Study program: Integrated Academic Studies in Pharmacy	
Course title: Drug Stability	
Teacher: Jelena M. Cvejić, Milica T. Atanacković Krstonošić, Mira P. Mikulić	
Course status: Compulsory	
ECTS Credits: 2	
Condition: Pharmaceutical technology I	

Course aim

Main goals of Drug Stability course are acquisition with procedures of drug stability investigation (according to specification) referring to capacity of drug substances and drug preparations for maintaining their identity, potency, quality and purity during shelf life, using retesting methods.

Expected outcome of the course:

Analyzing of drug substance and drug preparation stability, which are obliged by regulatory agencies. Introduction to the regulatory procedures of stability verification and its relevance, in order to learn how to design and implement relevant drug stability program. Application of knowledge into the practice- designing and implementing of stability protocol.

Course description

Theoretical education

1. Critical elements of stability program and stability testing
2. Chemical stability of drug substances
3. Physical stability of drug substances
4. Stabilization of drug substances
5. Stability of dosed forms
6. Development of stability-indicating method
7. Nonchromatographic methods in stability studies
8. Routine and development studies of stability

Practical education

1. WHO and ICH guidelines; Q1A, Q1C, Q1D, Q1E, Q1F, Q2A, Q2B, Q3A and Q3B
2. Stability report
3. The effect of pH on the stability of the drug in solution
4. Stability testing of pharmaceutical preparations using UV / TLC
5. Stability testing of pharmaceutical preparations using HPLC
6. Comparison of the stability of the tablet before and after expiration date
7. Performing of the stability studies

Literature

Compulsory

1. Yoshioka S, Stella VJ. Stability of drugs and dosage forms. New York: Kluwer academic publishers; 2002.

Additional

1. Carstensen JT, Rhodes CT. Drug Stability, Revised, and Expanded: Principles and Practices. 3rd ed. CRC Press 2000.
2. Huynh-Ba H. Handbook of stability testing in pharmaceutical development. Springer; 2009.
3. Xu QA, Trissel LA. Stability-indicating HPLC methods for drug analysis. Apha; 2003.

Number of active classes	Theoretical classes: 30	Practical classes: 30

Teaching methods

Lectures, laboratory work.

Student activity assessment (maximally 100 points)

Pre-exam activities	points	Final exam	points
Lectures	10	Written	70
Practices		Oral	
Colloquium	20	....	
Essay			