



COURSE DESCRIPTION CARD - SYLLABUS

Course name

Pharmaceutical materials science [S1IFar2>MF]

Course

Field of study

Pharmaceutical Engineering

Year/Semester

4/7

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

0

Laboratory classes

0

Other

0

Tutorials

30

Projects/seminars

0

Number of credit points

2,00

Coordinators

dr Maria Popielarz-Brzezińska

dr Agnieszka Sobczak

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Lecturers

Prerequisites

The scope of knowledge about organic, analytical, pharmaceutical chemistry and pharmaceutical technology.

Course objective

Review of the issues correlated with the chosen materials chemistry used in the pharmacy, types of medical devices and types of packaging and their importance for the quality of the pharmaceutical product and pharmaceutical waste management.

Course-related learning outcomes

Knowledge:

1. Student knows the fundamental techniques and methods concerning the identification of plastics used in pharmaceutical engineering. Student knows the classical and instrumental methods used in assessment of the quality of packaging materials for pharmaceutical applications and production of medical devices. Student knows the physicochemical properties of packaging materials. [K_W7]

2. Student knows the rules of environmental preservation in regard to pharmaceutical technology and waste management. [K_W8]
3. Student knows the natural and synthetic raw materials, products and processes used in pharmaceutical industry. [K_W13]
4. Student knows the development of pharmaceutical engineering (in the field of pharmaceutical materials) and appropriate methods. [K_W14]
5. Student knows the details concerning materials used for production of containers, packaging for pharmaceutical applications and production of medical devices, their manufacturing, analysis and technology. Student knows the criteria described in the Pharmacopeia concerning the assessment of plastic quality to be used for production of containers, packaging for pharmaceutical applications and for production of medical devices. Student knows the principles of forming an information leaflet for patients and the principles of creating labeling on the packaging of medicinal products or medical devices. [K_W25]

Skills:

1. Student understands the literature in the field of pharmaceutical engineering in Polish; Student is able to acquire the information from the literature, databases and other sources connected with pharmaceutical engineering, also in foreign language. Student is able to integrate, interpret, draw a conclusion and express a view based on obtained information. [K_U1]
2. Student is able to prepare and present in the Polish language the oral presentation concerning the details of pharmaceutical engineering. [K_U6]
3. Student chooses the appropriate techniques and methods for the assessment of the quality of materials used in the production of containers and packaging for pharmaceutical applications, and for production of medical devices (in accordance with pharmacopoeial guidelines). [K_U11]

Social competences:

1. Student is prepared for critical assessment of possessed knowledge, student understands the need of improving the skills, complementing the principal knowledge and lifting the professional competences, personal and social. Student understands the significance of knowledge in solving the problems and is prepared to ask expert advise. [K_K1]

Methods for verifying learning outcomes and assessment criteria

Learning outcomes presented above are verified as follows:

The base for course evaluation will be the student attendance in the classes, pass the test, as well as verification of the Student's knowledge based on questions asked and evaluation of discussions between students during classes. The ability to search and work with source materials furthermore their interpretation when preparing a presentation on a topic betokened by the teacher will also be evaluate. (stationary or remote form depending on the epidemiological situation).

At the end of the class a short answer test will be applicable, where questions requiring the student to construct their responses (a passing threshold is at 60%).

Programme content

The program covers the following topics:

1. Substances used in the production of medical devices, containers and closures for pharmaceutical purposes.
2. Chemistry of selected materials used in pharmacy.
3. Methods of testing pharmaceutical packaging and/or medical devices.
4. Packaging materials and selected excipients used in pharmacy.
5. Types of pharmaceutical packaging.
6. The impact of packaging on the quality of a pharmaceutical product.
7. Methods of sterilization of medical devices and pharmaceutical packaging.
8. Characteristics of packaging and information placed on it.
9. Disposal of medical devices and packaging.

Course topics

Classes will include the following issues, subjects:

- types of substances used in the production of medical devices, containers and closures for

- pharmaceutical purposes (plastics, silicones, polymers, glass),
- chemistry of selected materials used in pharmacy,
- physicochemical properties of the substances contained in the packaging,
- selected methods for testing pharmaceutical packaging and medical devices (visual inspection during packaging production, use of appropriate analytical techniques),
- characteristics of selected analytical and microbiological methods used to quality estimation of materials used in the production of containers for pharmaceutical purposes and medical devices,
- packaging materials and selected auxiliary substances used in pharmacy (searching for the ideal packaging, materials with antibacterial properties),
- types of pharmaceutical packaging and the criteria for their selection depending on the routes of API administration, the fold of the therapeutic dose of API,
- the impact of packaging on the quality of the pharmaceutical product, medical device and dietary supplement (requirements for pharmaceutical packaging depending on the storage conditions of selected APIs),
- API and pharmaceutical products stability tests, the impact of packaging on their stability (procedures for conducting API and pharmaceutical product stability tests),
- methods of sterilization of medical devices and pharmaceutical packaging,
- the characteristics of the packages and the information placed on them (trademarks, bar codes, unique identifiers).
- guidelines for the disposal of medical devices and packaging (including pharmaceutical packaging).

Teaching methods

Perform multimedia presentations by assistant on the issues discussed.

Preparation of materials by student in the topic given by the Assistant.

Analysis and solution of problem issues of selected topics raised during the classes.

Bibliography

Basic:

1. Polish Pharmacopoeia XII, Warsaw 2020
2. ICH and WHO guidelines
3. Red. M. Sznitowska, Farmacja stosowana technologia postaci leku, PZWL Wydawnictwo Lekarskie, Warszawa 2017
4. M. Zając, A. Jelińska, I. Muszalska, M. Nogowska, B. Stanisław, Ocena jakości substancji leczniczych i preparatów farmaceutycznych według wymagań farmakopealnych i ICH, Wydawnictwo Kontekst, Poznań 2000

Additional:

1. Scientific paper including requirements and problems related to pharmaceutical materials science.

Breakdown of average student's workload

	Hours	ECTS
Total workload	55	2,00
Classes requiring direct contact with the teacher	30	1,00
Student's own work (literature studies, preparation for laboratory classes/ tutorials, preparation for tests/exam, project preparation)	25	1,00