FACULTY OF CHEMISTRY

SUBJECT CARD

Name of subject in Polish: Farmaceutyki i Biofarmaceutyki
Name of subject in English: Pharmaceuticals and Biopharmaceuticals
Main field of study: Chemical technology
Specialization: Technology of Fine Chemicals
Profile: academic
Level and form of studies: 2nd level, full-time
Kind of subject: obligatory
Subject code: TCC024008
Group of courses: NO

	Lecture	Classes	Laboratory	Project	Seminar
Number of hours of organized classes in University (ZZU)	30		30		
Number of hours of total student workload (CNPS)	90		60		
Form of crediting	Examination		crediting with grade		
For group of courses mark (X) final course	X				
Number of ECTS points	3		2		
including number of ECTS points for practical (P) classes			2		
including number of ECTS points for direct teacher-student contact (BK) classes	1		1		

PREREQUISITES RELATING TO KNOWLEDGE, SKILLS AND OTHER COMPETENCE

1. Principles of organic chemistry, theoretical and practical.
2. Knowledge in the field of basis of analytical chemistry, theoretical and practical.

SUBJECT OBJECTIVES

C1 Acquaintance with the knowledge on the distribution of medicinal products and medical devices on basic groups, according to their mechanism of action on the human body.
C2 Acquaintance with issues of the elementary production processes units in the area of pharmaceutical technology and biopharmacy.
C3 Acquaintance with the generally applicable operating in the pharmaceutical industry and related sectors quality standards, concerning the manufacturing process and the final product, including the ways of managing waste and REACH requirements.

SUBJECT EDUCATIONAL EFFECTS

Relating to knowledge:

PEK_W01 – has knowledge on the distribution of medicines and medical products on the basic groups,
PEK_W02 – has knowledge on the methods of obtaining biologically active substances and the elementary production processes units in the area of pharmaceutical technology and biopharmacy,
PEK_W03 – can define the various forms of medicines and medical devices, and has knowledge on the technology of receiving them,
PEK_W04 – has knowledge on the generally applicable operating in the pharmaceutical industry and related sectors quality standards, concerning the manufacturing process and the final product, taking into account REACH directive.

Relating to skills:

PEK_U01 – has skills in the qualitative and quantitative analysis of a pharmaceutical formulation, due to the principles of proper samples preparation, precision and repetition in measurements and proper interpretation of the results,

PEK_U02 – has the ability to prepare simple biopharmaceutical preparation,
PEK_U03 – has skills in working in accordance with the principles of good laboratory practice (GLP), in the interpretation of the results of analyzes, error assessment, and the preparation of a laboratory report.

PROGRAMME CONTENT

	Lectures	**Number of hours**
Lec1	Pharmacokinetic and pharmacodynamic bases of use pharmaceuticals and biopharmaceuticals. Routes of distribution and elimination, bioavailability and bioequivalence.	2
Lec2	Division of pharmaceuticals and biopharmaceuticals. Ways of obtaining biologically active substances - API.	2
Lec3	Synthetic APIs. The catalysis on the industrial scale in synthesis of API.	2
Lec4	Physical and physicochemical bases of pfarmaceutical formulation.	2
Lec5	The excipients in the drug formulations – division, functions.	2
Lec6	Basic processes and unit operations in the thechnology of pharmaceuticals and biopharmaceuticals production.	2
Lec7	Powders and granules in the solid drugs forms.	2
Lec8	Solid formulations of pharmaceuticals – capsules and controlled release forms.	2
Lec9	Semi-solid forms of drugs.	2
Lec10	Liquid formulations and inhalational forms of pharmaceuticals.	2
Lec11	Botanical drugs.	2
Lec12	Dietary supplements. Special medicinal supplies.	2
Lec13	Impact of the REACH regulation on the pharmaceutical industry - REACH requirements for different types of chemical compounds.	2
Lec14	Restrictions resulting from the REACH regulation for the use of polymers in medical and pharmaceutical products.	2
Lec15	Quality control systems in the pharmaceutical industry.	2
	Total hours	30
	Laboratory	**Number of hours**
Lab1	Safety rules in the laboratory of chemistry, good laboratory practice (GLP) and the rules of the reports preparation.	2
Lab2	Solid formulation in the form of tablet – qualitative and quantitative analysis of API, without isolation from the tablet mass.	4
Lab3	Suspension for oral use - extraction of API from a liquid formulation, qualitative and quantitative analysis. Error estimation of the isolation procedure.	4
Lab4	Ointment - a semi-solid formulation with 2 biologically active ingredients. Methods of separation of them from the drug form. Qualitative and quantitative analysis.	4
Lab5	Botanical drug - dragees containing a medicinal herbal extract. Phytopharmaceutical analysis based on a calibration curve of the equivalent of a biologically active ingredient (CE).	4
Lab6	Cream with a herbal extract isolated from a medicinal plant – extraction of API, preparation of the biopharmaceutical formulation. Stabilization of the final product with ultrasound support.	4
Lab7	Hydrogel with antiseptic properties - preparation of a medicinal product, analysis of the active substance.	4
Lab8	Repeating of the not successful realized experiments. Consultation of the reports	4

	results.	
	Total hours	30

TEACHING TOOLS USED

N1. Lecture with multimedial presentation.
N2. Laboratory experiments realized by a student.
N3. Reports preparation.

EVALUATION OF SUBJECT EDUCATIONAL EFFECTS ACHIEVEMENT

Evaluation (F – forming (during semester), P – concluding (at semester end)	Educational effect number	Way of evaluating educational effect achievement
F1	PEK_U01 – PEK_U03	Report of Lab2.
F2	PEK_U01 – PEK_U03	Report of Lab3.
F3	PEK_U01 – PEK_U03	Report of Lab4.
F4	PEK_U01 – PEK_U03	Report of Lab5.
F5	PEK_U01 – PEK_U03	Report of Lab6.
F6	PEK_U01 – PEK_U03	Report of Lab7.
P (laboratory) = (F1+F2+F3+F4+F5+F6)/6		
P (lecture)	PEK_W01 – PEK_W04	Final Exam - test of choice Grades: 3.0 if 50-55% 3.5 if 56-60 % 4.0 if 61-70% 4.5 if 71-80% 5.0 if 81-95% 5.5 if 96-100%

PRIMARY AND SECONDARY LITERATURE

PRIMARY LITERATURE:

[1] Alfred Fahr, Voigt's Pharmaceutical Technology. John Willey & Sons Inc., 2018.
[2] Marshall Sittig. Pharmaceutical manufacturing encyclopedia. Noyes Pubications, USA.
[3] James I. Wells, Michael H. Rubinstein. Pharmaceutical Technology. Controlled Drug Release. Ellis Horwood Limited, Taylor & Francis,1991
[4] Dilip M. Parikh. Handbook of Granulation Pharmaceutical Technology. Taylor & Francis. 2005.

SECONDARY LITERATURE:

[5] Kurt H. Bauer, Karl-Heinz Frömming, Claus Führer. Technologia Postaci leku z elementami biofarmacji. Pod red. Janusza Pluty, MedPharm Polska, 2012
[6] R. H. Müller i G.E. Hildebrand, Technologia nowoczesnych postaci leków Wydawnictwo Lekarskie, PZWL, Warszawa, 2003
[7] EudraLex, The Rules Governing Medicinal Products in the European Union, Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, European Commission, health and consumers directorate-general, Ref. Ares(2012)778531 - 28/06/2012
[8] Mark Gibson. Pharmaceutical Preformulation and Formulation Second Edition. A Practical Guide from Candidate Drug Selection to Commercial Dosage Form. Informa Healthcare USA, Inc. 2009

SUBJECT SUPERVISOR (NAME AND SURNAME, E-MAIL ADDRESS)

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