MEDBIOT-07: **BIOTECHNOLOGY OF PHARMACEUTICAL PRODUCTS**	
GENERAL INFORMATION	
Course Coordinator(s)	Stela Jokić, PhD, full prof.
Associate(s)	Krunoslav Aladić, PhD, assist. prof.
Study Programme	Interdisciplinary Graduate Study Programme in English: Biotechnology
Course Status	Obligatory
Year of Study, Semester	2nd Year / 3rd Semester
Credits (ECTS)	**5.5**
Teaching Method (number of classes)	Lectures 30; Seminars 15; Exercises 30
Expected Number of Students in the Course	25-30
COURSE DESCRIPTION	
Course Aims	
Familiarisation with the basic operations and processes in the pharmaceutical industry, as well as the operational principles of specific devices. Acquiring basic knowledge about the types of pharmaceutical forms, their properties, production technology, and product control, as well as advanced engineering knowledge in the area of pharmaceutical industry.	
Prerequisites for Enrolment and the Entry Competencies Required for the Course	
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Learning Outcomes at the Programme Level Contributed by the Course	
BIOTECH-1; MEDBIOT-1; MEDBIOT-2	
Learning Outcomes at the Course Level	
After completing the course, the student will be able to: 1. Estimate the basic principles of mechanical operations in the pharmaceutical industry. 2. Critically explain the influence of process parameters on the implementation of a specific operation. 3. List the most commonly used devices for implementing specific operations in the pharmaceutical industry and describe their operating principles in detail. 4. List the most common problems encountered in practice, in the course of implementing specific operations in the pharmaceutical industry. 5. Apply their knowledge in the process of producing specific pharmaceutical forms.	
Course Content	
Lectures. Basics of Pharmaceutical Technology. Demand and Requirements of the Pharmaceutical Industry. Process Schematics – Devices, Symbols. Sterilisation in the Pharmaceutical Industry – Procedures, Processes. Powders – Grinding, Sieving, Mixing, Homogenisation. Granulation – Granulation Procedures; Wet, Dry. Centrifugation and Filtration Operations – Devices. Emulsions in the Pharmaceutical Industry – Liquid Emulsions, Cremes. Heat Transfer Devices in the Pharmaceutical Industry (Heat Exchangers). Distillation – Basic Principles, Methods and Devices. Traditional and Modern Extraction Procedures (Maceration, Digestion, Percolation, Re-Percolation, Evacolation and Diacolation; Soxhlet Extraction, Liquid-Liquid Extraction, Ultrasound-Assisted Extraction, Microwave-Assisted Extraction, Accelerated Solvent Extraction, Supercritical Fluid Extraction, Subcritical Water Extraction). Drying – Basic Principles, Methods and Devices. Spray Drying and Lyophilisation. Tableting – Procedures and Devices. Capsuling – Procedures and Devices, Types of Capsules. Basics of Pharmacopeia. Pharmacologically Active Substances. Forms and Preparation of Medicinal Drugs in Pharmacy. Natural Cosmetic Pharmaceutics. **Seminars.** Calculations for Heat Exchangers, Distillers, Extractors, Driers. Forms and preparation of pharmaceutical drugs. **Laboratory exercises.** Grinding and Determining the Particle size distribution – Granulometric Analysis. Production of Macerates and Tinctures. Isolation of Essential Oil from Various Medicinal	

Plants Using a Hydrodistillation Apparatus Described in the European Pharmacopeia. Isolation of Essential Oils from Various Medicinal Plants Using Steam Distillation in a Pilot Facility. Modern Extraction Procedures (Supercritical CO_2 Extraction, Subcritical Water Extraction, Microwave-Assisted Extraction, Ultrasound-Assisted Extraction). Production of Dry Extracts using Spray Drying and the Lyophilisation Procedure. Capsuling and Tableting – Production of Herbal Food Additives. Development and Production of Api-Syrup. Production of Natural Herbal Cosmetics. Optimisation of the Pharmaceutical Industrial Process with the Application of Computer Program Suites.

Teaching Methods

Lectures; seminars; laboratory exercises

Students' Obligations

Attendance at all forms of classes is mandatory and the students are obligated to attend all knowledge tests. The students may be absent from 30% (full-time students) and 50% (part-time students) of each of the forms of classes, provided that the absence is justified. An exercise or a seminar which has not been completed must be made up through a midterm exam.

Monitoring the Activity of the Students *(Connecting Learning Outcomes, Teaching Methods, and Grading)*

Class-related activity	ECTS	Learning outcome	Student activity	Evaluation method	Grade points	
					Min.	Max.
Attending classes	0.5	1-5	Attendance at classes	Keeping records	2	10
Seminars	1.5	2-4	Seminar work preparation	Presentation of seminar work	16	30
Laboratory exercises	0.5	5	Practical work	Laboratory exercises report	2	10
Final exam	3	1-5	Studying for the final exam	Written exam	30	50
Total	**5.5**				**50**	**100**

Evaluation of the written part of the final exam

Percentage of correct answers (%)	Grade
>95.00	50
90.00-94.99	47
85.00-89.99	45
80.00-84.99	40
75.00-79.99	38
70.00-74.99	35
65.00-69.99	33
60.00-64.99	30

Forming the final grade:
The points granted for the final exam are added to the grade points awarded during class attendance. The grading process is conducted by absolute distribution, i.e. based on total achievements, and compared to the numerical system in the following manner:
A – Excellent (5): 90-100 grade points; B – Very Good (4): 80-89.99 grade points; C – Good (3): 65-79.99 grade points; D – sufficient (2): 50-64.99 grade points

Mandatory Literature (available in the library and via other media)		
Title	Number of copies in the library	Availability via other media
Tekade RK: Dosage form Design considerations (Advances in pharmaceutical product Development and research series), Elsevier Inc., 2018.		yes
Hickey AJ, Ganderton D: Process Engineering (Drugs and the Pharmaceutical Sciences) 2nd ed. CRC Press, 2009.		yes
Additional Literature		
European Pharmacopoeia (Ph. Eur.) 2018 Scientific and professional papers related to specific chapters (available online)		
Quality Assurance Procedures Designed to Ensure the Acquisition of Outcomes and Competencies		
Anonymous, quantitative, standardised student survey on the course and the teacher's work implemented by the Quality improvement office of the Faculty of Food Technology Osijek and/or the Faculty of Medicine Osijek.		
Note		
E-learning is not included in the class quota, but it is used in teaching and it contains links to various sites and video and audio materials available on websites.		