

2023/2024. ACADEMIC YEAR

PROGRAM OF STUDY

Full (Hungarian) name of the subject: GYÓGYSZER-TECHNOLÓGIA I.							
Program: Undivided program (pharmaceutical)							
Schedule:							
Short name of the subject: Pharm. tech. I.							
English name of the subject: Pharmaceutical Technology (theory+practice) I							
German name of the subject: Pharmazeutische Technologie I.							
Type of registration: <u>obligatory</u> /obligatory elective/elective/criteria requirement							
Neptun code of the subject: GYKGYI249G1A							
Responsible Department: Department of Pharmaceutics							
Responsible tutor Dr. István Antal Contact information: phone: +36-1-217-0914 email: antal.istvan@semmelweis.hu				Title, academic degree: Professor, Ph.D., Habil.			
Name of the persons responsible for the teaching of the subject: Dr. István Antal Dr. Nikolett Kállai-Szabó Dr. Mária Hajdú Dr. Miléna Lengyel Dr. Lívia Budai Dr. Noémi Anna Niczinger Dr. Dóra Farkas Dr. Nóra Mike-Kaszás Dr. Petra Szalkai				Title, academic degree: Professor, Ph.D., Habil. Associate professor, Ph.D. Senior lecturer, Pharm.D. Senior lecturer, Ph.D. Senior lecturer, Ph.D. Assistant lecturer, Ph.D. Assistant lecturer, Ph.D. Assistant lecturer, Ph.D. Assistant lecturer, Pharm.D.			
Class per week: lectures: 2 hours/week practices: 3 hours/week				Credit point(s): 5 credits			
Professional content, intent of acquirement and its function in order to implement the goals of the program: 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.							
Short description of the subject: 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.							
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
5. semester	28	42	--	--	70	<u>Autumn semester*</u> Spring semester Both semesters (* Please underline)	--

Program of semester**

Topics of theoretical classes (pro week):

1. The scope of pharmaceutical technology. Technological aspects of medicinal product quality. Preparation of pharmaceutical dosage forms, basic operations.
2. Magistral products. Quality standards. Pharmacopoeia Hungarica Ph. Hg. VIII and Formulae Normales (FoNo VIII). Basics of pharmaceutical compounding (books, instruments, signatures).
3. Fundamentals of the physical chemistry of pharmaceutical technology.
4. Properties of pharmaceutical substances (active substances and excipients) and packaging materials, containers.
5. Technological operations I. (weighing, distillation, ion exchange, reverse osmosis, dissolution, filtration, separation, decantation, centrifugation).
6. Technological operations II. (heat transfer, drying, mixing, homogenisation, grinding).
7. Liquid dosage forms. Solutions and solubility. Solubility and dissolution rate. Excipients for liquid dosage forms. Operation of solution preparation.
8. True solutions, colloidal solutions, aromatic waters, syrups, mucilages. Elixirs, mixtures, gargles. Rectal solutions (klyisma, enema).
9. Droplet dosage forms. Drops for ingestion (gutta). Drops for external use (oto-nasogutta).
10. Technology of ophthalmic preparations.
11. Preparations prepared by extraction. Extraction and influencing factors. Tinctures, extracts, decoctions, infusions, tea mixtures.
12. Sterilization, aseptic drug preparation in the pharmacy.
13. Storage of medicines. Packaging materials used in pharmacy and their quality requirements.
14. Personalised prescription of medicines. Problems encountered when ordering and preparing liquid dosage forms and how to solve them.

Topics of practical classes (pro week):

1. Laboratory regulations, safety rules. Study requirements, syllabus. Basics of pharmaceutical compounding, introduction to basic operations in pharmaceutical technology.
2. Basic operations in pharmaceutical technology I. Mixing, homogenization
3. Basic operations in pharmaceutical technology II.
4. Basic operations in pharmaceutical technology III. Filtration
5. Basic operations in pharmaceutical technology IV. Drying. Equipment for pharmaceutical compounding.
6. Weighing, scales. Rules of dose calculations, technical terms, nomenclature, synonyms. Prescription reading. Excipient knowledge. Rules of solution preparation. Preparation of simple and complex solutions.
7. Preparation of complex solutions. FoNo VIII. base solutions. Dilutio, trituratio. Magistral preparations. *Dose calculation test I.*
8. Supplementary practice. Consultation.
9. **1st midterm.** *Dose calculation test II.*
Preparation of new, modern liquid medicinal preparations.
Interpretation of the composition of marketed medicinal preparations I.
10. Preparation and dose calculation of drops. Determination of droplet number, droplet weight. Nasal and ear drops.
Preparation of gargles, enemas. Magistral preparations. *Dose calculation test III.*
11. General guidelines for eye drop preparation. Preparation of eye drops. Sterile filtration, membrane integrity testing. Determination of osmolality of eye drops. *Dose calculation test IV.*
12. Decoctions, infusions, elixirs, syrups, mixtures. Magistral preparations. Determination of viscosity of syrups and mucilages. *Dose calculation test V.*
13. **2nd midterm. Excipient test.** *Dose calculation test VI.*
Problems encountered during the preparation of magistral solutions. Solubility testing.
Interpretation of composition of marketed medicinal preparations II.
14. Supplementary practice. Consultation.

Schedule of consultations: During the semester 2 consultations are offered at pre-arranged times (during practice time). Further possibility is ensured upon request, individually.

Course requirements

Prerequisites:

Physiological Pharmaceutics and Pharmaceutical Dosage Forms
Nanotechnology
The Latin Basics of Pharmaceutical Technology

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 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.
- It is not mandatory to make up the absences, but opportunity is provided to complete the exercise in the make-up classes. Supplementation is recommended, as the course material is part of both the midterms, and later examinations.
- 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*:**

	Topics	Expected date	Expected dates for retakes	
1st midterm	Materials of week 1-8	31 October, 2023 (week 9) in class	week 10	11 December, 2023
2nd midterm	Materials from week 9-12 + excipient test	28 November, 2023 (week 13) in class	week 14	11 December, 2023

The written tests include the material of the practices, including the theoretical background, the related calculations, the prescriptions, and also the lectures.

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 midterms and the excipient test.

Dose calculation tests:

During the semester there will be 6 short dose counting tests in the practices (weeks 7 and 9-13). These are graded with 0 and 1 point respectively. Absences from the tests, for whatever reason, will be counted as 0 points.

To obtain a signature, at least 5 tests must be solved, and min. 5 points must be reached. In case of absence, the test can be made up in the make-up classes, and 2 tests can be corrected during the semester.

Requirements of signature:

Signature shall be granted upon the successful completion of all conditions:

- Meet at least 75% attendance and participation requirement per lab for practical sessions.
- The lab reports of the basic operations (week 2-5.) must be accepted (appropriate measurement data, calculations, evaluation, interpretation of the results).
- From the 6 dose calculation tests at least 5 must be written and min. 5 points must be reached.
- The student must achieve at least a pass grade (2) individually in each of the two midterms.
- Preparation of the following dosage forms: solutio, gutta, oculogutta, nasogutta, otogutta, gargarisma, klysma, syrup, elixirium.

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

--

<p>Type of the semester-end examination: signature*/<u>practical grade</u>*/semi-final*/final* (<i>Please underline</i>)</p> <p>Examination requirements: --</p>
<p>Form of the semester-end examination: written*/oral*/combined examination* (<i>Please underline</i>)</p>
<p>The possibility and conditions for offering grades:</p> <p>--</p>
<p>Scientific, course related researches, publications, essays:</p> <p>The lecture materials, the supplementary material for the excipients and the practical work are available in electronic form on Moodle.</p> <p><u>Additional literature:</u> European and Hungarian Pharmacopoeia</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****:</p> <p>yes*/no*/<u>on and individual assesment basis</u>* (<i>Please underline</i>)</p>
<p>The course description was prepared by:</p> <p>Dr. István Antal</p>