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
3/6
Profile of study
general academic
Course offered in
polish
Requirements
compulsory

Number of hours

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

Number of credit points

1

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 the subject should have a basic knowledge of physical chemistry, general and analytical chemistry in the field of phenomena and calculations used when preparing solid, semi-solid and liquid forms of the drug on a laboratory and industrial scale. In addition, should have knowledge of issues related to the development of a pharmaceutical product, including technology and quality control of solid, oral drug forms, dispersed systems (therapeutic aerosols) and semi-solid drug forms.

Course objective

Acquisition by students the 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 the formulation, • 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, • 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. has knowledge of products and processes used in the pharmaceutical industry in the context of the development of selected drug forms,[K_W20]

2. knows the rules of construction and selection of devices used in the pharmaceutical and cosmetics industry,[K_W18][K_W16]

3. has basic knowledge of the life cycle of products in the pharmaceutical industry,[K_W13][K_W20]

4. 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_W14]

Skills

1. 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_U8][K_U12]

2. is able to analyze and evaluate the functioning of the basic apparatus of the pharmaceutical industry [K_U14]

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:

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. Depending on the epidemic situation the exam will take a stationary or on-line form.

Programme content

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

• 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, • thermal analysis of drugs.

Teaching methods

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

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	30	1,0
Classes requiring direct contact with the teacher	15	0,5
Student's own work (literature studies, preparation for exam) [1]	15	0,5

[1] delete or add other activities as appropriate