| University of Niš<br>Faculty of Medicine | Study program: INTEGRATED ACADEMIC STUDIES OF MEDICINE<br>Accreditation 2018 | |
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**Course: Pharmaceutical dosage forms**

**Course head:** Prof. dr Vesna Savić

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| **Course status:** | Elective |
| **Semester:** VI | **Study year**: III |
| **ECTS**: 4 | **Course mode**: M-III-20.д |

**Course purpose:**

Introduction to pharmaceutical dosage forms and routes of administration: oral, rectal, vaginal, dermal, parenteral. Therapeutic systems and controlled drug delivery. Sterile pharmaceutical products-formulation requirements.

**Course outcome: (knowledge, skills, attitudes)**

The knowledge about different dosage forms and routes of administration, their biopharmacy and characteristics will help future doctors of medicine to choose drugs in a proper way regarding the patients needs.
Acquisition of knowledge about characteristics of generic and brand name drugs, differences between registered , magistral and galenic drugs.
Students learn to select the appropriate pharmaceutical form of drug for certain indications, in the appropriate route of administration and in appropriate therapeutic doses.

**Nr. of classes of active teaching: 45**

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| **Lectures**: **30** | **Practice: 15** |

**Course content:**

**Active teaching:**

| **1. Lectures** | | **Број часова:** |
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| 1. | Definition of medicine. Legal framework governing medicinal products for human use in Serbia and worldwide. Pharmacopoeial standards and requirements. | 1 |
| 2. | Drug registration. Generic and brand name drugs. | 2 |
| 3. | Compounded and galenic drugs- differences and characteristics. Differences between drug doses and dosage. Expression of drug amount in a given dosage form. | 2 |
| 4. | Isotonicity in pharmacy-legal requirements for parenteral dosage forms. Proper dilution of a drug solution. | 2 |
| 5. | Suppositories and pessaries | 2 |
| 6. | Hard and soft capsules | 2 |
| 7. | Tablets | 2 |
| 8. | Eye preparations | 1 |
| 9. | Infusions | 1 |
| 10. | Injections | 4 |
| 11. | Therapeutic systems and controlled drug delivery | 2 |
| 12. | Semi-solid preparations for cutaneous application. | 2 |
| 13. | Liquid preparations for cutaneous application and for oral use. Solutions, suspensions, emulsions. | 2 |
| 14. | Biologics-formulation and legal requirement | 4 |
| 15. | Drug dosing calculations using the appropriate literature. | 1 |
| | **Total** | **30** |

| **2. Practical teaching** | | **Број часова:** |
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| 1. | Panel on biopharmaceutical characteristics of generic and brand name drugs. | 2 |
| 2. | Pharmaceutical dosage forms and routes of administration: examples and analysis. | 1 |
| 3. | Analysis of similarities and differences about administration of tablets, capsules, injections with the same active substance | 2 |
| 4. | Workshop on biologics: what a patient can expect and how to prepare them. | 1 |
| 5. | Student research work on the topic of adequate therapy of a specific health problem with registered, galenic and compounded drug. | 9 |
| | **Total** | **15** |

Recommended literature:

1. European Medicines Agency, http://www.ema.europa.eu
2. The Medicines and Medical Devices Agency of Serbia (ALIMS), https://www.alims.gov.rs
3. Pravilnik o obrascu i sadržini lekarskog recepta, načinu izdavanja i propisivanja lekova,
4. Sl. glasnik RS , br. 74/2018, 87/2018 i 4747/2019
5. Pravilnik o sadržaju i načinu obeležavanja spoljnjeg i unutrašnjeg pakovanja leka,
6. dodatnom obeležavanju, kao i sadržaju uputstva za lek, Sl. glasnik RS, br. 41/201
7. The European Pharmacopoeia, 9th edition (Ph. Eur. 9.0), Volume I; Strasbourg: Council of Europe; 2017.
8. Zakon o lekovima i medicinskim sredstvima; Narodna skupština RS, Beograd;2010.
9. Swarbrick J. Encyclopedia of pharmaceutical technology, third edition. Informa Healthcare, New York London, 2007, 1891-1896

**Teaching metods:**

- Interactive theoretical and practical teaching
- Consultations
- Seminars in small groups

Required previously passed exams:

- None

Grade (max. 100 points)

Pre-exam obligations

- Activity at lectures: 0-10 points
- Activity at panels: 0-10 points
- Seminars (researches conducted by smaller groups of students): 0- 30 points

Final exam

- Written/oral exam: 0- 50 points

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