

UČNI NAČRT PREDMETA / COURSE SYLLABUS

Predmet:	Farmaceutika za inženirje
Course title:	Pharmaceutics for engineers

Študijski program Study programme and level	Študijska smer Study field	Letnik Academic year	Semester Semester
Inženiring in avtomobilska industrija		1. oz. 2.	drugi (1. letnik) oz. prvi (2. letnik)
Engineering and Automotive Industry		1 st or 2 nd	second (1 st year) or first (2 nd year)

Vrsta predmeta / Course type Izbirni / Optional

Univerzitetna koda predmeta / University course code: MAG_21023

Predavanja Lectures	Seminar Seminar	Sem. vaje Tutorial	Lab. vaje Laboratory work	Teren. vaje Field work	Samost. delo Individ. work	ECTS
45	-	45	-	-	150	8

Nosilec predmeta / Lecturer: Doc. dr. Igor Simonič

Jeziki / Languages:	Predavanja / Lectures:	Slovenski / Slovenian
	Vaje / Tutorial:	Slovenski / Slovenian

Pogoji za vključitev v delo oz. za opravljanje študijskih obveznosti:

Prerequisites:

<ul style="list-style-type: none"> Vpis v 1. oz. 2. letnik magistrskega študija. 	<ul style="list-style-type: none"> Enrollment in the first or second year of master degree study.
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Vsebina:

Content (Syllabus outline):

<ul style="list-style-type: none"> Uvod v farmaceutiko: <ul style="list-style-type: none"> osnovni pojmi: zdravilo vs. farmacevtske učinkovine, ekonomski, socialni in strateški vidiki zdravil oz. farmacevtskih učinkovin, kratka zgodovina zdravil. Usoda učinkovine v telesu: <ul style="list-style-type: none"> osnovni procesi ob aplikaciji zdravila, absorbpcija / distribucija / metabolizem / eliminacija, primeri metabolizma zdravil. Razvoj in raziskave ter proizvodnja farm. učinkovin in zdravil: <ul style="list-style-type: none"> razvoj učinkovin in zdravil, osnovni procesi pri proizvodnji učinkovin in zdravil. 	<ul style="list-style-type: none"> Introduction to pharmaceuticals: <ul style="list-style-type: none"> basic concepts: drug vs. active pharmaceutical ingredients (API), economic, social and strategic aspects of drugs and API's, short history of drugs. Fate of API in the body: <ul style="list-style-type: none"> basic processes at drug application, absorbption / distribution / metabolism / elimination, examples of drug metabolism. R&D and manufacturing of API's and drugs: <ul style="list-style-type: none"> R&D of API's and drugs, basic processes at the production of API's and drugs. Regulation of drugs:
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<ul style="list-style-type: none"> • Regulativa zdravil: <ul style="list-style-type: none"> ○ zakonske zahteve za zdravila, ○ Dobra proizvodna praksa in sorodna priporočila, ○ registracija učinkovin in zdravil. • Kakovost in stabilnost farm. učinkovin in zdravil: <ul style="list-style-type: none"> ○ parametri za zagotavljanje kakovosti učinkovin in zdravil, ○ nečistote v učinkovini/zdravilih, ○ stabilnost učinkovin, ○ rok uporabe zdravil. • Osnove intelektualne lastnine <ul style="list-style-type: none"> ○ industrijska lastnina, ○ blagovne znamke, ○ modeli, ○ patenti. 	<ul style="list-style-type: none"> ○ requirements for drug production, ○ Good Manufacturing Practice and related recommendations, ○ registration of API's and drugs. • Quality in stability of API's and drugs: <ul style="list-style-type: none"> ○ parameters of API and drug quality assessment, ○ impurities in API and drug, ○ stability of API, ○ shelf life of drugs. • Basics of intellectual properties <ul style="list-style-type: none"> ○ industrial property, ○ trademarks, ○ industrial designs, ○ patents.
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Temeljna literatura in viri / Readings:

- J. J. Li, D. S. Johnson, D. Sliskovic, B. D. Roth: Contemporary drug synthesis, John Wiley & Sons, Inc., Hoboken, New Jersey, 2004, dostopno na: <http://onlinelibrary.wiley.com/doi/10.1002/0471686743.fmatter/pdf> .
- O. Repič: Principles of process research and chemical development in the pharmaceutical industry, John Wiley & Sons, Inc., New York, Chichester, Weinheim, Brisbane, Singapore, Toronto, 1998.
- European Pharmacopoeia, 4th Edition, EDQM, Strasbourg, 2004 (in druge izdaje ter dodatki).
- Inventing the future: an introduction to patents for small and medium-sized enterprises, WIPO (2006), dostopno na: <http://www.wipo.int/patentscope/en/patents> .
- E-gradiva predmeta | E-Course material

Priporočljiva literatura / Recommended Textbooks

- R. M. Felder, R. W. Rousseau: Elementary Principles of Chemical Processes, 3th Ed., John Wiley and Sons, Inc., New York, 2005, dostopno na: [http://appliedchem.unideb.hu/Unit%20Operations%20I/2.%20Week/Elementary%20Principles%20of%20Chemical%20Processes%203\(1\).pdf](http://appliedchem.unideb.hu/Unit%20Operations%20I/2.%20Week/Elementary%20Principles%20of%20Chemical%20Processes%203(1).pdf) .
- J. Fisher, C. R. Ganellin (Ed.): Analogue-based Drug Discovery, Wiley-VCH Verlag, Weinheim 2006 (ISBN-10: 3-527-31257-9), dostopno na: <https://the-eye.eu/public/Books/Medical/texts/Analogue-Based%20Drug%20Discovery%20-%20J.%20Fischer%2C%20C.%20Ganellin%20%28Wiley%2C%202006%29%20WW.pdf>
- D. A. Williams, T. L. Lemke: Foye,s Principles of Medicinal Chemistry, 6th Edition, Lippincott Williams & Wilkins, Baltimore 2007.
- G. Thomas: Medicinal Chemistry: An Introduction, Wiley, 2000

Cilji in kompetence:

<p>Cilji</p> <ul style="list-style-type: none"> • Študent spozna in razume specifične zahteve farmacevtike ter multidisciplinarnost obvladovanja tega področja. • Pridobi osnovno razumevanje dejavnosti razvoja, kontrole ter proizvodnje zdravilnih (farmacevtskih) učinkovin ter izdelkov. • Študent pridobi osnove za sodelovanje v timih s strokovnjaki na področju farmacevtike. <p>Kompetence</p> <ul style="list-style-type: none"> • Sposobnost projektno-timskega dela. • Sposobnost vodenja tehnoloških procesov ter vpeljevanje sodobnih metod. • Razumevanje, uporaba in sinteza različnih znanj.
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Objectives and competences:

<p>Objectives</p> <ul style="list-style-type: none"> • Student acknowledges and understands specific requirements of pharmaceuticals and multidisiplinarity of the field. • Acquires crucial expertise for taking part in developing production and quality control technologies, as well as mastering of pharma production. • Student gets basics for team work in the field of pharma. <p>Competences</p> <ul style="list-style-type: none"> • Ability of project-team work. • Ability of manage technological processes and introduction of modern methods. • Understand, the use and synthesis of different skills.

Predvideni študijski rezultati:

<p>Študent/-ka:</p> <ul style="list-style-type: none"> • Spozna osnovno terminologijo in klasifikacije, ključne strukturne in terapevtske tipe učinkovin ter značilne tehnologije v kemiji in farmacevtiki. • Spozna principe in postopke razvoja tehnologij na področju kemije in farmacevtike. • Razume pomen in medsebojne vplive parametrov kakovosti in jih zna specificirati. • Razume principe sistemov kakovosti v razvoju, kontroli kakovosti in proizvodnji farmacevtike. • Spozna osnovne predpise za zdravila ter osnove zaščite intelektualne lastnine in pomen za delo na področju zdravil. • Študent (-ka) razvije sposobnost integracije znanj ter reševanja kompleksnih interdisciplinarnih problemov.

Intended learning outcomes:

<p>Student:</p> <ul style="list-style-type: none"> • is familiar with basic terminology and classifications, crucial structural and therapeutic types of API, as well as characteristic technologies of pharmacy. • Knows principles and procedures of production and quality control technologies in pharmacy. • Understands significance and correlations of quality parameters, and is familiar with approaches to determine them. • Student understands principles of quality systems in development, quality control and production in pharmacy, and is aware of relevant regulations, as well as of IPR and its relevance for working in the field. • Student develops ability to integrate his knowledge, and to solve complex interdisciplinary problems.
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Metode poučevanja in učenja:

<ul style="list-style-type: none"> • predavanja, • individualno in skupinsko delo s študenti v obliki konzultacij, • projektna/seminarska naloga s praktičnim primerom. <p>Predmet je oblikovan na kombinirani način študija, ki vključuje aktivnosti preko elektronskega (on-line) okolja: te aktivnosti so sestavljene iz samostojnih in skupinskih aktivnosti z uporabo učnega okolja Moodle in drugih elektronskih vsebin. Praviloma vključujejo diskusije v forumih, spletne strani, ogled posnetih predavanj in vaj, preverjanje znanja, odgovori na vprašanja, iskanje po spletu (bazah) itd.</p>

Learning and teaching methods:

<ul style="list-style-type: none"> • lectures, • individual and group work with students in the form of consultations, • project work with a practical example. <p>The course is designed as blended learning that includes online activities: Online activities consist of independent and group activities using the LMS Moodle and other electronic or online content. Activities usually include discussions in forums, websites, viewing of recorded lectures and tutorials, assessments, answering questions, searching the web (databases), etc.</p>
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Načini ocenjevanja:
Delež/Weight (%)
Assessment:

<ul style="list-style-type: none"> • projektna/seminarska naloga • pisni ali ustni izpit <p>Ocenjevalna lestvica je skladna z ECTS in Pravilnikom o preverjanju in ocenjevanju znanja FINI NM.</p>	<p>50 50</p>	<ul style="list-style-type: none"> • project work • written or oral examination <p>Evaluation scale in accordance with ECTS and the Rules on the Evaluation and Assessment of Knowledge FINI NM.</p>
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Reference nosilca / Lecturer's references:

1. STANOVNIK, Branko, SVETE, Jurij, TIŠLER, Miha, ŽORŽ, Lilijana, HVALA, Aleš, SIMONIČ, Igor. Transformation of amines and N-heterorylformamidines into esters of substituted [beta]-amino-[alpha],[beta]dehydro-[alpha]-amino acids. Heterocycles, 1988, vol. 27, no. 4, str. 903-909. [COBISS.SI-ID 19499269]
2. HVALA, Aleš, SIMONIČ, Igor, STANOVNIK, Branko, SVETE, Jurij, TIHI, Jaroslav, TIŠLER, Miha. Methyl 2-benzoylamino-3-dimethylaminopropenoate, a versatile reagent in organic synthesis. The transformation of various heterocyclic amines into methyl 2-benzoylamino-3-heteroarylamino-propenoates. Vestn. Slov. kem. druš., 1989, let. 36, št. 3, str.305-323. [COBISS.SI-ID 11185410]
3. STANOVNIK, Branko, BOVENKAMP, Henry van der, SVETE, Jurij, HVALA, Aleš, SIMONIČ, Igor, TIŠLER, Miha. Methyl 2-benzoylamino-3-dimethylaminopropenoate in the synthesis of heterocyclic systems. An attempt to prepare benzoylamino substituted azolo- and azinopyrimidines with a bridgehead nitrogen atom. J. heterocycl. chem., February 1990, vol. 27, no. 2, str. 359-361. [COBISS.SI-ID 19424261]
4. SIMONIČ, Igor. Synthesis of some new potential biologically active 1,4-dihydropyridines. Acta chim. slov.. [Tiskana izd.], 1997, 44, 1, str. 95-104. [COBISS.SI-ID 19403269]
5. SIMONIČ, Igor, STANOVNIK, Branko. The synthesis of some dialkyl 4-(3-substituted amino)phenyl-1,4-dihydro-2,6-dimethylpyridine 3, 5-dicarboxylates. J. heterocycl. chem., 1997, letn. 34, št. 6, str. 1725-1730. [COBISS.SI-ID 9464537]
6. SIMONIČ, Igor. Hantzscheva sinteza dihidropiridinov. Kem. šoli, oktober 1999, letn. 11, št. 3, str. 17-

21. [COBISS.SI-ID 3262025]
7. SIMONIČ, Igor, ZUPANČIČ, Silvo, GOLIČ, Ljubo, STANOVNIK, Branko. Fotokemična pretvorba dietil (E)-4-[2-[2-(tert-butoksikarbonil)vinil]fenil]-2,6-dimetil-1,4-dihidropirid in-3,5-dikarboksilata. V: GLAVIČ, Peter (ur.), BRODNJAK-VONČINA, Darinka (ur.). Slovenski kemijski dnevi 2001, Maribor, 20. in 21. september 2001. Zbornik referatov s posvetovanja. Maribor: Slovensko kemijsko društvo, 2001, str. 339-342. [COBISS.SI-ID 23838469]
8. SIMONIČ, Igor, ZUPANČIČ, Silvo, GOLOBIČ, Amalija, GOLIČ, Ljubo, STANOVNIK, Branko. The crystal structure of lacidipine phototransformation product. Acta chim. slov.. [Tiskana izd.], 2008, vol. 55, no. 2, str. 458-461. [COBISS.SI-ID 29570053]
9. ZUPANČIČ, Vinko, SMRKOLJ, Matej, BENKIČ, Primož, SIMONIČ, Igor, PLEVNIK, Miha, RITLOP, Gregor, KRISTL, Albin, VREČER, Franc. Preformulation investigation of some clopidogrel addition salts. Acta chim. slov.. [Tiskana izd.], 2010, vol. 57, no. 2, str. 376-385. [COBISS.SI-ID 2822769]
10. SIMONIČ, Igor, BENKIČ, Primož, VAJS, Anamarija, KRAMAR, Andrejka, ŠTIMAC, Anton. Process for preparing crystalline form II of orlistat : EP1973893 B1. München: European Patent Office, 2016. [COBISS.SI-ID 4284529]
11. SIMONIČ, Igor, BENKIČ, Primož, ZUPET, Rok, SMRKOLJ, Matej, ŠTUKELJ, Mitja. Process for the synthesis of clopidogrel and new forms of pharmaceutically acceptable salts thereof : EP2078025 B1. München: European Patent Office, 2016. [COBISS.SI-ID 4281969]
12. KOTAR-JORDAN, Berta, SIMONIČ, Igor, ZUPET, Rok, RUŽIČ, Miloš, GRČMAN, Marija, PEČAVAR, Anica. Crystallisation of solid forms of clopidogrel addition salts : EP 1656381 B1 : patent. München: European Patent Office, 2011. [COBISS.SI-ID4281457]