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 Metody Analityczne w Projektowaniu i Technologii Wytwarzania Leku

Name of subject in English Analytical Methods in Drug Design and Technology

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-SM2019W, W03BSS-SM2019L

Group of courses NO

	Lecture	Classes	Laboratory	Project	Seminar
Number of hours of organized classes in University (ZZU)	15		30		
Number of hours of total student workload (CNPS)	50		50		
Form of crediting (Examination / crediting with grade)	crediting with grade		crediting with grade		
For group of courses mark (X) final course	X				
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)	0.65		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 chromatographic and spectroscopic methods.
3. Knowledge in the field of basis of analytical chemistry is recommended.

SUBJECT OBJECTIVES

C1 To acquaint student with the theoretical and practical aspects of good laboratory practice (GLP) and good manufacture practice (GMP).

C2 Gaining of the knowledge on the modern chromatographic techniques and their applications in drug design and technological process of drugs production.

C3 Acquaintance with the different technological concepts of application of spectroscopic methods in drugs design and quality control in the production system.

C4 Expanding the knowledge in the field of electrochemical methods applications in the design

of biologically active compounds and the production procedures of them.
C5 Acquaintance with the different concepts in the field of mixed analytical methods.

SUBJECT EDUCATIONAL EFFECTS

relating to knowledge:
Student, who has completed the course:
PEU_W01 – has knowledge on good laboratory practice (GLP) rules, good manufacture practice (GMP) rules, and validation procedures necessary to be used in analytical methods,
PEU_W02 – has knowledge about the modern chromatographic, spectroscopic, electrochemical and mixed analytical techniques and their applications in drug design and technological process of drugs production,
PEU_W03 – can define the advantages and disadvantages of the analytical techniques, the sensitivity level of each of them.

relating to skills:
Student, who has completed the course:
PEU_U01 – has skills of use chromatographic techniques for separation of a mixture of different compounds, to detect them, do interpretation of the results and prepare the report according to GLP,
PEU_U02 – has knowledge about using different types of spectrometric instruments, and about the parameters of the sample ready to analyze,
PEU_U03 – has skills to do the analysis of the biologically active compounds using electrochemical methods, do interpretation of the results and prepare the report according to GLP,
PEU_U04 – has skills to detect the biologically active compounds in a drug formulation using physical and physicochemical methods.

PROGRAMME CONTENT

	Lecture	**Number of hours**
Lec 1	Introduction to analytical techniques as tools for drug design and production. Good practice rules in analytical chemistry. Error estimation in analytical methods used in drugs design and technology.	2
Lec 2	Validation techniques. Pharmacopoeias. GLP, GMP and drugs production normalization rules.	2
Lec 3	Chromatographic techniques in drugs design and control of production process. Solving of popular troubles.	2
Lec 4	Spectroscopic techniques in drugs design and control of production process.	2
Lec 5	Mixed advanced analytical techniques as a tool in drugs design and control of their activity.	2
Lec 6	The electrochemical methods in drug design and technology.	2
Lec 7	Methods of the analysis of solid state drug formulation ingredients - powders and granules.	2
Lec 8	Novel advanced applications in quality control systems in the pharmaceutical industry.	1
	Total hours	**15**

Laboratory		Number of hours
Lab 1	Safety rules in the laboratory of organic chemistry, good laboratory practice and the rules of the reports preparation.	2
Lab 2	HPLC technique – a scheme of the procedure of a sample preparation. Preparation of a sample to HPLC analysis.	2
Lab 3	HPLC – the equipment scheme. The analysis of biologically active components of a pharmaceutical formulation. Gas chromatography equipment and the procedure of analysis. Detection techniques.	2
Lab 4	GC analysis - diagram of API separation procedure. Sample preparation for GC analysis.	2
Lab 5	GC-MS – the equipment diagram. Chromatographic analysis and interpretation of the results.	2
Lab 6	Turbidimetry – the analytical method useful to drug design and quality control of it using microplates reader.	4
Lab 7	Comparison of thermostability and photostability of the active substance in solid, semi-solid and liquid pharmaceutical formulations.	4
Lab 8	Potentiometry – the method used for potentiometric titration of the biologically active molecules possessing positive or negative charge. Application of potentiometric titration to pH-metric analysis.	4
Lab 9	UV-Vis spectrophotometry – principles of the method and procedure of measurement. The quality analysis of a pharmaceutical formulation.	4
Lab 10	Infrared spectroscopy (FT-IR) of a biologically active compound. Sample preparation and spectrum collection.	4
	Total hours	**30**

TEACHING TOOLS USED
N1 Multimedial presentation. 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 – PEU_W03	grades for the short queries in the topics of the laboratory experiments.
F2	PEU_U01 – PEU_U4	grades for reports on the experiments conducted.
P1 (laboratory)		Average from N grades for the queries (F1) and N for the reports on the experiments conducted (F2) **P1 = Σ (F1+F2)/N**
P2 (lecture)	PEU_W01– PEU_W03	Final test.

PRIMARY AND SECONDARY LITERATURE

PRIMARY LITERATURE:

[1] J. Ermer, J.H.McB. Miller, Method Validation in Pharmaceutical Analysis. A Guide to Best Practice. Wiley-VCH, Weincheim. 2005.

[2] Farmakopea Polska, Urząd Rejestracji Leków, Wyrobów Medycznych i Produktów Biobójczych, Warszawa.

[3] W. Jennings, E. Mittlefehldt, P. Stremple, Analytical Gas Chromatography. 2nd Ed. Academic Press, 1997.

[4] R.P.W. Scott, Tandem Techniques. John Wiley & Sons, 1997.

[5] M.S. Lee, Integrated Strategies in Drug Discovery Using Mass Spectrometry. John Wiley & Sons, 2005.

[6] A.J. Bard, R.L. Faulkner, Electrochemical Methods. Fundamental and Applications. John Wiley & Sons, 2001.

SECONDARY LITERATURE:

[1] D.M. Bliesner, Validating Chromatographic Methods. A Practical Guide. John Wiley & Sons, 2006.

[2] P.A. Christensenand A. Hamnett, Techniques and Mechanisms in Electrochemistry. Kluver Academic Press, 1994.

[3] AC Moffat, MD Osselton, B Widdop, Clarke's analysis of drugs and poisons. Pharmaceutical Press, 2005.

[4] F.A. Settle, Handbook of Instrumental Techniques for Analytical Chemistry. Prentice-Hall Inc., 1997.

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

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