

| 2023/2024. ACADEMIC YEAR | | | | | | | |
|---|-------------------------------|--------------------------------|-------------------------------|---|---|--|-------------------|
| PROGRAM OF STUDY | | | | | | | |
| Full (Hungarian) name of the subject: GYÓGYSZER-TECHNOLÓGIA II. GYÓGYSZER-TECHNOLÓGIA (gyakorlat) II. | | | | | | | |
| Program: Undivided program (pharmaceutical) | | | | | | | |
| Schedule: | | | | | | | |
| Short name of the subject: | | | | | | | |
| English name of the subject: Pharmaceutical Technology (theory) II. Pharmaceutical Technology (practice) II. | | | | | | | |
| German name of the subject: Pharmazeutische Technologie II. | | | | | | | |
| Type of registration: <u>obligatory</u> /obligatory elective/elective/criteria requirement | | | | | | | |
| Neptun code of the subject: GYKGYI249E2A (lecture) GYKGYI249G2A (practice) | | | | | | | |
| 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. Livia 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: 6 hours/week | | | | Credit point(s): theory: 3 credits practice: 3 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) | Individu al lectures | Total number of contact hours/sem ester | Normal course offer | Consult ations |
| 6. semester | 28 | 84 | -- | -- | 112 | Autumn semester* Spring semester Both semesters (* Please underline) | -- |

Program of semester**

Topics of theoretical classes (pro week):

1. Liquid heterogeneous disperse systems: emulsions
2. Liquid heterogeneous disperse systems: suspensions
3. Topical preparations. Coherent systems.
4. Rheological properties of dermatological preparations, test methods, stability
5. Ointments, creams, gels, pastes
6. The importance of cosmetics in pharmacy practice
7. Rectal and vaginal dosage forms, preparations for use in body cavities. Medical sticks.
8. Pharmaceutical powders. Pills. Medicinal chewing gum
9. Veterinary medicinal products
10. Guidelines for the preparation of medicinal products in the event of incompatibilities I.
11. Guidelines for the preparation of medicinal products in the event of incompatibilities II.
12. Medical aids and dressings in pharmacy
13. Aerosols. Medicated foams.
14. Interpretation of composition of marketed medicinal preparations

Topics of practical classes (pro week):

Laboratory regulations, safety rules. Study requirements, syllabus.

Emulsions for internal and external use.

Preparation of suspensions without excipients

Preparation of suspensions with excipients

General guidelines for the preparation of ointments. Preparation of solution and emulsion type ointments.

Preparation of emulsion and suspension type ointments.

Preparation of complex ointments. Eye Ointments

Investigation of the water absorption capacity of lubricant base materials. Testing of emulsion lubricants. The role of emulsifiers (water retention test). Examination of the removable mass and volume of semi-solid preparations Ph. Hg. VIII (test of squeezability from tube)

General guidelines for the preparation of creams, hydrogels. Preparation of creams, gels. Testing the swelling capacity of gels. Testing gel setting time.

Aspects of the preparation of pastes. Preparation of pastes Determination of density of pastes

Preparation of cosmetics in the pharmacy. Ointments, creams. Consistency and rheological testing (viscosity measurement)

General principles of suppository preparation. Preparation of rectal suppositories by pressing. Preparation of rectal suppositories by moulding.

Calibration of suppositories moulds. Preparation of suppositories

Preparation of suspension, composite suppositories. Qualification of the suppositories produced, determination of individual and average weight. Determination of displacement factor

Preparation of vaginal dosage forms. Determination of the breaking strength of suppositories

General aspects of powder preparation. Production of undivided powders.

Preparation of divided powders, powder division. Deviation of individual mass from average mass.

Preparation of pills, boluses. Classification of the pills produced, determination of individual and average mass. Analysis of the disintegration of pills

Individual prescriptions from the hospital manual. Specialities in magistral medicine preparation

Guidelines for the preparation of veterinary medicinal products. Preparation of some veterinary medicinal products

General guide on dose calculation of divided pharmaceutical forms.

Independent practice I-II.

Medical aids in the pharmacy

Incompatibility problems in the pharmacy I-II.

Interpretation of composition of marketed medicinal preparations I-II.

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:**

Pharmaceutical technology I.

Pharmaceutical Chemistry I.

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 | emulsions, suspensions, ointments, creams, gels, pastes + excipient test | week 5-8 | week 5-8 | 1 st week of exam period |
| 2nd midterm | suppositories, pills, powders, incompatibilities + excipient test | week 12 | week 14 | 1 st week of exam period |
| Individual practice | emulsions, suspensions, ointments, creams, gel, pastes, suppositories, powders | week 13 | week 14 | 1 st week of exam period |

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

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. 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 for practical sessions.
- 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: emulsio, suspensio, unguentum, oculentum, cremor, gel, pasta, pulvis, suppositorium, ovulum.

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

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| <p>Type of the semester-end examination: signature*/<u>practical grade</u>*/<u>semi-final</u>*/final* (* Please underline)</p> <p>Examination requirements: as published by the department on the MOODLE interface by the start of the academic term</p> |
| <p>Form of the semester-end examination: written*/oral*/<u>combined examination</u>* (* Please underline)</p> <ul style="list-style-type: none"> • Written part: <ul style="list-style-type: none"> ○ Calculation (assessment on a two-point scale: pass/fail) ○ Excipients (assessment on a five-point scale) ○ Definition (assessment on a two-point scale: pass/fail) • Oral part: <ul style="list-style-type: none"> ○ Broad theoretical topic (assessment on a five-point scale) ○ Short theoretical topic (assessment on a five-point scale) ○ FoNo preparations (assessment on a five-point scale) ○ Modern dosage form (assessment on a five-point scale) |
| <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></p> <p>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 assessment basis</u>* (* Please underline)</p> |
| <p>The course description was prepared by:</p> <p>Dr. István Antal</p> |