

2023/2024. ACADEMIC YEAR	
PROGRAM OF STUDY (FOR STUDENTS OF 4TH YEAR)	
Full (Hungarian) name of the subject: Biológiai gyógyszerek (elmélet)	
Program: Undivided program (pharmaceutical)	
Schedule: full-time	
Short name of the subject:	
English name of the subject: Biological Drugs (theory)	
German name of the subject: Biopharmazeutika (Vorlesung)	
Type of registration: obligatory/obligatory elective/elective/criteria requirement	
Neptun code of the subject: GYKGYI088E1A	
Responsible Department: Semmelweis University, Department of Pharmaceutics	
Responsible tutor Dr. Krisztina Ludányi Contact information: - phone: 36 1 476-3600/53017 - email: ludanyi.krisztina@semmelweis.hu	Title, academic degree: associate professor, PhD
Name of the persons responsible for the teaching of the subject: Dr. István Antal Dr. Romána Zelkó/Dr. Szilvia Sebők Dr. Borbála Dalmadi-Kiss Dr. Katalin Baranya-Ganzler (Richter G. Plc.) Dr. László Drahos (ELKH TTK Research Centre for Natural Sciences, MS Proteomics Research Group) Dr. Ádám Fizil/Dr. Zoltán Szakács (Richter G. Plc.) Dr. Erik Bogsch/Dr. László Tóth (Richter G. Plc.) Dr. Veronika Harmat/Dr. Zsolt Dürvanger (ELTE Institute of Chemistry) Tímea Erdősi (National Public Health Centre) Dr. Hilda Kószegi-Szalai, OGYÉI	Title, academic degree: professor, PhD professor, DSc research fellow, PhD scientific advisor, PhD senior research fellow, research group leader, PhD PhD director, PhD/ HoD, PhD senior lecturer, PhD/ research fellow, PhD honorary associate professor, PhD
Class per week: 2 hour lecture(s)	Credit point(s): 2 credits
Professional content, intent of acquirement and it's function in order to implement the goals of the program: The aim of the course "Biological drugs" is to give the student an overview of macromolecules important in biological therapy, their production, official regulation of marketing and the most commonly used analytical techniques for qualitative and quantitative determination, especially the methods used in the development and manufacture (quality control) of biological preparations.	
Short description of the subject: The course summarizes the possibilities of the production and introduction of biologics, biosimilar preparations, its regulation for official licensing, as well as the sample preparation (digestion, enrichment, etc.), separation techniques (chromatography, electrophoresis), spectroscopy (MS, NMR, CD, fluorescence, X-ray diffraction, etc.), molecular biological methods (PCR, Elisa, etc.) reviews the research results in the fields of quantification, and the challenges of the clinical application of the biological drugs.	
Course data	

Recommended term	Contact hours (lecture)	Contact hours (practice)	Contact hours (seminar)	Individual lectures	Total number of contact hours/semester	Normal course offer	Consultations
7th semester	2	0	0	0	28	Autumn semester* Spring semester Both semesters (* Please underline)	--

Program of semester**

Topics of theoretical classes (pro week):

1. Definitions, structure, properties (biologics, biosimilar drugs)
2. Grouping of biological drugs, industrial aspects
3. Possibilities of the administration of biological drugs, aspects of formulation and technological aspects of quality
4. Pharmacokinetic properties of biological drugs
5. Regulation and authorization of biological medicinal products
6. Proteins produced by recombinant technology
Monoclonal antibodies
7. Advanced therapy medicinal products: gene therapy, cell therapy, tissue engineered products
8. Qualitative characterization of biological drugs: Molecular biological techniques (Elisa, Westernblot, immunoprecipitation, PCR, microarray)
9. Qualitative characterization of biological drugs:
Sample preparation (extraction, cell extraction, solubilisation, digestion, purification/enrichment, filtration)
Separation techniques (chromatography: IEX, RP-HPLC, HILIC, nanoLC, 2D; gel and capillary electrophoresis)
Spectroscopic methods: fluorescence, UV-VIS, infrared, CD
10. Qualitative characterization of biological drugs: Mass spectrometry: LC-MS/MS, MALDI-MS, imaging, lab-on-a-chip
Protein sequencing: bottom up / top down, peptide sequencing, post-translational modifications (glycosylation)
11. Qualitative characterization of biological drugs: Nuclear magnetic resonance analysis
12. Structure determination by protein crystallography technique, cryo-electron microscope
13. Quantitative characterization of proteins
14. Aspects of the clinical application of biological drugs

Topics of practical classes (pro week):

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

Biochemistry, Biotechnology, Pharmacology, Pharmaceutical chemistry, Instrumental drug analysis

There is no overlap

Schedule of consultations: According to individual student demand, at an agreed time.

Course requirements

Prerequisites:

Pharmaceutical Chemistry II.

Pharmacology and toxicology I.

Biotechnology

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

according to the Examination and Studies Regulation

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):

Requirements of signature (as provided for in STUDY AND EXAMINATION REGULATIONS § 29):

Number and type of projects students have to perform independently during the semester and their deadlines:

Type of the semester-end examination: signature*/practical grade*/semi-fnal*/final* (*Please underline*)

Examination requirements: as published by the education-research department on the MOODLE interface by the start of the academic term.

Topic list:

1. Definitions, structure, properties (biological drugs, biosimilar medicines)
2. Grouping of biological drugs, industrial aspects
3. Possibilities of introducing biological drugs into the body, aspects of formulation
4. Technological aspects of quality
5. Pharmacokinetic properties of biological drugs
6. Regulation and authorization of biological medicinal products
7. Proteins produced by recombinant technology (grouping, expression strategies, production)
8. Monoclonal antibodies, structure-effect relationship, design, production and quality assurance
9. Advanced therapy medicinal products: gene therapy, cell therapy, tissue engineered products
10. Application of Elisa, Western blot, immunoprecipitation, microarray in the analysis of biological substances
11. PCR and its application in the analysis of biologicals
12. Sample preparation: extraction, cell extraction, solubilization, digestion, purification / enrichment, filtration
13. Separation techniques: chromatography, electrophoretic methods in the production and characterization of biologicals
14. Mass spectrometry: LC-MS/MS, MALDI-MS, imaging, protein sequencing (bottom up/top down, determination of peptide sequence), post-translational modifications (glycosylation)
15. Nuclear magnetic resonance analysis (de novo structure determination, verification of higher order structural similarity based on spectral fingerprinting, 2D spectra, ligand-detected NMR protein binding studies)
16. Application of protein crystallography and cryo-electron microscope in the analysis of biological substances
17. Quantitative characterization of proteins
18. Aspects of the clinical use of biological drugs

Form of the semester-end examination: written*/oral*/combined examination/practical examination/the assessment of completing project work (according to STUDY AND EXAMINATION REGULATIONS 30.5)* (*Please underline*)

The possibility and conditions for offering grades:

Conditions for offering an exam mark:

- correctly answering five questions at the end of the lectures (the questions are related to the material of the lecture that day)
- the student have to be present at 75 % of lectures
- at the end of the semester, the offer of a mark is determined based on the overall result in accordance with the the Examination and Studies Regulation: "(a) students who achieve the top 10% can terminate the subject with excellent grade,(b) students who achieve the top 10.1-20% can receive an offer of a mark with a good grade"

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:**

Slides presented at lectures

Recommended literatures:

- K. Vékey, A. Telekes, A. Vertes: Medical Applications of Mass Spectrometry, Elsevier, 2006
L. Endrényi, P. J. Declerck, S. C. Chow: Biosimilar drug product development, CRC Press, 2017
K. M. Nagel: Introduction to Biologic and Biosimilar Product Development and Analysis, Springer, 2018
R. Sheets: Fundamentals of Biologicals Regulation:Vaccines and Biotechnology Medicines, Elsevier, 2017

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**:**

yes*/no*/on and individual assesment basis* (*Please underline*)

The course description was prepared by:

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