the Pharmaceutical Industry, 2006.

3. Mollah H, Baseman H, Long M. Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing, Wiley, 2013.

The total of active learning classes

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

Teaching methods:

Grading system:

Grading system:

Exam prerequisites	Points	Final exam	Points
Active participation in lectures	10	Practical	60
Practical classes		Written	
Colloquia	20	Oral	
Seminars			
Other activities			

University of Belgrade Faculty of Pharmacy	Specialized Academic Studies **INDUSTRIAL PHARMACY**	

Study programme: Industrial Pharmacy

Course title: Final Work

Teachers:

Course status: mandatory

Semester: II	**Year of studies:** I
ECTS points: 10	**Course code:** СИФА3Р

Requirements: All items on the curriculum modules

Course aims:

Specialist work should include all knowledge acquired during the specialist studies and mastering methodology and specific skills to successfully work in the field of industrial pharmacy.

Course outcomes:

A multidisciplinary approach to problem solving, and critical evaluation of data in areas related to: pharmaceutical research and development of drugs; quality assurance in the manufacture of drugs; preparation and assessment registration documentation; aspects of the production of various medicinal preparations; risk management.

Course contents:

Lectures

As part of the final work is research in which student introduces the methodology of research in the field of research and development, registration, quality assurance and manufacturing of medicines for human and veterinary use and the principles of risk management. After conducting research student prepares a final paper in the form of thesis that can be experimental or bibliographic. Specialist work must include chapters as defined by the regulations of the Faculty. After completing work student access to the public defense of thesis - oral specialist examination in fromt of Commission.

Practical classes

Recommended literature:

The total of active learning classes

Lectures: 0	**Practical classes:** 0
Research work:	**Other forms of teaching:**

Teaching methods:

Grading system:

Grading system:

Exam prerequisites	Points	Final exam	Points
Active participation in lectures		Practical	
Practical classes		Written	
Colloquia		Oral	
Seminars			
Other activities			