SYLLABUS

1. Course title:

QUALITY CONTROL OF BIOPHARMACEUTICALS

2. Code:

3. Cycle of study:

1

4. ECTS credits:

2

5. Type of course:

○ Mandatory ◉ Elective

6. Prerequisites:

None

7. Class restrictions:

None

8. Duration / semester:

1 8.

9. Weekly contact hours:

9.1. Lectures: 2

9.2. Seminars: 0

9.3. Laboratory/Practice classes: 0

10. Faculty:

Faculty of Pharmacy

11. Department/study program:

Pharmacy (integrated 1st and 2nd cycle)

12. Lecturer:

dr. sc. Nahida Srabović, associate professor

13. Lecturer's e-mail:

nahida.srabovic@untz.ba

14. Web site:

www.frmf.untz.ba

15. Course aims:

The aim of this course is to acquire basic knowledge about methods and standards for ensuring the quality of biological medicines. To gain knowledge on how to conduct analysis, interpret results, and apply regulatory guidelines in the production of biological medicines. Developing the ability to critically evaluate processes to ensure the safety, efficacy, and reliability of biopharmaceuticals

16. Learning outcomes:

-to acquire theoretical knowledge about a wide range of studies and investigations of the properties of biopharmaceuticals for quality control purposes, using spectroscopic and physicochemical methods (circular dichroism, UV, visible and NIR spectroscopy, fluorescence spectroscopy, FTIR, Raman spectroscopy, HPLC, FPLC, SDS-PAGE, NMR, analytical ultracentrifugation, etc.)
-to acquire theoretical knowledge about general tests used for examining the properties of biopharmaceuticals, and about methods used for confirming identity and heterogeneity, purity, the presence of possible impurities, activity, and stability

17. Course content:

General tests for the analysis of biopharmaceuticals; Quantification of biopharmaceuticals; Identification and heterogeneity of biopharmaceuticals; Molecular mass (SEC, MS, SDS-PAGE); Primary structure of biopharmaceuticals; Higher-order structures (NMR, X-ray crystallography); Glycosylation heterogeneity; Protein amino-terminus for heterogeneity determination. N-terminal sequencing using automated Edman chemistry and HPLC analysis; Identification of the C-terminus and truncated variants for heterogeneity; Purity of biopharmaceuticals and their impurities; Dimers and higher aggregates — SEC, analytical ultracentrifugation, fluorescence spectroscopy, SDS-PAGE; Post-translational modifications in the context of therapeutic proteins; Host cell proteins; Examples of impurity-dependent processes; Efficacy of biopharmaceuticals. Seminar papers in the course Quality Control of Biopharmaceuticals.

18. Learning methods:

Lectures and seminar papers.The course includes 30 hours of theoretical instruction and seminars.Students are required to attend the lectures and actively participate in discussions.The student seminar paper is mandatory and is completed as a group team project.

19. Assessment methods:

Student knowledge assessment is carried out through pre-exam obligations and the final exam. Within the pre-exam obligations, students can earn points from activities in lectures, individual and group projects, and a test which students take in the 15th week of the semester. If students achieve at least 55 points during the pre-exam obligations, they gain the right to register for the final exam grade, which they take during regular examination periods. Students at the final and retake exams only take the parts of the exam for which they did not achieve the minimum required points during previous knowledge assessments.
The point value of the pre-exam obligations/knowledge assessment is:

	min - max
- activity in lectures,	5 - 10 points
- test,	40 - 70 points
- project,	10 - 20 points
TOTAL,	55 - 100 points

20. Assessment components:

10 (A) -95-100- outstanding performance without errors or with minor errors
9 (B) - 85-94-above the average, with some errors
8 (C) - 75-84- average, with noticeable errors
7 (D) - 65-74 generally good, but with significant shortcomings
6 (E) - 55-64- meets the minimum criteria
5 (F, FX) <55- does not meet the minimum criteria

21. Required reading list:

Smajlović A. Experimental Biochemistry, 2015. Tuzla.

22. Web sources:

23. Applicable starting from the academic year:

2023/2024.

24. Adopted in the Faculty/Academy session:

17.11.2025.