COURSE DESCRIPTION CARD - SYLLABUS

Course name
The medicinal product quality assurance [S1IFar1>ZJPL]

Course

Field of study
Pharmaceutical Engineering

Year/Semester
3/6

Area of study (specialization)
–

Profile of study
general academic

Level of study
first-cycle

Course offered in
polish

Form of study
full-time

Requirements
elective

Number of hours

Lecture
0

Laboratory classes
0

Other (e.g. online)
0

Tutorials
15

Projects/seminars
0

Number of credit points

1,00

Coordinators

dr Barbara Jadach
barbara.jadach@put.poznan.pl

Lecturers

Prerequisites

Basic knowledge of drug and cosmetic form technologies.

Course objective

Acquisition by students the selected practical skills and / or knowledge in the areas of issues related to the development of a pharmaceutical and cosmetic product on a laboratory scale and its production on an industrial scale. Manufacturing Practice; packaging; registration of pharmaceutical products.

Course-related learning outcomes

Knowledge:
1. student knows the physicochemical properties of substances for pharmaceutical use affecting the biological activity of drugs. [k_w13]
2. student knows the principles of good manufacturing practice and documenting technological processes. [k_w23]
3. student has basic knowledge of pharmacopoeial standards and norms; knows the methods and techniques of pharmaceutical product research.[k_w24]
4. the student has detailed knowledge of substances for pharmaceutical and cosmetic use, quality

analysis and control, technology, knows the rules for creating selected fragments of the characteristics of the medicinal product, knows the pharmacopoeial requirements in the field of quality assessment of substances and medicinal products. [k_w25]

Skills:
1. student is able to use scientific literature.[k_u1]
2. student is able to: perform tests in the field of assessing the quality of the drug form, interpret and document the results of product quality tests. [k_u8]
3. can use the basic equipment and apparatus used in drug form technology, performs research in the field of assessing the quality of the drug form, interprets and documents the results of product quality tests. student demonstrates the ability to discuss the technology of drug form and cosmetic. student understands the principles of marketing medicinal products and medical devices. [k_u9]

Social competences:
he is ready to critically assess his knowledge, understands the need for further education, supplementing disciplinary 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:

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Students are required to actively participate in the issues discussed and to submit correctly completed documentation regarding the issues of the given exercise. Completion of the course will be based on the final written test (min. 60% of correct answers), containing test and open questions.
Depending on the epidemic situation the final test will take a stationary or on-line form.

Programme content

Students will learn about:
- GMP Good Manufacturing Practice (definition; requirements that must be met if a permit for the manufacture of medicinal products is obtained; documentation of technological processes). Case studies.
- Packaging of various forms of medicine and cosmetics. Role and requirements imposed on the packaging of pharmaceutical and cosmetic preparations; types of packaging depending on the form of the drug and cosmetic, methods of testing the integrity and barrier of packaging and packaging methods; discussion of packaging processes in the aspect of GMP.
- Registration of the medicinal product.
- Calculations on pharmaceutical availability. Pharmacopoeial and non-pharmacopoeial methods of testing pharmaceutical availability; drug release process kinetics. Discussion of the methodology for comparing release profiles (methods dependent and independent on the model). Case study.

Teaching methods

The subject is implemented in the form of practical classes in the laboratory, combined with a theoretical introduction. As part of independent work during classes, students work with source materials, participate in discussions, formulate their own opinions, prepare a presentation.

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

Breakdown of average student's workload

	Hours	ECTS
Total workload	30	1,00
Classes requiring direct contact with the teacher	15	0,50
Student's own work (literature studies, preparation for laboratory classes/ tutorials, preparation for tests/exam, project preparation)	15	0,50