**UNIVERSITY OF NOVI SAD**
**FACULTY OF MEDICINE**

**Study program:** Doctoral Academic Studies in Biomedical Sciences

**Course title: PHARMACEUTICS**

**Teacher:** Nataša P. Milošević, Mirjana B. Bećarević, Mladena N. Lalić-Popović, Božana S. Nikolić, Nataša B. Milić, Mja Lj. Milanović, Jelena S. Jovičić Bata

**Course status:** elective

**ECTS Credits: 20**

**Condition: -**

**Course aim**

Introduction to the principles of turning new chemical entity (small molecule or larger molecular structures) into safe and effective medication.

**Expected outcome of the course:**

Knowledge: Introduction to the all aspects of design of dosage forms
Skills: Application of acquired knowledge in the research, development and registration of new pharmaceutical dosage form.

**Course description**

*Theoretical education*

1. Drug design as an integral part of preformulation studies and formulation design. Ligand-based drug design. Structure-based drug design. Optimization of an active molecular entity. Determination of chemical properties. Physical characterization of a molecule. Drug-excipient compatibility.
2. Small molecule formulations: Decision making algorithm in selection of most appropriate dosage form and method of administration for drug candidate. Quality by design approach and critical characteristics determination approach to formulation development and drug delivery systems development. Quality considerations of materials used in drug formulations. In vitro investigations in selection of most promising drug formulation. Application of experimental design in formulation development. Innovative pharmaceutical dosage form development studies and modern drug delivery systems (improvement of bioavalability and drug targeting).
3. Application of pharmacokinetics in new drug development, dosage form design and new drug delivery systems. Pharmacokinetics software application in formulation development.
4. Preclinical studies of new drug dosage form and new drug delivery systems. Clinical studies of new drug dosage form and new drug delivery systems. Drug discovery and development: preclinical trials; clinical trials, clinical trial regulation, statistics in clinical trials.
5. Macromolecule formulation: Techniques for proteins isolation and purification, structure of protein biopharmaceutics, biopharmaceutical aspects of protein biopharmaceutics and their preparation into pharmaceutical dosage forms, processing of biopharmaceutics in the organism, safety, efficiency and adverse effects of biopharmaceutics.
6. Post-marketing safety reporting: of biopharmaceutics. Regulatory consideration in dosage form design and new drug delivery systems. Regulation of excipients. Rules and regulations on packaging and labelling of pharmaceutical products. Post-marketing safety reporting on new dosage form and new drug delivery systems. Drug interaction – design and data analysis

*Practical education*

1. Software application in optimization of an active molecular entity and physico-chemical properties determination.
2. Steps of formulation development of small molecules: selection of excipients, small molecule consideration, therapeutic consideration.
3. Implementation of experimental design in formulation development
4. Pharmacokinetic parameters determination in clinuical trials, new pharmaceutic dosage forms and new drug delivery systems
5. Steps in biopharmaceuticals dosage forms preparation
6. Case studies of drug discovery and development based on actual examples

**Literature**

*Compulsory*:


1. Aulton M, editor. Aulton´s Pharmaceutics – The Design and Manufacure od Medicines. 4th ed. Philadelphia: Elsevier; 2013
2. Fahr A. Voigt´s Pharmaceutical Technology. Scherphof G, translator. Hoboken, NJ: Wiley; 2018.
3. Crommelin DJA, Sindelar RD, Meibohm B. Pharmaceutical biotechnology. Fundamentals and applications. Informa Healthcare London-New York, 2008.
4. Banga AK. Therapeutic peptides and proteins. Formulation processing and delivery systems. Technomic Lancaster, Pennsylvania

1995.
5. Francetić I. Klinička farmakologija. II promenjeno i dopunjeno izdanje.Zagreb: Medicinska naklada, 2014.
6. Bonate P, HowardP. Pharmacokinetics in Drug Development,Clinical Study Design and Analysis (Volume 1). Springer,2004.
7. Spruill W, Wade W, DiPiro JT, Blouin RA, Pruemer JM. Concepts in Clinical Pharmacokinetics, 6th Edition, ASHP, 2014
8. Tovey GD, editor. Pharmaceutical Formulation: The Science and Technology of Dosage Forms, Royal Society of Chemistry, 2018.

*Additional:*

1. OECD Principles of Good Laboratory Practice. http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/mc/chem(98)17&doclanguage=en
2. Guideline for good clinical practice E6(R2). https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf
3. ICH E9 Statistical Principles for Clinical Trials. https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-9-statistical-principles-clinical-trials-step-5_en.pdf
4. Guideline on the investigation of drug interactions. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-drug-interactions-revision-1_en.pdf
5. Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms (EMA/CPMP/EWP/280/96 Corr1)https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-pharmacokinetic-clinical-evaluation-modified-release-dosage-forms_en.pdf

| **Number of active classes** | **Theory:** 60 | **Practices**: 45 |
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**Teaching methods**
Theoretical and practical teaching.

**Student activity assessment** (maximally 100 points)
lectures: 15
practices: 15
written exam: 70