SYLLABUS

1. Course title:

Quality control of biopharmaceuticals

2. Code:

(max. 20 characters)

3. Cycle of study:

1

4. ECTS credits:

3

5. Type of course:

○ Mandatory ◉ Elective

6. Prerequisites:

7. Class restrictions:

8. Duration / semester:

1 IX

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:

(max. 100 characters)

12. Lecturer:

Ph.D. Aida Smajlović, associate professor

13. Lecturer's e-mail:

aida.krijestorac@untz.ba

14. Web site:

15. Course aims:

The aim of this course is to acquire knowledge on the methods used to test biopharmaceutical properties and, on this basis, control quality of biopharmaceuticals. Because of the recombinant proteins used as biopharmaceuticals (immunoglobulins, coagulation factors, immunostimulators, various antigens, etc.), knowledge of modern methods that can give biopharmaceutical properties information is needed.

16. Learning outcomes:

- acquire theoretical knowledge of a wide spectrum of biopharmaceutical studies and research for biopharmaceutical quality control, using spectroscopic and physico-chemical methods (circular dihroism, UV, visible and NIR spectroscopy, fluorescence spectroscopy, FTIR, Raman spectroscopy, HPLC, FPLC, SDS-PAGE , NMR, analytical ultracentrifugation, ...)
- Acquire theoretical knowledge of general tests used to propagate biopharmaceutical properties, methods used to prove identity and heterogeneity, purity, eventual contamination, activity, stability

17. Course content:

General tests for biopharmaceutical analysis; Quantification of biopharmaceuticals; Identification and heterogeneity of biopharmaceuticals; Molecular mass. (SEC, MS, SDS-PAGE); Primary structure of biopharmaceuticals; Higher levels of structure. (NMR, circular dihroism); Glycosylation heterogeneity; Amino-terminal protein for heterogeneity. N-terminal sequencing by automatic Edman's chemistry and HPLC analysis; C-terminus identification and bold version for heterogeneity; The purity of biopharmaceuticals and their pollution; Dimers and higher aggregates. SEC, Analytical Ultracentrifugation, Fluorescence Spectroscopy. SDS-PAGE; Post-translaction modification in the context of therapeutic proteins; Host cell proteins; Examples of impurity-dependent processes; Efficacy of biopharmaceuticals. Seminar papers from the subject of Quality Control of Biopharmaceuticals.

18. Learning methods:

Teaching subjects. The quality control of biopharmaceuticals has a fund of 30 hours of theoretical teaching and seminars.
Students are obliged to attend lectures and participate actively in them through discussion, based on already acquired theoretical knowledge. Seminar work is mandatory as a team team project.

19. Assessment methods:

Lecture (P): Regularity of class attendance: 5 points. Min 2
Teaching Activity: 10 points. Min 2
The student actively participates in the lecture during the lecture. During the course of the lecture, the activity can achieve a maximum of 10 points. Based on the activity of the lecture, it is obligatory to collect a minimum of 2 points. During the semester, the student completes 2 tests (2 partial examinations), which comprise the complete theoretical instruction from the subject of Quality Control of Biopharmaceuticals. Part I includes theoretical instruction: General tests for biopharmaceutical analysis; Quantification of biopharmaceuticals; Identification and heterogeneity of biopharmaceuticals; Molecular mass. (SEC, MS, SDS-PAGE); Primary structure of biopharmaceuticals; Higher levels of structure. (NMR, circular dihroism). Test I carries a maximum of 28 points. The minimum number of points that must be obtained on the test is 18. Part II includes theoretical instruction: Heterogeneity of glycosylation; Amino-terminal protein for heterogeneity. N-terminal sequencing by automatic Edman's chemistry and HPLC analysis; C-terminus identification and bold version for heterogeneity; The purity of biopharmaceuticals and their pollution; Dimers and higher aggregates. SEC, Analytical Ultracentrifugation, Fluorescence Spectroscopy. SDS-PAGE; Post-translaction modification in the context of therapeutic proteins; Host cell proteins; Examples of impurity-dependent processes; Efficacy of biopharmaceuticals. Test II carries a maximum of 42 points. The minimum number of points that must be achieved on the test is 25.Seminar papers from the subject of Quality Control of Biopharmaceuticals.
During the semester a student is working (final exam), which includes theoretical instruction from the subject of Quality Control of Biopharmaceuticals, and refers to the verification of the knowledge of the test I and the test II from theoretical teaching which are not passed in regular terms ie no minimum points have been achieved .
Seminar work of a student: a student is obliged to do one seminar work as a group project. Successfully prepared and defended seminar work is evaluated with a maximum of 15 points. The minimum number of credits required to complete the seminar is 8 points. The number of credits obtained on the basis of the conducted seminar work is calculated by the total number of points achieved on other bases in the (final) grade.

20. Assessment components:

Score Rating (BiH) (ECTS Rating)

<54	5	F
54 - 63	6	E
64 - 73	7	D
74 - 83	8	C
84 - 93	9	B
94 - 100	10	A

21. Required reading list:

Authorized lectures
Šober M, Nikolin B, Selected chapters from "Pharmaceutical analytics" course for postgraduate study "Pharmaceutical Research", Sarajevo, 2003.
Luttrell A, Farb D, Kirsch R, Pharmaceutical Quality Control Lab Guidebook, Co

22. Web sources:

(max. 687 characters)

23. Applicable starting from the academic year:

2012/2013

24. Adopted in the Faculty/Academy session:

(max. 10 char.)