COURSE DESCRIPTION CARD - SYLLABUS

Course name
Synthesis and Technology of Therapeutic Products

Course

Field of study
Pharmaceutical Engineering
Area of study (specialization)
-
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

Number of hours

Lecture
25
Laboratory classes
35
Other (e.g. online)
0
Tutorials
0
Projects/seminars
0

Number of credit points

3

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:

Demonstarting - 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. 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. anesthesin, aspirin, dulcine, caffeine, nipagine A, paracetamol, salol, sulfanilamide, thiocol, lecithin, lycopene, tanalbine , methicillin, N-acetylcysteine, 5,5-diphenylhydantoin) and at least one biotechnological preparation (using, among others, Saccharomyces cerevisiae cells and lipase from Candida antarctica). As part of the exercises, 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 and (ii) using appropriate computer programs, analyze models of single molecules and observe their interaction with receptors (enzymes).

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. D. Skwarski, L. Seńczuk, J. Kalinowska-Torz, Ćwiczenia z technologii chemicznej środków leczniczych, Wydawnictwo AM, Poznań, 1987.

2. K. Kieć-Kononowicz, Wybrane zagadnienia z metod poszukiwania i otrzymywania środków leczniczych, WUJ, Kraków, 2000.

3. P. Harrington. Pharmaceutical process chemistry for synthesis, John Wiley@Sons, Hoboken, 2011

Additional

1. R.B. Silverman, Chemia organiczna w projektowaniu leków, WNT, 2004.

2. G.L. Patrick, Chemia medyczna podstawowe zagadnienia, WNT, 2003.

3. A. Vogel, Preparatyka organiczna, WNT, Warszawa 2006.

4. H. Marona (red.), Syntezy środków leczniczych, WUJ, Kraków, 2006.

5. J. Gawroński, K. Gawrońska, K. Kacprzak, M. Kwit, Współczesna synteza organiczna. Wybór eksperymentów, PWN, Warszawa 2004.

6. F. Gualtieri, New trends in synthetic medicinal chemistry, Wiley-VCH, Weinheim, 2000.

7. A. Chmiel, S. Grudziński, Biotechnologia i chemia antybiotyków, PWN, Warszawa 1998.

8. O. Kayser, R. Műller (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) [1]	15	0,6

[1] delete or add other activities as appropriate