

2023/2024. ACADEMIC YEAR	
PROGRAM OF STUDY	
<b>Full (Hungarian) name of the subject:</b> GYÓGYSZER-TECHNOLÓGIA IV. GYÓGYSZER-TECHNOLÓGIA (gyakorlat) IV.	
<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) IV. Pharmaceutical Technology (practice) IV.	
<b>German name of the subject:</b> Pharmazeutische Technologie IV.	
<b>Type of registration:</b> <u>obligatory</u> /obligatory elective/elective/criteria requirement	
<b>Neptun code of the subject:</b> GYKGYI249E4A (lecture) GYKGYI249G4A (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, PharmD. 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>6</b> credits practice: <b>4</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>Recommend ed term</b>	<b>Contact hours (lecture)</b>	<b>Contact hours (practice)</b>	<b>Contact hours (seminar)</b>	<b>Individu al lectures</b>	<b>Total number of contact hours/sem ester</b>	<b>Normal course offer</b>	<b>Consult ations</b>
8. semester	28	112	--	--	140	Autumn semester* <b>Spring semester</b> Both semesters (* Please underline)	--
<b>Program of semester**</b>							
<b>Topics of theoretical classes (pro week):</b> <ol style="list-style-type: none"> <li>1. Development of solid pharmaceutical forms, solid state characterization I. Excipients.</li> <li>2. Particle systems, granules</li> <li>3. Capsules</li> <li>4. Tablets I.</li> <li>5. Tablets II.</li> <li>6. Coating</li> <li>7. Modern dosage form design: testing and evaluation of drug release profile; modified drug release; tablets</li> <li>8. Modern dosage form design: improvement of dissolution and solubility</li> <li>9. Modern dosage form design: transdermal and other therapeutic systems.</li> <li>10. Molecular pharm. tech. microfabrication, nanotechnology, delivery of biopharmaceuticals Liposomal preparations.</li> <li>11. Formulation of biological drugs.</li> <li>12. Modern dosage form design: the role of the quality of excipients; patient-centered drug release systems</li> <li>13. Pharmaceutical technology and quality assurance. Quality by Design, PAT, nondestructive analysis</li> <li>14. Radiopharmaceuticals. Other preparations. Medical aids.</li> </ol>							

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

Production of solutions on an industrial scale, testing  
Production of ointments on an industrial scale, testing\*  
Production of suppositories on an industrial scale, testing\*  
Aspects of evaluation of dissolution tests, methods of comparing profiles  
Production of granules, testing\*  
Production of pellets, testing\*  
Production of tablets, testing\*  
Production of coated dosage forms, testing\*  
Digital technology (3D printing)

**Parenteral practices**

Preparation, IPC testing of injections\*  
Study and testing of membrane filters\*  
Isotonization\*  
Study and tests of aerosols  
Study and tests of foams  
Ampule filling, closure  
Lyophilization

**Chemical practices**

Study of the interaction of methyl p-hydroxybenzoate (methylparaben) and macromolecules  
Maillard reaction: interaction between primary and secondary amines (caffeine) and lactose  
HPLC study of Ciprofloxacin containing film-coated tablet in milk (SPE sample preparation)  
Hydrolytic resistance testing of pharmaceutical vials  
Quality testing of plastic containers  
Examination of extractable and leachable compounds: determination of ethyl 3-ethoxy propionate from the preparation/packaging material  
Identification of potentially leachable and/or extractable substances  
Method validation: precision, determination of linearity range (for E&L testing)  
Measurement validation: accuracy, specificity, limit of detection (for E&L test)

**Physical practices**

Determination of slip point and dropping point for suppository vehicles and ointment bases  
Examination of the compression strength and disintegration time of suppositories; Studies on vehicles of ointments and suppositories with penetrometry  
Softening point determination of ointments and suppository vehicles; Determination of the congealing point of vehicles  
Study of the temperature dependence of viscosity  
Homogeneity of active ingredient distribution in suppositories\*  
Examination of drug release from suppositories  
Preparation of suppositories by the Münzel method and their pharmacopoeial control tests  
Statistical evaluation of uniformity of mass of single-dose uncoated capsules\*  
Examination of polymorph crystals  
Examination of drug release from tablets in the presence of activated charcoal  
Determination of the real density of granules; Examinations of granules and powders\*  
Factors affecting the drug release of pharmaceutical dosage forms in connection with the application\*

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 III.

**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\*\*\*:**

	Expected date	Expected date for retake 1	Expected date for retake 2
<b>1st midterm</b>	week 6	week 7	1 <sup>st</sup> week of exam period
<b>2nd midterm</b>	week 12	week 13	1 <sup>st</sup> week of exam period

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 per lab.
- 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.
- 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**

- Quality requirements, principles and control methods for medicinal products (e.g. Ph.Hg. VIII General Chapters 1. Principles and 2. Importance of analytical methods).
- Preformulation and formulation, aspects of formulation development. Salt selection, importance of polymorphic and amorphous materials, structure analysis, biopharmaceutical aspects.
- Importance of compatibility, testing. Physical and chemical incompatibilities in pharmaceutical technology.
- Production of stable pharmaceutical formulation, drug stability and testing. Unwanted physical, chemical, microbiological changes during shelf life of drugs. Options for stabilisation.
- Preparatory and basic operations in the manufacture of pharmaceuticals, significance.
- Particle size: significance, reduction, testing.
- Packaging, packaging materials. Testing.
- Technical fundamentals of pharmaceutical manufacturing, scale-up, in-process control, critical quality characteristics and process parameters.
- Technological aspects of pharmaceutical manufacturing and quality, conditions. GMP, authorised person. planned quality (QbD). process analytical technology (PAT).
- Preparation and testing of solution preparations.
- Emulsion preparation and quality control (HLB concept, surfactants).
- Preparation and quality control of suspensions.
- Extraction operation, preparation and testing of a preparation containing extracts.
- Preparation and quality control of ophthalmic, otological and nasal preparations.
- Preparation and testing of sterile preparations (aseptic drug preparation, clean room and isolation techniques, sterilisation, pyrogen-free, parametric release).
- Formulation of injections, parenteral additives.
- Formulation of infusions, large volume parenteral preparations.
- Preparation and quality control of rectal and vaginal preparations. Medicinal sticks.
- Manufacturing and quality control of dermal formulations.
- Preparation and quality control of inhalation formulations, aerosols.
- Preparation and quality control of powders, granules for ingestion.
- Preparation and quality control of pharmaceutical pellets. Medicinal chewing gum.
- Preparation and quality control of capsules.
- Preparation and quality control of tablets.
- Production and quality control of film-coated formulations.
- Modified release formulations. Pharmaceutical technology options and testing of drug delivery. Patient-centric drug delivery systems.
- Manufacturing and quality control of transdermal formulations.
- Production and quality control of enhanced bioavailability formulations (dissolution and absorption promotion, solubilisation, complexation).
- Preparation and quality control of colloidal nanoparticle delivery systems.
- Formulation aspects and quality control of biological drug formulation.

### **Modern dosage forms**

- Inhalation powder, pre-dispensed
- Dragee
- Gene-therapy medicine (infusion solution)
- Gastroresistant hard capsule
- Gastroresistant tablet
- Inhalation powder, hard capsule
- Injection
- Concentrate for solution for infusion
- Soft capsule
- Modified-release film-coated tablets
- Solution for infusion
- Solution for injection

- Nasal spray solution
- Nasal drops
- Osmotic, retard film-coated tablet
- Prolonged release tablet with pellets
- Powder and solvent for solution for injection
- Powder and solvent for prolonged-release suspension for intramuscular injection
- Powder for dispersion for infusion (albumin nanocarrier)
- Prolonged-release film-coated tablet
- Prolonged-release hard capsule
- Retard tablets
- Orodispersible granules
- Orodispersible tablet
- Sublingual spray
- Eye drops, solution
- Suspension for injection
- Suspension for injection in cartridges
- Transdermal patch
- Pressurised suspension for inhalation

**Calculations, practical examination topics, 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*)

- Practical examination (assessment on a five-point scale)
- Written part:
  - Calculation (assessment on a two-point scale: pass/fail)
  - 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:

Practical examination: Partial grade can be offered in two ways: either by achieving an outstanding result in the student competition, or by meeting the following conditions:

- Excellent (5) grade is offered if:
  - the practical grade in the previous semester is 5 AND
  - the result of the pop-tests in the 2nd semester is at least 90.00%.
- Good (4) grade is offered if:
  - the practical grade in the previous semester is at least 4 AND
  - the result of the pop-tests in the 2nd semester is at least 80.00%.

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%.

Calculation: If the student completes 5 of the 6 slips correctly in the lectures of week 2-7, the calculation can be passed early, on week 8.

Excipients: Based on the performance in the related 45-minute consultations.

**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