

2026/2027

UČNI NAČRT PREDMETA / COURSE SYLLABUS

Predmet:	Farmaceutska tehnologija I.
Course title:	Pharmaceutic Technology I.

Študijski program in stopnja Study programme and level	Študijska smer Study field	Letnik Academic year	Semester Semester
Farmacija, 2. stopnja		2.	3. in 4.
Pharmacy, 2. level		2.	3. in 4.

Vrsta predmeta / Course type obvezni/obligatory

Univerzitetna koda predmeta / University course code:

Predavanja Lectures	Seminar Seminar	Vaje Tutorial	Klinične vaje Clinical training	Druge oblike študija Other forms of study	Samost. delo Individual work	ECTS
65		70			195	11

Nosilec predmeta / Lecturer: izr. prof. dr. Amrit Paudel, mag. farm.

Jeziki / Predavanja / Lectures: slovenski/slovene
Languages: Vaje / Tutorial: slovenski/slovene

Pogoji za vključitev v delo oz. za opravljanje študijskih obveznosti: / **Prerequisites:** /

Vsebina:

PRVI DEL:
Osnovne farmacevtsko-tehnološke operacije in njihova uporaba pri pripravi farmacevtskih oblik:

- Drobljenje
- Sejanje
- Mešanje
- Ločevanje
- Sušenje
- Fizikalne in fizikalno-kemijske osnove farmacevtskih oblik
- Velikost in površina delcev
- Topnost, hitrost raztapljanja in povečanje topnosti
- Znižanje točke zmrzišča
- Gostota
- Pojav na fazni meji
- Reologija

DRUGI DEL:

- Uporaba različnih oblik zdravilnih učinkovin.
- Dobra proizvodna praksa (Good manufacturing practice – GMP).

Content (Syllabus outline):

FIRST PART:
Basic pharmaceutical technology and operations with emphasis on their use in preparation of pharmaceutical formulations:

- Crushing
- Sowing
- Mixing
- Separation
- Drying
- Physical and physico-chemical basic of the pharmaceutical forms
- Particle size and surface
- Solubility, dissolution rate and increase the solubility
- Freezing point reduction
- Density
- Phase-interface phenomena
- Rheology

SECOND PART:

- Using of various forms of active substances.
- Good manufacturing practice – GMP.

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- Oblika zdravilne učinkovine v porazdelitvenem sistemu.
- Molekularno-disperzijski sistem, koloidno-disperzijski sistem, grobi disperzijski sistem.
- Osnovne in pomožne snovi pri oblikovanju zdravilnih učinkovin in farmacevtskih oblik.
- Sistematika.
- Medsebojni vplivi (makro)molekul pomožnih snovi in zdravilnih snovi.
- Voda.
- Osnove biofarmacije (biološka uporabnost, bioekvivalenca).
- Absorpcija zdravil in zdravilnih učinkovin ter faktorji, ki vplivajo na sproščanje in absorpcijo zdravilnih učinkovin.
- Prašek in puder (pridobivanje praškastih zdravilnih učinkovin in lastnosti, proizvodnja praškastih farmacevtskih oblik, posebni pudri, kontrola in testiranje pudrov).
- Tablete (šaržno tabletiranje, granuliranje, komprimiranje, pomožne učinkovine za tabletiranje, napake tabletiranja, biofarmacevtski vidik, kontrola in testiranje tablet, dražeje, filmsko obložene tablete z dodatki).

- Form of active substance as a dispersed system.
- Molecular-dispersion system, colloidal-dispersion system, coarse-dispersion system.
- Basic and auxiliary materials in a formation of active substances and pharmaceutical formulations.
- Systematics.
- (Macro)molecules interactions of excipients and active substances.
- Water.
- Basics of biopharmacy (bioavailability, bioequivalence).
- Drug's absorption and factors affecting the release and absorption of active substances.
- Powders (Extraction of powdered medicinal substances, properties, production of pharmaceutical powders, special powders, controlling and testing of powders).
- Tablets (batch tableting, granulating, compression, auxiliary substance for tableting, tableting defect, biopharmaceutical aspects, controlling and testing of tablets, dragees, film-coated tablets with additives).

Temeljni literatura in viri / Readings:

TEMELJNA LITERATURA:

1. A. Fahr, et al., Voigt's Pharmaceutical Technology 1st Edition, Wiley; 1st edition (2018).
2. K. M. G. Taylor et al., Aulton's Pharmaceutics: The Design and Manufacture of Medicines, Elsevier; 6th edition (2021).

DODATNA LITERATURA:

1. K.H. Bauer, K.H. Froemming, C. Fuehrer: Lehrbuch der pharmazeutischen Technologie, 9. ausgabe, Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart 2012.
2. V. Ozim, Ž. Knez: Mehanska procesna tehnika, FKKT (1995)
3. A.J. Winfield, R.M.E. Richards: Pharmaceutical Practice, 3rd Edition, Churchill Livingston, Edinburgh 2004.
4. A.T. Florence, D. Attwood, Physicochemical principles of pharmacy, 3rd Edition, Macmillan press Ltd., London, 1998.
5. Pharmacopoeia Europea 9th Edition (2016) (ali novejša, vključno z dopolnitvami), EDQM, Strassbourg.
6. Formularium Slovenicum.

Cilji in kompetence:

- Spoznati področje farmacevtske tehnologije in ključne metode osnovnih tehnoloških operacij na področju farmacije.
- Spoznati pomen farmacevtske tehnologije v znanstvenem, strokovnem in industrijskem pomenu.
- Ločiti med različnimi vejami farmacevtske tehnologije.
- Spoznati nove trende razvoja sodobnih tehnik in osnovnih načel priprave zdravil.

Objectives and competences:

- To understand the field of pharmaceutical technology and key methods of basic technological operations in the field of pharmacy.
- To understand the importance of pharmaceutical technology in scientific, professional, and industrial sense.
- Separate between different branches of pharmaceutical technology.
- To learn about new trends in the development of modern techniques and basic principles of drug preparation.

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- Umestiti tehnološki razvoj v širšem smislu na področje farmacije.
- Razumeti pomen tehnoloških postopkov za korist zdravljenja.
- Uvesti študenta v razumevanje farmacevtske tehnologije ter ga seznaniti z metodami izdelave različnih farmacevtskih učinkovin.

- Placing technological development in the broader sense in the field of pharmacy.
- Understand the importance of technological procedures for the benefit of treatment.
- Basic knowledge of the Pharmaceutical Technology enables students to understand the methods of production of various pharmaceutical substances.

Predvideni študijski rezultati:

Znanje in razumevanje:

- Študent pozna osnovne farmacevtsko-tehnoloških postopkov in zna utemeljiti njihovo uporabo pri pripravi farmacevtskih oblik.
- Razložiti zna pomen termodinamskih in transportnih lastnosti sistemov pri procesu proizvodnje/oblikovanja dostavnih sistemov oz. farmacevtskih oblik.
- Razložiti zna pomen raztapljanja v zvezi s sproščanjem in absorpcijo učinkovin v človeškem telesu..

Prenosljive ključne spretnosti in drugi atributi:

Študent pozna osnovne farmacevtsko-tehnološke procese, kar bo osnova za nadaljevanje spoznavanja tehnoloških procesov v farmaciji.

Intended learning outcomes:

Knowledge and understanding:

The student is familiar with basic pharmacotechnological operations and can justify their use in the preparation of pharmaceutical dosage forms. The student is able to explain the importance of thermodynamic and transport properties of systems in the production/formulation of delivery systems or dosage forms. They can explain the importance of dissolution in relation to the release and absorption of active substances in the human body.

Transferable/Key Skills and other attributes:

The student acquires the knowledge of the processes in this subject, which will serve as the basis for continuing to learn about technological processes in pharmacy.

Metode poučevanja in učenja:

Predavanja
Vaje (laboratorijske)

Learning and teaching methods:

Lectures
Tutorials (lab work)

Načini ocenjevanja:

Način (pisni izpit, ustno izpraševanje, naloge, projekt)

- Pisni izpit
- Laboratorijsko delo

ŠTUDIJSKE OBVEZNOSTI ŠTUDENTOV

- 80 % prisotnost na vajah

POGOJ ZA PRISTOP K IZPITU

- Opravljene vaje
- Opravljen kolokvij iz vaj (na koncu laboratorijskega dela)

Delež (v %) /

Weight (in %) /

Assessment:

Type (examination, oral, coursework, project):

- Written examination
- Laboratory work

ACADEMIC OBLIGATIONS OF STUDENTS

- 80 % attendance at tutorials

CONDITIONS FOR TAKING THE EXAM

- Completed tutorials
- Passed partial exam on tutorials (at the end of laboratory work)

Reference nosilca / Lecturer's references:

AMRIT PAUDEL:

1. Beretta, M., J. T. Pinto, P. Laggner and A. Paudel (2022). "Insights into the Impact of Nanostructural Properties on Powder Tribocharging: The Case of Milled Salbutamol Sulfate." *Mol Pharm* 19(2): 547-557.
2. Saraf, I., R. Roskar, D. Modhave, M. Brunsteiner, A. Karn, D. Neshchadin, G. Gescheidt and A. Paudel (2022). "Forced Solid-State Oxidation Studies of Nifedipine-PVP Amorphous Solid Dispersion." *Mol Pharm* 19(2): 568-583.



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3. Zupancic, O., M. Spoerk and A. Paudel (2022). "Lipid-based solubilization technology via hot melt extrusion: promises and challenges." *Expert Opin Drug Deliv* 19(9): 1013-1032.