COURSE DESCRIPTION CARD - SYLLABUS

Course name
Technology of the drug form [S1IFar2>TPL]

Course

Field of study
Pharmaceutical Engineering

Year/Semester
3/5

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
15

Laboratory classes
45

Other (e.g. online)
0

Tutorials
0

Projects/seminars
0

Number of credit points

5,00

Coordinators

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Lecturers

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, • determining the impact of technological factors and the physicochemical properties of medicinal and additive substances on the properties of the final product, • ICH guidelines regarding the quality requirements for the formulation development and stability of the specific drug dosage forms, • 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, • advances in pharmaceutical technology in relation to new/modern carriers of active substances as well as drug and cosmetic forms, • Design of Experiments (DoE) • principles of Good Manufacture Practice (GMP).

Course-related learning outcomes

Knowledge:
1. Student 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. Student 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. Student has knowledge of the basic conceptual categories and terminology used in drug form technology.[K_W9]
4. Student has basic knowledge in the field of apparatus and installation construction in the pharmaceutical industry and related industries.[K_W16]
5. Student has knowledge of products and processes used in the pharmaceutical industry in the context of the development of selected drug forms.[K_W13]
6. Student knows the rules of construction and selection of devices used in the pharmaceutical and cosmetics industry.[K_W16]
7. Student has basic knowledge of the life cycle of products in the pharmaceutical industry.[K_W13]
8. Student has knowledge of the development of drug form technology and research methods used in it, as well as directions of development of the pharmaceutical industry in the country and in the world.[K_W1]

Skills:
1. Student 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. Student 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. Student 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. Student is able to identify the basic processes and unit operations of the drug form technology and formulate their specification.[K_U15]
5. Student uses basic techniques, research equipment and apparatus useful in the analysis of pharmaceutical active substances and drug form technologies, uses pharmacopoeial methods, prepares documentation.[K_U9]
6. Student is able to analyze and evaluate the functioning of the basic apparatus of the pharmaceutical industry.[K_U10; K_U11]

Social competences:
1. Student 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 on the basis of presence on the labs and recived marks. When the student will not recive proper amount of point during the labs described in the regulatory will have to pass the final test (min. 60% of correct answers).
The exam will be in the form of a series of test and/or open questions. It covers the content presented in lectures and laboratories. The Chair allows examination in the form of test questions in the OLAT system or in the contact form. Positive assessment is given to students who will obtain 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, • pharmaceutical and technological aspects of designing various drug forms, • biopharmaceutical drug classification system, • selected ICH guidelines regarding quality requirements for the formulation development and stability of individual drug forms, • advances in pharmaceutical technology with respect to new / modern carriers of active substances and drug forms and cosmetic, • modified-release drug form technology, • transdermal drug form technology, • Good Manufacturing Practice (GMP) principles, • design and analysis of experiments (DOE) - formulation selection and technological process optimization.
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.
• Dissolution study- testing the release of active 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

Course topics

none

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. Sznitowska M., Farmacja Stosowana: Technologia Postaci Leku, PZWL, wydanie I, Warszawa 2017
2. Jachowicz R., Czech A., Mycek B., Postać leku. Optymalizacja leków doustnych i do oczu w nowoczesnej technologii farmaceutycznej, PZWL, Wyd. I, Warszawa 2013
3. Farmakopea Polska XII, PTFarm, Warszawa 2020

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	128	5,00
Classes requiring direct contact with the teacher	64	3,00
Student's own work (literature studies, preparation for laboratory classes/ tutorials, preparation for tests/exam, project preparation)	64	2,00