



COURSE DESCRIPTION CARD - SYLLABUS

Course name

Pharmaceutical Materials Science

Course

Field of study

Pharmaceutical Engineering

Area of study (specialization)

-

Level of study

First-cycle studies

Form of study

full-time

Year/Semester

4/7

Profile of study

general academic

Course offered in

polish

Requirements

compulsory

Number of hours

Lecture

0

Laboratory classes

0

Other (e.g. online)

0

Tutorials

30

Projects/seminars

0

Number of credit points

3

Lecturers

Responsible for the course/lecturer:

dr n. farm. Agnieszka Sobczak

Responsible for the course/lecturer:

dr hab. Małgorzata Geszke-Moritz

Prerequisites

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

Course objective

Review of the issues correlated with the 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

K_W7 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. Student knows the classification of analytical techniques accompanied by criteria of their choosing and validation.

K_W8 Student knows the rules of environmental preservation in regard to pharmaceutical technology and waste management. Student knows the risks of realization of chemical and pharmaceutical processes

K_W13 Student knows the natural and synthetic raw materials, products and processes used in pharmaceutical industry

K_W14 Student knows the development of pharmaceutical engineering (in the field of pharmaceutical materials) and appropriate methods. Student knows the national and world trends in the pharmaceutical industry development

K_W25 Student knows the details concerning materials used for production of containers, packaging for pharmaceutical and cosmetic applications and production of medical devices, their manufacturing, analysis and technology. Students know the criteria described in the Pharmacopeia concerning the assessment of plastic quality to be used for production of containers, packaging for pharmaceutical and cosmetic applications and for production of medical devices

Skills

K_U1 Student understands the literature in the field of pharmaceutical engineering in Polish; Student reads with understanding uncomplicated scientifically-technical texts in foreign language. 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_U3 Student uses properly the chemical and pharmaceutical terminology and nomenclature of chemical compounds, also in foreign language

K_U6 Student is able to prepare and present, both in the Polish and foreign language, the oral presentation concerning the details of pharmaceutical engineering

K_U11 Student chooses and uses the appropriate techniques for qualitative and quantitative analysis and for the assessment of the quality of materials used in the production of containers and packaging for pharmaceutical and cosmetic applications, and for production of medical devices

Social competences

K_K1 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

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, 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. At the end of the class, an initial test will be conducted (5-10 open questions). Passing threshold: 60%.

Programme content

Classes will include the following issues, subjects:

- chemistry of materials used in pharmacy for the production of containers, closures, as well as medical devices such as transfusion sets, catheters and surgical threads,
- types of substances used in the production of containers for pharmaceutical purposes (plastics, silicones, polymers),
- methods for testing materials used in the production of containers for pharmaceutical purposes (visual inspection during packaging production, use of appropriate analytical techniques),
- packaging materials and auxiliary substances used in pharmacy (searching for the ideal packaging, materials with antibacterial properties),
- physicochemical properties of the substances contained in the packaging,
- 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,
- characteristics and limitations of the analytical and microbiological methods used to test pharmaceutical packaging,
- 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),
- the characteristics of the packages and the information placed on them (trademarks, bar codes, unique identifiers).

Under the practical section of the exercise, the student will confirm by classical and instrumental methods of the quality of selected packages according to pharmacopoeial requirements. The student will familiar with types of physicochemical tests used in the evaluation of packaging materials. After



independently performed analysis of the topics of exercises will prepare a report on the tests carried out.

Teaching methods

Perform multimedia presentations on the issues discussed pictured with illustrated examples on the board developed by the lecturer likewise developed by the student on the issues discussed given by the Assistant. Analysis and solution of problem issues and the implementation of practical tasks of selected issues raised during the classes.

Bibliography

Basic

Polish Pharmacopoeia XI, Warsaw 2017

ICH and WHO guidelines

Additional

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

Breakdown of average student's workload

	Hours	ECTS
Total workload	75	3,0
Classes requiring direct contact with the teacher	40	1,6
Student's own work (literature studies, preparation for tutorials, preparation for tests) ¹	35	1,4

¹ delete or add other activities as appropriate