УНИВЕРЗИТЕТ У БАЊОЈ ЛУЦИ
UNIVERSITY OF BANJA LUKA
ПРИРОДНО-МАТЕМАТИЧКИ ФАКУЛТЕТ
FACULTY OF NATURAL SCIENCES AND MATHEMATICS

CHEMISTRY DEPARTMENT | PhD STUDIES

Course name	Thermal Stability of Active Components and Excipients in Solid Formulations			
Course code	**Course status**	**Semester**	**Hours of instruction**	**ECTS**
DHEM23TSK	**elective**	**I, II, III or IV**	**5+0**	**10**
Teacher(s)	**Prof. Dijana Jelić, PhD**			

Prerequisite course(s)	**Entry requirements**
none	**/**

Course goals

The course aims to apply physic-chemical principles in pre-formulation and formulation studies of drug development. The backbone of the course consists of stability studies and compatibility studies of active components and excipients in pharmaceutical formulation using thermal analysis methods (TGA, DTA, and DSC), as well as finding strategies to increase the bioavailability of poorly soluble drugs.

Learning outcomes

Upon successful mastering of this course, the student should learn and master strategies to improve the bioavailability of poorly soluble drugs, to apply the methods of thermal analysis of TGA, DTA, and DSC to perform physicochemical characterization of amorphous solid dosage forms of drugs. Also, the student should be able to evaluate the thermal stability of the active component and excipients and evaluate the interaction between active components and excipients in the pharmaceutical formulation by interpreting TGA, DTA, and DSC curves, as well as explain the mechanisms of active component crystallization kinetics.

Course content

Solid state chemistry in drugs. Solid state characteristics. Crystalline and non-crystalline state. Crystal growth and nucleation, crystallization process. Polymorphism: definition, the significance of polymorphism in drug formulation, polymer thermodynamics, enantiotropy and monotropy, concept of the transition temperature. Hydrates, salts, and amorphous materials. Amorphous system: definition, disorder of amorphous system, glass state temperature concept, glass state thermodynamics, thermally stimulated processes α, β, and gamma processes. The role of amorphous systems in drug delivery systems. Poorly soluble drugs. Solubility and bioavailability. Strategies to increase the bioavailability of poorly soluble drugs. Physical stability/instability of drugs and parameters affecting it. Physical instability of amorphous systems, techniques for characterization of amorphous systems, amorphous solid dispersions. Amorphous polymer-based solid dispersions to improve solubility and oral drug absorption. Application of polymers as carriers. Micro and nanoconfigurations of polymer structure. Supersaturation in the drug delivery system. Physic-chemical characterization of amorphous solid dispersions. Application of thermal methods (TGA, DTA, DSC) for assessment of thermal stability of active components and excipients. Stability studies and compatibility studies between active components and excipients. Preformulation studies and formulation studies in drug development. Case report: indomethacin, felodipine, nifedipine, malonic acid, bisoprolol fumarate, amlodipine besylate, ambroxol hydrochloride, pantoprazole, vitamin D, vitamin C, folic acid, etc.

Teaching methods

Lectures, consultative classes, seminar work

Books and other learning materials

Thermal Analysis of Pharmaceuticals, Duncan Q.M. Craig, Mike Reading, 2020 by CRC Press ISBN 9780367577742,
Pharmaceutical Thermal Analysis: Techniques and Applications, James L. Ford, Peter Timmins, E. Horwood, 1989, ISBN 0745803466, 9780745803463;
Thermal Analysis in Practice, Matthias Wagner, © Carl Hanser Verlag, Munich 2018, ISBN 978-1-56990-643-9,
Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, Yihong Qiu, Yisheng Chen, Geoff G.Z. Zhang, Lirong Liu, William Porter, Academic Press, 2009.

Course activities and grading method

Seminar paper, Final exam

Seminar paper and defense of seminar paper	**40**	**Final exam**	**60**

Additional course notes

Name of the teacher who prepared this form	**Prof. Dijana Jelić, PhD**

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