SYLLABUS

1. Course title:

DRUGS ANALYSIS AND CONTROL I

2. Code:

3. Cycle of study:

1

4. ECTS credits:

7

5. Type of course:

(●) Mandatory ( ) Elective

6. Prerequisites:

NONE

7. Class restrictions:

NONE

8. Duration / semester:

1 5

9. Weekly contact hours:

9.1. Lectures:	3
9.2. Seminars:	0
9.3. Laboratory/Practice classes:	2

10. Faculty:

Faculty of Pharmacy

11. Department/study program:

Pharmacy (Integrated study I and II cycle)

12. Lecturer:

Maida Šljivić Husejnović, PhD, Assoc.Prof.

13. Lecturer's e-mail:

maida.sljivic-husejnovic@untz.ba

14. Web site:

www.frmf.untz.ba

15. Course aims:

Acquisition of knowledge and skills in the field of drug analysis and control. Introduction to the requirements and methods for drug control.

16. Learning outcomes:

At the end of the semester/course, successful students, who continuously performed their duties during the entire teaching period, will be able to:
-apply the acquired knowledge in drug control in routine drug analysis in drug control laboratories as well as for research.

17. Course content:

1. Introduction to pharmaceutical analysis
2. Agency for medicines and medical devices
3. Regulations and regulations related to testing and control of medicines in Bosnia and Herzegovina (national and European) 4. EMA, EDQM, OMCL network
5. Pharmacopoeia, official regulations and drug monograph
6. Basics of pharmaceutical analysis. Qualitative-quantitative analysis of drugs according to the pharmacopoeia. Overview of physico-chemical methods
7. Examination of impurities and degradation products of medicines according to official regulations
8. Validation of analytical methods
9. Calibration methods in drug analysis
10. Profile of physico-chemical properties of pharmaceutical substances as a criterion for choosing a method for pharmaceutical analysis
11. Melting temperature in drug control
12. Titration methods in drug analysis and control
13. Identification by chemical reactions
14. Biological control of medicines
15. Legislation related to drugs and medical devices on the market in Bosnia and Herzegovina
16. Legal and by-law acts: state, entity and cantonal

18. Learning methods:

Lectures, consultations, practical laboratory work, independent seminar work.

Lectures - Students are required to attend lectures and actively participate in them.
Consultations - Through consultations, students can clarify doubts and deepen their acquired knowledge.
Practical laboratory work - Students are required to complete a specified number of practical laboratory work and pass colloquium.
Seminar work - Students write a seminar paper based on collected literature on the assigned topic and orally defend it.

19. Assessment methods:

Pre-exam activities (minimum 55, maximum 100 points)
- Student's activity - 0-5 points
- Seminar paper - 5.5-10 points
- Colloquium - 8-15 points
- First partial exam - 16-30 points
- Second partial / final exam - maximum 40 points

Student's activity: Students actively participate in classes and demonstrate engagement. Student activity is assessed with 0-5 points.
Seminar paper: Students write a seminar paper based on collected literature on the assigned topic and orally defend it. Independent student work is scored with 5.5-10 points.
Colloquium : Students can score 8 out of a total of 15 points allocated for the material covered in practical laboratory work. The test is conducted in writing.
Exam: Students can take the exam in two parts, orally and/or in writing. The first partial exam covers 40% of the course content. The exam is taken during the semester, after completing the designated teaching units. To pass the first partial exam, students need to score 16-30 points. The second partial/final exam covers the remaining 60% of the course content. Students take the second partial/final exam at the end of the semester, after attending all lectures. In the second partial/final exam, students accumulate points for grade registration. Students need to achieve a total number of points from the planned activities and knowledge assessments during the semester that meets the criteria for a passing grade.

If a student does not earn enough points for grade registration in the pre-exam activities, the final exam and any failed parts of the exam are taken in the regular and remedial exam sessions.

20. Assessment components:

A student's performance is continuously monitored throughout the course and is expressed in points.

The final grade of a student after all planned forms of assessment is evaluated and graded as follows:
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:

Analitika lijekova,Nikolin,Šober,2003
Odabrane metode za farmaceutsku analizu, Živanović, 2003
Analitika lekova, Ivanović,Zečević, 2004
Ph. Eur. 11
USP 45-NF 40
BP 2024

22. Web sources:

23. Applicable starting from the academic year:

2023/2024.

24. Adopted in the Faculty/Academy session:

17.11.2025.