

2023/2024. ACADEMIC YEAR							
PROGRAM OF STUDY (FOR STUDENTS OF 5TH YEAR)							
Full (Hun) name of the subject: Klinikai farmakokinetika és biofarmácia (elmélet+gyakorlat)							
Program: Undivided program (pharmaceutical)							
Schedule: full-time							
Short name of the subject:							
English name of the subject: Clinical Pharmacokinetics and Biopharmacy (theory+practice)							
German name of the subject: Klinische Pharmakokinetik und Biopharmazie (Vorlesung+Praktikum)							
Type of registration: obligatory/obligatory elective/elective/criteria requirement							
Neptun code of the subject: GYKGYI097E1A							
Responsible Department: Semmelweis University, Department of Pharmaceutics							
Responsible tutor Prof. Antal István				Title, academic degree: professor, Dr. habil			
Contact information: - phone: 061-217-0914 - email: antal.istvan@semmelweis.hu							
Name of the persons responsible for the teaching of the subject: Prof. Antal István Prof. Balogh György Prof. Klebovich Imre Dr. Ludányi Krisztina Bertalanné dr. Balogh Emese Dr. Lengyel Miléna Dalmadiné dr. Kiss Borbála Dr. Farkas Dóra Dr. Király Márton Dr. Kohod Zsófia				Title, academic degree: university professor, PhD, habilitated doctor university professor, PhD, habilitated doctor Professor emeritus, Doctor of MTA associate professor, PhD assistant professor, PhD assistant professor, PhD research associate, PhD assistant lecturer, PhD assistant lecturer, PhD teaching resident, PharmD			
Class per week: 2 hours lectures 3 hours practices				Credit point(s): 4 credits			
Professional content, intent of acquirement and it's function in order to implement the goals of the program: The aim of the subject to provide the students with theoretical knowledge and practical skills in the field of biopharmacy and pharmacokinetics.							
Short description of the subject: The course focuses on the therapeutical response and relationships between the fate of the drug in the body, the time course of drug action and intensity and the physico-chemical properties of the drug as well as the dosage form. The evaluation needs the pharmacokinetic interpretation of processes in the body (drug absorption, distribution, metabolism and excretion) as well as qualitative and quantitative description of the time course changes regarding also clinical considerations. During the practical training students perform tasks using in vitro and in vivo methods and bioanalytical procedures. Furthermore they learn the mathematical calculations of pharmacokinetic parameters and computer simulations.							
Course data							
Recommend ed term	Contact hours (lecture)	Contact hours (practice)	Contact hours (seminar)	Individual lectures	Total number of contact hours/semester	Normal course offer	Consult ations
9th semester						Autumn semester* Spring semester Both semesters (* Please underline)	

Program of semester**

Topics of theoretical classes (pro week):

1. The importance of clinical pharmacokinetics and biopharmaceutics. Fate and characterisation of the drug in the body.
2. Release of active ingredients and practical significance of the Biopharmaceutical Classification System
3. Absorption and transport processes.
4. Metabolism and its biopharmaceutical implications. Significance of bioanalytics.
5. Elimination, excretion processes and influencing factors.
6. Pharmacokinetic models and parameters, analysis I.
7. Pharmacokinetic models and parameters, analysis II.
8. Bioavailability, bioequivalence, biosimilarity.
9. Pharmacokinetic studies in drug discovery and development
10. Biopharmaceutical and pharmacokinetic studies, in vitro and in vivo correlation.

Topics of practical classes (pro week):

1. Study of the distribution of salicylic acid in a three-phase liquid bridge model. Effect of surfactant on transport processes.
2. Investigation of the drug release rate of diclofenac-containing tablets using a rotary basket method
3. Investigation of drug release of topical ointment under in vitro conditions. Study of drug penetration from a semi-solid dosage form using a device based on Franz cell theory.
4. Study of diclofenac release from drug patch.
5. Study of urinary excreted acetylsalicylic acid (ASA) in different suppositories.
6. Study of the drug content of plasma samples following iv administration of theophylline in beagle dogs. Mid-term I.
7. Study of the recoverability of diclofenac sodium in synovial fluid.
8. Plasma samples after per os administration of theophylline tablets in beagle dogs.
9. Pharmacokinetic calculations. Mid-term II.
10. Application of computational methods in biopharmacy and pharmacokinetics. Substitution, retake, consultation

Other subjects (both compulsory and optional) relating to the transversal issues of the subject. Possible overlaps between subjects:

Schedule of consultations: on request

Course requirements

Prerequisites:

Pharmacology and Toxicology III.
Pharmaceutical Technology IV.

Conditions of attending the classes, amount of acceptable absents, way of presentation of leave, opportunity for makeup:

Max. 25% absence is accepted.

The grading method; the conditions for getting the signature; the number, topic(s) and date(s) of the mid-term assessments, (reports, term tests), and the process in which they contribute to the final grade; and the possibility of their retake or their upgrading retake (as provided in §§ 25-28 of the STUDY AND EXAMINATION REGULATIONS):

Written mid-term report in weeks 7 (theory, background, counting of in vitro exercises) and 10 (theory, background, counting of in vivo exercises).

Retake and corrections are possible in week 10 and week 1 of the exam period. at an agreed time. The result of the corrected mid-term will overwrite the original grade.

The practical retake (optional) is in week 10 and week 1 of the exam period.

<p>Requirements of signature(as provided for in STUDY AND EXAMINATION REGULATIONS § 29): The course culminates in an oral colloquium and is taught through theoretical lectures (2 hours per week for 10 weeks) and 3 hours per week of practicals. Both written mid-terms must reach at least. 50.00%.Min. 50.00% of the written reports have to be accepted. A maximum of 25% of the absences, as specified in the Study Regulation.</p>
<p>Number and type of projects students have to perform independently during the semester and their deadlines: Written reports of the practices have to be submitted by the end of week of practice (Sunday 23:59)</p>
<p>Type of the semester-end examination: <u>signature</u>*/practical grade*/ comprehensive examination*/final/end-term examination* Examination requirements: as published by the education-research department on the MOODLE interface by the start of the academic term.</p>
<p>Form of the semester-end examination: written*/oral*/combined examination/practical examination/the assessment of completing project work (according to STUDY AND EXAMINATION REGULATIONS 30.§)* (<i>Please underline</i>) The exam has written and oral parts. Written part: calculation* based on practical tasks and reports (accepted/ not accepted). Oral part: Theoretical topic, Practical topic* Definition* (accepted/not accepted) Innovative dosage form (pharmacokinetics)</p>
<p>The possibility and conditions for offering grades: parts of exam marked with * can be offered as follows: The calculation can be offered based on the result of the practical reports. The practical topic is accepted as a 5 when min 90.00% as a 4 when min 80.00% of mid-terms are reached.</p>
<p>A list of the basic notes, textbooks, resources and literature that can be used to acquire the knowledge necessary to master the curriculum and to complete the assessments, ****with exact description about which of them is required to acquire which part of the syllabus (e.g. description based on topics)), as well as the main technical and other aids and study aids that can be used: The lecture slides are available for the students. Michael E. Aulton, Kevin Taylor: Aulton's Pharmaceutics: The Design and Manufacture of Medicines, Elsevier Health Sciences, 2013 James Swarbrick, Marcel Dekker Encyclopedia of Pharmaceutical Technology, Second Edition - Volume 1 of 3, 2002 Remington Pharmaceutical Sciences, Ed. 20. (Easton, Pennsylvania, 1999) Rácz, I.: Drug formulation. (Wiley, New York, 2001.)</p>
<p>In the case of a subject lasting more than one semester, the position of the teaching/research department on the possibility of parallel enrolment and the conditions for admission****: <u>yes</u>*/<u>no</u>*/on and individual assessment basis* (<i>Please underline</i>)</p>
<p>The course description was prepared by: Dr. István Antal</p>