1. COURSE DECRIPTION – GENERAL INFORMATION			
1.1. Course teacher	Assistant Professor Željka Vanić, PhD Associate Professor Mario Jug, PhD	1.6. Year of study	4th
1.2. Name of the course	**Drug formulation**	1.7. Credit value (ECTS)	9
1.3. Associate teachers	Zora Palac, MPharm	1.8. Type of instruction (number of hours L+E+S+e-learning)	60+45+0
1.4. Study programme (undergraduate, graduate, integrated)	Integrated study of Pharmacy	1.9. Expected enrolment in the course	130
1.5. Status of the course	Compulsory	1.10. Level of use of e-learning (1, 2, 3 level), percentage of instruction in the course on line (20% maximum)	2nd
2. COURSE DESCRIPTION			
2.1. Course objectives	The course objectives include studying of scientific principles relative to the design, manufacture and quality control of pharmaceutical formulations; fundamentals on excipients and their influence on drug stability and therapeutic efficiency as well as features of pharmaceutical formulations. The course provides basis for: Prescription pharmacy, Cosmetology, Innovative drug delivery systems, Industrial pharmacy, Clinical pharmacy with pharmacotherapy, Quality assurance and registration of drugs, Student practice II, Pharmaceutical care and Professional Training for Pharmacists.		
2.2. Enrolment requirements and required entry competences for the course	Enrolment: Pharmaceutics-passed examination, Biopharmacy and Pharmacokinetics-course completed Requirement for exam: Biopharmacy and Pharmacokinetics-passed examination		
2.3. Learning outcomes at the level of the study programme to which the course contributes	• Expert knowledge on the development of pharmaceuticals in order to produce drug formulations by selecting and applying technological processes as well as their innovations to ensure quality in the process of the production by applying the rules of good laboratory and manufacturing practice, as well as relevant European and ISO directives. • Professional skills which would allow to recommend an optimal pharmaceutical drug formulation regarding the pathology, route of application, patient age and general condition; consulting the patient about proper application of pharmaceuticals. • Critical assessment and application of relevant scientific knowledge in development of advanced drug delivery		

	systems as well as improvement of existing and design of new technologies for production of pharmaceuticals.
2.4. Expected learning outcomes at the level of the course (4-10 learning outcomes)	After completing this course the student will be able to: 1. Define and distinguish between different drug formulations and to discuss advances and/or limitations of their use; 2. Categorize various pharmaceutical excipients, describe their application in production of pharmaceuticals and analyse their impact on stability and therapeutic efficiency of drugs; 3. Define and describe the preparation of various drug dosage forms, analyse their advantages/disadvantages and assess their influence on stability and therapeutic efficiency of drugs; 4. Select an appropriate preparation conditions and technology based on physico-chemical properties of drug/excipients, application pathway and targeted patient groups; 5. List and describe protocols for quality insurance of various drug dosage forms and to estimate the impact of excipients and technology used on their quality; 6. Recognize technologically relevant incompatibilities between drugs, excipients and/or containers; 7. Formulate and evaluate various drug dosage forms.
2.5. Course content broken down in detail by weekly class schedule (syllabus)	LECTURES: • Introduction, definition of drug dosage forms, preformulation. • Excipients-classification, requirements, preservatives, antioxidants, flavoring agents and colorants. • Cyclodextrines as pharmaceutical excipients. • Sterilization of pharmaceuticals, principles of sterilization, aseptic procedure and sterility control. • Herbal dosage forms-tea mixtures, extraction methods, extracts, tinctures, infusions, decocts, elixirs, quality control. • Liquid dosage forms-solutions, (co)solvents, solubility issues, micelar solubilization, osmolarity and tonicity, preparation methods. • Small volume parenterals-routes of applications, types of injections, solvents, excipients and technology of their preparation. • Large volume parenterals-electrolytes, plasma expanders, admixtures for parenteral and enteral nutrition, dialysis solutions. • Parenterals for prolonged drug delivery-principles and examples, delivery of pharmaceutical proteins. • Liposomes as drug carriers for parenteral application. • Production of parenterals-aseptic preparation, clean rooms, quality control, containers. • Radiopharmaceuticals-radionuclide generator, quality control. • Liquid formulations for ophthalmic, nasal, otic and oral application-drops, rinsing solutions, syrups, liquid mixtures. • Suspensions as pharmaceutical dosage form-excipients, stability aspects, preparation methods (technology), flocculated and deflocculated systems, quality control.

<table>
<tr><td></td><td colspan="6">• Emulsions as pharmaceutical dosage form-emulsifiers, stability aspects, preparation methods (technology), quality control.
• Aerosols-propelents, metered dose inhalers, dry powder inhalers, preparation methods (principles), innovative delivery systems for pulmonary delivery, quality control.
• Semisolid drug dosage forms-ointments, creams and gels, excipients and ointment bases, preparation methods (technology)
• Semisolid formulations for ophthalmic and transdermal drug delivery, quality control of semisolid dosage forms
• Medicinal soaps and suppositories for rectal and vaginal delivery-bases, excipients, preparation methods (technology), quality control
• Solid oral dosage forms-powders, soft/hard gelatin capsules, excipients, preparation methods (technology), quality control
• Tablets as solid oral dosage form-classification, excipients
• Tablets as solid oral dosage form-granulation methods and tableting process
• Sugar coated and film coated tablets
• Modified release tablets, quality control of solid dosage forms
• Pharmaceutical packaging-classification, materials, regulatory and quality considerations
LABORATORY EXERCISES:
• Preparation and technological evaluations of herbal dosage forms: tea mixtures, tinctures, extracts, syrups.
• Preparation and technological evaluations of liquid dosage forms: solutions for internal/external application, aromatic waters.
• Preparation and technological evaluations of liquid dosage forms: suspensions and emulsions.
• Preparation and technological evaluations of semisolid dosage forms: ointment bases, ointments, hydrogels, pastes.
• Preparation and technological evaluations of semisolid dosage forms: medicinal soaps and liniments.
• Preparation and technological evaluations of solid dosage forms: suppositories for rectal and vaginal application.
• Preparation and technological evaluations of solid dosage forms: granules and tablets.</td></tr>
<tr><td rowspan="2">2.6.Type of instruction</td><td colspan="2"><u>lectures</u>
seminars and workshops
<u>exercises</u>
online in entirety
mixed e-learning
field work</td><td colspan="2">independent study
multimedia and the internet
<u>laboratory</u>
work with the mentor
(other)</td><td colspan="2">2.7. Comments:</td></tr>
<tr><td colspan="6"></td></tr>
<tr><td>2.8. Student responsibilities</td><td colspan="6">Regular class attendance and completed laboratory exercises</td></tr>
<tr><td rowspan="6">2.9. Screening of student’s work (specify the proportion of ECTS credits for each activity so that the total number of CTS credits is equal to the credit value of the course)</td><td>Class attendance</td><td>2</td><td>Research</td><td></td><td>Practical training</td><td>2</td></tr>
<tr><td>Experimental work</td><td></td><td>Report</td><td></td><td></td><td></td></tr>
<tr><td>Essay</td><td></td><td>Seminar essay</td><td></td><td>(Other--describe)</td><td></td></tr>
<tr><td>Tests</td><td>1</td><td>Oral exam</td><td>2</td><td>(Other—describe)</td><td></td></tr>
<tr><td>Written exam</td><td>2</td><td>Project</td><td></td><td>(Other—describe)</td><td></td></tr>
<tr><td colspan="6"></td></tr>
<tr><td>2.10. Grading and evaluation of student work over the course of</td><td colspan="6">Continuous assessment over 3 partial written exams or final written exam and oral exam.
Monitoring and evaluation of experimental work and final test.</td></tr>
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instruction and at a final exam	
2.11. Required literature (available at the library and via other media)	**Title**
	1. R. Senjković, Osnove oblikovanja lijekova, Školska knjiga, Zagreb, 2003, (1994).
	2. R. Senjković, V. Petričić, M. Bećirević, Oblikovanje lijekova (praktikum), Liber, Zagreb, 1997.
2.12. Optional literature	Pharmaceutics, the science of dosage form design, edited by M.E. Aulton, Churchil Livingstone, Edinburgh, London, Melbourne, New York, 1st ed. 1998, 2nd ed. 2002, 3rd ed. 2007.
2.13. Methods of monitoring quality that ensure acquisition of exit competences	Assessment of learning outcomes during laboratory exercise and final test (learning outcome 7) as well as written and oral exams (learning outcomes 1-6); harmonization of teaching methodology with the obtained results.