Zał. nr 5 do ZW 78/2023

Attachment no. 4. to the Program of Studies

FACULTY of CHEMISTRY

SUBJECT CARD

Name of subject in Polish Nowoczesne Leki i Biofarmaceutyki
Name of subject in English Modern Pharmaceuticals and Biopharmaceuticals
Main field of study (if applicable): **Biosciences**
Specialization (if applicable): **Medicinal Chemistry**
Profile: academic / ~~practical~~*
Level and form of studies: ~~1st~~/ 2nd level, ~~uniform magister studies~~*, full-time / ~~part-time~~*
Kind of subject: obligatory / ~~optional~~ / ~~university-wide~~*
Subject code W03BSS-SM2023W, W03BSS-SM2023L
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)	50		50		
Form of crediting (Examination / crediting with grade)	Exam		crediting with grade		
For group of courses mark (X) final course					
Number of ECTS points	2		2		
including number of ECTS points for practical classes (P)			2		
including number of ECTS points corresponding to classes that require direct participation of lecturers and other academics (BU)	1,3		1,4		

*delete as not necessary

PREREQUISITES RELATING TO KNOWLEDGE, SKILLS AND OTHER COMPETENCES

1. Principles of organic chemistry, theoretical and practical.
2. Basic knowledge on biochemistry.
3. Knowledge in the field of basis of analytical chemistry is recommended.

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:

PEU_W01 – has knowledge on the distribution of medicines and medical products on the basic groups,

PEU_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,

PEU_W03 – can define the various forms of medicines and medical devices, and has knowledge on the technology of receiving them,

PEU_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:

PEU_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,

PEU_U02 – has the ability to prepare simple biopharmaceutical preparation,

PEU_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.

Relating to social competences:

PEU_K01 - Student is able to interact in a group and to plan an experiment.

PEU_K02 - Student is able to discuss the quality of an experimental result.

PEU_K03 - Student works consciously and effectively in a sub-group to searches information and can subject them to critical analysis.

PROGRAMME CONTENT

	Lecture	**Number of hours**
Lec1	The modern pharmaceutical industry: key assets to scientific and medical progress.	2
Lec2	Drug targets – the idea of „golden bullet" for proteins, carbohydrates, lipids, DNA, and RNA.	2
Lec3	From discovery to clinical trials – the phases of pharmaceutical development. Good Clinical Practice rules (GCP) established by WHO.	2
Lec 4	Quality assurance of pharmaceuticals and biopharmaceuticals.	2
Lec 5	Ways of obtaining active pharmaceutical ingredients (API).	2
Lec 6	Biotechnology-derived drug product development.	
Lec 7	Biopharmaceuticals – historical perspectives and future directions.	2
Lec 8	Biopharmaceuticals of animal and microbial origin.	
Lec 9	Physical and physicochemical bases of pharmaceutical formulation.	2
Lec 10	Pharmaceutical preformulation: types of naturally occurred excipients. Purity problem.	2
Lec 11	Pharmaceutical preformulation: synthetic and semisynthetic excipients.	2

Lec 12	Tablets and capsules design. Modern solid dosage systems.	2
Lec 13	Controlled release of API from solid and semisolid formulations – bioavailability problem.	2
Lec 14	The role of micro- and nanotechnology in pharmaceutical industry. Pharmaceutically accepted micro- and nanosystems.	2
Lec 15	Modern control mechanisms of the pharmaceutical industry. The influence of worldwide trends on the drug regulatory system.	2
	Total hours	**30**

Laboratory		**Number of hours**
Lab 1	Safety rules in the laboratory of organic chemistry, good laboratory practice (GLP) and the rules of the reports preparation. Introduction to the separation and identification techniques of API.	2
Lab 2	Identification and qualitative analysis of drotaverine hydrochloride in NO-SPA tablet according to Pharmacopoeia regulations.	4
Lab 3	Suspension form of a drug for children containing ibuprophen – isolation and purification techniques of API. Analysis of the main compound.	4
Lab 4	Three compounds drug: Etopiryna (ethenzamide + acetylsalicylic acid + caffeine) – strategies of APIs separation from a tablet form.	4
Lab 5	Three compounds drug – analysis of the isolated APIs.	4
Lab 6	Polymeric nanocarriers for oral delivery of lipophilic vitamins – synthesis and characterization.	4
Lab 7	Kinetics of the release of clotrimazole from the ointment for epidermal application.	4
Lab 8	Electrophoresis as a tool for qualitative and quantitative analysis of high-protein dietary supplement.	4
	Total hours	**30**

TEACHING TOOLS USED

N1 Multimedial presentations.
N2 Performing experiments with different laboratory equipment and instruments.
N3 Preparation of report including analysis and interpretation of obtained results.

EVALUATION OF SUBJECT LEARNING OUTCOMES ACHIEVEMENT

Evaluation (F – forming during semester), P – concluding (at semester end)	Learning outcomes code	Way of evaluating learning outcomes achievement
F1	PEU_W01-W04, PEU_U01 – PEU_U03	Exam - the grade for the final test of the lectures part
F2	PEU_U01 – PEU_U04 PEU_K01 – PEU_K03	grades of the laboratory experiments (reports)
P = the grade for the final test of the lectures part + average grade of the laboratory reports		

PRIMARY AND SECONDARY LITERATURE

PRIMARY LITERATURE:

[1] House of Commons Health Committee. The Influence of the Pharmaceutical Industry. HC 42-I [Incorporating HC 1030-i-iii], Published by authority of the House of Commons London: The Stationery Office Limited. 2005.

[2] The European Federation of Pharmaceutical Industries and Associations. The Pharmaceutical Industry in Figures. 2022.

[3] Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Vol. 2, Good manufacturing practices and inspection. – 2nd ed. WHO Press. 2007.

[4] Shayne Cox Gad, Pharmaceutical Manufacturing Handbook. Production and Processes. John Wiley & Sons, Inc. 2008.

[5] Alfred Fahr, Voigt's Pharmaceutical Technology. John Willey & Sons Inc., 2018.

[6] Introduction to Biopharmaceuticals. Mongomery County Community College, 2016.

SECONDARY LITERATURE:

[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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