

**Faculty of Medicine / PHARMACY / PHARMOCOKINETICS**

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| <b>Course:</b>                       | PHARMOCOKINETICS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                 |                     |                                               |
| <b>Course ID</b>                     | <b>Course status</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Semester</b> | <b>ECTS credits</b> | <b>Lessons</b> (Lessons+Exercises+Laboratory) |
| 7625                                 | Mandatory                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 8               | 6                   | 3+2+0                                         |
| <b>Programs</b>                      | PHARMACY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                 |                     |                                               |
| <b>Prerequisites</b>                 | Does not have                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                 |                     |                                               |
| <b>Aims</b>                          | Understand the kinetic processes by which a drug undergoes in the body, kinetic analysis and the importance of pharmacokinetic parameters in setting and correcting regimen of the drug dosage in order to conduct a rational pharmacotherapy.                                                                                                                                                                                                                                                                                                                                                          |                 |                     |                                               |
| <b>Learning outcomes</b>             | 1. know pharmacokinetic processes and factors that affect them; 2. understand different approaches to pharmacokinetics analysis of data; 3. estimate and calculate pharmacokinetic parameters (single and multiple dosages); 4. know the factors that influence the variability of therapeutic response; 5. understand the ways of researching bio availability and bio equivalence of medicinal products; 6. use the acquired knowledge for therapeutic drug monitoring, as appropriate; 7. interpret measured concentrations of drugs; 8. know and apply the principles of clinical pharmacokinetics. |                 |                     |                                               |
| <b>Lecturer / Teaching assistant</b> | Asst.Dr. Tanja Vojinović                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                 |                     |                                               |
| <b>Methodology</b>                   | interactive course                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                 |                     |                                               |
| <b>Plan and program of work</b>      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                 |                     |                                               |
| Preparing week                       | Preparation and registration of the semester                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                 |                     |                                               |
| I week lectures                      | Introduction to pharmacokinetics – place of pharmacokinetics in the contemporary approach to the discovery, development and use of medicines. Compartment(s) definition. Drug absorption. Processes of absorption. Physico-chemical properties of drugs and the                                                                                                                                                                                                                                                                                                                                         |                 |                     |                                               |
| I week exercises                     | Single-compartment model, open pharmacokinetic mode of 2 compartments-presentation of pharmacokinetic data, calculation of pharmacokinetic parameters. Accounting tasks. The division of topics for seminars.                                                                                                                                                                                                                                                                                                                                                                                           |                 |                     |                                               |
| II week lectures                     | Routes of drug absorption and factors which influence the process of absorption. Drug distribution.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                 |                     |                                               |
| II week exercises                    | Extravascular drug administration - Calculation of resorption and half-life of resorption. Mathematical computational tasks.                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                 |                     |                                               |
| III week lectures                    | Distribution of drugs in the blood. Distribution of drugs in tissues. Volume of distribution. Blood-brain barrier, hemato-liquor barrier. Placenta. Accumulation of drugs in tissues.                                                                                                                                                                                                                                                                                                                                                                                                                   |                 |                     |                                               |
| III week exercises                   | Initial distribution of drugs. Redistribution of drugs. Passage of drugs through physiological barriers (hematoencephalic barrier, placenta). Distribution volume. Mathematical computational tasks.                                                                                                                                                                                                                                                                                                                                                                                                    |                 |                     |                                               |
| IV week lectures                     | Drug biotransformation. Phases of drug biotransformation. Phase I biotransformation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                 |                     |                                               |
| IV week exercises                    | Monitoring of drugs and metabolites and determination of pharmacokinetic parameters, Michaelis-Mentens kinetics, determination of parameters of Michaelis-Mentens kinetics, various mathematical procedures. Mathematical computational tasks.                                                                                                                                                                                                                                                                                                                                                          |                 |                     |                                               |
| V week lectures                      | Phase II biotransformation. Kinetics of drug metabolism.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                 |                     |                                               |
| V week exercises                     | Monitoring of drugs and metabolites and determination of pharmacokinetic parameters. Mathematical computational tasks.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                 |                     |                                               |
| VI week lectures                     | Induction and inhibition of drug metabolism. Importance of induction and inhibition of drug metabolism in clinical practice.                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                 |                     |                                               |
| VI week exercises                    | Clinical consequences of drug metabolism change (induction, inhibition of enzymes that metabolize drugs).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                 |                     |                                               |
| VII week lectures                    | Factors affecting drug metabolism. Influence of genetic variation on biotransformation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                 |                     |                                               |
| VII week exercises                   | Influence of different factors on drug metabolism (genetic factors, sex, age, pathological conditions, environment). Colloquium                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                 |                     |                                               |
| VIII week lectures                   | Drug excretion. Routes of excretion of the drug from the body. Enterohepatic cycling. First order and zero-order kinetics.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                 |                     |                                               |
| VIII week exercises                  | Study of drug excretion based on determination of urine concentration, study of pharmacokinetic parameters from data on urinary excretion. Calculation tasks.                                                                                                                                                                                                                                                                                                                                                                                                                                           |                 |                     |                                               |
| IX week lectures                     | Pharmacokinetic parameters. Single dose and multiple dose kinetics.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                 |                     |                                               |

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| IX week exercises                                                                                                                                                                                          | Calculation of pharmacokinetic parameters, interpretation of results in continuous intravenous infusion. Starting dose and initial infusion. Multiple dosage dosing, the time of reaching the steady state. Dosage interval and half-timing elimination ratio. |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| X week lectures                                                                                                                                                                                            | Influence of gender on drug administration. Pharmacokinetic properties of drugs in pregnancy.                                                                                                                                                                  |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| X week exercises                                                                                                                                                                                           | Pharmacokinetics of medicines of special populations (children, elderly, pregnant women)                                                                                                                                                                       |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XI week lectures                                                                                                                                                                                           | Drug administration in lactation. Bioavailability and bioequivalence of drugs.                                                                                                                                                                                 |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XI week exercises                                                                                                                                                                                          | Biological availability and biological equivalence of medicines                                                                                                                                                                                                |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XII week lectures                                                                                                                                                                                          | Bioequivalence studies.                                                                                                                                                                                                                                        |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XII week exercises                                                                                                                                                                                         | Tests of biological equivalence of medicines and bioequivalence studies.                                                                                                                                                                                       |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XIII week lectures                                                                                                                                                                                         | Drug interactions. Classification of drug interaction.                                                                                                                                                                                                         |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XIII week exercises                                                                                                                                                                                        | The importance of pharmacokinetic interactions                                                                                                                                                                                                                 |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XIV week lectures                                                                                                                                                                                          | Importance of drug interactions in clinical practice. Adverse drug reactions.                                                                                                                                                                                  |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XIV week exercises                                                                                                                                                                                         | The importance of clinical pharmacokinetics and therapeutic monitoring of patients                                                                                                                                                                             |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XV week lectures                                                                                                                                                                                           | The influence of pharmacokinetic factors of the drugs on adverse drug reactions. Importance of monitoring of adverse drug reactions.                                                                                                                           |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| XV week exercises                                                                                                                                                                                          | The importance of pharmacokinetics in monitoring adverse drug reactions.                                                                                                                                                                                       |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| <b>Student workload</b>                                                                                                                                                                                    | 45 theoretical units                                                                                                                                                                                                                                           |                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                            |                                    |
| <b>Per week</b>                                                                                                                                                                                            |                                                                                                                                                                                                                                                                |                                                            | <b>Per semester</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                            |                                                            |                                    |
| <b>6 credits x 40/30=8 hours and 0 minuts</b><br>3 sat(a) theoretical classes<br>0 sat(a) practical classes<br>2 excercises<br><b>3 hour(s) i 0 minuts</b><br>of independent work, including consultations |                                                                                                                                                                                                                                                                |                                                            | Classes and final exam:<br><b>8 hour(s) i 0 minuts x 16 =128 hour(s) i 0 minuts</b><br>Necessary preparation before the beginning of the semester (administration, registration, certification):<br><b>8 hour(s) i 0 minuts x 2 =16 hour(s) i 0 minuts</b><br>Total workload for the subject:<br><b>6 x 30=180 hour(s)</b><br>Additional work for exam preparation in the preparing exam period, including taking the remedial exam from 0 to 30 hours (remaining time from the first two items to the total load for the item)<br><b>36 hour(s) i 0 minuts</b><br>Workload structure: <b>128 hour(s) i 0 minuts (courses), 16 hour(s) i 0 minuts (preparation), 36 hour(s) i 0 minuts (additional work)</b> |                                                            |                                                            |                                    |
| <b>Student obligations</b>                                                                                                                                                                                 |                                                                                                                                                                                                                                                                |                                                            | Compulsory attendance thematic units of the subject. Required knowledge of previous thematic units.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                            |                                                            |                                    |
| <b>Consultations</b>                                                                                                                                                                                       |                                                                                                                                                                                                                                                                |                                                            | by e-mail, after thematic units.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                            |                                                            |                                    |
| <b>Literature</b>                                                                                                                                                                                          |                                                                                                                                                                                                                                                                |                                                            | Pokrajac M. Farmakokinetika. 3 izdanje. Beograd: Birograf, 2007 Momir Mikov. Osnovi farmakokinetike sa biofarmacijom. Ortomedics Novi Sad, Podgorica, Banja Luka, Beograd, 2014.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                            |                                                            |                                    |
| <b>Examination methods</b>                                                                                                                                                                                 |                                                                                                                                                                                                                                                                |                                                            | Lecture Attendance: 0-5+0-10 points Colloquium I: 0-20 points. Preparation and presentation of the seminar: 0-15 points; Final exam (0-50 points) Final exam is written. Minimum Cumulative Grade Point is 50 points and more.                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                            |                                                            |                                    |
| <b>Special remarks</b>                                                                                                                                                                                     |                                                                                                                                                                                                                                                                |                                                            | All necessary information for the subject can be obtained from the subject teacher                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                            |                                                            |                                    |
| <b>Comment</b>                                                                                                                                                                                             |                                                                                                                                                                                                                                                                |                                                            | Does not have                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                            |                                                            |                                    |
| <b>Grade:</b>                                                                                                                                                                                              | F                                                                                                                                                                                                                                                              | E                                                          | D                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | C                                                          | B                                                          | A                                  |
| <b>Number of points</b>                                                                                                                                                                                    | less than 50 points                                                                                                                                                                                                                                            | greater than or equal to 50 points and less than 60 points | greater than or equal to 60 points and less than 70 points                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | greater than or equal to 70 points and less than 80 points | greater than or equal to 80 points and less than 90 points | greater than or equal to 90 points |