# PROSPECTUS MASTER'S

# PROGRAMME

# INDUSTRIAL PHARMACY

## FACULTY OF PHARMACY, UNIVERSITY OF LJUBLJANA

**Presentation of the study programme:**

1. **Information on the study programme:**

The *Industrial pharmacy* master's programme consists of 2 years (4 semesters) of studies and comprises 120 credit points in total.
Academic title awarded to the graduates is Magister/Magistrica industrijske farmacije (mag. ind. farm.) (Master of Industrial Pharmacy).

2. **Fundamental objectives of the programme and general competences**

The main objective of the master's programme is to provide the graduates who have completed the first cycle of Bologna natural (chemical, biotechnical, biotechnological, etc.) and technical science programmes (mechanical engineering, electrotechnology, etc.) with an appropriate second cycle education that will enable them to work in the field of medicinal product manufacture within the pharmaceutical industry.

General competences:

Post-graduate master's programme and the curriculum of the envisaged programme were created based on national and international experience in the functioning and envisaged development of pharmaceutical industry home and abroad.
The programme consists mainly of lectures held by domestic and foreign professors as well as industrial experts, discussions of practical examples, individual and team work, electronic work supported by information technology, and innovative problem solving. Upon completion of the studies, the students should be able to:

- analyse, synthesise and solve complex problems related to the pharmaceutical industry,
- understand technical and scientific problems locally and globally,
- have a command of the research methods, tools and skills,
- know how to use their knowledge in practice,
- be competent and independent in their work and committed to their professional ethics,
- develop communication skills,
- work in a team and co-operate, also in the international environment,
- develop continuous learning skills and be open for new development opportunities.

3. **Enrolment requirements and selection criteria in case of restricted enrolment**

Enrolment requirements include a successful completion of the first cycle of Bologna curricula from the field of natural science, technical or biotechnical science and medicine or equivalent university programmes that existed prior to the implementation of Bologna study programmes. Graduates of the first cycle study programmes from other professional areas may be obliged to pass bridge exams determined by the FFA Academic Affairs Commission that are essential for further studying and must be passed prior to the enrolment in the study

programme. These obligations are based on the diversity of the professional field and comprise 10 to no more than 60 ECTS credits.

The conditions apply also to the candidates who have completed an equivalent training abroad.

In case of restricted enrolment, candidates shall be selected based on their first cycle study results (average grade).

## 4. Criteria for recognition of knowledge and skills acquired prior to the enrolment in the programme

Upon the candidate's request, the Academic Affairs Commission may submit to the Senate a proposal for recognition of knowledge and skills that have been acquired by the candidate prior to their enrolment in the study programme Pharmacy and may be recognised as fulfilled study obligations. Passed foreign language exam, for example, may therefore be recognised within the general optional courses in the fourth year.

## Information on manners and forms of study programme implementation

The Industrial Pharmacy master's study programme is implemented in full-time and – upon request – also in part-time form.

Full-time study programme is carried out during the week (Monday to Friday) in form of organized activities, whereby one study year corresponds to one academic year as determined in the academic calendar adopted by the Senate of the University of Ljubljana.

In case of part-time study, the programme can be carried out in form of organized activities (lectures, practice, seminars, seminar practice, etc.) outside normal working hours, usually Thursday through Saturday. Examination is generally scheduled for work-free days. The time frame of the complete programme implementation equals to that of full-time (two years). Organized activities are more intense, whereas students make up for reduced direct contact hours with more extensive homework. In agreement with the pro-dean of the FFA academic affairs the course holders decide on which forms of organized work shall be implemented in concise form and what the extent of direct contact hours reduction shall be. In doing so, they shall ensure that there will be at least 60% of direct contact hours implemented annually and that the students shall acquire all general and course-specific competences prescribed in the curriculum.

The lectures and seminars shall be carried out with the entire group of students, whereas the other forms of organized work shall be implemented in the manner and in forms determined in the curricula of individual learning units.

## 5. Requirements for advancement within the programme

- *Advancement to the next year of study*

Students may enrol in the next year of study if they complete all the obligations determined in the curriculum by the end of the year. Requirements for advancement within the programme comply with the Statute of the University of Ljubljana.
To be able to enrol in the second year of the study programme, students must fulfil academic requirements for all main courses and one optional course, which translate to at least 50 ECTS credits.

With respect to Article 135 of the Statute of the University of Ljubljana, students may exceptionally advance to the next year without fulfilling all the requirements determined in the curriculum due to grounded reasons (such as maternity, protracted illness, exceptional

domestic or social circumstances, special needs status, active participation in top professional, cultural and sports events, active participation in the university bodies, etc.). These reasons are decided on by the FFA Academic Affairs Commission.

- *Requirements for the repetition of the year*

According to the Statute of the University of Ljubljana, students who have failed to fulfil academic requirements for the enrolment to the next year, determined with the study programme, have a possibility to repeat a year once during their studies, provided they meet the requirements defined with the study programme regarding the repetition. To be able to repeat a year within a proposed study programme, students must achieve a total of 30 ECTS credits (50% of all the ECTS credits for individual year).

Conditions for renewal of the student status are specified in the Statute of the University of Ljubljana and in the FFA Academic Regulations.

## 6. Requirements for completion of study

Requirements for completion of the Industrial Pharmacy master's programme comply with the Statute of the University of Ljubljana and the Rules of the Faculty of Pharmacy (University of Ljubljana). To complete the study programme, students must meet all academic requirements laid down in the curriculum and individual course schemes amounting to a total of 120 ECTS credits. This includes the preparation and presentation of the master's thesis, which is an independent research project work.

## 7. Transfers between study programmes

**a.)** Transfers between the Faculty of Pharmacy study programmes are regulated by the Statute of the University of Ljubljana and the Criteria for Transfers between Study Programmes.

When transferring between the programmes, the following criteria must be observed:

- fulfilment of the enrolment requirements,
- number of available places.

Candidates may transfer from non-Bologna university programmes, including natural science, technical, biotechnical, medical and other programmes, to the Industrial Pharmacy master's programme if they meet the enrolment requirements. After the enrolment, the FFA Academic Affairs Commission decides on which obligations fulfilled within the course of study may be recognised.

Transfers are also possible from other Bologna master's programmes of the same fields that are predicted for the admission in the programme and last no less than two years. After the enrolment, the FFA Academic Affairs Commission deliberates the recognition of the tasks completed at the other faculties or determines the year the candidate may enrol in.

**b.)** According to the last paragraph of Article 38 a and Article 16 of the previous Higher Education Act provisions, students of the Industrial Pharmacy master's programme may, upon completion of their studies and achievement of 120 ECTS credits, enrol in doctoral programmes.

In the field of medicinal product design, manufacture and evaluation, the uniform master's pharmacy programme is the only programme that provides the education for a regulated pharmacist profession, and is therefore subject to stricter verification in case of potential transfers of students from other programmes than in case of pharmacy students transferring to other programmes.

## 8. Assessment schemes

Examination regime is governed by the Statute of the University of Ljubljana, Rules on Examination and Assessment of Knowledge, and Examination Rules of the Faculty of Pharmacy (University of Ljubljana). Forms of examinations are: written and oral exams, seminar papers and reports on laboratory exercises and project work reports.

The constituent parts of knowledge examination and assessment are indicated in the curricula of individual courses.

Assessment is connected to the goals and methodology of the course implementation. Assessment schemes comprise final products (written and oral exams) as well as on-going examination and assessment of knowledge (laboratory and auditory exercises and seminar papers).

Students are required to pass written and oral exams. To be able to take an exam, one must complete all laboratory exercises, seminars and projects. The assessment scale ranges from 6-10 (positive) and 1-5 (negative), or passed/not passed.

## 9. Programme curriculum

Credit evaluation, presentation of the entire programme, individual learning units per years and total number of hours

| | ***First year*** | ***Contact hours*** | | | | | | ***ECTS*** |
|---|---|---|---|---|---|---|---|---|
| | | L | P | S, SP | OW | Σ | ΣSL | |
| | **Semester 1** | | | | | | | |
| 1. | Pharmaceutical Technology | 60 | 50 | 10 | | 120 | 300 | 10 |
| 2. | Pharmaceutical Chemistry | 75 | | 20 | 25 | 120 | 300 | 10 |
| | Optional Course | 45 | 15 | | | 60 | 150 | 5 |
| | Optional Course | 45 | 15 | | | 60 | 150 | 5 |
| | **Semester Total** | | | | | **360** | **900** | **30** |
| | | | | | | | | |
| | **Semester 2** | | | | | | | |
| 3. | Biopharmaceutics and Pharmacokinetics | 60 | 30 | 30 | | 120 | 300 | 10 |
| 4. | Pharmaceutical Biotechnology I | 45 | | 15 | | 60 | 150 | 5 |
| 5. | Pharmaceutical Nanotechnology I | 30 | 30 | | | 60 | 150 | 5 |
| 6. | Analysis of Medicinals | 30 | 30 | | | 60 | 150 | 5 |
| | Optional Course | 45 | 15 | | | 60 | 150 | 5 |
| | **Semester Total** | | | | | **360** | **900** | **30** |
| | ***First Year Total*** | ***435*** | ***185*** | ***75*** | ***25*** | ***720*** | **1800** | ***60*** |

L - lectures; S - seminar; P - practice; OW - other forms of direct pedagogical work (especially project work); SL – student load; ECTS - European Credit Transfer System (1 credit point equals to 30 hours of student workload)

| | ***Second year*** | ***Contact hours*** | | | | | | ***ECTS*** |
|---|---|---|---|---|---|---|---|---|
| | | L | P | S, SP | OW | Σ | ΣSL | |
| | **Semester 3** | | | | | | | |
| 7. | Industrial Development of Medicinals | 60 | | 60 | | 120 | 300 | 10 |
| 8. | Intellectual Property, Legislation and Regulations | 45 | | 15 | | 60 | 150 | 5 |
| 9. | Pharmaceutical Engineering | 45 | | 15 | | 60 | 150 | 5 |
| | Optional Course | 45 | 15 | | | 60 | 150 | 5 |
| | Optional Course | 45 | 15 | | | 60 | 150 | 5 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Semester Total** | | | | | **360** | **900** | **30** |
| | | | | | | | | |
| | **Semester 4** | | | | | | | |
| 10. | Public Presentation of the Topic and Preparation of Master's Thesis | | | | 100 | | 750 | 25 |
| 11. | Defence of Master's Thesis | | | | | | 150 | 5 |
| | **Semester Total** | | | | | **100** | **900** | **30** |
| | ***Second Year Total*** | ***240*** | ***30*** | ***90*** | **100** | ***460*** | **1800** | ***60*** |

L - lectures; P - practice; S - seminar; SP - seminar practice; OW - other work; SL – student load

**List of optional courses:**

| | ***First year*** | ***Contact hours*** | | | | | | ***ECTS*** |
|---|---|---|---|---|---|---|---|---|
| | **Semester 1** | L | P | S, SP | OW | Σ | ΣSL | |
| 12. | Design of New Active Substances | 45 | 15 | | | 60 | 150 | 5 |
| 13. | Biological and Toxicological Properties of Pharmaceutical Materials | 45 | 15 | | | 60 | 150 | 5 |
| 14. | Pharmaceutical Packaging | 45 | 15 | | | 60 | 150 | 5 |
| 15. | Spectroscopic and Separation Analytical Methods | 45 | 15 | | | 60 | 150 | 5 |
| 16. | Design of Particle Properties | 45 | 15 | | | 60 | 150 | 5 |
| | | | | | | | | |
| | **Semester 2** | | | | | | | |
| 17. | Analysis of Active Substances and Metabolites in Biological Materials | 45 | 15 | | | 60 | 150 | 5 |
| 18. | Quality Management in Pharmaceutical Production | 45 | 15 | | | 60 | 150 | 5 |
| 19. | Biopharmaceutical Evaluation of Pharmaceutical Forms | 45 | 15 | | | 60 | 150 | 5 |
| 20. | Pre-clinical Studies | 45 | 15 | | | 60 | 150 | 5 |
| 21. | Cosmetology and Cosmetic Products | 45 | 15 | | | 60 | 150 | 5 |
| 22. | Pharmaceutical-Technological Analysis | 45 | 15 | | | 60 | 150 | 5 |
| 23. | Biological Molecules Evaluation Methods | 45 | 15 | | | 60 | 150 | 5 |
| 24. | Pharmaceutical Biotechnology II | 45 | 15 | | | 60 | 150 | 5 |
| | | | | | | | | |
| | ***Second year*** | | | | | | | |
| | **Semester 3** | | | | | | | |
| 25. | Medicinal Product Stability | 45 | 15 | | | 60 | 150 | 5 |
| 26. | Pharmacokinetic and Clinical Studies | 45 | 15 | | | 60 | 150 | 5 |
| 27. | Pharmaceutical Nanotechnology II | 45 | 15 | | | 60 | 150 | 5 |
| 28. | Microbiological Quality of Pharmaceutical Products | 45 | 15 | | | 60 | 150 | 5 |
| 29. | Prolonged Release Pharmaceutical Forms | 45 | 15 | | | 60 | 150 | 5 |
| 30. | Industrial Media and Industrial Environment Management | 45 | 15 | | | 60 | 150 | 5 |
| 31. | Pharmaceutical Marketing | 45 | 15 | | | 60 | 150 | 5 |
| 32. | Phytopharmaceuticals | 45 | 15 | | | 60 | 150 | 5 |
| 33. | Pharmaceutical Industry Administration and Management | 45 | 15 | | | 60 | 150 | 5 |
| 34. | Process Analytical Technologies | 45 | 15 | | | 60 | 150 | 5 |
| 35. | Pharmaceutical Processing Equipment | 45 | 15 | | | 60 | 150 | 5 |

**Additional optional courses:**

- Uniform master's pharmacy programme

| | ***Optional courses of the uniform master's pharmacy programme*** | L | P | S, SP | OW | Σ | ΣSL | ***ECTS*** |
|---|---|---|---|---|---|---|---|---|
| 36. | Pharmacoeconomics | 45 | | 15 | | 60 | 150 | 5 |
| 37. | Pharmacogenomics and Genetic Medicines | 45 | | 15 | | 60 | 150 | 5 |
| 38. | Selected Topics in Pharmaceutical Biotechnology | 45 | | 15 | | 60 | 150 | 5 |
| 39. | Selected Methods of Pharmaceutical Analysis | 45 | | 15 | | 60 | 150 | 5 |
| 40. | Nutritional Supplements | 45 | | 15 | | 60 | 150 | 5 |

- Optional courses at other UL faculties

## 10. Information on available optional courses and mobility

Students may choose as many available optional courses per semester as they need to gain 30 ECTS credits without the main courses. The main courses are worth 10 and 5 ECTS credits respectively, whereas the optional courses are always worth 5 ECTS credits.

Professional optional courses can be chosen from the optional courses within the available study programme or the ones within the uniform master's pharmacy programme. General optional courses include the ones from other UL members or other universities. Optional learning units comprise also the preparation of the master's thesis, an individual research work prepared by a student under the mentorship of a selected professor. Instructions on the preparation and writing of the master's thesis shall be described in detail in the Preparation and Defence of the Master's Thesis published in a brochure which is available on the FFA website.

**Main courses** include fundamental pharmaceutical knowledge, i.e. "materia medica", pharmaceutical technology, biopharmaceutics and pharmacokinetics, pharmaceutical biotechnology and nanotechnology, analysis of medicinal products, pharmaceutical engineering and intellectual property with relevant legislation and regulations. Main courses fall under mandatory learning units. Holders of mentioned courses are habilitated professors at the Faculty of Pharmacy and habilitated professors from the field of pharmaceutical industry. Courses shall be carried out at the Faculty of Pharmacy, but other locations are also possible (industry, institutes, other UL members). Practical exercises shall be mainly carried out at the Faculty of Pharmacy, whereas specific industrial tasks shall also be carried out in the industry. The main courses represent 70 ECTS credits, i.e. 58.33% of total credit points.

**Optional courses** offer in-depth knowledge from strictly specialised fields with respect to students' professional interest and desired profession. At the same time, they represent a welcome acquaintance with a relevant field of research necessary for the preparation of the master's thesis. Topical subjects and wide offer enable free selection. Their percentage in the programme amounts to 50 ECTS credits or 41.67%. Holders and providers of optional courses are habilitated professors from the Faculty of Pharmacy, other UL members, institutes and pharmaceutical industry. Some visiting professors from abroad are also expected to lecture in the optional courses.

Table 8 lists courses by names and according to the pillars of the programme content, whereas tables 9 and 10 indicate their percentage in relation to the number of courses and credit evaluation.

## 11. Presentation of individual courses

*1. Pharmaceutical Technology (10 ECTS credits):*

Development of medication and pharmaceutical forms and conditions for the manufacture. Acquaintance with Ph.Eur., FS, USP and professional periodical publications. Basic technological operations. Physical and chemical basics for development of medicinal products. Storage of medicinal products and pharmaceutical packaging: destination, requirements. Excipients, pharmaceutical water requirements. Introduction to basic pharmaceutical forms and technologies. Solid pharmaceutical forms: powders, granules, tablets, capsules, pellets, granulation, pelleting, tabletting, coating. Rectal and vaginal forms: suppositories, pessaries, compression, moulding. Pharmaceutical forms as molecular disperse systems: oral solutions, nasalia, auricularia. Colloidal dispersion, division, properties. Polymer molecular colloids, nanoparticles. Association colloids. Mycelia, liquid crystals, liposomes. Crude dispersions: emulsions, suspensions, microemulsions, nanosuspensions. Dermal pharmaceutical forms: creams, gels, ointments. Microbiological quality of pharmaceutical forms, preservatives. Sterile pharmaceutical forms: injections, infusions, ophthalmologic products, sterilisation, depyrogenation. Inhalational pharmaceutical forms. Pharmaceutical forms under pressure. Pharmaceutical preparations of plant origin.

*2. Pharmaceutical Chemistry (10 ECTS credits):*

Active substance classification and sources - lead compound. Changing a compound into a therapeutically useful substance. Physicochemical properties of a compound and transport possibilities to biologically relevant targets. Physicochemical properties of a compound and possibilities of interaction with biologically relevant targets, connection between the structure and pharmacological or toxicological action. Significance of structure and functional groups in metabolism and active substance toxicity. The most common active substance targets (receptors, enzymes, membranes, nucleic acids, transport ions and other endogenous substances) in humans and pathogens. Inspection of active substances after chemism and related toxic action - toxicity mechanisms. Physicochemical properties of active substances with antibacterial, antiviral or anticancer effects, effects on signal transfer in nervous and endocrine systems, and effects on haemostasis. Inspection of active substances after chemism and related toxic action - toxicity mechanisms.

*3. Biopharmaceutics and pharmacokinetics (10 ECTS credits):*

LADME system: definition, description, interactions among an active substance, pharmaceutical form or route of administration, and an organism, biopharmaceutics classification system, in vitro – in vivo correlation, pharmacokinetic-pharmacodynamic relationship. Processes: liberation: mechanisms, kinetics, methods, technological and biological parameters. Absorption: mechanisms, kinetics, methods, technological and biological parameters. Distribution: physiological transport systems, interactions among the active substance and macromolecules in blood, tissues and sites of action, methods, chemical, technological and biological parameters, volumes of substance distribution. Metabolism: presystemic and systemic metabolism, physiological systems, mechanisms, kinetics. Elimination: physiological systems, mechanisms, kinetics, active substance clearances. Pharmacokinetics: definition, description, pharmaceutical forms, routes of administration. multi-compartment pharmacokinetic models, structure, parameters. Single-dose pharmacokinetics: one-compartment model, different routes of administration, pharmacokinetic analysis of plasma concentration profile and cumulative quantity profile of urine. Multiple-dose pharmacokinetics: one-compartment model, different routes of administration, pharmacokinetic analysis of plasma concentration profile. Biological applicability and biological equivalence: basic terms.

*4. Pharmaceutical Biotechnology I (5 ECTS credits):*

Classification of the fields of pharmaceutical biotechnology. Molecular and general genetics and pharmacogenetics. Overview of expression systems. Overview of biopharmaceuticals. Isolation, identification and characterisation of biological medicinal products. Monoclonal antibodies: production, use in indication areas. Basics of gene therapy and medicinal products. Cell engineering. Plant and animal tissue cultures. Blood products. Regulations and ethics in the field of pharmaceutical biotechnology.

*5. Pharmaceutical Nanotechnology I (5 ECTS credits):*

Introduction to nanotechnology (historical development, intersection of two scientific disciplines, ethics in nanoscience, legislation). Material properties as a consequence of nanodimensions. From scientific discovery to technological process. Nanomedicines and therapeutic fields of application. Nanoscale devices for examination of substances. Technological approaches leading to nanosystems. Introduction of modern technologies based on the properties of the included active substance (small/large molecules, peptides, proteins, DNA, etc.) Introduction of technologies based on the routes of administration (local, systemic delivery). Review of efficiency, safety and limitations: Optimisation of processes and quality.

*6. Analysis of Medicinals (5 ECTS credits):*

Validations of methods of analysis (error control, specificity/selectivity, accuracy, precision, area of linearity, limit of detection, limit of quantification, reporting of results). Qualification of analytical equipment, efficiency parameters. Pharmaceutical analytical documentation. Surveillance of medicinal products, current legislation and regulations. Systems of quality control, GLP, GCLP. European Pharmacopoeia, USP: structure, general provisions, general monographs (e.g. substances for pharmaceutical use), overview of analytical methods. Volumetric and chemical analytical methods according to European and American Pharmacopeia (e.g. acidimetry and alkalimetry, oxidation/reduction measurement, potentiometry, etc.). Impurities, limit tests, solvent residue, determination of water in active substances/medicinal products. Spectroscopic and chromatographic methods according to European and American Pharmacopeia: atomic spectrometry, UV/VIS spectrometry, IR, IR in near region. Raman spectroscopy, fluorometry, thin layer chromatography, liquid chromatography, gas chromatography. Modern approaches to the analysis of medicinal products in pharmaceutical industry (HTS, NMR, MS, coupling of separation and spectroscopic methods). Analysis of active substances based on chemical groups (alcohols and derivatives, carbonyl compounds, carboxylic acid and its derivatives, nitro compounds, amines, sulphur compounds, polycyclic compounds, heterocyclic compounds). Complex approach to the analysis of active substances and medicinal products in connection with the preparation of samples to be analysed, and interpretation of analytical results. Exercises are set individually and are based on actual dispensatory provisions.

*7. Industrial Development of Medicinals (10 ECTS credits):*

Industrial development of pharmaceutical forms from concept to realization. Concept: Selection of active substances and pre-clinical study (screening). Pre-formulation studies: Physicochemical properties of active substance (solubility and dissolution rate and methods for urgent modification, crystal and amorphous forms, hygroscopicity, lipophilicity, partition coefficient, flow properties, etc.). Preliminary stability of active substance. Compatibility of an active substance with excipients, other active substances and packaging. Planning of experiments. Selection of pharmaceutical form. Selection of a process and development of technological procedure. Optimization of pharmaceutical form composition. Optimization of technological procedure. Critical parameters of pharmaceutical form and technological

process. Stability of pharmaceutical forms (guidelines, planning, types of studies, etc.). Hardware for development, PIL, and production purposes. Scale-up. Changes after the registration of pharmaceutical product – SUPAC. PAT in pharmaceutical-technological procedures. Development of biopharmaceutical methods and biopharmaceutical evaluation of pharmaceutical products. Pre-clinical and clinical studies.
Bio-equivalence and pharmacokinetic studies. Packaging novelties regarding pharmaceutical products. Novelties in delivery systems for controlled release of active substances. Industrial media and industrial environment management. Quality assurance in pharmaceutical industry.

*8. Intellectual Property, Legislation and Regulations (5 ECTS credits):*

Patent legislation and the TRIPs Agreement. Examples of the EU and RS case law in the field of intellectual property. Secondary EU and national legislation in the field of medicinal products. Strategies in the EU regulatory network. EU regulatory authorisation procedures for a medical product. Patent and regulatory protection in the field of medicinal products. Regulatory telematics. Absolute and relative therapeutic value of a medicinal product. Empowerment of the roles of patients, users and consumers. Elements of competition policy on medicinal products. Elements of health policy on medicinal products.

*9. Pharmaceutical Engineering (5 ECTS credits):*

Basics: fluid flow, transfer of heat and mass, powder rheology, selection criteria for new technological equipment. Processes: drying, mixing of powder compounds, agglomerations, solid particle compression, layering of particles, pellets and tablets, use and optimization of fluid bed technology, emulsifying / homogenising, molten metal technology procedures. Tools of process analytical technology: online measurement of particle sizes (FB agglomeration), “population balance” particle growth modelling, agglomeration monitoring by means of mechanical parameters, use of NIR in agglomeration processes.

*10. Public Presentation of the Topic and Preparation of Master’s Thesis (25 ECTS credits):*

Master's thesis is an independent research project. Each student selects a topic and a supervising faculty member. Contents overview: definition of the central question, the aim of the study, scientific approach and methods. Understanding of the mentoring process. Use and overview of available bibliography data. Understanding of the central question. Basic approaches, methods and experimental techniques. Independent experimental work with adequate recording. Analysis of results, making partial decisions and their testing. Written submission of the scientific work. Research as a creative interdisciplinary teamwork.

*11. Defence of Master's Thesis (5 ECTS credits):*

The student presents his/her own research project and demonstrates a broader understanding of the selected research topic. The master's thesis structure contains all elements of a scientific article (title, contents, summary, list of abbreviations, introduction, aim of the study with a working hypothesis, materials and methods, results, discussion, conclusions, bibliography). The thesis defence is marked by a clearly presented research topic, methods used, results obtained and the evaluation of the results. Master exam's aim is to test the student's ability to synthesize knowledge of a broader research area.

*12. Design of New Active Substances (5 ECTS credits)*

This course introduces basics of design and synthesis of active substances with desired and appropriate physicochemical properties according to the industrial standards, and prepares students for independent solving of problems in this field. The content includes basics of molecular modelling, discovering new points of application for active substances, sources of lead compounds, screening of natural, semi-synthetic and synthetic compounds, structural development of enzyme inhibitors and receptor modulators, semi-industrial and industrial synthesis of active substances, regulation of synthetic procedures, methods for cleaning and isolation of active substances, alternative synthetic routes for known active substances.

*13. Biological and Toxicological Properties of Pharmaceutical Materials (5 ECTS credits):*

Structural recognition and evaluation of substance interaction in biological systems and effects of these interactions in living organisms. Mechanisms causing substance toxicity. Effect of metabolism on substance toxicity. Biological and toxicological properties of: sweeteners, corrigents, excipients, polymers, suppositories, solvents, acids, bases, gases, reagents in compound synthesis, small particles.
Pharmaceutical waste management. Ensuring safety at work when handling pharmaceutical materials. Evaluating or estimating the risks of use of pharmaceutical materials in technological processes and negative effects on the environment. Regulatory requirements for the use and integration of pharmaceutical materials in pharmaceutical products.

*14. Pharmaceutical Packaging (5 ECTS credits):*

Introduction to pharmaceutical wrapping and packaging. Function of packaging: planning, development and expiration date of the product. Regulatory aspects of pharmaceutical packaging. Specifications and evaluation of packaging quality and materials used for packaging. Primary and secondary packaging. Packaging selection and design. Packaging for solid pharmaceutical forms. Packaging for semi-solid pharmaceutical forms. Packaging for liquid pharmaceutical forms. Packaging for sterile pharmaceutical forms. Glass. Plastic materials. Films, foils and laminates. Metal materials. Closures and closing systems. Technological wrapping procedures. Printing and design. Wrapping hardware.

*15. Spectroscopic and Separation Analytical Methods (5 ECTS credits):*

Analytical process, signals. Spectroscopic methods: UV+VIS, infrared spectroscopy, different IR spectroscopy techniques, Raman spectroscopy, fluorescent spectroscopy, polarimetry, refractometry, atomic magnetic resonance, $^{1}$H-NMR, NMR in solid form, mass spectrometry, mass spectrum interpretation, sample ionization methods. Separation methods: extraction methods, basics of chromatographic processes, high resolution liquid chromatography, gas chromatography, planar chromatography, capillary electrophoresis. Coupling of separation and spectroscopic methods. Automation of analytical procedures. Validation of separation and spectroscopic methods. regulatory conditions (ICH, USP, FDA), specificity, area of linearity, precision, accuracy, limit of detection, limit of quantification, ruggedness.

*16. Design of Particle Properties (5 ECTS credits):*

Methods for characterization of molecular, microscopic and macroscopic properties of particles. Significance of molecular, microscopic and macroscopic properties of particles in the development and production of pharmaceutical forms. Polymorphism, pseudopolymorphism and amorphism related theories. Crystal systems: crystal structure, bonds and crystal symmetry, crystal system notation (Miller indices, space lattice), crystal habit. Isomorphism, polymorphism, pseudopolymorphism, amorphism. Physical stability of forms (enantiotropism, monotropism, crystal transitions). Methods for crystallization process monitoring. Physicochemical properties of crystal systems: solubility and phase diagrams, enthalpy/concentration diagram. Nucleation: theory and types of nucleation (homogenous,

heterogeneous, secondary, nucleation kinetics, nucleation on an industrial scale. Crystal growth: basic concept and theory of crystal growth, crystal growth kinetics, crystal growth in a multi-component system, effects on crystal growth mechanisms and kinetics (temperature, solvents, movement (stirring), impurities and additives). Particle size, agglomeration. Crystallizers (laboratory and industrial), working with crystallizers, crystallization process optimization, crystallization control). Peptide and protein crystallization.

*17. Analysis of Active Substances and Metabolites in Biological Materials (5 ECTS credits):*

Physicochemical, biopharmaceutical and pharmacokinetic properties of active substances and metabolites; determination and significance for the analysis. Sampling in biosystems and sample preparation for the analysis; processes of precipitation, microdialysis, liquid-liquid and solid-liquid extraction, process automation and evaluation of preparation effectiveness. Significance and selection of methods for quantification and identification of active substances and their metabolites in biological materials. Chromatographic techniques with emphasis on HPLC. Spectroscopic and electrochemical characterization of active substances and metabolites for their determination in biosystems. Coupling of chromatographic methods with detection systems based on the nature of analyzed compounds; coupling with mass spectrometry; labelling, radioanalytical and immunoanalytical methods. Development, optimization and validation of methods. Practical implementation of measurement, data processing and interpretation of results depending on the purpose of studies.

*18. Quality Management in Pharmaceutical Production (5 ECTS credits):*

Quality management system (globalization, trends in the business environment, strategic management, significance of quality for organization, quality policy, management review). Comprehensive quality management (history, development, approach). Quality management standards. Quality assurance legislation. Rules of procedure regarding quality. Documentation, documentation management, quality recording management. Design, quality objectives, design of quality management system. Development management (design, entry requirements, validation, changes). Logistics. Storage management. Production process or service delivery process (customers, determination of requirements, customer communication, purchasing, process management). Production management, control, measurement equipment. Control (control procedures, sampling, analysing, final control). Change management. Contractual relations (preparation of contracts, demarcation and determination of responsibilities, implementation of provision). Management of non-compliant product. Internal audits. Training. Preventive/corrective measures. Constant improvement, measuring customer satisfaction, analysis, studies. Environmental protection. Safety and health at work.

*19. Biopharmaceutical Evaluation of Pharmaceutical Forms (5 ECTS credits):*

Pharmaceutical form: constituents, interactions. Physicochemical properties of forms and constituents; effects on biopharmaceutical properties. Effects of changes in pharmaceutical forms and constituents on biopharmaceutical properties. Application of analytical methods in evaluation of biopharmaceutical properties. Physiological / pathological conditions at the site of administration.
Oral administration. Digestive tract. Conditions: pH, volumes, media, flows, movement, etc.
Behaviour of pharmaceutical forms after the administration. Behaviour of an active substance in a pharmaceutical form after the administration, release, absorption. Presystemic metabolism.
Stability after the administration under *in vivo* conditions. In vitro models for behavioural simulation of pharmaceutical forms after the administration. release models and absorption models.

In vitro - in vivo corellation. Regulatory aspects. Industrial approaches to biopfarmaceutical evaluation.

*20. Pre-clinical Studies (5 ECTS credits):*

Determination of toxicodynamic properties of a substance. Binding and interaction of substances in biological systems, induction of toxic effects. Determination of toxicokinetic properties of a substance. Barriers in administration of toxic substances, absorption (uptake), distribution and metabolism and elimination of toxic substances, sequestration of toxic substances. Selection of substance dosage, route of administration, duration of the test and sampling of biological material in pre-clinical studies of medicinal products for human use. Extrapolation of the pre-clinical toxicokinetic study results to man.
Toxicology (safety pharmacology): classification of substance toxicity, acute toxicity tests, subacute / chronic toxicity tests, reproductive toxicity, fertility, teratogenicity, genotoxicity and mutagenicity, carcinogenicity, local toxicity (eye and skin irritation) specific studies, impurities, solvent residues, classification of medicinal product use during pregnancy. Regulatory aspects: non-clinical pharmacological-toxicological testing of medicinal products (experiments on laboratory animals, organs, tissues and cells used as a model for demonstration of adverse reactions in humans), common technical document, module 2.4: pre-clinical summary, module 2.6: pre-clinical review, module 4.0: pre-clinical study reports.

*21. Cosmetology and Cosmetic Products (5 ECTS credits):*

Difference between cosmetic and pharmaceutical products. Cellular structure of the skin (keratinocytes, corneocytes, melanocytes, fibroblasts, Langerhans cells; epidermis, dermis, hypodermis, glands). Hair and nails. Skin matrix compounds – keratin, collagen and other dermal matrix proteins, polysaccharides and proteoglycans, skin lipids. Skin surface properties: acid and lipid mantle, secretion and composition of sweat and sebum, skin surface microflora. Skin as an organ. Nomenclature of cosmetic ingredients. Cosmetically active ingredients (moisturizers, urea, vitamins, plant extracts, ceramides, AHA and BHA, antioxidants, enzymes…). Excipients – vehicle ingredients (lipophilic, hydrophilic, amphiphilic), thickeners, preservatives, antioxidants. Ingredient specification: methods for evaluation of chemical, physical and microbiological properties of compounds. General principles for the manufacture of cosmetic products, conditions for successful industrial development. Production of dispersions, liposomes and nanoparticles. Technological equipment: homogenizers, colloid mills, propeller mixers, ultrasound based devices. Cosmetic products packaging. Legal provisions in the RS, EU, USA and Japan. Evaluation of safety and efficacy. Skin cleansing products. Body care products for different age groups. Natural cosmetic products. Mouth-care products. Sun protection products. Deodorants, antiperspirants, perfumes, lipsticks, other cosmetic products.

*22. Pharmaceutical-Technological Analysis (5 ECTS credits):*

Principles of method selection and validation. Formulation of sampling protocols. Specification in industry. Control of pharmaceutical forms in the development stage, in-process control and control of finished products. Pharmaceutical-technological analysis in pharmacopeia (chapter 2.9). Evaluation of liquid pharmaceutical forms: relative density, refractive index, pH, water content, ethanol content, surface tension, conductivity, colligative properties, rheological properties, particle size, uniformity of mass and content, dose uniformity in multi-dose pharmaceutical forms. Evaluation of parenteral pharmaceutical forms and pharmaceutical forms for eye. ph, conductivity, osmolality, optical density, clarity and colour of eye drops, test for impurities with particles, rheological properties, contamination with particles and invisible particles, ampoule seal test, filling test, uniformity of mass and content, dose uniformity in multi-dose pharmaceutical forms. Evaluation of semi-solid pharmaceutical forms: physicochemical constants. Determination of water: moisture content,

water content, determination of emulsion type, binding of water in a structure (DSC). Dispersion. Thermoanalytical tests: melting point, dripping point, solidification point, clarification temperature… Mechanical tests: consistency by penetrometry, rheological properties. Tests regarding release from semi-solid pharmaceutical forms. Evaluation of rectal pharmaceutical forms: disintegration, measuring the softening time of lipophilic suppositories, resistance to rupture of suppositories and pessaries, test on homogeneity of suppositories, uniformity of mass and content, release from suppositories. Evaluation of solid pharmaceutical forms: Density. Porosity. Flow properties. Particle size. Crystallographic state. Water and moisture content; hygroscopicity – adsorption isotherms. Mechanical strength: strength, rupture, pressure, traction, wear, bending, capsule shell strength. Uniformity of content. Solubility. Dissolution tests. Disintegration. Gastro-resistance.

*23. Biological Molecules Evaluation Methods (5 ECTS credits):*

Knowledge of biological materials: proteins, nucleic acids, lipids, carbohydrates.
Peptide and protein analysis: colorimetric methods, liquid chromatography,
electrophoretic methods, capillary electrophoresis, peptide mapping, amino acid analysis, determination of amino acid sequence, surface plasmon resonance, fluorescent and confocal microscopy, FRET, circular dichroism, FTIR, protein microarray, immunological methods, ELISA, Western blot transfer, quick immunological tests, precipitation immunological methods. Nucleic acid analysis: PCR, RT-PCR, Southern blot transfer, Northern blot transfer, nucleotide sequence determination, DNA, RNA microarrays, siRNA methods. Analysis of biopharmaceuticals: regulatory requirements, determination of biological activity, determination of toxicity, determination of pyrogenicity, determination of hosting proteins and nucleic acids.

*24. Pharmaceutical Biotechnology II (5 ECTS credits):*

Erythropoietic growth factors. Insulins, interleukins and interferons. Other biotechnological recombinant medicinal products. Development of biological medicinal products of second generation. Genetic medicines: manufacture, advantages and disadvantages, ethics. Virus systems of genetic medicine administration. Non-virus systems of genetic medicine administration. Alternative methods and use of monoclonal antibodies. Blood and blood products. Development and use of tissue and cell engineering. Classic and recombinant vaccines. Regulatory process in the field of pharmaceutical biotechnology.

*25. Stability of Medicinals (5 ECTS credits):*

Significance and development of the field of medicinal product stability and related regulations. Quality criteria and terminology in the field of stability. Incorporation of medicinal product stability studying in the QAS. Studying and testing of the stability of medicinal products: organization and realization within pharmaceutical development and industrial production. Premises, equipment and instruments needed for conducting stability studies. Thermodynamic and kinetic aspects of medicinal product stability. Reaction kinetics in medicinal product stability: simple and complex reactions, the effect of the solvent and catalysts. The effect of temperature on the rate of processes: accelerated isothermal and non-isothermal tests. Chemical changes of active substances and excipients and their characteristics: hydrolyses, oxidations, isomerisations and others. Physical changes of substances and final pharmaceutical forms. Changes in microbiological quality, use of preservatives and stress testing. Protection of medicinal products and use of pharmaceutical packaging. Evaluation of critical parameters of stability; selection of analytical methods and their applicability for the purpose of use (stability indication). Implementation of medicinal product stability tests according to the ICH directives and other recommendations.

*26. Pharmacokinetic and Clinical Studies (5 ECTS credits):*

Pharmacokinetic studies: clinical pharmacokinetics of medicinal products in connection with different routes of administration in volunteers and patients, evaluation of therapeutic equivalence of generic medicinal products with small molecules. *Biological applicability:* definitions, description, methods, parameters. *Biological equivalence:* definitions, description, methods, clinical, analytical, kinetic and statistical aspects. Interchangeable and comparable medicinal products. Evaluation of therapeutic equivalence of generic biotechnological medicinal products: *Biological similarity.* definitions, description, methods, parameters. Clinical studies: monitoring therapy results of medicinal products (clinical, humanistic, economical) in patients. *Meta-analysis: definition, description, methods.* Regulatory aspects: clinical testing of medicinal products (experiments on humans to prove safety and efficacy of medicinal products in a certain indication), common technical document, module 2.5, clinical summary, module 2.7, clinical overview, module 5.0: clinical study reports. EMEA guidelines for evaluation of biological equivalence / biological similarity of medicinal products with small and large molecules.

*27. Pharmaceutical Nanotechnology II (5 ECTS credits):*

Support biocompatible materials – synthetic and semi-synthetic polymers, natural materials such as lipids, various polymers and proteins and their properties. New delivery systems: polymer therapeutics (covalent bond of an active substance with a carrier: polymer-active substance, polymer-protein, polymer-antibody). Colloidal carriers (noncovalent physical inclusion of an active substance in mycelia, nanoemulsions, nanoparticles, nanocapsules, nanogels, liposomes, nanotubes, nanofibres, dendrimers, lipoplexes or a combination. Development of nanotechnological systems. Self-associating systems, gene delivery vectors. Biotechnological approaches and use of antibodies for DDS. Tissue engineering and regenerative medicine, wound healing. Dendrimer technology. Molecular mapping, affixed polymers. Evaluation of nanosystems (physical, chemical, biological in cell models). Industrial aspects of nanosystem development (use of new technologies).

*28. Microbiological Quality of Pharmaceutical Products (5 ECTS credits):*

Microbiological quality of pharmaceutical products. Microorganisms as contaminants, bioburden. Classification of pharmaceutical forms, requirements for individual groups. Microbiological quality of pharmaceutical waters. Procedures for decreasing the number of MO. Sterilization, terminology, sterility assurance levels (SAL), officinal and non-officinal sterilization methods – sterilization with saturated water vapour under pressure, dry sterilization process, chemical methods, ionizing radiation, isolators, sterile filtration and aseptic procedure. Validation of sterilization processes and aseptic filling processes. Depyrogenation procedures, validation and control of pyrogenic substances / bacterial endotoxins in pharmaceutical substances, packaging and final products. Quality control of sterilization procedures, process control, final product control – sterility test, microbiological control of pharmaceutical substances and final products, quick methods as an alternative to the pharmacopeia methods. Sterile pharmaceutical forms. Overview of individual pharmaceutical forms and their properties – injections, infusions, powders for the preparation of injections and infusions, implants, parenteral forms with peptides and proteins, diagnostic means. Formulation requirements. Production of sterile pharmaceutical forms on an industrial scale. Classification of clean premises and microbiological control of conditions during production. Production of small and large volume parenterals. Robotization in sterile production. Secondary contamination prevention. Packaging for sterile pharmaceutical forms, types of packaging, materials, glass, plastic materials, elastomeric materials for closures. Preservatives groups, dependent on chemism, mechanism of action, requirements for different groups of products.

*29. Prolonged Release Pharmaceutical Forms (5 ECTS credits):*

Modified release related terminology. Modified release mechanisms. Excipients for the production of modified release systems. Quickly / slowly swelling / eroding polymer systems. Biopolymers. Synthetic biocompatible polymers. Intelligent polymers. Solid pharmaceutical forms with modified release. Tablets (matrix, multilayer, gastro-resistant, floating, bioadhesive, mouth dissolving, etc.). Capsules. Microcapsules, microspheres. Pellets. Colloidal carrier systems: nanoparticles, liposomes, micro- and nanoemulsions. Peptide and protein delivery systems. Modern technological approaches to modelling. Nanolayering, micronization with supercritical fluids, etc.

*30. Industrial Media and Industrial Environment Management (5 ECTS credits):*

Industrial media. Drinking water – requirements, delivery to the customer, maintenance of chemical and microbiological (MCB) quality. Purified water (PW). Water for injections. PH EUR and USP requirements, preparation, distribution to the users, maintenance of chemical and MCB quality. Clean steam. Pure steam. Compressed air for pharmaceutical purposes. Pure gases. Liquid filters. Gas filters. Management of industrial environment for pharmaceutical production. Clean premises, cleanliness class. Preparation and provision of clean premises. Air-conditioning devices for clean premises. Air-conditioning filters. Validation procedures from the design qualification (DQ) to performance qualification (PQ) and system reliability.

*31. Pharmaceutical Marketing (5 ECTS credits):*

Market (definition, characteristics, types, pharmaceutical market). Marketing (definition, types, marketing environments, basic differences between prescription and non-prescription medicinal product marketing). Marketing web (model 4 P (6 P), model 4 C, introduction of models and characteristics). Communication web (introduction and characteristics). Concept of product / service life cycle (life cycle curve, BCG matrix). Marketing researches and SWOT analysis (research types, data sources, significance and applicability of SWOT analysis). Marketing plan (content, structure). Strategic marketing planning (segmentation, positioning).

*32. Phytopharmaceuticals (5 ECTS credits):*

European legislation in the field of phytopharmaceuticals. Terminology related to phytopharmaceuticals: herbal medicinal product, traditional herbal medicinal product, herbal drug, herbal substance, herbal preparation, standardized extracts, quantified extracts. Specific problems connected with the herbal medicinal product manufacture: quality assurance of starting materials (Guideline on Good Agricultural and Collection Practice for starting materials of Herbal Origin EMEA/HMPC/246816/05), preparation methods for herbal preparations (extracts, juices, etheric oils, etc.). Specific problems regarding quality assurance and verification of herbal medicinal products: description of quantitative and qualitative content of an active substance (Guideline on Declaration of Herbal Substances and Herbal Preparations in Herbal Medicinal Products/Traditional Herbal Medicinal Products in the SPC - EMEA/HMPC/CHMP/CVMP/287539/05), drug to extract ratio (herbal substance to herbal preparation ratio): definition, calculation, use, examples for liquid extracts, examples of dry extracts, chemical analysis: substance with known therapeutic effect, active marker, analytical marker, fingerprint analysis, use of group standards (total triterpene glycosides expressed as escin), herbal medicinal product stability (Guideline on quality of herbal medicinal products / traditional herbal medicinal products), solvents as excipients and as an active substance component. Specific problems in demonstrating quality of herbal medicinal products: level testing of genotoxicity, carcinogenicity test in case of suspicion (Guideline on Non-Clinical Documentation for Herbal Medicinal Products in Applications for Marketing Authorisation (Bibliographical and Mixed Applications) and in Applications for

Simplified Registration). Specific problems in demonstrating efficacy of herbal medicinal products: level of evidences needed for the category of herbal medicinal products made of a medicinal product of well-established use, and for traditional medicinal products.

*33. Pharmaceutical Industry Administration and Management (5 ECTS credits):*

Industrial process administration and management. Innovation management. Project management. Research and development management. Strategic R&D management. Technological strategy. Determination of R&D sources. Project portfolio management. Business models such as cooperation and integration. Risk management. Knowledge management. Application of informatics in project administration, management and coordination. Quality management in pharmaceutical industry.

*34. Process Analytical Technologies (5 ECTS credits):*

What are process analytical technologies (PAT)? History of PAT. PAT and legislation.
Analytical methods (acoustics, mass flow control, fluorescence, gas chromatography, process mass spectroscopy, nuclear magnetic resonance, UV-VIS spectroscopy, vibrational spectroscopy, population equilibrium modelling, positron emission particle tracking, neural network, NIR spectroscopy, torque measurements, CFD, DEM modelling, statistical models and other methods in the PAT function). PAT application in pharmaceutical product manufacture: determining the final point of the process (granulation, drying, mixing), scale up, particle growth control (granulation), ensuring layer evenness, increasing the availability of a process, content, uniformity of content, structure effect, particle size, distribution of particle size and active substance form and excipients regarding the dissolution rate, analysing effects on solidity and disintegration of tablets, PAT support for tabletting process monitoring, optimization of new pharmaceutical form development, PAT and wrapping.

*35. Pharmaceutical Processing Equipment (5 ECTS credits):*

Solid pharmaceutical forms: mills (roller, ball, centrifugal, air-pressure, colloid), sifter machines (dry and wet sieving), mixers (container, shear plough), granulators (planetary, (low and high shear) high speed, single pot, whirl-layer, roller compactor), tabletting machines (rotary, single stroke), capsule machines, extrusion and pelleting apparatus, dryers (drying cabinets, drum dryers, vacuum dryers, whirl-layer dryers, liophilizator), tablet coating machines (fluid bed technology, perforated drum), machines for continuous drying, granulating and coating, closing machines (induction welder), packaging machines. Semi-solid and liquid pharmaceutical forms: mixing and homogenizing apparatus (emulsions, suspensions, semi-solid systems), crucibles, membrane and depth filters, circulation and deaeration pump. Sterile pharmaceutical forms: sterilizers (dry, autoclave, sterilizing tunnels, membrane), clean premises and LAF chamber, monoblock in aseptic production of dry injections, eye drops, particle presence viewer, closing machines, organization of aseptic production.

*36. Pharmacoeconomics (5 ECTS credits)*

Therapy outcomes. Pharmacotherapy costs. Pharmacoeconomic analyses: cost analysis, cost-minimization analysis, cost-effectiveness analysis, cost-benefit analysis and cost-utility analysis. Types of pharmacoeconomic studies. Modelling in pharmacoeconomics. Organization of healthcare systems. Healthcare costs. Healthcare policy design based on pharmacoeconomic principles.

*37. Pharmacogenomics and Genetic Medicines (5 ECTS credits)*

Pharmacogenetics/pharmacogenomics. The human genome. Genotype/phenotype of individual variations. Biomarkers. Pharmacogenetics of metabolizing enzymes, receptors, transporters. Individualized therapy. DNA microarrays. Pharmacogenomics in the project of medicinal product design. Pharmacogenomics/proteomics. Applicative bioinformatics. Social, ethical and legal aspects of pharmacogenomic research. Genetic medicines.

*38. Selected Topics in Pharmaceutical Biotechnology (5 ECTS credits):*

Broadening the knowledge base of pharmaceutical biotechnology. State-of-the-art techniques of formation. Recombinant biopharmaceuticals: state-of-the-art techniques of formation, pharmacology with pharmacokinetics, pharmaceutical forms. Application and developmental potential of various groups of biopharmaceuticals. Analytics of active substances of biotechnological origin.

*39. Selected Methods of Pharmaceutical Analysis (5 ECTS credits):*

Broadening the knowledge base of pharmaceutical analysis methods: spectroscopic methods (UV, IR, fluorescence). Resonance methods (NMR, EPR). Mass spectrometry. X-ray cristallography. Surface plasmon resonance. Electron microscopy. Complex analysis systems (coupling of separation and spectroscopic methods). Complex analytics design.

*40. Nutritional Supplements (5 ECTS credits):*

Legislation in the area of nutritional supplements. Definitions of basic terms: nutraceuticals, functional food, diet food. Recommended daily intake of nutrients. Vitamins. Vitaminoids. Minerals. Amino acids. Lipids. Carbohydrates. Prebiotics and probiotics. Antioxidants. Bee products. Enzymes. Phytoestrogens.