Study programme: Industrial Pharmacy

Course title: Drug Formulation

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

Course status: elective

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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*

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

The total of active learning classes

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Research work: Other forms of teaching:

Teaching methods:
Grading system:

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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

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:

The total of active learning classes:

Lectures: 45
Practical classes: 15
Research work:

Grading system:

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**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

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**ECTS points:** 10

**Course code:** СИФАО1

**Requirements:** none

**Course aims:**
To provide knowledge 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 development in pharmaceutical industry. Role of intellectual property in research and development in pharmaceutical industry.


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

**Recommended literature:**
2. ICH Q8 Pharmaceutical Development
5. Pharmaceutical Experimental Design, Gareth A. Lewis, Marcel Dekker, 1999

**The total of active learning classes**

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**Research work:**

**Teaching methods:**
Grading system:

**Grading system:**

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**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 knowledge 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 of 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. GXP 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. Practical 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
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 od 7.5.2010.

**The total of active learning classes**

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**Research work:**

**Other forms of teaching:**

**Teaching methods:**

**Grading system:**

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**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:** СИФАИЗ

**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 dosage forms. Packaging 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 to 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:**

**The total of active learning classes**
- **Lectures:** 15
- **Practical classes:** 30

**Teaching methods:**
Grading system:

**Grading system:**

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</table>
# 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:** СИФАОЗ

### 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


#### 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

### Other forms of teaching:

### Teaching methods:

Grading system:

### Grading system:

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**Study programme:** Industrial Pharmacy

**Course title:** Drug Stability

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

**Course status:** elective

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**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**

**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)

**The total of active learning classes**

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**Teaching methods:**

**Grading system:**

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**Study programme:** Industrial Pharmacy

**Course title:** Risk Management

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

**Course status:** elective

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**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 following: 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:**

**The total of active learning classes**

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**Research work:**

**Teaching methods:**

**Grading system:**

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**Study programme:** Industrial Pharmacy

**Course title:** Final Work

**Teachers:**

**Course status:** mandatory

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**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 front of Commission.

*Practical classes*

**Recommended literature:**

**The total of active learning classes**

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**Research work**

Other forms of teaching:

**Teaching methods:**

Grading system:

**Grading system:**

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