

STANDARD 1: STUDY PROGRAMME STRUCTURE

Study program Postgraduate studies - Industrial Pharmacy for acquiring title “specialist in pharmacy” lasts for 1 year (2 semesters). The study program comprises 600 hours and is rated at 60 ECTS. Within the program, students have four compulsory subjects (3 in the first and one in the second semester), one elective course (in the second semester) and specialist (final) work. Teaching activities are aligned with the needs of the knowledge of experts that perform different tasks in the pharmaceutical industry and covers the knowledge and skills relating to: (1) research and development of new products; (2) quality assurance system ; (3) the drug manufacture and (4) the process of obtaining marketing authorization for a pharmaceutical products in accordance with the modern approach based on the application of scientific knowledge and risk management , as well as relevant national and international legislation. All courses last one semester. For each of the subjects after completion of the teaching is provided a written examination (test), and the number of points earned is added to the Pre- commitments (colloquia, assignments, seminars , discussion) . Completion of study program for Postgraduate studies - Industrial Pharmacy is followed with public defense of thesis. Teaching methods include lectures, seminars, problem-based, small-group work, colloquia, and visits to pharmaceutical industry. Classes are designed in a way that students have presentations for lectures in advance and other teaching materials and literature are available on the platform for virtual learning. The classes are implemented with the active participation of students and the high level of interactive teaching. Students are involved in the implementation of the study program through the creation of individual and group assignments, the presentation of results, discussion, active exchange of ideas and experiences , in the presence of a teacher who facilitates the discussion. Case studies are used to show the situation in the real working environment in pharmaceutical industry and are related to specific topics and tasks that are important for the acquisition of competence to perform a variety of jobs in the pharmaceutical industry.

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

Upon completion of the study program of Postgraduate studies - Industrial Pharmacy, participants will be trained in the management and implementation of a number of jobs in the pharmaceutical industry and pharmaceutical companies, regulatory authorities (relevant ministries and Agency for Medicines and Medical Devices of Serbia - ALIMS). The study program has been developed in accordance with the knowledge and competences needs of the person responsible for the process of production of medicines in accordance with Article 22 and Article 23 of the Regulation on conditions for drug production (Službeni Glasnik Republike Srbije 18/ 2012). Existence of staff who are able to adequately monitor and apply the latest knowledge in the field of industrial pharmacy is a necessary condition for the development and progress of the pharmaceutical industry. In this sense, this study program provides training of professional staff who will be able to follow the latest developments in the field of industrial pharmacy and apply them appropriately in their professional practice, whether performed by the appropriate activity in the pharmaceutical industry, offices and dealerships or regulatory bodies. The curriculum is designed with the purpose to provide:

- a multi-disciplinary approach to problem-solving in areas related to : research and development of pharmaceutical dosage forms; Quality assurance in the manufacture of drugs; preparation of registration dossiers; different aspects of the production of medicinal products, medical devices and dietary supplements;
- training and professional development of staff in the field of industrial pharmacy,
- modern methods of education of professional staff that are comparable to the standards in the European Union and other developed countries,
- a high level of technical and scientific competence of graduates,
- effective studying.

According to educational goals and its contents, this study program is unique in the university area of the Republic of Serbia and the wider region and appealing to colleagues from neighboring countries.

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

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

STANDARD 3: GOALS OF THE STUDY PROGRAMME

The main objective of the study program is to prepare competent professionals (pharmacists, technology engineers, veterinarians, graduate chemists and others who can legally work in the drugs manufacture) in the development, research, registration, quality assurance and manufacturing of medicines for human and veterinary use, that will possess the knowledge and skills necessary to perform all the complex functions in the pharmaceutical industry.

The overall objective of the study program is that students are well-trained to work independently, as head of production in the pharmaceutical industry. One of the most significant and strategically important goals is to acquire a good basis for further professional and scientific training of specialists in industrial pharmacy.

Accordingly, the general objective of the study program of Postgraduate studies - Industrial Pharmacy is to enable students to independently organize and conduct the production of drugs, to critically evaluate the latest scientific and technical achievements in the field of industrial pharmacy, as well as to enable monitoring the development of the profession through the acquisition of new knowledge. It is expected that graduated students contribute to a faster technology transfer and application of modern techniques and methods in the pharmaceutical industry, with the aim that users always receive a product of specified quality, efficiency and safety. The specific objective is the acquisition of knowledge related to the legislation relating to the development, research, pharmaceutical quality system registration and production of drugs .

The specific aims of the program are:

- Mastering methodology and specific skills to successfully work in the field of industrial pharmacy.
- Education of highly competent professionals for specific jobs in the pharmaceutical industry in the formulation of pharmaceutical dosage forms, planning and organization of production , and deployment requirements for quality assurance .
- Training for independent and team work, critical thinking and leadership in manufacturing drugs in the pharmaceutical industry .
- Provision of additional knowledge in the field of industrial pharmacy necessary for monitoring and understanding of typical unit operations that are used in the manufacture of drugs, with special emphasis on validation, process control and process automation .
- Acquisition of high competence and knowledge of legal regulations and professional principles in the process of obtaining a license for medicinal products and medical devices related to the registration dossier related to the drug quality.
- Gaining knowledge on risk management related to processes in the pharmaceutical industry .
- Ability to accept continuing education and advancement in industrial pharmacy.

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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

After graduation, according to the study program of Postgraduated studies - Industrial Pharmacy, a graduate student receives the title specialist in pharmacy and is qualified to perform work in the pharmaceutical industry, representation offices, regulatory authorities and pharmaceutical laboratories.

Students who successfully complete this program of study , acquire the ability to :

- Manages the production of drugs ;
- independently and within a team work competently deal with complex issues in the areas of research and development and evaluation of the stability of pharmaceuticals, medical devices and dietary supplements ;
- Manages the planning, organization and control of the production of pharmaceuticals, medical devices and dietary supplements;
- Participate in the implementation and enforcement of requirements for quality assurance in the production of pharmaceuticals, medical devices and dietary products ;
- Participate in the development of validation protocols;
- Participate in the preparation of the registration documentation .
- Participate in teams to manage risk related to processes in the pharmaceutical industry .
- Recognize problems in production and access to their own solution.
- It has the competence and knowledge of legal regulations in the pharmaceutical industry .
- Realize the various forms of technical cooperation and communication in the country and abroad .
- Have a professional and ethical responsibility of a specialist in industrial pharmacy.
- Improve their knowledge and follow the development of industrial pharmacy throughout life.

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[Supplement 4.1. Diploma supplement](#)

STANDARD 5: CURRICULUM

Postgraduate studies - Industrial Pharmacy last one (1) year and are carried out in two (2) semesters. The curriculum of the study program of postgraduate studies - Industrial Pharmacy contains a study schedule, a list of required and elective courses and description. According to the curriculum of the study program there are five subjects that student have to complete: four mandatory and one elective, as well as preparation and defense of thesis. All courses last one semester. The study program comprises 600 hours and is rated with 60 ECTS. The study program comprises mandatory and elective courses with a clearly defined position of the subject in the curriculum. For each of the subjects, number of active classes is determined and the numbers of ECTS in accordance with the students load. Description of the subject contain the name of the subject, status (mandatory or optional), a teacher, semester, number of ECTS credits, course content and a list of method units of theoretical and practical classes, literature lists for exam preparation, teaching methods, the method of assessment and examination with the number of points allocated for each exam obligations and the final exam.

Student can access the public defense of thesis after the completion of all the courses and passed all the exams that are prescribed. Specialist (final) work has also been assigned a corresponding number of ECTS credits (10 ECTS), which is expressed by the students' work on the final work and the number included in the total number of credits required for completion of the study.

In addition, students will learn about the organization and processes in several pharmaceutical factories in Serbia, as well as the Agency for Medicinal Products and Medical Devices of Serbia, and will gain knowledge about product development, product testing, quality assurance of medicines, as well as the production processes of various dosage forms. Within the classes of offered elective courses, students acquire additional and broader knowledge of drug formulations, drug stability, risk management, drug packaging.

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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

Study program of postgraduate studies - Industrial pharmacy is in compliance with the basic principles of the Bologna Declaration and recommendations for training pharmacists that are adopted by the European professional and academic associations of pharmacists. The program is comparable to programs for postgraduate training in the field of industrial pharmacy at many universities in Europe and the world in areas that are analogous to areas that are given through the curriculum of the study program of postgraduate studies - Industrial Pharmacy, or accredited courses.

The study program is fully in line with the latest developments in the fields of industrial pharmacy and other disciplines with which it is closely related, as follows the latest trends in the education of pharmacists in Europe and the world and allows students to actively participate in the educational process through the mechanisms of control of the teaching process.

Faculty of Pharmacy , University of Helsinki, Finland Adequate documentation is available on the website of the Faculty: <http://www.pharmtech.helsinki.fi/english/industrialpharmacy/>

Faculty of Pharmaceutical Sciences , University of Ghent , Belgium

<http://studiegids.ugent.be/2011/EN/FACULTY/J/MAMA/JNINFA/JNINFA.html>

Faculty of Pharmacy, University of Manchester

<http://www.pharmacy.manchester.ac.uk/postgraduate/taught/piat/coursedetails/index.aspx?code=02310&pg=all>

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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

To the program of postgraduate studies - Industrial Pharmacy may enroll a person who has completed the integrated study of pharmacy, veterinary medicine , technology , chemistry , dentistry (educational profiles that are prescribed by law that can work in the production of drugs) .

Admission to the first year of studies is carried out on the basis of a competition announced by the Faculty. The announcement shall be published in the media and on the website of the Faculty.

Competition (announcement) include:

- The number of students ,
- requirements for enrollment ,
- criteria for determining the order of candidates
- The process and pace of implementation of the competition .

Head of postgraduate studies carries out announcement as well as Commission for postgraduate studies. Proposed ranking list and the admission list of candidates adopt the Academic Council of the Faculty. Foreign nationals are enrolled in a study program under the same conditions as nationals with prior validation undergraduate diploma in order to continue their education.

Maximum number of participants is 30, while 20 is optimal number, regarding the methods used in teaching. If there are more applicants than anticipated number of participants, admission is made on the basis of the average grade of completed programs of study and work experience in the pharmaceutical industry. When enrolling in postgraduate academic studies - Industrial Pharmacy, students and faculty conclude a contract that specify mutual obligations .

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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

Student achieved scores during the study program of postgraduate studies - Industrial Pharmacy acquiring and testing knowledge through teaching (lectures, exercises, seminars and other forms of teaching), with 45 ECTS credits related to the acquisition of knowledge in the mandatory areas of importance for the pharmaceutical industry; 5 ECTS credits through the acquisition of knowledge in specific areas of study program (elective). Student gains 10 ECTS in writing and oral defense of thesis whose topic proposed mentor and approved at the meeting of the Academic Council of the Faculty. Students are monitored throughout the teaching process of the study program. The work of students in mastering certain subjects is continuously monitored during the school day and is expressed in points. Final grade is based on the total number of points a student earned by completing pre-exam requirements and passing the exam, according to the quality of the acquired knowledge and skills. Assessment and evaluation is based on participation in class, individual work (assignments, essays, seminars) and final test. The final grade is based on regular attendance and participation in class (10%), individual work (20-30%) and scores on the final test (60-70%). Precise evaluation of pre-exam requirements and exams is contained in each particular subject.

Written final work that brings 10 ECTS defended in front of a committee to be approved at the meeting of the Academic Council of the Faculty, at the suggestion of the manager (a Head of) of postgraduate academic study of industrial pharmacy.

General principles of grading students are:

1. The formation of grades on the exam affects the structure of the total number of points achieved by the student during the study.
2. The work of the student in mastering the particular subject shall be continuously monitored during the school day and is expressed in points.
3. Fulfilling exam commitments and exams a student can earn a maximum of 100 points.
4. At least 30 point of all number of points is provided for activities and assessment tests in the semester (exam commitments).
5. The students' success on the exams are:
 - Grade 10 (outstanding) for the actual 91-100 points
 - Grade 9 (excellent) achieved for 81-90 points
 - Grade 8 (very good) for earned 71-80 points
 - Grade 7 (good) for earned 61-70 points
 - Grade 6 (sufficient) for earned 51-60 points
 - Grade 5 (failed) for 0-50 points earned
6. Faculty keeps permanent records of examinations passed.
7. The passing grade is entered in index and in the records, while grade 5 (failed) is entered only in the records.

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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 the needs of the teaching on study program postgraduate studies - Industrial Pharmacy engaged five teachers employed full-time and one teacher employed part-time at the Faculty of Pharmacy, University of Belgrade. Of the total number of teachers, one teacher has a full professor three teachers with associate professor and two teachers with the rank of assistant professor. Average load of teachers in the program of study is 1.25 hours per week, and the Institution 6.32 hours per week. Percentage of teaching held by teachers employed full-time is 98.89 %.

Conditions and procedure for selection of teachers and staff are clearly defined in the Statute of the Faculty of Pharmacy and publicly available assessment experts. Decisions of Electoral Council on the selection of teachers and staff and the Regulations on the conditions and procedure for approval of higher vocational universities regarding the selection of teachers are on the website of the Faculty and the University website. The choice of university teachers in teaching positions is based on actual and measurable results of the entire work of the individual (educational work, scientific research, technical and professional contributions).

After each course, students fill out a survey (containing a number of issues related to the quality of teaching and teachers, as well as teaching courses in specified cases), which are analyzed and used to further improve the curriculum.

Quality control of the pedagogical and scientific research work of teachers and assistants carried out in the framework of the Commission for monitoring, improving and developing the quality of academic programs. Control the quality of educational work is carried out continuously by means of questionnaires completed by students. Continuous training of teachers and staff takes place through individual scientific research, research within the project of the Ministry of Education, Science and Technological Development of Republic of Serbia, international projects and study visits to renowned research institutions in the country and abroad.

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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

Study program in postgraduate academic studies - Industrial Pharmacy can be run on the Faculty of Pharmacy, University of Belgrade since Faculty and Department of Pharmaceutical Technology and Cosmetology meets the standards for the teaching staff, space, equipment , technological, library and other resources necessary for the implementation of the study program.

Accommodation capacities Faculty of Pharmacy include amphitheatres, classrooms , halls and these units are equipped with specialized technical equipment which ensure quality performance of the study program.

Faculty of Pharmacy in Belgrade has a computer center with equipment and higher professional staff who provide services to students. Faculty has the equipment for video conferences connection that allows distance lectures.

The library provides students with textbooks and other literature necessary for mastering the material in industrial pharmacy. Classes in all subjects are covered by the corresponding literature, which is available to students. References required students to master the material available on the platform for e -learning .

For preparation of the final work students can perform research in the pharmaceutical industry, the Medicines and Medical Devices Agency of Serbia (ALIMS) , as well as at the Faculty.

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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

Quality control of the curriculum of academic postgraduate studies in industrial pharmacy are regularly and systematically self-evaluated and evaluated by the students through anonymous surveys after completing and passing each course. The parameters estimates are considered : the clarity of presentation of course content , lectures used skills / leadership exercises , comprehension of the content , usefulness of course materials , participate actively in the learning process , preparation of teachers and teaching assistants , teachers satisfactory answer to the questions posed by the students and the overall grade items . In order to improve the organization of teaching are discussed and questions answered what was great in teaching and what could be improved.

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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 Institution does not organize distance learning.