COURSE DESCRIPTION CARD - SYLLABUS

Course name
Technology of the Drug Form

Course

Field of study
Pharmaceutical Engineering
Area of study (specialization)
-
Level of study
First-cycle studies
Form of study
full-time

Year/Semester
3/5
Profile of study
general academic
Course offered in
polish
Requirements
compulsory

Number of hours

Lecture
15
Laboratory classes
45
Other (e.g. online)
0
Tutorials
0
Projects/seminars
0

Number of credit points

4

Lecturers

Responsible for the course/lecturer:
Tomasz Osmałek, DSc (tosmalek@ump.edu.pl)

Responsible for the course/lecturer:
Barbara Jadach, PhD (bajadach@ump.edu.pl)

Prerequisites

The student starting this subject should have a basic knowledge of physical chemistry, general and analytical chemistry in the area of phenomena and calculations used when preparing solid, semi-solid and liquid drug dosage forms on a laboratory and industrial scale.

Course objective

Students acquire selected practical skills and/or knowledge in the areas of issues related to the development of a pharmaceutical product on a laboratory scale and its production on an industrial

scale, including in particular: • designing of the drug form, • technology of preparing and assessing the quality of solid oral dosage forms, dispersed drug systems (aerosols) and semi-solid formulations, • determining the impact of technological factors and physico-chemical properties of actives and additives on the pharmaceutical availability of the drug from various dosage forms.

Course-related learning outcomes

Knowledge

1. has general knowledge in the field of pharmacy, technology and chemical engineering as related fields directly related to the technology of the drug form [K_W1]

2. has knowledge on the basic techniques and methods for characterizing and identifying pharmaceutical products and research tools used in drug form technology, knows the physico-chemical properties of substances for pharmaceutical use and their influence on biological activity of drugs, knows the classification of analytical techniques along with the criteria for choosing a proper method and its validation [K_W7]

3. has knowledge of the basic conceptual categories and terminology used in drug form technology [K_W9]

4. has basic knowledge in the field of apparatus and installation construction in the pharmaceutical industry and related industries [K_W16]

Skills

1. understands literature on the technology of drug forms in Polish; reads with understanding uncomplicated scientific and technical texts in a foreign language, is able to obtain information from literature, databases and other sources related to the technology of the form of the drug, also in a foreign language, integrate them, interpret them, draw conclusions and formulate opinions [K_U1]

2. is able to use the basic equipment and apparatus used in drug form technology, develops the form of the drug, performs research in the field of assessing the quality of the drug form, interprets and documents the results of product quality tests [K_U8] [K_U9]

3. is able to plan and carry out simple experiments in the field of drug form technology, both experimental and simulation, as well as interpret their results and draw conclusions [K_U12]

4. is able to identify the basic processes and unit operations of the drug form technology and formulate their specification [K_U15]

Social competences

1. Is ready to critically assess knowledge, understands the need for further education, supplementing specialized knowledge and raising his professional, personal and social competences, understands the importance of knowledge in solving problems and is ready to consult experts. [K_K1]

Methods for verifying learning outcomes and assessment criteria

Learning outcomes presented above are verified as follows:

Students are required to: participate in all classes, prepare for them theoretically. Checking the

student's knowledge may take place in oral or written form. After the practical performance of the exercise, students each time present the teacher with a report of performance.

Completion of the classes will take place after the 5th semester, based on the final written test (min. 60% of correct answers), containing test and open questions.

The final exam in the subject is carried out after lectures (semester 6), in the form of a series of test and open questions. It covers the content presented in lectures (semester 5 and 6) and exercises (semester 5). 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

The series of lectures includes discussion of the basic issues related to:

• pharmaceutical and technological aspects of designing various drug dosage forms,

• the purpose and scope of pre-formulation research and their significance in the technology of selected drug forms,

• characteristics of active and additive substances in terms of the possibility of developing various pharmaceutical forms,

• possibilities of increasing the solubility / dissolution rate of sparingly soluble active substances,

• classification, characteristics and technology of various solid drug forms (powders, granules, tablets, capsules), modified and controlled release drug forms, therapeutic systems and distributed systems,

• the concept of pharmaceutical availability and methods of its assessment in relation to selected forms of medicine.

• the technology of semi-solid dosage forms and basics of pharmaceutical rheology

Laboratory classes:

As part of the practical classes, students will learn about topics related to:

• The technology of solid drug dosage forms, including: practical aspects of the design and manufacture of solid drug forms on a laboratory and industrial scale (methods for preparing granules, tablets, coated tablets and hard and soft capsules, the role of functional excipients). Calculations related to the production and evaluation of granules, tablets and capsules. Practical implementation of selected solid drug forms (wet and dry granulation method, direct and post-granulation tableting, coating of cores in a dragee drum (coating, polymer coating). Assessment of quality parameters of solid drug forms produced

by pharmacopoeial and non-pharmacopoeial methods (hardness, mass uniformity, disintegration time, friability) Planning the production cycle of basic solid forms of the drug, taking into account the manufacturing conditions and the type of apparatus.

• Technology of semi-solid drug forms, including: practical aspects of the design and production of semi-solid drug and cosmetics on a laboratory and industrial scale (methods for making ointments, creams, hydrogels, the role of functional auxiliaries). Practical implementation of selected semi-solid drug forms. Evaluation of quality parameters of semi-solid drug forms and cosmetics produced by pharmacopoeial and non-pharmacopoeial methods. Rheological tests (explanation of the concept: plasticity, thixotropy, flow limit), use of a rheometer for qualitative research.

• Pharmaceutical availability - testing the pharmaceutical availability of medicinal substances from selected forms by pharmacopoeial and non-pharmacopoeial methods, conducting a release study, plotting and comparing the release profiles of the drug substance from test and reference products, assessment of the impact of technological processes and excipients on the release of medicinal substances from selected drug forms, biopharmaceutical evaluation of the tested drug forms.

• Pharmaceutical aerosols - pharmacopoeial methods of examining therapeutic aerosols: assessment of uniformity of a single dose, aerodynamic measurement of the particle size using a glass impactor, analysis of the composition of nasal aerosols by the TLC method

Teaching methods

1. Lecture: informative, problem-oriented, multimedia presentation, participation in discussions, formulation of own opinions.

2. Laboratory classes: individual or group preparation of the dosage form and its quality control, correct performance of necessary calculations and protocol, formulation of own conclusions, demonstration of the operation and operation of specialized equipment.

Bibliography

Basic

1. Jachowicz R., Czech A., Mycek B., Postać leku. Optymalizacja leków doustnych i do oczu w nowoczesnej technologii farmaceutycznej, PZWL, Wyd. I, Warszawa 2013

2. Sznitowska M., Farmacja Stosowana: Technologia Postaci Leku, PZWL, wydanie I, Warszawa 2017

3. Farmakopea Polska XI, PTFarm, Warszawa 2017

Additional

1. Sznitowska M., Kaliszan R. (red.): Biofarmacja, Elsevier Urban & Partner, Wrocław 2014

2. Rowe R.C, Sheskey P.J., Owen S.C.: Handbook of Pharmaceutical Excipient 5th Edition, Development Editor, Royal Pharmaceutical Society, UK Pharmaceutical Press (PhP) 2006

3. Montgomery D.C.: Design and Analysis of Experiments, 8th ed., Wiley, 2012.

4. Bauer K.H., Frömming K.-H., Führer C., Technologia postaci leku z elementami biofarmacji, MedPharm Polska, tłumaczenie wydania 8, Wrocław 2012

5. Scientific papers concerning the presented subject

Breakdown of average student's workload

	Hours	ECTS
Total workload	120	4,0
Classes requiring direct contact with the teacher	60	2,0
Student's own work (literature studies, preparation for laboratory classes, preparation for tests) [1]	60	2,0

[1] delete or add other activities as appropriate