SYLLABUS

1. Course title:

QUALITY CONTROL OF BIOPHARMACEUTICALS

2. Code:

3. Cycle of study:

1

4. ECTS credits:

3

5. Type of course:

○ Mandatory ◉ Elective

6. Prerequisites:

None

7. Class restrictions:

None

8. Duration / semester:

1 9.

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:

Students will be able to understand and apply the basic principles of quality control in the production of biopharmaceuticals;
They will be able to analyze and interpret laboratory results and draw conclusions about product compliance with standards;
They will develop the ability to recognize potential problems in the production process and propose solutions to ensure the safety and efficacy of biopharmaceuticals.

17. Course content:

General tests for biopharmaceutical analysis;
Quantification of biopharmaceuticals;I
dentification and heterogeneity;
Determination of molecular weight (SEC, MS, SDS-PAGE);
Determination of the primary structure of protein biopharmaceuticals (Edman degradation);
Determination of higher-order protein structure - biopharmaceuticals (NMR, X-ray crystallography);
Glycosylation heterogeneity;
Purity of biopharmaceuticals - dimers and aggregates (analytical ultracentrifugation, SEC...);
Immunogenicity of biopharmaceuticals;
Regulatory standards in biopharmaceutical production.

18. Learning methods:

Interactive lectures using multimedia tools and active discussion. Individual and group projects
Consultations.

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:

2018/19

24. Adopted in the Faculty/Academy session:

17.11.25.