

Project:	„Innovating quality assessment tools for pharmacy studies in Bosnia and Herzegovina“ – IQPharm
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Title:	Proposal of free modules
Lead Organization:	UNTZ
Participating Organization:	SUM, UNSA, UBL, UNS, UNIST, Ud'A, TCD
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Deliverable data	Work Package and Outcome ref.nr	WP 2 - T 2.5	
	Title	Proposal of free modules	
	Type	<input type="checkbox"/> Teaching material <input type="checkbox"/> Event <input type="checkbox"/> Learning material <input checked="" type="checkbox"/> Report <input type="checkbox"/> Training material <input type="checkbox"/> Service / Product	
	Description	<p>Free modules are designed as elective courses allowing the students and/or masters of pharmacy the opportunity to personalize their additional education by engaging a mentored experience in a particular area of pharmacy which will help them to advance in the pharmaceutical profession.</p> <p>After one year of activities on collecting information about the shortcomings of pharmacy studies and numerous meetings and roundtables that involved healthcare professionals, academic staff, students, representatives from Ministries of Education and Health, Chambers and Associations, as well as managers of pharmaceutical industries, companies and pharmacies, each partner HEI proposed adequate and innovative free modules.</p>	
	Date	March 2023	
	Language	Bosnian/Croatian/Serbian and English	
Target groups	<input checked="" type="checkbox"/> Teaching staff <input checked="" type="checkbox"/> Students <input type="checkbox"/> Trainees <input type="checkbox"/> Administrative staff <input type="checkbox"/> Technical staff <input type="checkbox"/> Librarians <input checked="" type="checkbox"/> Industry partners, WB Higher education authorities		
Dissemination level	<input checked="" type="checkbox"/> Department/ Faculty <input checked="" type="checkbox"/> Institution	<input type="checkbox"/> Local <input type="checkbox"/> Regional	<input checked="" type="checkbox"/> National <input checked="" type="checkbox"/> International
Lead Organization	UNTZ		
Participating Organization	UNSA, UBL, SUM, UNS, UNIST, Ud'A		
Task	2.5. Proposal of free modules		

Revision History				
Version	Date	Author(s)	Organization(s)	Brief description of change
v.00	January, 2023	Maida Šljivić Husejnović, Alisa Elezović, Anđelka Račić, Martin Kondža	UNTZ, UNSA, UBL, SUM	Document (free module syllabi) preparation
v.01	07.03.2023.	Task group members	UNSA, UBL, UNTZ, SUM, UNIST, UNS, Ud'A	Approved
v01	13.07.2023.	QAT members	UNSA, UBL, UNTZ, SUM, UNIST, UNS, Ud'A, TCD	Approved
v01	19.07.2023.	SC members	UNSA, UBL, UNTZ, SUM, UNIST, UNS, Ud'A, TCD	Approved
v02	September, 2023	Maida Šljivić Husejnović, Alisa Elezović, Anđelka Račić, Martin Kondža	UNTZ, UNSA, UBL, SUM	Final meeting in Split conclusions added

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## 1. Introduction

Work package two (2) „Development“ of „Innovating quality assessment tools for pharmacy studies in Bosnia and Herzegovina / IQPharm“ project includes task 2.5. „*Proposal of free modules*“. Task group 2.5. includes members of all partner institutions: Alisa Elezović (UNSA), Anđelka Račić (UBL), Ivica Brizić (SUM), Doris Rušić (UNIST), Biljana Božin (UNS), Lucia Recinella (Ud'A) and task group leader Maida Šljivić Husejnović (UNTZ). Colleagues who also contributed in achieving the task goals were Adaleta Softić (UNTZ), Tamer Bego (UNSA) and Martin Kondža (SUM).

Nine meetings were held online (Google meet and/or Zoom platform) according to the Work Plan of TG\_2.5. The main risks and problems in achieving the goals of these activities for each institution are emphasized and explained. All participants contributed to solving problems in their or partner HEIs.

In the first month of activities analysis of data from the published Report (Quality of pharmacy studies: Required Changes and Improvements Report) was carried out. In the following months, collecting data of the needs of the labour market in the field of pharmacy (pharmacies, pharmaceutical distributors, pharmaceutical representatives, pharmaceutical industries, Ministries of Education and Health, Chambers, Associations, academic staff, and students) was carried out by all four HEIs from Bosnia and Herzegovina. All participants were included in the analysis and discussion of collected data about the needs of the labour market in the field of pharmacy, shortcomings of pharmacy studies in Bosnia and Herzegovina obtained by the meetings with pharmacists and managers of pharmaceutical representatives in different cities in B&H.

At the eighth meeting held in mid-January 2023, draft versions of the free modules were proposed by each HEI according to data regarding the shortcomings of pharmacy studies and needs of the labour market. University of Split also proposed their two free modules. Other partners contributed with their valuable comments and suggestions in the final preparation of free module proposals. The final meeting, after reviewing all proposed syllabi, was held on March 7, 2023. The documents are approved by each HEI representatives.

Link with the additional information:

<https://drive.google.com/drive/u/0/folders/1vDFhKCiu6Y6BO8kBWdXFyALHRdnZtMNE>

## 2. Objectives of the Deliverable

The main objective of the task was to prepare and propose innovative free modules by each HEI in Bosnia and Herzegovina after organizing thematic meetings with stakeholders. The proposed free modules are prepared with the aim to enrich the students' and pharmacists' knowledge and help them to achieve their personal goals through the professional development in the fields of their personal interests.

Additional aim was to provide opportunities for increased student mobility among HEIs, which could be beneficial for students, staff and partner institutions in developing and strengthening cooperation at national and international level.

## 3. Conclusions

The task group 2.5 Proposal of free modules achieved the set goals. The following free modules are proposed by each partner institutions and delivered as syllabi annexes:

HEI	Free module (subject) name
University of Tuzla	<ol style="list-style-type: none"> <li>1. Responsible co-treatment: interactions, side, and toxic effects of medicines, food and supplements</li> <li>2. Drug development – the path from synthesis to the market</li> </ol>
University of Sarajevo	<ol style="list-style-type: none"> <li>1. Establishment of an internationally recognized laboratory</li> <li>2. Introduction to 3D Printing in Pharmacy</li> </ol>
University of Banja Luka	<ol style="list-style-type: none"> <li>1. Pharmacotherapy of special group of patients – contemporary approaches</li> <li>2. Regulation in pharmacy</li> </ol>
University of Mostar	<ol style="list-style-type: none"> <li>1. Development of biologics and biosimilars</li> </ol>

Also University of Split proposed their two free modules:

1. Communication skills for pharmacy students
2. Pharmaceutical marketing.

The main risks and problems in achieving the goals of these activities for each institution were related to the different legal frameworks (within cantons and federation/republic laws). All partners made an effort to create legal prerequisites for recognition of free modules in the future at all partner universities. To ensure that there is no overlapping of the free module syllabi proposed by each HEIs, all task group members reviewed all prepared documents.

At the final meeting activities in Split, the syllabi of all partner institutions were presented in details and thoroughly discussed. It was concluded that the syllabi were very valuable additions to pharmacy programs at partner universities, they were complementary and will serve well the pharmaceutical community in preparing students for labor force as well as lifelong learning programs for pharmacists. Even though the syllabi are the final deliverable of this task, perspectives and challenges (legal and organisational) were discussed as they pertain to the future implementation of free modules after and outside of the scope of the Project. It was concluded that there are legal grounds for their implementation, but with still serious difficulties in implementation due to the poorly defined local laws as well as lacking institutional rules at some partner institutions.

#### 4. Annexes

##### *Annex 1. Free modules proposed by University of Tuzla*

<https://docs.google.com/document/d/1Kxl1sJYntlfCSpnNU1SbcefYM5iPGOW3/edit>

<https://docs.google.com/document/d/1-LuyIVDU2Sn5sbUeIq-wI-m7IIfdV-g8/edit>

*Annex 1a. Responsible co-treatment: interactions, side, and toxic effects of medicines, food and supplements*

<b>Su bje ct cod e:</b>	<b>Subject name: Responsible co-treatment: interactions, side, and toxic effects of medicines, food and supplements</b>		
<b>Level: Integrated studies of first (I) and second (II) cycle</b>	<b>Year: V</b>	<b>Semester: IX</b>	<b>Number of ECTS credits: 3</b>
<b>Status:</b> Free module		<b>Total number of hours: 45</b> Lectures (L): 30 Practicals (P): 15	
<b>Teaching staff</b>	Aida Smajlović, PhD, Full Professor Adaleta Softić, PhD, Associate Professor Nahida Srabović, PhD, Associate Professor Maida Šljivić Husejnović, PhD, Assistant Professor Ermina Cilović Kozarević, PhD, Assistant Professor Esmeralda Dautović, PhD, Assistant Professor Merima Ibišević, PhD, Assistant Professor Amra Džambić, PhD, Assistant Professor		
<b>Prerequisite for enrollment:</b>	Master degree in Pharmacy or Medicine/ Attended subjects: Pharmacology, Toxicology, Biochemistry		
<b>Goal(s) of the subject:</b>	A subject providing theory and applications which will prepare students for the safe self-medication consoling.		
<b>Subject structure/Topics: Lectures Practicals</b>	<b>Subject structure:</b> <b>a) Theory (Lectures):</b> <ul style="list-style-type: none"> <li>- The role of the pharmacist in self-care and self-medication</li> <li>-Regulation and quality control of OTC drugs</li> <li>-OTC drugs safety and regulation</li> <li>-Food supplements safety and regulation</li> <li>-Cosmeceuticals safety and regulation</li> <li>-OTC drug interactions, adverse and toxic effects</li> <li>-Food-drug interactions, adverse and toxic effects</li> <li>-Drug-food supplement interactions, adverse and toxic effects</li> <li>-Herb-drug interactions, adverse and toxic effects</li> </ul> <b>b) Practical/auditory (problem-solving approach):</b>		

	<p><b>-The influence of non-enzymatic glycation of human serum albumin (HAS) on the interaction of HAS with drugs</b>  <b>-Cytotoxic and genotoxic effects of food additives-<i>in vitro</i> study</b>  <b>-Supplements in the treatment of autoimmune diseases-<i>in vivo</i> study</b>  <b>-Predicting drug-supplement interactions-QSAR study</b></p>
<p><b>Learning outcomes:</b></p>	<p><b>Knowledge:</b> After attending classes and passing the exam, the student will pose a sound knowledge of the subject in the following areas:</p> <ul style="list-style-type: none"> <li>- basic principles of self-care and self-medication;</li> <li>- basic principles in professional communication;</li> <li>- quality control and quality assurance in pharmacy;</li> <li>- safe use of OTC drugs, drug supplements, cosmeceuticals, and herbal drugs;</li> <li>- polypharmacy and potential drug-drug interactions, drug-food interactions, drug-food supplement interaction.</li> </ul> <p><b>Skills:</b> After attending classes and passing the exam, the student will be able to:</p> <ul style="list-style-type: none"> <li>- perform a number of professional activities (advising the patient about combining drugs and other natural or synthetic substances, therapeutic drug monitoring, distinguishing between high and poor quality of dietary supplements, noticing drug interaction symptoms, using an online interaction checker, pharmacovigilance, pharmacoepidemiology, etc.)</li> <li>- plan and conduct toxicity studies and clinical trials;</li> <li>- adequate communicate (both written and verbal) with patients, co-workers, pharmacists, doctors, and other public regarding relevant aspects of responsible co-treatment;</li> <li>- formulate and conduct problem based teaching/learning exercises</li> <li>- implement the legal and ethical regulations related to OTC drugs, dietary supplements, cosmetic products, and herbal drugs.</li> </ul> <p><b>Competences:</b> After attending classes and passing the exam, the student will be trained to:</p> <ul style="list-style-type: none"> <li>- ensure patient safety;</li> <li>- apply a patient-centered approach to pharmaceutical practice;</li> <li>- monitor the drugs, dietary supplements and other healthcare needs of the patient on a regular basis</li> <li>- make recommendations for reducing adverse and/or toxic reactions;</li> <li>- advice about improvement in the self-medication and self-care;</li> <li>- maintain a high standard of pharmaceutical practice;</li> <li>- understand and apply the requirements of national recommendations and laws;</li> <li>- recognize ethical dilemmas in practice and to ensure quality in pharmaceutical practice by applying normative ethical principles;</li> <li>- understand and accept the importance of continuous self-improving through life-long learning;</li> </ul>

	<ul style="list-style-type: none"> <li>- identify the health risks from inappropriate self-medications;</li> <li>- gather information from a number of reliable sources;</li> <li>- distinguish between important and unimportant issues;</li> <li>- consult with the doctor or patient for further information and clarification when required.</li> </ul>
<b>Teaching methods:</b>	<p>1. Theoretical (theory) (70%)                  2. Practical /auditory- problem-solving approach exercises (30%)                  (the percentage was calculated according to the number of hours for lectures and exercises, respectively, in regards to the total number of hours)</p>
<b>Evaluation system<sup>1</sup>:</b>	<p>Evaluation system:                  THE SUBJECT OF EVALUATION:                  1. ACTIVITY ON CLASS                  2. PRACTICAL EXAM                  3. INDEPENDENT STUDENT ASSIGNMENTS                  4. MIDTERM PARTIAL EXAM                  5. FINAL EXAM * (In the final exam, the student can access each part of the exam (based on what she/he did not pass in term (at the time) of the partial exam or practical exam)).</p> <p><i>KNOWLEDGE ASSESSMENT:</i> Knowledge assessment will be carried out continually through activity in class, independent student assignments, practical exam (problem-solving approach), theoretical partial (midterm) exam and final exam.</p> <p><i>THE SUBJECT OF EVALUATION:</i>                  1. ACTIVITY ON CLASS  <i>Student activity in class is scored with 0-10 points.</i></p> <p>2. PRACTICAL EXAM  <i>Using a problem-solving approach, the student solves a practical task (challenge in pharmacy practice) based on previously acquired biochemical, pharmacological and toxicological knowledge taking into account legal and ethical principles in the decision making process. The practical exam is held at the end of the semester. The practical exam is scored with 10-20 points.</i></p> <p>3. INDEPENDENT STUDENT ASSIGNMENTS  <i>Based on the available literature, the student conducts independent research on a given topic and writes a seminar paper and presents it orally during the semester. Independent student assignments are scored with 5-10 points.</i></p> <p>4. PARTIAL (MIDTERM) EXAM  <i>The student's knowledge is assessed by a test based on multiple choice questions (MCQ) which provides respondents with multiple answer options. The partial exam is held after the first third of the semester. First MCQ is scored with 11-20 points.</i></p>

<sup>1</sup> The structure of grading and point criteria for each subject is determined by the Law on Higher Education of Tuzla Canton, the Statute of the University of Tuzla, and the Ruled on the method of passing exams and assessing students at the University of Tuzla. Additional information regarding method and procedures for evaluating knowledge and taking exams are provided by the syllabus/curriculum of each subject.

	<p><b>5. FINAL EXAM</b>  <i>The student's knowledge is assessed by a test based on multiple choice questions (MCQ) which provides respondents with multiple answer options. The final exam is held at the end of the semester. Second MCQ is scored with 22-40 points.</i></p> <p><b>TOTAL:</b>          Number of points: 100          Maximum number of points (100.0 points – acquired on all individual segments);          Requirement (54.0 points – acquired on all individual segments)</p> <p><b>EVALUATION MANNER</b></p> <p><i>10 (A) – 94–100 points          9 (B) – 84-93 points          8 (C) – 74-83 points          7 (D) – 64-73 points          6 (E) – 54-63 points          5 (F, FX) – 0-53 points.</i></p>
<p><b>Literature<sup>2</sup>:</b></p>	<p><b>Mandatory:</b></p> <ol style="list-style-type: none"> <li>1. Smajlović A, Softić A, Srabović N, Šljivić Husejnović M, Cilović Kozarević E, Dautović E, Ibišević M, Džambić A. Lectures of the subject, 2023.</li> <li>2. Bonevski M, Kujundžić K, Mandić L, Radošević M, urednici. Priručnik za samoliječenje, 1. izdanje Zagreb, CASI, 2017.</li> <li>3. Ugrešić N, Stepanović-Petrović R, Savić M. Farmakoterapija za farmaceute, 2. dopunjeno izdanje, Beograd, Farmaceutski fakultet u Beogradu, 2021.</li> </ol> <p><b>Additional:</b></p> <ol style="list-style-type: none"> <li>1. Tasić Lj, Krajnović D, Jocić D, Jović S. Komunikacija u farmaceutskoj praksi, 1. izdanje, Beograd, Farmaceutski fakultet u Beogradu, 2011.</li> <li>2. Joksović D. Akutna trovanja lekovima, 1. izdanje, Beograd, Rivel Co, 1999.</li> </ol>

<sup>2</sup>The Senate of the University of Tuzla determines mandatory and recommended textbooks and manuals, as well as other recommended literature on the basis of which student prepares for and takes the exam. The syllabus/curriculum determines mandatory and supplementary literature for each subject.

Annex 1b. Drug development – the path from synthesis to the market

<b>Subject code:</b>	<b>Subject name: Drug development – the path from synthesis to the market</b>		
<b>Level:</b> Integrated studies of first (I) and second (II) cycle	<b>Year: V</b>	<b>Semester: X</b>	<b>Number of ECTS credits:</b> 3
<b>Status:</b> Free module		<b>Total number of hours: 45</b> Lectures (L): 30 Practicals (P): 15	
<b>Teaching staff</b>	Aida Smajlović, PhD, Full Professor Adaleta Softić, PhD, Associate Professor Nahida Srabović, PhD, Associate Professor Maida Šljivić Husejnović, PhD, Assistant Professor Ermina Cilović Kozarević, PhD, Assistant Professor Esmeralda Dautović, PhD, Assistant Professor Merima Ibišević, PhD, Assistant Professor Amra Džambić, PhD, Assistant Professor		
<b>Prerequisite for enrollment:</b>	Master degree in Pharmacy or Medicine/ Attended subjects: Pharmaceutical chemistry, Biochemistry, Pharmaceutical Analysis, Pharmaceutical Technology, Pharmacognosy, Pharmacology, Toxicology,		
<b>Goal(s) of the subject:</b>	A subject providing theory and applications which will prepare students for the work required in drug development process		
<b>Subject structure/Topics:</b> Lectures Practicals	<b>Subject structure:</b> <ol style="list-style-type: none"> <li>a) <b>Theory (Lectures):</b> <ul style="list-style-type: none"> <li>- The role of the pharmacist in drug development</li> <li>- Drug discovery – principles and applications</li> <li>- Drug design – from molecule to drug</li> <li>- Organic synthesis in drug discovery</li> <li>- Recombinant engineering in the design of biopharmaceuticals</li> <li>- Plant-based drug and medicines – discovery and regulation</li> <li>- Sustainable technologies for liposome preparation</li> <li>- Nanotechnology in drug delivery</li> <li>- Evaluation the safety and effectiveness in preclinical toxicology studies</li> <li>- Clinical trials regulation</li> <li>- Regulation and quality control of newly developed drug</li> <li>- The patent process for drug discovery and development</li> </ul> </li> <li>b) <b>Practical/auditory (problem-solving approach):</b> <ul style="list-style-type: none"> <li>- Cytotoxic and genotoxic assays in drug discovery process</li> </ul> </li> </ol>		

	<ul style="list-style-type: none"> <li>- <b>Requirements for quality documentation concerning herbal drugs – document preparation process</b></li> <li>- <b>Design, formulation, biochemical and physicochemical evaluation of preparation for vaginal use</b></li> <li>- <b>Design, formulation, biochemical and physicochemical evaluation of preparation for vaginal use</b></li> <li>- <b>Case study</b></li> </ul>
<p><b>Learning outcomes:</b></p>	<p><b>Knowledge:</b> After attending classes and passing the exam, the student will pose a sound knowledge of the subject in the following areas:</p> <ul style="list-style-type: none"> <li>- fundamental principles of drug discovery and development (synthetic drugs, biopharmaceuticals, and herbal drugs);</li> <li>- implementation of the new drug in the clinics;</li> <li>- basic principles in contemporary approaches in drug discovery and drug formulation;</li> <li>- an integrated approach in drug discovery from plant sources;</li> <li>- quality control and quality assurance in drug discovery and development;</li> <li>- the phases and procedures of preclinical and clinical trials;</li> <li>- evaluation of both successful and unsuccessful drug candidates based on provided case studies;</li> <li>- methodologies for assessing the safety, effectiveness, and quality of new drugs;</li> <li>- post-market drug safety monitoring.</li> </ul> <p><b>Skills:</b> After attending classes and passing the exam, the student will pose:</p> <ul style="list-style-type: none"> <li>- skills strategic thinking and planning;</li> <li>- skills in experimental design;</li> <li>- technical skills with <i>in vitro</i> assays;</li> <li>- ethical and technical skills with <i>in vivo</i> assays;</li> <li>- critical evaluation of literature relevant drug design and development;</li> <li>- analytical skills,</li> <li>- chemistry skills related with toxicology, biochemistry and pharmacology experiments;</li> <li>- organizational skills,</li> <li>- decision making skills.</li> </ul> <p><b>Competences:</b> After attending classes and passing the exam, the student will be trained to:</p> <ul style="list-style-type: none"> <li>- critically evaluate and solve different problems in drug development process;</li> <li>- prepare the documentation required for marketing authorization of medicines, herbal and biological drugs</li> <li>- understand and apply the requirements of national recommendations and laws;</li> <li>- evaluate scientific, ethical and market-related considerations of importance in drug development,</li> <li>- share and apply knowledge related to recent developments and applications of drug design principles in the pharmaceutical industry;</li> </ul>

	<p>- construct, review and evaluate preclinical and clinical pharmaceutical studies with a general understanding of aim, choice of procedures, results, conclusions and importance.</p>
<b>Teaching methods:</b>	<p>1. Theoretical (theory) (70%) 2. Practical /auditory- problem-solving approach exercises (30%) (the percentage was calculated according to the number of hours for lectures and exercises, respectively, in regards to the total number of hours)</p>
<b>Evaluation system<sup>3</sup>:</b>	<p>Evaluation system: <b>THE SUBJECT OF EVALUATION:</b> 1. ACTIVITY ON CLASS 2. PRACTICAL EXAM 3. INDEPENDENT STUDENT ASSIGNMENTS 4. MIDTERM PARTIAL EXAM 5. FINAL EXAM * (In the final exam, the student can access each part of the exam (based on what she/he did not pass in term (at the time) of the partial exam or practical exam)).</p> <p><b>KNOWLEDGE ASSESSMENT:</b> Knowledge assessment will be carried out continually through activity in class, independent student assignments, practical exam (problem-solving approach), theoretical partial (midterm) exam and final exam.</p> <p><b>THE SUBJECT OF EVALUATION:</b> <b>1. ACTIVITY ON CLASS</b> <i>Student activity in class is scored with 0-10 points.</i></p> <p><b>2. PRACTICAL EXAM</b> <i>Using a problem-solving approach, the student solves case studies of both successful and unsuccessful drug candidates based on previously acquired knowledge taking into account the legal and ethical principles in drug discovery, drug development, and decision making process. The practical exam is held at the end of the semester. The practical exam is scored with 10-20 points.</i></p> <p><b>3. INDEPENDENT STUDENT ASSIGNMENTS</b> <i>Based on the available literature, the student conducts independent research on a given topic and writes a seminar paper and presents it orally during the semester. Independent student assignments are scored with 5-10 points.</i></p> <p><b>4. PARTIAL (MIDTERM) EXAM</b> <i>The student's knowledge is assessed by a test based on multiple choice questions (MCQ) which provides respondents with multiple answer options. The partial exam is held after the first third of the semester. First MCQ is scored with 11-20 points.</i></p> <p><b>5. FINAL EXAM</b></p>

<sup>31</sup> The structure of grading and point criteria for each subject is determined by the Law on Higher Education of Tuzla Canton, the Statute of the University of Tuzla, and the Ruled on the method of passing exams and assessing students at the University of Tuzla. Additional information regarding method and procedures for evaluating knowledge and taking exams are provided by the syllabus/curriculum of each subject.

	<p><i>The student's knowledge is assessed by a test based on multiple choice questions (MCQ) which provides respondents with multiple answer options. The final exam is held at the end of the semester. Second MCQ is scored with 22-40 points.</i></p> <p><b>TOTAL:</b> Number of points: 100 Maximum number of points (100.0 points – acquired on all individual segments); Requirement (54.0 points – acquired on all individual segments)</p> <p><b>EVALUATION MANNER</b></p> <p><i>10 (A) – 94–100 points 9 (B) – 84-93 points 8 (C) – 74-83 points 7 (D) – 64-73 points 6 (E) – 54-63 points 5 (F, FX) – 0-53 points.</i></p>
<p><b>Literature<sup>4</sup>:</b></p>	<p><b>Mandatory:</b></p> <ol style="list-style-type: none"> <li>1. Smajlović A, Softić A, Srabović N, Šljivić Husejnović M, Čilović Kozarević E, Dautović E, Ibišević M, Džambić A. Lectures of the subject, 2023.</li> <li>2. Blass B.E. Basic Principles of Drug Discovery and Development, Elsevier Science, 2015.</li> <li>3. Osakwe O, Rizvi S.A.A. Social Aspects of Drug Discovery, Development and Commercialization, Elsevier Science, 2016.</li> </ol> <p><b>Additional:</b></p> <ol style="list-style-type: none"> <li>1. Medicinal Products and Medical Devices Act. Official Gazette of B-H, no.58/08</li> <li>2. Ordinance on clinical trials on medicinal products and medical devices. Official Gazette of B-H, no.4/10</li> <li>3. <a href="http://www.almbih.gov.ba/en/documents/">http://www.almbih.gov.ba/en/documents/</a></li> </ol>

<sup>42</sup>The Senate of the University of Tuzla determines mandatory and recommended textbooks and manuals, as well as other recommended literature on the basis of which student prepares for and takes the exam. The syllabus/curriculum determines mandatory and supplementary literature for each subject.

**Annex 2. Free modules proposed by University of Sarajevo**

<https://docs.google.com/document/d/1SDVsoQ8NFnP-0q5VjlIDXchr1QKVWG05/edit>

[https://docs.google.com/document/d/1LTlikK\\_EMEcFKemH6vjDKqcRD88oxL-n/edit](https://docs.google.com/document/d/1LTlikK_EMEcFKemH6vjDKqcRD88oxL-n/edit)

**Annex 2a. Establishment of an internationally recognized laboratory**

<b>Subject code:</b>	<b>Subject name: Establishment of an internationally recognized laboratory</b>		
<b>Level:</b> Integrated studies of first (I) and second (II) cycle	<b>Year: V</b>	<b>Semester: IX</b>	<b>Number of ECTS credits:</b> 3
<b>Status:</b> Free module		<b>Total number of hours:</b> Lectures (L): 30 Practicals (P): 15	
<b>Teaching staff</b>	UNSA and Verlab Research Institute Staff		
<b>Prerequisite for enrollment:</b>	Control of drugs I and II; Clinical biochemistry I; Industrial pharmacy I		
<b>Goal(s) of the subject:</b>	The aim of this course is to introduce participants to international and regional requirements, procedures, as well as international and local context in order to establish an internationally recognized laboratory. The participants will learn general and specific technical and metrology requirements as well as quality management system requirements of the laboratory. Additional, the aim is to provide participants with an understanding of quality and its role in the organization together with techniques to enable them to make a significant contribution to an organization's strategic vision for success.		
<b>Subject structure/Topics:</b> <b>Lectures</b> <b>Practicals</b>	<p><b>Subject structure:</b></p> <p><b>a) Theory (Lectures):</b> Lectures:</p> <ol style="list-style-type: none"> <li>1. Introduction to Quality Management</li> <li>2. International Standards Terms and definitions</li> <li>3. General requirements</li> <li>4. Structural requirements</li> <li>5. Resource requirements</li> <li>6. Process requirements</li> <li>7. Management system documentation</li> <li>8. Management review</li> <li>9. Independence requirements – Working procedures</li> </ol> <p><b>b) Practical (exercises):</b> Laboratory exercises:</p> <ol style="list-style-type: none"> <li>1. Development of quality procedures in accordance with international standard</li> </ol>		

	<ol style="list-style-type: none"> <li>2. Development of Quality manual in accordance with international standard</li> <li>3. Development of working procedures in accordance with international standard</li> <li>4. Development and implementation of Proficiency testing (PT) scheme and interlaboratory comparison</li> <li>5. Establishment of traceability chain of measurement in accordance with international standard</li> </ol>
<p><b>Learning outcomes:</b></p>	<p>After having passed the course the participant is expected to:</p> <ol style="list-style-type: none"> <li>a) have understanding of scientific concepts and procedures according to quality management,</li> <li>b) have understanding of application specific International standards and meeting all the requirements;</li> <li>c) develop management skills related to inventory, personnel and operations in quality management system</li> </ol> <p>During the course students will present information in oral, written or graphic forms in order to communicate effectively with peers and tutors.</p> <p>Within this course through theoretical and practical classes, the participants will gain knowledge on how to define the needs of their laboratory and how to bring that laboratory, appreciating the international requirements and context, towards the recognition of its competences by the international relevant bodies, both in the field of technique and metrology and in areas of proving the quality management system.</p>
<p><b>Teaching methods:</b></p>	<ol style="list-style-type: none"> <li>1. Theoretical (theory) (67%)</li> <li>2. Practical - exercises (33%)</li> </ol> <p>(the percentage was calculated according to the number of hours for lectures and exercises, respectively, in regards to the total number of hours)</p> <p>The course program is carried out through two forms of teaching activities:</p> <ul style="list-style-type: none"> <li>- Lectures conducted by the teaching staff, supported by presentations on slides. Attendees become familiar with basic theoretical concepts from the course content.</li> <li>- Laboratory practices in which the participants, with guidance and accompanied by a responsible person, conduct the experimental part of the course.</li> </ul> <p>It is mandatory to attend all types of classes, which will be accompanied by written records and scored.</p>
<p><b>Evaluation system <sup>5</sup>:</b></p>	<p>Evaluation system: THE SUBJECT OF EVALUATION:</p> <ol style="list-style-type: none"> <li>1. Development of Quality Manual in accordance with ISO standard, Development of quality procedures in accordance</li> </ol>

<sup>51</sup> The structure of grading and point criteria for each subject is determined by the council of the organizational unit before the beginning of the academic year in which the subject is taught in accordance with article 64, paragraph 6 of the Law on Higher Education of Sarajevo Canton.

<sup>2</sup> The Senate of the Higher Education Institution as an institution or the council of the organizational unit of the Higher Education Institution as a public institution determines mandatory and recommended textbooks and manuals, as well as other recommended literature on the basis of which student prepares for and takes the exam, by a special decision which must be published on its website before the beginning of the academic year in accordance with article 56, paragraph 3 of the Law on Higher Education of Sarajevo Canton.

	<p>with ISO standard, Development of working procedures in accordance with ISO standard – maximum 70 points</p> <p>2. Presentation of laboratory quality management system – maximum 30 points.</p> <p><i>KNOWLEDGE ASSESSMENT:</i> Knowledge assessment will be carried out through written quality management and procedures and presentation.</p> <p><i>TOTAL:</i> Number of points: Maximum number of points (100.0 points – acquired on all individual segments); Requirement (55.0 points – acquired on all individual segments)</p> <p><i>EVALUATION MANNER</i> Grades are assigned based on the following scale: Grade 10 (A): from 95.0 to 100 points, Grade 9 (B): from 85.0 to 94.9 points, Grade 8 (C): from 75.0 to 84.9 points, Grade 7 (D): from 65.0 to 74.9 points, Grade 6 (E): from 55.0 to 64.9 points, Grade 5 (F,FX): less than 55.0 points - the student failed.</p>
<p><b>Literature<sup>6</sup>:</b></p>	<ol style="list-style-type: none"> <li>1. Barrie G. Dale, Ton van der Wiele, Jos van Iwaarden , Managing Quality, 5th Edition, BlackWell Publishing, 2007</li> <li>2. International Standard ISO/IEC 17020:2012,</li> <li>3. International Standard ISO 9001:2008,</li> <li>4. 2015 Handbook of International Quality Control, Auditing, Review, Other Assurance, and Related Services Pronouncements</li> </ol> <ol style="list-style-type: none"> <li>1. Overview and implementation of the CIPM MRA CIPM MRAP-11ILAC Mutual Recognition Arrangement (MRA): Policy and Management ILA AC M C-P4:05</li> <li>2. Measurement comparisons in the CIPM MRA Guidelines for organizing, participating and reporting CIPM MRA-G-11</li> <li>3. Quality management systems in the CIPM MRA Guidelines for monitoring and reporting CIPM MRA-G-12</li> <li>4. Calibration and measurement capabilities in the context of the CIPM MRA Guidelines for their review, acceptance and maintenance CIPM MRA-G-13</li> </ol> <p><b>Additional:</b></p> <ol style="list-style-type: none"> <li>1. Evaluation of measurement data — Guide to the expression of uncertainty in measurement (GUM), JCGM 100:2008</li> </ol>

*Annex 2b. Introduction to 3D Printing in Pharmacy*

<b>Subject code: TBD</b>	<b>Subject name: Introduction to 3D Printing in Pharmacy</b>		
<b>Level:</b> Integrated studies of first (I) and second (II) cycle	<b>Year: IV</b>	<b>Semester: VII</b>	<b>Number of ECTS credits:</b> 3
<b>Status:</b> Free module		<b>Total number of hours: 45h</b> Lectures (L): 15h Practicals (P): 30h	
<b>Teaching staff</b>	UNSA and Fablab Staff		
<b>Prerequisite for enrollment:</b>	Senior students		
<b>Goal(s) of the subject:</b>	<p>The subject "Introduction to 3D Printing in Pharmacy" is to provide students with a comprehensive understanding of the basic principles and process of 3D printing, as well as the materials and applications of this technology in the field of pharmacy. By the end of the course, students should have the knowledge, skills, and competences necessary to critically evaluate the potential benefits and limitations of 3D printing in pharmacy, design and create basic solutions using 3D printing, and communicate effectively about 3D printing and its applications to a range of audiences. The course aims to equip students with the necessary skills and knowledge to be able to contribute to the growing field of 3D printing in pharmacy.</p>		
<b>Subject structure/Topics:</b> <b>Lectures</b> <b>Practicals</b>	<p><b>Subject structure:</b></p> <p><b>a) Theory (Lectures):</b></p> <ul style="list-style-type: none"> <li>- Introduction to 3D printing: history, principles, and process</li> <li>- 3D printing techniques</li> <li>- Materials for 3D printing: properties and selection</li> <li>- 3D printing in pharmacy: drug delivery and personalized medicine</li> <li>- Design for 3D printing: software and techniques</li> <li>- Quality control and testing in 3D printing</li> <li>- Ethical and regulatory considerations in 3D printing</li> </ul> <p><b>b) Practical (exercises):</b></p> <ul style="list-style-type: none"> <li>- Hands-on training on operating a 3D printer</li> <li>- Designing and printing a simple 3D model</li> <li>- Post-processing 3D printed objects: cleaning and finishing techniques</li> <li>- Case studies in applying 3D printing to pharmacy-related problems</li> <li>- Group project: designing and printing a 3D model</li> </ul>		

	<ul style="list-style-type: none"> <li>- Presentations on current and trends in 3D printing in pharmacy</li> </ul>
<p><b>Learning outcomes:</b></p>	<p><b>Knowledge:</b> After attending classes and passing the exam, the student will:</p> <ul style="list-style-type: none"> <li>- gain an understanding of the principles and process of 3D printing.</li> <li>- learn about the materials used in 3D printing and their properties.</li> <li>- understand the potential applications of 3D printing in pharmacy, including drug delivery and personalized medicine.</li> </ul> <p><b>Skills:</b> After attending classes and passing the exam, the student will be able to:</p> <ul style="list-style-type: none"> <li>- design and create 3D models for printing.</li> <li>- develop skills in operating 3D printers and troubleshooting any issues that may arise.</li> <li>- post-process 3D printed objects, including cleaning and finishing techniques.</li> </ul> <p><b>Competences:</b> After attending classes and passing the exam, the student will be trained to:</p> <ul style="list-style-type: none"> <li>- critically evaluate the potential benefits and limitations of 3D printing in pharmacy.</li> <li>- apply their knowledge and skills in 3D printing to design and create basic solutions for pharmacy-related problems.</li> <li>- communicate effectively about 3D printing and its potential applications in pharmacy to a range of audiences.</li> </ul>
<p><b>Teaching methods:</b></p>	<p>1. Theoretical (theory) (33%): The teaching methods for the theoretical component of the course include lectures, seminars, and class discussions to provide students with a solid foundation in the principles and process of 3D printing, materials used, and applications in pharmacy.</p> <p>2. Practical - exercises (67%): The teaching methods for the practical component of the course include hands-on training in operating a 3D printer, designing and printing 3D models, and post-processing printed objects. There may also be case studies and group projects to allow students to apply their knowledge and skills in a more realistic and practical setting.</p> <p>(The percentage was calculated according to the number of hours for lectures and exercises, respectively, in regards to the total number of hours)</p>

<p><b>Evaluation system <sup>7</sup>:</b></p>	<p><i>THE SUBJECT OF EVALUATION:</i></p> <p><i>1. TESTS (COLLOQUIUMS)</i></p> <p>- Two written tests (Week 4 and Week 11) will be used to assess students' progress throughout the course and ensure they are retaining the material covered in lectures and practical exercises.</p> <p><i>2. PARTIAL (MIDTERM) EXAM (Week 7)</i></p> <p>- Will cover the theoretical aspects of the course, including the principles and process of 3D printing, materials used, and applications in pharmacy.</p> <p><i>3. PRACTICAL EXAM (Week 13)</i></p> <p>- Will assess students' hands-on skills in operating a 3D printer, designing and printing 3D models, and post-processing printed objects.</p> <p><i>4. FINAL EXAM (End of Semester – Week 15)</i></p> <p><i>TOTAL: Number of points: 100 pts</i></p> <p><i>1. TESTS (COLLOQUIUMS) 2 x 5 pts – 10 pts.</i>  <i>2. PARTIAL (MIDTERM) EXAM 30 pts</i>  <i>3. PRACTICAL EXAM 30 pts</i>  <i>4. FINAL EXAM 30pts</i></p> <p>Requirement (55.0 points – acquired on all individual segments)</p> <p><i>EVALUATION MANNER</i>  The student on the final exam can take an exam of only practical, only the first, only the second or both partial exams (based on what she/he did not pass in term (at the time) of the partial exam or practical exam).</p>
<p><b>Literature<sup>8</sup>:</b></p>	<p><b>Mandatory:</b></p> <ol style="list-style-type: none"> <li>1. "3D Printing: A Beginner's Guide" by S. Gibson. This book provides a comprehensive introduction to 3D printing, including the principles, process, materials, and applications of this technology.</li> <li>2. "3D Printing: A Practical Guide for Pharmacists" by D. Grinstead and J.F. Hilton. This book provides a</li> </ol>

<sup>7</sup> The structure of grading and point criteria for each subject is determined by the council of the organizational unit before the beginning of the academic year in which the subject is taught in accordance with article 64, paragraph 6 of the Law on Higher Education of Sarajevo Canton.

<sup>2</sup> The Senate of the Higher Education Institution as an institution or the council of the organizational unit of the Higher Education Institution as a public institution determines mandatory and recommended textbooks and manuals, as well as other recommended literature on the basis of which student prepares for and takes the exam, by a special decision which must be published on its website before the beginning of the academic year in accordance with article 56, paragraph 3 of the Law on Higher Education of Sarajevo Canton.

comprehensive overview of 3D printing in pharmacy, including the principles and process of 3D printing, materials used, and applications in drug delivery and personalized medicine

**Additional:**

1. "3D Printing in the Pharmaceutical Industry: Current Status and Future Directions" by M. Raza et al. This review article discusses the current state of 3D printing in the pharmaceutical industry and outlines the potential benefits and challenges of this technology
2. "3D Printing: A Review of Materials and Methods" by S.C. McAleer et al. This review article discusses the various materials and methods used in 3D printing, including the advantages and limitations of each.

**Annex 3. Free modules proposed by University of Banja Luka**

[https://docs.google.com/document/d/1J\\_i9ETImeOCn0Y0dCd54pgI\\_Fw5FfX-S/edit](https://docs.google.com/document/d/1J_i9ETImeOCn0Y0dCd54pgI_Fw5FfX-S/edit)

<https://docs.google.com/document/d/1VbhfnHtV7Vtryyx6mbz0eyVOphnJ1E9h/edit>

**Annex 3a. Pharmacotherapy of special group of patients – contemporary approaches**

<b>Subject code:</b>	<b>Subject name: Pharmacotherapy of special group of patients – contemporary approaches</b>		
<b>Level: Integrated studies of first (I) and second (II) cycle</b>	<b>Year:</b>	<b>Semester:</b>	<b>Number of ECTS credits:5</b>
<b>Status: Free module</b>		<b>Total number of hours: 75</b> Lectures (L): 45 Practicals (P):30	
<b>Teaching staff</b>	Assistant Professor Nataša Bubić Pajić, PhD, Assistant Professor Biljana Gatarić, PhD, Assistant Professor Anđelka Račić, PhD		
<b>Prerequisite for enrollment:</b>	Master degree in Pharmacy or Medicine/Attended subjects: Pharmaceutical technology 1, Pharmaceutical technology 2, Pharmaceutical technology 3, Pharmacotherapy		
<b>Goal(s) of the subject:</b>	Acquaint students with the specifics of the use of drugs in medicine for special group of patients (dose adjustment, acceptability, comfort, etc.), pharmaceutical forms of drugs for special group of patients, production of pharmaceutical preparations, pharmaceutical-technological tests and methods of biopharmaceutical characterization of pharmaceutical preparations, legal regulations and regulatory guidelines related to the development, production/production, quality assessment and marketing authorization of medicines intended for special group of patients.		
<b>Subject structure/Topics: Lectures Practicals</b>	<b>Subject structure:</b> <b>a) Theory (Lectures):</b> <ul style="list-style-type: none"> <li>● acquiring knowledge on the most significant characteristics of the pediatric and geriatric population, pregnant and nursing women, affecting pharmacokinetics/pharmacodynamics of the drug, drug selection, dosing regimens, administration routes and pharmaceutical drug form;</li> <li>● acquiring/widening of knowledge on etiopathogenesis, pathophysiology, clinical presentation and diagnosis of the most common diseases in the pediatric and geriatric population, pregnant and nursing women;</li> </ul>		

	<ul style="list-style-type: none"> <li>● acquiring knowledge on current pharmacotherapy of the most common diseases in the pediatric and geriatric population, pregnant and nursing women;</li> <li>● introducing students to the specific aspects of drug formulation and usage in pediatric and geriatric medicine, and medicines for pregnant and nursing women (dose adjustment, acceptability, palatability etc);</li> <li>● providing an overview of pediatric dosage forms, compounding of pediatric drugs, pharmaceutical technical procedures and methods to assess biopharmaceutical properties of pediatric drugs;</li> <li>● introducing regulatory requirements and guidelines related to the research and development, manufacturing, quality control and marketing authorization of pediatric drugs.</li> </ul> <p><b>b) Practical (exercises):</b></p> <ul style="list-style-type: none"> <li>● training for critical evaluation of drugs and advising patients, family members and healthcare professionals regarding the proper and safe drug use in the pediatric and geriatric population, pregnant and nursing women;</li> <li>● dose adjustment calculations for pediatric and geriatric patients, pregnant and nursing women;</li> <li>● compounding of pediatric and geriatric drugs and the assessment of biopharmaceutical properties of pediatric and geriatric drugs;</li> <li>● compounding medicines and extemporaneous preparation of age-appropriate dosage forms for pediatric and geriatric population and pregnant and nursing women from the licensed medicines.</li> </ul>
<p><b>Learning outcomes:</b></p>	<p><b>Knowledge:</b> After attending classes and passing the exam, the students will be able to:</p> <ul style="list-style-type: none"> <li>● understand and distinguish pathophysiology, clinical presentation, clinical course, prognosis and pharmacological and nonpharmacological treatment of various disorders in pediatric and geriatric population, pregnant and nursing women;</li> <li>● compare different pharmacological options for certain diseases based on their therapeutic efficacy/adverse effects potential;</li> <li>● understand the specificities of drug formulation in pediatric and geriatric medicine, types, pharmaceutical technical characteristics and biopharmaceutical aspects of different pediatric and geriatric dosage forms;</li> <li>● know about regulatory requirements and guidelines related to research and development, manufacturing, quality control and marketing authorization of pediatric drugs.</li> </ul> <p><b>Skills:</b> After attending classes and passing the exam, the student will be able to:</p> <ul style="list-style-type: none"> <li>● compound pediatric and geriatric medicines, and extemporaneous preparation of age-appropriate dosage forms.</li> </ul> <p><b>Competences:</b> After attending classes and passing the exam, the students will be trained to:</p>

	<ul style="list-style-type: none"> <li>• present patients, family members and healthcare professionals with evidence-based information or advice on drug use in special groups of patients (pediatric, geriatric and pregnant and nursing women)</li> <li>• to critically select the appropriate dosage form, depending on patient age, condition and therapeutic aim.</li> </ul>
<b>Teaching methods:</b>	<p>1. Theoretical (theory) (53.33 %) 2. Practical - exercises (46.67 %) (the percentage was calculated according to the number of hours for lectures and exercises, respectively, in regards to the total number of hours)</p>
<b>Evaluation system:</b>	<p>Evaluation system: THE SUBJECT OF EVALUATION:</p> <p>1. PRACTICAL EXAM(makes up 30% of the final grade) 2. FINAL EXAM (makes up 70% of the final grade)</p> <p><i>KNOWLEDGE ASSESSMENT:</i> Knowledge assessment will be carried out through tests practical exam and final exam.</p> <p><i>THE SUBJECT OF EVALUATION:</i></p> <p><i>1. PRACTICAL EXAM</i> Compounding of pediatric and geriatric medicines, and extemporaneous preparation of age-appropriate dosage forms.</p> <p><i>2. FINAL EXAM</i></p> <ul style="list-style-type: none"> <li>• Pathophysiology, clinical presentation, clinical course, prognosis and pharmacological and nonpharmacological treatment of various disorders in pediatric and geriatric population, pregnant and nursing women;</li> <li>• Different pharmacological options for certain diseases based on their therapeutic efficacy/adverse effects potential;</li> <li>• The specificities of drug formulation in pediatric and geriatric medicine, types, pharmaceutical technical characteristics and biopharmaceutical aspects of different pediatric and geriatric dosage forms;</li> <li>• Regulatory requirements and guidelines related to research and development, manufacturing, quality control and marketing authorization of pediatric drugs.</li> </ul> <p><i>TOTAL:</i> Number of points: Maximum number of points (100.0 points – acquired on all individual segments); Requirement (51.0 points – acquired on all individual segments)</p>
<b>Literature:</b>	<p><b>Mandatory:</b> Bubić Pajić N, Gatarić B, Račić A. (2023)Lectures of the subject</p> <p><b>Additional:</b> Cvijić S, Krajišnik D, Đuriš J, Pantelić I. (2022) Farmaceutski oblici lekova za pedijatrijsku populaciju, Farmaceutski fakultet, Beograd.</p>

	Wehling M. Drug Therapy for the Elderly, Springer ...
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*Annex 3b. Regulation in pharmacy*

<b>Subject code:</b>	<b>Subject name: Regulation in pharmacy</b>		
<b>Level: Integrated studies of first (I) and second (II) cycle</b>	<b>Year:</b>	<b>Semester:</b>	<b>Number of ECTS credits:5</b>
<b>Status:</b> Free module		<b>Total number of hours: 75</b> Lectures (L): 45 Practicals (P):30	
<b>Teaching staff</b>	Assistant Professor Irena Kasagić Vujanović, PhD, Assistant Professor Žarko Gagić, PhD		
<b>Prerequisite for enrollment:</b>	Master degree in Pharmacy or Medicine/Attended subjects: Pharmaceutical technology 2, Pharmaceutical technology 3, Drug analysis, Bromatology		
<b>Goal(s) of the subject:</b>	Acquaintance of students with legal regulations and processes in the field of pharmacy. Acquiring knowledge in the field of applicable regulations. Training students to interpret regulatory requirements		
<b>Subject structure/Topics: Lectures Practicals</b>	<p><b>Subject structure:</b></p> <p><b>a) Theory (Lectures):</b></p> <ul style="list-style-type: none"> <li>● acquiring knowledge of the laws related to health insurance and pharmacy practice</li> <li>● acquiring/widening of knowledge about <i>Good manufacturing practice (GMP)</i>, <i>Good laboratory practice (GLP)</i> and <i>Good distribution practice (GDP)</i> in pharmaceutical industry</li> <li>● familiarizing students with the role of Agency for medicinal products and medical devices in Bosnia and Herzegovina</li> <li>● introducing regulatory requirements and guidelines related to marketing authorization of drug products and medical devices</li> <li>● acquiring knowledge of the regulatory guidelines related to biological drugs</li> <li>● current dietary supplements and food for special medical purposes guidance documents and regulatory information</li> <li>● providing an overview of guidance documents and regulatory information for the cosmetics industry</li> <li>● Introduction to Regulatory Toxicology</li> </ul> <p><b>b) Practical (exercises):</b></p>		

	<ul style="list-style-type: none"> <li>● training students to recognize failure of pharmaceutical industry to comply with GMP, GLP and GDP regulations and to propose effective corrective measures</li> <li>● preparation of documentation required for marketing authorization of drug products and medical devices</li> <li>● preparation of documentation required for marketing authorization of biological drugs</li> <li>● categorization of dietary supplements and preparation of dietary supplement labeling guideline</li> <li>● categorization of cosmetic product</li> <li>● toxicological risk assessment</li> </ul>
<p><b>Learning outcomes:</b></p>	<p><b>Knowledge:</b> After attending classes and passing the exam, the students will be able to:</p> <ul style="list-style-type: none"> <li>● understand the laws related to health insurance and pharmacy practice;</li> <li>● understand the specificities of GMP, GLP, GDP;</li> <li>● know about regulatory requirements and guidelines related to biological drugs, dietary supplements, food for special medical purposes, cosmetic products and toxicology</li> </ul> <p><b>Skills:</b> After attending classes and passing the exam, the student will be able to:</p> <ul style="list-style-type: none"> <li>● understand and apply different pharmacy laws and regulations to solve practical problems</li> </ul> <p><b>Competences:</b> After attending classes and passing the exam, the students will be trained to:</p> <ul style="list-style-type: none"> <li>● critically evaluate and solve different regulatory problems in pharmacy practice and industry</li> <li>● prepare the documentation required for marketing authorization of drug products, medical devices and biological drugs</li> <li>● categorize dietary supplements and prepare dietary supplement labeling guideline</li> <li>● categorize cosmetic product</li> <li>● make toxicological risk assessment</li> </ul>
<p><b>Teaching methods:</b></p>	<p>1. Theoretical (theory) (53.33 %) 2. Practical - exercises (46.67 %) (the percentage was calculated according to the number of hours for lectures and exercises, respectively, in regards to the total number of hours)</p>
<p><b>Evaluation system:</b></p>	<p>Evaluation system: THE SUBJECT OF EVALUATION: 1. COLLOQUIUM(makes up 30% of the final grade) 2. FINAL EXAM (makes up 70% of the final grade)</p> <p><i>KNOWLEDGE ASSESSMENT:</i> Knowledge assessment will be carried out through tests colloquium and final exam.</p> <p><i>THE SUBJECT OF EVALUATION:</i></p>

	<p><b>1. COLLOQUIUM</b> Dealing with and solving practical situations and problems arising from acts valid in the Republic of Serbia and Bosnia and Herzegovina.</p> <p><b>2. FINAL EXAM</b> Verification of acquired knowledge related to applicable laws in health care and pharmacy practice, regulatory requirements and guidelines related to biological drugs, dietary supplements, food for special medical purposes, cosmetic products and toxicology in the Republic of Srpska.</p> <p><b>TOTAL:</b> Number of points: Maximum number of points (100.0 points – acquired on all individual segments); Requirement (51.0 points – acquired on all individual segments)</p>
<p><b>Literature:</b></p>	<p><b>Mandatory:</b></p> <ul style="list-style-type: none"> <li>● Law on health care of the Republic of Srpska</li> <li>● Law on pharmacy activities of the Republic of Srpska</li> <li>● Ordinance on the type, amount and method of payment of of fees for retail sales of medicines and medical devices (Official gazette of Republic of Srpska, number 27/13)</li> <li>● Ordinance on the amount of fees for manufacturing and wholesale distribution of medicines and medical devices (Official gazette of Republic of Srpska, number 27/13)</li> <li>● Ordinance on conditions for prescribing and dispensing medicines (Official gazette of Republic of Srpska, number 116/12)</li> <li>● Ordinance on the content and method of keeping reports on the expenditure and utilization of medicines ("Official Gazette of the Republic of Srpska", number 65/11)</li> <li>● Ordinance on the content and manner of the Pharmacy Register and the Register of Specialized Stores keeping ("Official Gazette of the Republic of Srpska", number 104/10)</li> <li>● Ordinance on special conditions for retail trade in specialized stores ("Official Gazette of the Republic of Srpska", number 55/16)</li> <li>● Ordinance on general and special conditions regarding personnel, space and equipment for retail trade in pharmacies ("Official Gazette of the Republic of Srpska", number 92/17)</li> <li>● Ordinance on the types of cosmetics and other means for health protection, other products sold at retail in pharmacies and specialized stores, and services that can be provided in pharmacies ("Official Gazette of the Republic of Srpska", number 9/10)</li> <li>● Ordinance on the guidelines of good manufacturing practice in the preparation of galenic products("Official Gazette of the Republic of Srpska", number 9/10)</li> <li>● Decision on determining the list of essential medicines of the Republic of Srpska ("Official Gazette of the Republic of Srpska", number 10/07)</li> </ul>

	<ul style="list-style-type: none"><li>● Medicinal products and medical devices act (“Official gazette of Bosnia and Herzegovina, number 58/08”)</li><li>● Ordinance on medical devices</li><li>● Ordinance on the content and manner of labeling of outer and immediate packaging of medicinal product</li><li>● Ordinance on the conditions, circumstances and procedure for the use of authorized laboratories</li><li>● Ordinance on quality control of the medicinal product</li><li>● Ordinance on the content and manner of labeling of outer and immediate packaging of medicinal product</li><li>● Ordinance on clinical trials on medicinal products and medical devices</li><li>● Ordinance on advertising of medicinal products and medical devices</li><li>● Ordinance on the methods of monitoring of quality defects in medicinal product</li><li>● Ordinance on the type, amount and method of payment of costs for the activities conducted by the agency for medicinal products and medical devices of Bosnia and Herzegovina</li><li>● Ordinance on dietary supplements in Republic of Srpska</li><li>● Ordinance on food with special nutritional purposes</li></ul>
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**Annex 4. Free modules proposed by University of Mostar**

<https://docs.google.com/document/d/1Ydf2iim3384QdF554zcppYXIf1JwOvk-/edit>

**Annex 4. Pharmacotherapy of special group of patients – contemporary approaches**

<b>Subject code:</b>	<b>Subject name:</b> Development of biologics and biosimilars		
<b>Level:</b> Integrated studies of first (I) and second (II) cycle	<b>Year:</b> 5 <sup>th</sup>	<b>Semester:</b> 9 <sup>th</sup>	<b>Number of ECTS credits:</b> 3
<b>Status:</b> Free module		<b>Total number of hours: 45</b> Lectures (L): 30 Practicals (P):15	
<b>Teaching staff</b>	Full Professor Ivica Brizić, PhD Assistant Professor Martin Kondža, PhD		
<b>Prerequisite for enrollment:</b>	Attended subjects: Pharmacology 1 Pharmacology 2		
<b>Goal(s) of the subject:</b>	The goals of this subject are the following: <ul style="list-style-type: none"> <li>- Achieve the student's understanding of the difference between biological drugs and biosimilars</li> <li>- Achieve students' understanding of the method of development and registration of biological drugs and biosimilars and the differences in this process</li> <li>- Achieve the student's understanding of individual proteins and their responsibility in the mechanism of action of biological drugs and biosimilars</li> </ul>		
<b>Subject structure/Topics:</b> <b>Lectures</b> <b>Practicals</b>	<b>Subject structure:</b> <p><b>a) Theory (Lectures):</b></p> <ul style="list-style-type: none"> <li>- nomenclature and definitions</li> <li>- innovator biologics and biosimilars</li> <li>- differences between biosimilars and generic medicines</li> <li>- interchangeability, switchability, and substitution</li> <li>- other clinical considerations with biosimilars</li> <li>- manufacture, delivery, and naming considerations</li> </ul>		

	<ul style="list-style-type: none"> <li>- regulatory status</li> <li>- major classes of biotherapeutics</li> <li>- drug targets for biologics</li> <li>- biologics vs. small molecule drugs</li> </ul> <p><b>b) Practical (exercises):</b></p> <ul style="list-style-type: none"> <li>- computer programs for biologics and biosimilars</li> <li>- approved biologics</li> <li>- pharmacokinetics</li> <li>- pharmacovigilance and side-effect reporting</li> <li>- pharmacogenomics</li> <li>- nomenclature</li> <li>- common terms and abbreviations</li> <li>- checklist for pharmacists on biologics and biosimilars</li> </ul>
<p><b>Learning outcomes:</b></p>	<p><b>Knowledge:</b> After attending classes and passing the exam, the student will:</p> <ul style="list-style-type: none"> <li>- Know the difference between biological drugs and biosimilars</li> <li>- Know the process of registration of biological drugs and biosimilars</li> <li>- Be able to propose improvements to drugs or the selection of other drugs from the same pharmacotherapeutic group</li> <li>- Propose new, more effective pharmaceutical forms that will lead to fewer side effects</li> </ul> <p><b>Skills:</b> After attending classes and passing the exam, the student will be able to:</p> <ul style="list-style-type: none"> <li>- Recognize biologics and biosimilars on the market</li> <li>- Recognize side-effects that can be attributed to these medicines</li> </ul> <p><b>Competences:</b> After attending classes and passing the exam, the student will be trained to:</p> <ul style="list-style-type: none"> <li>- independently carry out the registration process of biological drugs and biosimilars</li> <li>- independently determine the principles of the mechanism of action of biological drugs and biosimilars</li> <li>- use computer programs to predict the activity of certain biological drugs and biosimilars</li> <li>- determine potential side effects of preparations</li> </ul>
<p><b>Teaching methods:</b></p>	<p>1. Theoretical (theory) (66%) 2. Practical - exercises (34%) (the percentage was calculated according to the number of hours for lectures and exercises, respectively, in regards to the total number of hours)</p>
<p><b>Evaluation system<sup>9</sup>:</b></p>	<p>Evaluation system: THE SUBJECT OF EVALUATION:</p> <ol style="list-style-type: none"> <li>1. Practical exam</li> <li>2. Final exam</li> </ol>

<sup>91</sup> The structure of grading and point criteria for each subject is determined by the council of the organizational unit before the beginning of the academic year in which the subject is taught in accordance with article 55, paragraph 3 of the Study Rulebook of the University of Mostar

<sup>2</sup> The Senate of the Higher Education Institution as an institution or the council of the organizational unit of the Higher Education Institution as a public institution determines mandatory and recommended textbooks and manuals, as well as other recommended literature on the basis of which student prepares for and takes the exam, by a special decision which must be published on its website before the beginning of the academic year in accordance with article 114, paragraph 3 of the Law on Higher Education of Herzegovina-Neretva Canton.

	<p><b>KNOWLEDGE ASSESSMENT:</b> Knowledge assessment will be carried out continually through tests (colloquiums), practical exams, theoretical partial (midterm) exams (first and second) and final exam.</p> <p><b>THE SUBJECT OF EVALUATION:</b></p> <ol style="list-style-type: none"> <li>1. PRACTICAL EXAM (makes up 15% of the final grade)</li> <li>2. FINAL EXAM (makes up 85% of the final grade)</li> </ol> <p><b>TOTAL:</b> Number of points: Maximum number of points (100.0 points – acquired on all individual segments); Requirement (55.0 points – acquired on all individual segments)</p> <p><b>EVALUATION MANNER</b> The student on the final exam can take an exam of only practical, only the first, only the second or both partial exams (based on what she/he did not pass in term (at the time) of the partial exam or practical exam).</p>
<p><b>Literature<sup>10</sup>:</b></p>	<p><b>Mandatory:</b> Brizić I, Kondža M. (2023). Lectures of the subject Development of biologics and biosimilars. University of Mostar Faculty of Pharmacy.</p> <p><b>Additional:</b> Ramzan I. (2021). Biologics, Biosimilars, and Biobetters: An Introduction for Pharmacists, Physicians and Other Health Practitioners. Wiley, Hoboken.</p>

## 5. References

1. Agendas, Attendance sheets, Minutes of meeting  
<https://drive.google.com/drive/u/1/folders/1vDFhKCiu6Y6BO8kBWdXFyALHRdnZtMNE>