



## COURSE DESCRIPTION CARD - SYLLABUS

Course name

Synthesis and Technology of Therapeutic Products

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### Course

Field of study

Pharmaceutical Engineering

Area of study (specialization)

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Level of study

First-cycle studies

Form of study

full-time

Year/Semester

3/6

Profile of study

general academic

Course offered in

polish

Requirements

compulsory

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### Number of hours

Lecture

25

Tutorials

0

Laboratory classes

35

Projects/seminars

0

Other (e.g. online)

0

### Number of credit points

3

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### Lecturers

Responsible for the course/lecturer:

prof. Tomasz Gośliński, PhD, DSc

Responsible for the course/lecturer:

### Prerequisites

Students starting the course should have a solid knowledge of the basics of organic chemistry, physical chemistry and drug chemistry in theoretical and practical aspects. Before commencing experimental work, they should become familiar with selected procedures of good laboratory practice as well as health and safety and fire protection rules.

### Course objective

As part of the course, students learn the whole path leading to the development of a new therapeutic



agent, from the stage of designing the active substance to the phase of technological processes aimed at the industrial production of the active pharmaceutical ingredient. Students will learn in particular: (i) the technology of obtaining selected pharmaceutical active substances and auxiliary substances 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 scale industrial scale, resulting in the preparation of pharmaceutically active ingredients and excipients used in the pharmaceutical industry; (iii) principles of good manufacturing practice and laboratory work; (iv) methods of seeking and designing new therapeutic agents together with technological processes; (v) using modern computational techniques.

### Course-related learning outcomes

#### Knowledge

##### Student

K\_W4. has ordered, theoretically founded general knowledge in the field of inorganic, organic, physical and analytical chemistry enabling understanding, description and research of chemical phenomena and processes related to the synthesis and technology of therapeutic agents

K\_W7. has knowledge of the basic techniques, research tools used in the synthesis and technology of therapeutic agents, knows the physicochemical properties of substances for pharmaceutical use affecting the biological activity of drugs

K\_W9. has knowledge of the basic conceptual categories and terminology used in the synthesis and technology of therapeutic agents

K\_W13. has knowledge of natural and synthetic raw materials, products and processes used in the pharmaceutical industry

K\_W14. has knowledge of the development of pharmaceutical engineering and research methods used in it, as well as directions of development of the pharmaceutical industry in the country and in the world

K\_W16. knows the rules for the construction and selection of reactors and apparatus used in the pharmaceutical and chemical industries

K\_W24. has basic knowledge in the field of methods of searching for new pharmaceutically active ingredients, isolation of active ingredients from plant and synthetic approaches towards active substances

K\_W25. has detailed knowledge of molecules for pharmaceutical and cosmetic use, dietary supplements, plant raw materials, their production and technology

K\_W27. knows the basic principles of occupational health and safety

#### Skills

##### Student



K\_U1. understands literature on the synthesis and technology of therapeutic agents in Polish; reads and understands uncomplicated scientific and technical texts in a foreign language, is able to obtain information from literature, databases and other sources related to pharmaceutical engineering, also in a foreign language, integrate them, interpret them, draw conclusions and formulate opinions

K\_U2. based on general knowledge, explains the basic phenomena associated with relevant processes, distinguishes between types of chemical reactions and has the ability to select them for chemical processes, can characterize various states of matter, the structure of chemical compounds, including medicinal substances, using theories used to describe them, experimental methods and techniques

K\_U3. uses correct chemical and pharmaceutical terminology and nomenclature of chemical compounds, also in a foreign language

K\_U5. is able to prepare in Polish and in a foreign language a well documented study in the field of pharmaceutical engineering

K\_U8. uses basic techniques, research equipment and apparatus useful in the synthesis of pharmaceutically active substances, prepares documentation

K\_U9. receives pharmaceutically active substances by synthetic and biotechnological methods, isolates 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\_U10. has the ability to conduct chemical research, pharmaceutical pharmaceutically active substances

K\_U14. is able to analyze and evaluate the functioning of basic processes and unit operations of pharmaceutical engineering

K\_U22. complies with health and safety rules related to the work performed and is able to assess the hazards arising from unit operations of pharmaceutical engineering

K\_U25. in a professional and research environment can plan and organize individual and team work, and work both individually and as a team

#### Social competences

##### Student

K\_K1. is ready to make independent decisions and lead a team, critically assess his own actions and those of the team, take responsibility for the effects of these activities and is also able to cooperate and work in a group, inspire and integrate the professional environment.

K\_K3. is aware of the importance and understands the non-technical aspects and effects of engineering activities, including its impact on the environment and the associated responsibility for decisions, correctly recognizes the problems and makes the right choices related to the exercise of the profession, in accordance with the principles of professional ethics, care for achievements and traditions of the profession.



K\_K5. is able to properly set priorities for the implementation of the task specified by himself or others, has a habit of supporting assistance and remedial actions, is responsible for the safety of own and other work, knows how to deal with emergencies

### Methods for verifying learning outcomes and assessment criteria

Learning outcomes presented above are verified as follows:

Demonstrating - Students are required to pass an introductory colloquium checking knowledge of basic physical processes, laboratory equipment, health and safety rules and fire protection. During the demonstrating students take a colloquium covering individual chemical processes. After completing a given preparation, students each time present to the lecturer the exercises: (i) performance protocol and (ii) relevant technological diagrams. Selected pharmaceutically active substances are characterized in physico-chemical terms and analyzed using computer software in the field of predicting physico-chemical and pharmacological properties. The condition of completing the classes is passing the material included in the scope of two colloquiums, presentation of documentation of practical tasks completed and obtaining a positive result from a practical colloquium conducted by the OSPE method, i.e. a standardized practical exam consisting in direct observation of a student demonstrating the skill in standardized conditions.

Lectures and exam in the subject. The final exam in the subject is carried out in the form of a series of test and open questions. It includes the content presented in lectures and exercises. The Chair allows examination in the form of test questions in the OLAT system. If the pandemic restrictions remain, the exam will be held on Teams and will be an oral exam. Positive assessment is given to students who obtained a minimum of 60% of correct answers.

### Programme content

#### Lectures

1. Techniques of searching for and designing new drugs: (a) the concept of "lead compound", its search and role in drug design, (b) modification of lead compounds, (c) discovering new drugs bypassing lead compounds.
2. The role of interactions between receptors and enzymes and chemical substances in drug design.
3. The pharmaceutical industry in Poland and the principles of good manufacturing practice in the context of the preparation of active compounds (API) included in the synthetic drug. The problem of scaling chemical processes from laboratory to industrial scale as a significant technological goal.
4. Synthesis on the solid support and combinatorial chemistry as quick methods for the preparation of large libraries of biologically active compounds.
5. Methods for the preparation and separation of optically active compounds by means of separation of racemic mixtures, including chromatographic methods. Stereoselective synthesis.
6. Designing API synthesis and auxiliary substances included in various groups of drugs used in technology, taking into account their economics and ecology on selected examples.



7. The ability to modify the transport and bioavailability of drugs by chemical means (prodrugs) and by changing their physicochemical properties (polymorphs).

8. The use of biotechnological procedures in the production of antibiotics and selected biotechnological drugs. Technical issues in the production of antibiotics including the biosynthesis process and asepsis in the synthesis of antibiotics. Bioreactors and conditions of biotechnological processes in bioreactors. Selected procedures for receiving antibiotics include Beta-lactam antibiotics - penicillins, cephalosporins and other beta-lactams, tetracyclines, rifamycins, polypeptide, antifungal and anticancer antibiotics.

#### Demonstrating

Students perform chemical, physical and biotechnological processes leading to the receipt or isolation of not less than three medicinal or auxiliary substances (e.g. caffeine, nipagine A, paracetamol, sulfanilamide, lycopene, tanalbine, fluorescein). As part of the demonstrating, students determine the chemical purity of the substances obtained by means of chromatographic analysis, melting point measurement, spectrum analysis in the UV-VIS range. For selected active pharmaceutical ingredients and their derivatives, students: (i) conduct studies of the physico-chemical form in the field of polymorphic structures based on crystallographic databases, (ii) using appropriate computer programs, analyze models of single molecules and observe their interaction with receptors (enzymes), and perform the training using the Reaxys database along with submitting the documentation. .

#### Teaching methods

The subject is implemented in the form of lectures and laboratory exercises. The substantive content included in the lectures is provided to students in the form of a multimedia presentation. Students perform demonstrating based on materials that are given to them at the beginning of the course.

#### 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.
6. A. Chmiel, S. Grudziński, Biotechnologia i chemia antybiotyków, PWN, Warszawa 1998.
7. O. Kayser, R. Müller (red.), Biotechnologia farmaceutyczna, WL PZWL, Warszawa 2003.

**Breakdown** of average student's workload

	Hours	ECTS
Total workload	75	3,0
Classes requiring direct contact with the teacher	60	2,4
Student's own work (literature studies, preparation for laboratory classes, preparation for tests/exam) <sup>1</sup>	15	0,6

<sup>1</sup> delete or add other activities as appropriate