Study program: Integrated academic studies of Pharmacy

Type and level of the study program: integrated academic studies

Course title: DRUG STABILITY (PhV-DSTAB)

Teacher: Jelena M. Cvejić Hogervorst, 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 program stability and Stability testing
2. Chemical stability drug substances
3. Physical stability drug substances
4. Stabilization of 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: exercises, other forms of education, research related activities

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 UV / TLC
5. Stability testing of pharmaceutical preparations 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. Drug Stability: Principles and Practices. Dekker; 1995.
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				Other:
Lectures: 30	Practice: 30	Other types of teaching:	Research related activities:	

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			