

<b>2023/2024. ACADEMIC YEAR</b>	
<b>PROGRAM OF STUDY</b>	
<b>Full (Hungarian) name of the subject:</b> GYÓGYSZER-TECHNOLÓGIA III. GYÓGYSZER-TECHNOLÓGIA (gyakorlat) III.	
<b>Program: Undivided program (pharmaceutical)</b>	
<b>Schedule:</b>	
<b>Short name of the subject:</b> Pharm. Tech.	
<b>English name of the subject:</b> Pharmaceutical Technology (theory) III. Pharmaceutical Technology (practice) III.	
<b>German name of the subject:</b> Pharmazeutische Technologie III.	
<b>Type of registration: obligatory/obligatory elective/elective/criteria requirement</b>	
<b>Neptun code of the subject:</b> GYKGYI249E3A (lecture) GYKGYI249G3A (practice)	
<b>Responsible Department:</b> Department of Pharmaceutics	
<b>Responsible tutor</b> Dr. István Antal <b>Contact information:</b> <b>phone:</b> +36-1-217-0914 <b>email:</b> antal.istvan@semmelweis.hu	<b>Title, academic degree:</b> Professor, Ph.D., Habil.
<b>Name of the persons responsible for the teaching of the subject:</b> Dr. István Antal Dr. Nikolett Kállai-Szabó Dr. Krisztina Ludányi Dr. Emese Bertalan-Balogh Dr. Lívia Budai Dr. Mária Hajdú Dr. Miléna Lengyel Dr. Borbála Dalmadi-Kiss Dr. Dóra Farkas Dr. Andrea Kovács Dr. Nóra Mike-Kaszás Dr. Noémi Anna Niczinger Dr. Márton Király Dr. Petra Szalkai	<b>Title, academic degree:</b> Professor, Ph.D., Habil. Associate professor, Ph.D. Associate professor, Ph.D. Senior lecturer, Ph.D. Senior lecturer, Ph.D. Senior lecturer, Pharm.D. Senior lecturer, Ph.D. Research scientist, Ph.D. Assistant lecturer, Ph.D. Assistant lecturer, Ph.D. Assistant lecturer, Ph.D. Assistant lecturer, Ph.D. Assistant lecturer, Pharm.D. Assistant lecturer, Pharm.D.
<b>Class per week:</b> lectures: <b>2</b> hours/week practices: <b>8</b> hours/week	<b>Credit point(s):</b> theory: <b>2</b> credits practice: <b>5</b> credits
<b>Professional content, intent of acquirement and its function in order to implement the goals of the program:</b> The aim of the Pharmaceutical Technology course is to provide the student with the theoretical knowledge and practical skills necessary for the basic professional activity of a pharmacist, the preparation of pharmaceuticals.	
<b>Short description of the subject:</b> The subject covers the theoretical and practical knowledge required for the preparation of medicinal products. An overview of the history of pharmaceutical preparation. Pharmaceutical technology aspects of ensuring efficacy, quality requirements for the pharmaceutical formulation. Tasks and conditions of pharmaceutical preparation, basic operations. Individual (magistral) and factory production of pharmaceuticals. Aspects, excipients, quality requirements for formulation of medicinal products. Identification and resolution of possible incompatibilities of ingredients, compatibility, stability.	

<b>Course data</b>							
<b>Recommended term</b>	<b>Contact hours (lecture)</b>	<b>Contact hours (practice)</b>	<b>Contact hours (seminar)</b>	<b>Individual lectures</b>	<b>Total number of contact hours/semester</b>	<b>Normal course offer</b>	<b>Consultations</b>
7. semester	28	112	--	--	140	<u>Autumn semester*</u> Spring semester Both semesters (* Please underline)	--

**Program of semester\*\***

**Topics of theoretical classes (pro week):**

1. Introduction. The task, history, and evolution of pharmaceutical manufacturing.
2. Engineering principles of pharmaceutical manufacturing, scale-up, in-process control, critical quality attributes and process parameters.
3. Pharmaceutical development. Preformulation, formulation.
4. Packaging materials and operations, shelf life and stability aspects.
5. Drug stability and stabilization, stability testing.
6. Pharmaceutical technology operations and procedures: Particle size reduction, milling, grinding. Mixing, dispersing.
7. Pharmaceutical technology operations and procedures: Heat transfer, evaporation, distillation. Filtration, sedimentation, centrifugation, extraction.
8. Pharmaceutical technology operations: Crystallization, polymorphism. Amorphization.
9. Pharmaceutical technology operations: Drying. Fluidization.
10. Pharmaceutical technology operations: Spray drying. Freeze drying (lyophilization).
11. Conditions for pharmaceutical production, GMP. Safety aspects.
12. Parenteral medicinal products. Sterile pharmaceutical production.
13. Small-volume parenteral preparations, solution and suspension type injections. Additives.
14. Large-volume parenteral preparations. Development of sterile preparations.

**Topics of practical classes (pro week):****Pilot practices**

Study on the drying process  
Study on the filtration process  
Study on the mixing process\*  
Study on the fluidization  
Study on particle size reduction\*  
Preparation of suspensions. Suppository replacement factor  
Preparation and stability examination of emulsions\*  
Study on compression\*  
IPC for solid dosage forms

**Parenteral practices**

Preparation and examinations, IPC control of infusions (carbohydrate containing, electrolyte containing, infusions against acidosis)\*  
Study of infusion bottles  
Study of the Laminar air flow technology  
Autoclaving, autoclaving indicators\*  
Isotonization\*

**Chemical practices**

Study of the stability of penicillin containing solutions in the presence of other medicinal substances  
Study of the catalytic oxidation of ascorbic acid solutions\*  
In vitro investigation of the acid binding capacity of thermolabile aluminium hydroxide gels  
Testing the activity of antacid formulations with Rossett-Rice method  
Investigation of ASA content decreasing due to moisture in solid drug preparation\*  
Preparation of a KCl-containing capsule composition\*  
Preparation and encapsulation efficiency of theophylline-containing microcapsules  
Encapsulation of tocopheryl acetate into liposomes  
Study of the interaction of ASA and caffeine  
Project work: development of a biorelevant dissolution study

**Physical practices**

Water purification\*  
Studies on ion exchange resins\*  
Effect of pH on the solubility of drugs  
Evaluation of macromolecular colloids by viscometry\*  
Effect of permittivity on the solubility of salicylic acid  
Hydrotropic auxiliary materials. Solubilization of volatile oils by Tweens\*  
Effect of excipients on droplet number and surface tension of pharmaceutical preparations\*  
Analysis of the rheological behavior of hydrogels: effect of the pH  
Analysis of the rheological behavior of hydrogels: effect of electrolytes  
Determination of critical micelle concentration (CMC) of pharmaceuticals  
Measuring the sun protection effect of oily products by spectrophotometry, Study on the particle size distribution of suspensions by Andreasen's device, Determination of sedimenting velocity by Wiegner tube  
Formulation lecture: -technical background, -composition, -production elaboration

Completion of the practices marked with an asterisk\* is a condition of signature. In the case of absence from other practices, an oral report must be made by arrangement.

**Schedule of consultations:** Upon request, individually.

***Course requirements*****Prerequisites:**

Pharmaceutical technology II.

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

- Meet at least 75% attendance and participation requirement per lab for practical sessions
- In the event of late arrival (10 minutes) the practice can only be started with the permission of the teacher. Further guidelines are provided by the Study and Examination Regulations.
- Completion of the exercises marked with an asterisk\* in the practical topics is a prerequisite for signature.
- In case of absence, complete the exercise in the make-up exercises. Make-ups are recommended, as the material is part of both the written reports, the semi-final and the final examination. In case of non-completion of the exercises not marked with an asterisk, an oral report of the practical material must be given by arrangement.
- It is not mandatory to make up the absences, but opportunity is provided to complete the exercise in the make-up exercises. Supplementation is recommended, as the course material is part of both midterms, the semi-final, and the final examination.
- Due to failure to meet the attendance requirements, the responsible tutor determines the conditions of the signature and the order of the possibility of making up.

**Number, topics and dates of tests during the semester, opportunities of makeup and improvement of results\*\*\*:**

	<b>Expected date</b>	<b>Expected date for retake 1</b>	<b>Expected date for retake 2</b>
<b>1st midterm</b>	October 10. (week 6) 14.30-16.00	October 17. (week 7) 14.30-16.00	December 11.
<b>2nd midterm</b>	November 28. (week 13) 14.30-16.00	December 5. (week 14) 15.30-17.00	December 11.

The written tests include the material of the practices, including the calculations.  
In the case of a rewrite, the result of the rewrite will override the result of the previous assessment.

The practical grade is determined based on the average of the % result of the midterms as follows:

90.00-100%	excellent (5)
80.00-89.99%	good (4)
65.00-79.99%	fair (3)
50.00-64.99%	pass (2)
0-49.99%	fail (1)

**Requirements of signature:**

- To obtain a signature the student must attend at least 75% of the practical sessions.
- Complete the practices marked with an asterisk\* in the practical topics.
- From the 6 pop tests at least 5 must be written and min. 50.00% must be reached in each laboratory.
- The student must achieve a minimum of 50.00% individually in each of the two midterms.
- The 4 moodle calculation tests must be successfully completed by the end of the semester (December 18, 2023, 12.00).
- Completion of project works.

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

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

**Examination requirements:**

**Theoretical topics:**

1. The task, development, and evolution of pharmaceutical manufacturing
2. Condition system of manufacturing. Good Manufacturing Practice (GMP)
3. Pharmaceutical development, formulation, and manufacturing process
4. Engineering principles of pharmaceutical manufacturing, basic operations
5. Basics of drug stability, types of changes
6. Stabilization of pharmaceutical products, stability testing
7. Packaging technology and packaging materials, patient centricity
8. Critical quality attributes and parameters, scaling up, optimisation
9. Heat transfer, evaporation, and distillation
10. Particle size reduction, grinding, sieving, micronisation, particle design
11. Mixing, homogeneity testing, dosing aspects
12. Drying, spray drying
13. Freeze drying (lyophilisation)
14. Separation operations, filtration, centrifugation, extraction
15. Importance and characteristics of polymorphic and amorphous materials
16. Crystallisation, amorphisation
17. Principles of the formulation of parenteral preparations
18. Formulation of injections, parenteral additives
19. Formulation of infusions, large volume parenteral preparations
20. Manufacturing of sterile preparations

**Modern dosage forms:**

1. Inhalation powder, pre-dispensed
2. Gene therapy medicine (infusion solution)
3. Inhalation powder, hard capsules
4. Concentrate for solution for infusion
5. Solution for infusion
6. Solution for injection
7. Nasal drops
8. Nasal spray solution
9. Eye drops, solution
10. Powder and solvent for solution for injection
11. Powder and solvent for prolonged-release suspension for injection
12. Powder for dispersion for infusion (albumin bound nanoparticles)
13. Sublingual spray
14. Nebuliser Suspension
15. Suspension for injection
16. Suspension for injection in vial
17. Pressurised Inhalation Suspension

**Calculations, practical knowledge, excipients and definitions:**

as published by the department on the MOODLE interface by the start of the academic term.

**Form of the semester-end examination:** written\*/oral\*/combined examination\* (*Please underline*)

- Written part:
  - Calculation (assessment on a two-point scale: pass/fail)
  - Practical knowledge (assessment on a five-point scale)
  - Excipients (assessment on a five-point scale)
- Oral part:
  - Theoretical topic (assessment on a five-point scale)
  - Definition (assessment on a two-point scale: pass/fail)
  - Modern dosage form (assessment on a five-point scale)

**The possibility and conditions for offering grades:**

Exemption from subsections or partial grade may be offered for certain parts of the examination based on the mid-semester performance in the following ways:

Definitions: At the lectures, there will be a non-compulsory short assessment ("slip") of the knowledge presented that day, which results in exemption from the definition subsection of the oral part if the student completes at least 75%.

Practical knowledge:

Based on the performance on the pop tests – if the average is

- min. 80.00%, a good grade (4),
- min. 90.00%, an excellent grade (5) is offered for the practical topic.

Excipients: 2 prearranged times during the semester, in the form of a test, based on the overall result:

- min. 80.00%, a good grade (4),
- min. 90.00%, an excellent grade (5) is offered for the excipient topic.

**Scientific, course related research, publications, essays:**

The lecture materials, the supplementary material for the excipients and the practical work are available in electronic form on Moodle.

**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 an individual assessment basis\* (\* Please underline)

**The course description was prepared by:**

Dr. István Antal