COURSE DESCRIPTION CARD - SYLLABUS

Course name
Synthesis and technology of drugs [S1IFar2>SiTŚL]

Course

Field of study
Pharmaceutical Engineering

Year/Semester
2/4

Area of study (specialization)
–

Profile of study
general academic

Level of study
first-cycle

Course offered in
Polish

Form of study
full-time

Requirements
compulsory

Number of hours

Lecture
10

Laboratory classes
35

Other
0

Tutorials
0

Projects/seminars
0

Number of credit points

4,00

Coordinators

dr Dariusz Młynarczyk

Lecturers

Prerequisites

Students entering the course should have a well-established knowledge of the fundamentals of organic chemistry, physical chemistry and medicinal chemistry in both theoretical and practical terms. They should familiarize themselves with selected procedures of good laboratory practice, as well as with the rules of occupational health and safety and fire safety before starting experimental work.

Course objective

As part of the course, students will learn the pathway leading to the development of a new therapeutic agent, from the stage of designing the active substance to the stage of technological processes aimed at industrial production of the compound. In particular, students will learn about: (i) the technology of obtaining selected pharmaceutically active substances and excipients on a laboratory and industrial scale based on chemical and biotechnological synthesis processes; (ii) unitary physical and chemical operations both on a laboratory and large industrial scale leading to the obtaining of pharmaceutically active substances and excipients used in the pharmaceutical industry; (iii) principles of good manufacturing and laboratory work practices; (iv) methods of exploration and design of new medicinal agents together with technological processes.

Course-related learning outcomes

Knowledge:
1. Has a structured, theoretically supported general knowledge of inorganic, organic, physical and analytical chemistry allowing to understand, describe and study chemical phenomena and processes related to pharmaceutical engineering [K_W4]
2. Has knowledge of basic techniques, research tools used in pharmaceutical engineering, knows the physicochemical properties of substances for pharmaceutical use affecting the biological activity of drugs [K_W7]
3. Has knowledge of basic conceptual categories and terminology used in pharmaceutical engineering and related industries [K_W9]
4. Has knowledge of natural and synthetic raw materials, products and processes used in the pharmaceutical industry [K_W13]
5. Has knowledge of the development of pharmaceutical engineering and the research methods used in it, as well as the directions of development of the pharmaceutical industry in the country and the world [K_W14]
6. Knows the principles of construction and selection of reactors and apparatuses used in the pharmaceutical and chemical industry [K_W16]
7. Has basic knowledge of methods of searching for new medicinal substances, plant and synthetic drug [K_W24]
8. Has detailed knowledge of substances for pharmaceutical and cosmetic use, dietary supplements, plant raw materials, their production and technology [K_W25]
9. Knows the basic principles of occupational safety and health [K_W27]

Skills:
1. Understands literature in the field of pharmaceutical engineering in Polish; reads with comprehension uncomplicated scientific and technical texts in a foreign language, is able to acquire information from literature, databases and other sources related to pharmaceutical engineering, also in a foreign language, integrate them, interpret and draw conclusions and formulate opinions [K_U1]
2. On the basis of general knowledge explains the basic phenomena related to the relevant processes, distinguishes between the types of chemical reactions and has the ability to select them for the chemical processes carried out, is able to characterize different states of matter, the structure of chemical compounds, including medicinal substances, using theories used to describe them, methods and experimental techniques [K_U2]
3. Uses correctly chemical and pharmaceutical terminology and nomenclature of chemical compounds, including in a foreign language [K_U3]
4. Is able to prepare a well-documented study in Polish and in a foreign language in the field of pharmaceutical engineering [K_U5]
5. Applies basic techniques, equipment and research apparatus useful in the synthesis of pharmaceutically active substances relevant to pharmaceutical engineering, develops documentation [K_U8]
6. Is able to use basic equipment and apparatus used in pharmaceutical engineering, obtains pharmaceutically active substances by synthetic and biotechnological methods, conducts isolation of active bodies from plant raw materials based on knowledge of basic physical operations and chemical processes, interprets and documents the results of product quality tests [K_U9]
7. Has the ability to conduct chemical, pharmaceutical research of pharmaceutically active substances [K_U10]
8. Is able to analyze and evaluate the functioning of the basic processes and unit operations of pharmaceutical engineering [K_U14]
9. Observes the principles of occupational safety and health, related to the work performed and is able to assess the risks arising from unit operations of pharmaceutical engineering [K_U22]
10. In a professional and research environment, is able to plan and organize individual and team work and work both individually and in teams [K_U25]

Social competences:
1. Is ready to make decisions independently and to lead a team, to critically evaluate his/her own actions and the actions of the team, to accept responsibility for the consequences of these actions, and is able to interact and work in a group, to inspire and integrate the professional environment [K_K2]
2. Is aware of the importance of understanding non-technical aspects and consequences of engineering activities, including their impact on the environment and related responsibility for decisions taken, correctly recognizes problems and makes appropriate choices related to the performance of the profession, in accordance with the principles of professional ethics, care for the achievements and

traditions of the profession [K_K3]
3. Is able to appropriately determine priorities for the implementation of a task set by himself or others, has the habit of supporting supportive and remedial actions, is responsible for the safety of his own work and that of others, knows how to act in states of emergency [K_K5]

Methods for verifying learning outcomes and assessment criteria

Learning outcomes presented above are verified as follows:

Laboratory classes. Students are required to pass a preliminary colloquium testing their knowledge of physical processes, laboratory apparatus, health and safety and fire safety rules. During the laboratories, students take a colloquium covering chemical processes. After the completion of the assigned preparation, the students each time present to the instructor: (i) the protocol of execution and (ii) relevant technological schemes. Selected pharmaceutically active substances are characterized in physical and chemical terms. A prerequisite for passing the labortaory classess is passing the material covered by two colloquia, presenting documentation of the practical tasks performed, and obtaining a positive result from the practical colloquium conducted using the OSPE method, i.e., a standardized practical exam consisting of direct observation of a student demonstrating a skill under standardized conditions.
Lectures and exam. The final exam is conducted in the form of a series of test and open-ended questions. It covers the content presented in lectures and laboratory classess. Examination in the form of test questions in the OLAT system is allowed. In special cases, the exam will be held on the Teams platform and will be an oral exam. A passing grade is awarded to students who have obtained a minimum of 60% correct answers.

Programme content

Lectures
1. Synthesis on solid supports and combinatorial chemistry as rapid methods for creating large libraries of biologically active compounds.
2. Methods of obtaining and separation of optically active compounds by separation of racemic mixtures including chromatographic methods. Stereoselective synthesis.
3. Design of syntheses of APIs and excipients included in various groups of drugs used in technology taking into account their economics and ecology on selected examples.
Laboratory classess
Students perform chemical and physical processes leading to the preparation or isolation of no less than six medicinal substances or excipients (including caffeine, nipagin A, paracetamol, sulfanilamide, lycopene, anesthesin, fluorescein). As part of the laboratories, students determine the chemical purity of the substances obtained by chromatographic analysis, melting point measurement, UV-VIS spectrum analysis. For selected medicinal substances and their derivatives, students (i) carry out physico-chemical form studies, (ii) perform an exercise using the Reaxys database with submission of documentation.

Course topics

none

Teaching methods

The subject is implemented in the form of lectures and laboratory exercises. The substantive content covered in lectures is provided to students in the form of a multimedia presentation. Students perform laboratory exercises on the basis of the materials that are given to them at the beginning of the class cycle.

Bibliography

Basic:
1. K. Kieć-Kononowicz, Wybrane zagadnienia z metod poszukiwania i otrzymywania środków leczniczych, WUJ, Kraków, 2000.
2. P. Harrington. Pharmaceutical process chemistry for synthesis, John Wiley@Sons, Hoboken, 2011.
3. G.L. Patrick, Chemia medyczna podstawowe zagadnienia, WNT, 2003.

Additional:

1. R.B. Silverman, Chemia organiczna w projektowaniu leków, WNT, 2004.
2. A. Vogel, Preparatyka organiczna, WNT, Warszawa 2006.
3. H. Marona (red.), Syntezy środków leczniczych, WUJ, Kraków, 2006.
4. J. Gawroński, K. Gawrońska, K. Kacprzak, M. Kwit, Współczesna synteza organiczna. Wybór eksperymentów, PWN, Warszawa 2004.
5. F. Gualtieri, New trends in synthetic medicinal chemistry, Wiley-VCH, Weinheim, 2000.

Breakdown of average student's workload

	Hours	ECTS
Total workload	100	4,00
Classes requiring direct contact with the teacher	50	2,00
Student's own work (literature studies, preparation for laboratory classes/ tutorials, preparation for tests/exam, project preparation)	50	2,00