Study program: Integrated Academic Studies in Pharmacy

Course title: Biopharmacy 1

Teacher: Mirjana B. Bećarević

Course status: Compulsory

ECTS Credits: 2

Condition: Pharmaceutical Technology I, II, III

Course aim

The aim of the course is to introduce students to relations between physicochemical features of drug substances (and their dosage forms) and the bioavailability of drug substances in the organism. Also, students will acquire basic knowledge about factors that influence the intensity and duration of therapeutic effects of drug substances in the organism.

Expected outcome of the course:

The expected outcome of the course is the acquisition of knowledge about factors that have influence on the drug substances liberation from pharmaceutical dosage forms. Students will be introduced to all relevant factors that have influence on drug substance absorption.

Students should develop the skill of knowledge application in pharmaceutical practice that is related to considerations of physicochemical and pharmaceutical-technology factors that influence drug substance liberation from pharmaceutical dosage forms and their *in vivo* absorption.

Course description

Theoretical education

1. Basic terms and definitions: bioavailability (absolute, relative), equivalences (pharmaceutical, therapeutic, chemical and bioequivalence); factors that have influence on drug substances liberation (from their pharmaceutical dosage forms) and drug substance absorption.
2. Physiological factors that have influence on drug substances liberation and absorption: Cell membrane structure. Drug substance transport mechanisms. Routes of drug substances application. Interactions between drug substances and components of gastro-intestinal tract.
3. Physicochemical factors that have influence on drug substances liberation and absorption: ionization, dissociation constant, pH value, solubility, dissolution, formation of complexes, adsorption, particle size, viscosity, polymorphism, pseudo-polymorphism, partition coefficient, salt formation, the influence of surfactants. Stability of drug substances in body fluids.
4. Pharmaceutical-technology factors that have influence on drug substances liberation and absorption. Specific factors for particular pharmaceutical dosage forms.
5. The *in vitro* analysis of drug substances liberation kinetics from pharmaceutical dosage forms. Apparatus for drug substances dissolution testing (dissolution apparatus). Selection of experimental conditions (solvent, temperature, the amount of agitation, the presence of enzymes, surface tension, pH value). Membrane models. Tests for absorption monitoring.

Practical education:

Students are introduced to physicochemical features of drug substances that are relevant for drug substances liberation from pharmaceutical dosage forms and their absorption (coefficient of water-lipid distribution, particle size, solubility, dissolution, pH value, degree of ionization, dissociation constant, salt formation, formation of complexes, adsorption, polymorphism, pseudo-polymorphism, the presence of surfactants). Partition coefficient, particle size, solubility and dissolution of drug substances will be practically determined.

Literature

Compulsory:

1. Shargel L, Wu-Pong S, Yu ABC. Applied biopharmaceutics and pharmacokinetics. McGraw-Hills Pharmacy 2004.

Additional:

1. Remington. The science and practice of pharmacy. Lippincott, Williams &Wilcins, 20th ed, 2000.
2. Loebenberg R, Amidon GL. Modern bioavailability, bioequivalence and biopharmaceutics classification system. New scientific approaches to international regulatory standards. Eur J Pharm Biopharmaceutics 2000;50:3-12.

Number of active classes	**Theoretical classes:** 15	**Practical classes:** 15

Teaching methods: Lectures. Laboratory classes

Student activity assessment (maximally 100 points)

Pre-exam activities	**points**	**Final exam**	**points**
Lectures:	5	Written	60
Practices:	5	Oral	/
Colloquium	30	…….	
Essay	/		