

STANDARD 1: STUDY PROGRAMME STRUCTURE

Study program specialist academic studies Release of medical product on the market lasts two academic years (4 semesters), granting 120 ECTS points upon their completion. The program contains the mandatory courses, elective block, and making the project task work. Teaching is done by working with small groups of students, individual (mentor) work and working methods are adapted to the number of students (lectures, consultations, seminars, etc.). Teaching methods include lectures, exercises in workshops in which the teachers and associates also participate, while the exercises with the specific examples are independently done by students. Theoretical exercises, seminars and interactive sessions are also planned. In the framework of teaching, students have the opportunity to meet with some of the theoretical principles of the field relevant to the given module, the latest approaches to solving specific problems and case studies, whereby they acquire knowledge and skills relevant to the performance of future activities in the area that is specialized. Considerable attention is devoted to independent research. Especially motivated students have the option of directing in independent research through individual work with a mentor. Computers will be used in all types of classes.

TABLES AND SUPPLEMENTS

[Supplement 1.1. Faculty of Pharmacy website](#)

Supplement 1.1a. Publication of the Faculty: Prospective students informer

STANDARD 2: PURPOSE OF STUDY PROGRAMME

The purpose of the study program of specialist academic studies Release of the medical product on the market is to provide professional education and expertise in the field of batch release on the market and enable candidates to apply the acquired professional knowledge and skills in the development of critical thinking and making the right decisions in specific, complex and unpredictable situations in the field of release of the medicinal products on the market, ensuring their quality, efficacy and safety .

Students should acquire knowledge in the areas of release of the medical product on the market, which is of great importance for the pharmaceutical profession, to learn the skills and methods of conducting and implementation of the regulations relating to the drug release on the market, and to be able to work independently. This program should bring in the experts that will professionally and competently perform very delicate work in a specific pharmaceutical discipline of drug release on the market.

The outcome of the study program is a competent professional who knows the pharmaceutical legislation, both national and European, and all legal and technical regulations in the release of medicinal products and medical devices on the market, has improved knowledge concerning critical quality parameters, factors and the methods for their evaluation.

TABLES AND SUPPLEMENTS

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STANDARD 3: GOALS OF THE STUDY PROGRAMME

The primary objective of the study program specialist academic studies Release of the medical product on the market is to educate a professional in the field of pharmacy, which refers to the batch release on the market - qualified pharmacist. The candidates will be instructed in all the principles of pharmaceutical legislation and professional obligations of qualified pharmacists, quality management systems, modern methods of designing drugs and pharmaceutical analysis, microbiological control of drugs, the manufacture and formulation of drugs.

The acquisition of specific knowledge and skills important for the formulation of pharmaceutical dosage forms, specific pharmaceutical - technological operations applied in the industrial production of drugs, with special emphasis on validation, process control and process automation. Also, the understanding of principles of planning and organization of production, as well as the acquisition of knowledge in order to implement the requirements for quality assurance. Gaining knowledge about legal regulations and professional principles in the process of obtaining a license for medicinal products and medical devices related to the chemical-pharmaceutical and biological part of the documentation. Attending academic specialist studies Release of the medical product on the market, student broadens its fundamental knowledge in the field and later applies them in pharmaceutical practice. Through the study program students improve and acquire knowledge and skills that are recommend to be used in pharmaceutical industry, representative offices, and medicines agencies.

Specialist diplomas will be recognized by the European institutions, allowing students to continue their professional or scientific training (Ph.D. studies) in the field of pharmacy and related disciplines at national or European universities.

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[Supplement 1.1. Faculty of Pharmacy website](#)

Supplement 1.1a. Publication of the Faculty: Prospective students informer

STANDARD 4: COMPETENCIES OF GRADUATED STUDENTS

By completing the degree program specialist academic studies Release of the medical product on the market, student acquires professional education and becomes an expert in the field of the release of the drug on the market.

Pharmacist, responsible for batch release on the market, should be able to apply the acquired professional knowledge and skills in the development of critical thinking and making the right decisions in specific, complex and unpredictable situations in area of release of medicines on the market, ensuring their quality, efficacy and safety.

A specialist in the field of batch release on the market is a competent professional who knows the pharmaceutical legislation, both national and European, and all legal and technical regulations relevant for the release of medicinal products and medical devices on the market and has advanced knowledge related to critical quality parameters, factors that may affect them and methods for their evaluation.

Learning outcome is the extension and application of knowledge in the field of practical drug release on the market, introducing new and modern terminology in the field and developing the ability to solve technical problems by applying analytical and constructive critical approach. Students are allowed to be involved in scientific research, either independently or within a team.

Upon completion of these studies, the candidate is able to work independently in practice in the field of drug release to the market. After graduation, the student receives the title of specialist.

TABLES AND SUPPLEMENTS

[Supplement 4.1. Diploma supplement](#)

STANDARD 5: CURRICULUM

The study program specialist academic studies Release of the medical product on the market, consists of 8 mandatory courses (76 ECTS) and 14 elective courses organized in three elective block (36 ECTS). Within every elective block two of the courses are chosen (12 ECTS). The program ends with project task (8 ECTS). The program takes four semesters and brings 120 ECTS. The courses include lectures, exercises, laboratory exercises and other types of work (seminars, consultations).

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[Table 5.1. Semesters and year of studies timetables](#)

Table 5.2. Courses specifications

[Table 5.3. The study programme: list of the elective courses](#)

Table 5.4. List of courses according to the group of courses

Supplement 5.1. Timetable

[Supplement 5.2. The book of courses \(printed or electronic form at the institution website\)](#)

STANDARD 6: QUALITY, MODERNITY AND INTERNATIONAL HARMONIZATION OF THE STUDY PROGRAM

Within the specialist studies Release of the medical product on the market, at Faculty of Pharmacy, University of Belgrade, teaching is conducted through appropriate courses, whose programs provide students with the expansion and improvement of fundamental knowledge and skills from many important areas of pharmacy, that is necessary for insurance of the quality of the drug, their efficiency and safety. These are the areas related to the production, the pharmaceutical - chemical and microbiological control of drugs, pharmaceutical legislation and administration, as well as quality management system - QMS.

Specialist study program Release of medical product on the market, is harmonized with similar recognized European programs. Participation level of individual professional areas, the scope and content of the courses offered at the study program, as well as classes' organization is comparable with the corresponding educational programs at the foreign institutions of higher education. Students are thus ensured equal participation in national and international, multidisciplinary professional, and research and development projects.

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Supplement 6.1,2,3. Documentation of at least three accredited international programs to which the presented study program is harmonized to

Supplement 6.4a, 6.4b, 6.4v, 6.4g. Recommendations or accordance with the representative good practices of the European institutions

STANDARD 7: STUDENT ENROLLMENT

In accordance with the needs of the profession the specialist studies enrol students who meet the requirements stipulated in the Regulations of the specialist academic studies of Faculty of Pharmacy and the Regulations of the conditions, manner and procedure for admission to the second and third level studies of the University. The call for entry is open to the public. It is published by the University in the media.

The number of students to be enrolled in the specialist studies Release of the medical product on the market is determined by the general plan for study programs of the Faculty of Pharmacy adopted by the Academic board of the Faculty of Pharmacy, and is submitted to the Board of the University of Belgrade. University of Belgrade announced a joint call for the enrollment of students in specialist studies.

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Table 7.1. Review of the number of students being admitted to the study program

Table 7.2. Review of the number of students per year of the study program in the current school year

Supplement 7.1. Open call for the admission of applicants

Supplement 7.2. Rule book on Specialized Academic Studies

Supplement 7.3. Conditions for the enrolment of students (abstract from the institution Status or other document)

STANDARD 8: EVALUATION AND PROGRESS OF STUDENTS

Evaluation of students is done by monitoring the scientific and professional work of students on the basis of points gained by the implementation of pre-exam requirements, taking exams and preparing seminar papers. The exams can be written and / or oral. The examination in each course is defined in the curriculum. The final score is formed according to the total demonstrated success during classes and success in written and / or oral part of the exam, which was organized after the end of classes.

Communication between teachers and students is achieved through mentoring. The students are allowed to consult the course teacher in the time allocated for consultation, to be engaged in research or to study a given topic independently through the written essay.

The students' success is evaluated through the grades from five (5) to ten (10), based on the actual number of points.

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Table 8.1. Collective list of points for each of the courses that the student acquires through exam prerequisites and the final exam

Table 8.2. Statistical data on the progress of students on the study program

STANDARD 9: TEACHING STAFF

For successful and high-quality teaching the Faculty employs full-time the adequate teaching staff. In addition to full-time teachers and associates, the Faculty occasionally hires teachers and associates from other faculties and researchers from accredited scientific institutions. Major research area of all teachers is highly related to the curriculum, so that the lectures are covered by the competent scientific staff.

Faculty of Pharmacy, University of Belgrade pays great attention to the professional and scientific training of teachers and associates. The teaching staff of the Faculty of Pharmacy participates in the organization of expert meetings at home and abroad and the continuing education of colleagues in the profession. A large number of teachers are working on the projects funded by the Ministry of Science, while scientific work is confirmed by the number of papers published in leading international journals.

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Table 9.1. Scientific, artistic and professional qualifications of teachers and responsibility in teaching

Table 9.2. List of teachers engaged in the study program

Table 9.3. Summary review of number of teachers in certain scientific disciplines and narrow disciplines in scientific or artistic areas

Table 9.4. List of teaching associates engaged in the study program

Supplement 9.1. Copies of work cards or work contracts of teaching staff (if accreditation of study program is required)

Supplement 9.2. The Rulebook about election of teachers (if accreditation of study program is required)

[Supplement 9.3. The book of teachers \(with information specified in identical way as in tables from standards, if tables are not enclosed\)](#)

Supplement 9.4. Evidence about public availability of information about teachers and teaching associates (publication or website of the Institution)

Supplement 9.5. Teaching load and summary review of teachers and number of classes.

STANDARD 10: ORGANIZATION AND RESOURCES

For specialist academic studies Release of the medical product on the market, at Faculty of Pharmacy, University of Belgrade, the Faculty puts at students' disposal adequate space, laboratories for experimental activities with suitable equipment, amphitheater and equipped classrooms, library equipped with books, textbooks, handbooks and scientific journals, computer room. Within the faculty exists computer room for various exercises and room with internet connection. As part of the IT support for students, databases for searching of electronically available journals is provided.

To perform the study program necessary number of teachers, assistants, teaching associates and technicians are engaged.

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Table 10.1. List of rooms with areas in the faculty building in which lectures are conducted on this study program

Table 10.2. List of equipment for conducting study program

Table 10.3. List of library units which are relevant for study program

Table 10.4. List of books which are available to students on study program

Table 10.5. Literature coverage of mandatory courses (books, collections, practicum which are in libraries or in stock)

Supplement 10.1. Inventory book

Supplement 10.2. Proof of existing information technology, number of internet connections, etc.

STANDARD 11: QUALITY CONTROL

In order to control the quality of the study program Faculty of Pharmacy ensures the implementation of established standards and procedures for the evaluation of the study program quality through program evaluation during the study, as well as the evaluation of competence of graduates in order to continually monitor and improve the quality in terms of curriculum, instruction, teaching staff, evaluation of students, textbooks and literature.

The quality control of the study program is carried out periodically through self-assessment (annually) and external quality (every three years). The quality control of the study program includes the active participation of the students and their evaluations of program quality.

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Table 11.1. List of members of Commission for quality control

Supplement 11.1. Report about results of self-evaluation process of the study program

Supplement 11.2. Published document – Quality assurance politics

Supplement 11.3. Regulations on Textbooks

Supplement 11.4. Extract from the Statutes of the institution which regulates foundation and scope of work of Commission for quality assurance

STANDARD 12: DISTANCE LEARNING

The study program of specialist studies Release of the medical product on the market does not organize distance learning.